GMO dealing applications – a 'how-to' guide

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Overall Objective

This document aims to provide guidance to staff and students when completing an application to work with genetically modified organisms (GMOs) at the University of Tasmania.

All dealings with GMOs conducted by University staff and students must be approved by the Institutional Biosafety Committee (IBC) prior to commencement.

Background

A 'dealing' with a GMO involves any of the following activities:

a) conduct experiments with the GMO;
b) make, develop, produce or manufacture the GMO;
c) breed the GMO;
d) propagate the GMO;
e) use the material in the course of manufacture of a thing that is not the GMO;
f) grow, raise or culture the GMO;
g) import the GMO;
h) transport the GMO;
i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).

Dealings with GMOs are regulated under the *Gene Technology Act 2000* (Cwth) and the *Genetically Modified Organisms Control Act 2004* (Tas). Regulations are overseen by the Office of the Gene Technology Regulator (OGTR) at the Commonwealth level, and by the Department of Primary Industries, Parks, Water and the Environment (DPIPWE) at the state level. Import of plant GMOs is strictly regulated by the Department of Agriculture, Water and the Environment (DAWE; Cwth), and it is a DAWE requirement that import permit applications for plant GMOs are accompanied by a Record of Assessment by the IBC.

Dealings with GMOs are classified into four levels based on the end use and risk level.

Dealing Level	Definition	OGTR Licence required	Containment Level
Exempt Dealing	Activities with GMOs that have been assessed over time as posing a very low risk (ie. contained research involving very well understood organisms and processes for creating and studying GMOs).	**No** – must be assessed by the University of Tasmania IBC.	**Yes** – PC1 or PC2
Notifiable Low Risk Dealing (NLRD)	Activities with GMOs undertaken in containment (ie. not released to the environment) that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.	**No** – must be assessed by the University of Tasmania IBC and an annual report provided to the OGTR.	**Yes** – PC1 or PC2
Dealing Not Involving Intentional Release (DNIR)	Activities with GMOs of a higher risk than NLRDs which are undertaken in containment.	**Yes –** applications must be reviewed by the IBC and a risk assessment and management plan (RARMP) prepared prior to a licence decision by the OGTR.	**Yes –** usually PC2 or greater. Other conditions will apply.
Dealing Involving Intentional Release (DIR)	Activities with GMOs involving an intentional release into the Australian environment. The majority of DIR licences are for field trials or releases of plants, although GM vaccines also fall into the DIR category.	**Yes** – applications must be reviewed by the IBC, RARMP prepared, consultation on RARMP and licence decision by the OGTR.	Licence conditions apply (**Note**: agricultural DIRs are not currently permitted in Tasmania)

Dealings with GMOs classified as Exempt or NLRD do not require case-by-case assessment by the OGTR, and are instead reviewed and endorsed by the University of Tasmania Institutional Biosafety Committee (IBC).

Note: It is an offence under the *Gene Technology Act 2000* if NLRDs are not undertaken in accordance with the *Gene Technology Regulations 2001* ("the Regulations").

Schedule 2 of the Regulations describes the types of dealings with GMOs that are classified as Exempt Dealings. The only legislative requirement for Exempt Dealings is that they must not involve and intentional release of a GMO into the Australian environment. The University of Tasmania IBC considers that Exempt Dealings should be conducted in a certified PC1 or PC2 laboratory to meet this requirement. Dealings which are classified as Exempt are listed on the application form, and this information can also be found on the OGTR website.

Parts 1 and 2 of Schedule 3 of the Regulations describes the types of dealings with GMOs that are classified as NLRDs. This information is included on the application form, and can also be found on the OGTR website. These dealings must be conducted in a certified PC1 or PC2 laboratory.

DNIR and DIR applications (Part 3 of Schedule 3) should be discussed with the Biosafety and Biosecurity Officer or the IBC before preparing an application.

Please note that there are no PC3 or PC4 facilities in Tasmania, and as such work with Risk Group 3 or Risk Group 4 organisms at the University of Tasmania is strictly prohibited.

Guidelines for Completing the Application Form

General information

- Applications are assessed by the IBC during bi-monthly meetings. Please send your completed application to biorisk.management@utas.edu.au prior to the meeting deadlines provided on the IBC website.
- Prior to submission, please ensure all fields are completed, and relevant signatures obtained.
- Please do not complete the box labelled 'IBC use'.
- **Mac users** – please use Adobe Acrobat (rather than Preview) to complete the form.

Section 1 – Project title

Please include the complete Project title. Please ensure the title included is the same that will be used in any subsequent Ethics Committee applications.

Section 2 – Type of dealing

Please select the appropriate type of dealing and the relevant sections. Refer to tables A-D to determine the correct classification for your dealing.

Note: If your project contains aspects of dealings which cover multiple classifications, please select all classifications that apply.

Note: There have been some amendments and additions to the Schedules, following changes to the Gene Technology Regulations in September 2011. Please read the Description of dealing, host and vector systems and NLRD PC1 and PC2 schedules carefully. Further changes will occur in October 2019, and this document will be updated accordingly after this date.

Note: Schedule 3 of the Gene Technology Regulations (Parts 1 and 2) describes the types of dealings which are classed as NLRDs. Please review this information to determine the correct type of dealing. If the proposed dealing is a DNIR (Part 3 of Schedule 3), please contact the Biosafety and Biosecurity Officer prior to submitting the application.

Section 3 – Person responsible for dealing

Please ensure all details are completed, including contact details. If the Project Supervisor has not previously submitted a GMO Dealing Application to the UTAS IBC, please provide a one-page resume outlining relevant experience and qualifications in relation to GMO work with your application.

Section 4 – About the dealing

Please ensure all fields are completed. If you have already applied for a dealing for this project which has expired, please list the dealing number (e.g. NLRD-xxxx).

NLRDs have a maximum time limit of five years, and cannot be extended. If the research project is expected to continue beyond this time limit, a new application must be submitted prior to expiry of the NLRD.

Section 5 – Activities involved in the dealing

Only 'uncheck' items from the list of activities that you know will definitely **not** be undertaken. NLRDs cannot be varied, so it is prudent to include any activities in your application which may occur.

Note: If you are importing the GMO(s) from outside Australia, please ensure you complete the details regarding Biosecurity (DAWE) approval. If you are conducting your research within the Medical Science Precinct, please contact Dr David Steele (d.a.steele@utas.edu.au) to check if the MSP Import Permit will satisfactorily cover your importation. If you are conducting your research elsewhere within the University, please contact the relevant facilities manager or Biosafety and Biosecurity Officer.

Note: Imports of GM plant material (including seeds) from mainland Australia also require a permit issued by Biosecurity Tasmania. Please contact the Biosafety and Biosecurity Officer for details.

Note: Any proposed transportation, storage and disposal of the GMO is considered an aspect of the dealing and also requires approval and appropriate training. Guidelines for these aspects are covered in the OGTR Guidelines for the Transport, Storage and Disposal of GMOs.

Section 6 – Description of the dealing

Please ensure all information accurately includes all aspects of the dealing, including:

- The aims, benefits and expected impact of the research;
- How the GMOs will be created and/or used; and
- Any biosecurity conditions.

The description of the work and benefits of the work should be no more than 200 words and is to be written in lay terms. The IBC Members are from a range of University disciplines and require adequate detail to understand what the specific dealing(s) will involve.

Section 7 – Host organisms and sources of genetic material

Include details of host organisms, genetic materials, vectors and methods for transfer. Using Tables A-D, assign a dealing type to each line. The information in these tables is derived from the Schedules of the Gene Technology Regulations 2001.

Table A	This table describes dealings with GMOs which are classed as Exempt Dealings. If either Item 4 or Item 5 is selected, please indicate the host/vector system to be used in Table D.
Table B	This table describes dealings with GMOs which are classed as PC1 dealings. These dealings must be conducted in an OGTR-certified PC1 laboratory.
Table C	This table describes dealings with GMOs which are classed as PC2 dealings. These dealings must be conducted within an OGTR-certified PC2 facility. If a dealing of type

	(d), (e), (f), (h), (i), (j) or (l) is selected, please indicate the host/vector system to be used in Table D.
Table D	This table describes host/vector systems noted for the cases above.

Note: If your research is not an Exempt Dealing or NLRD (ie. it fits under Part 3 of Schedule 3 of the Gene Technology Regulations 2001), please contact the Biosafety and Biosecurity Officer for guidance in submission of a DNIR or DIR licence application.

Section 8 – Modified trait(s) and gene(s) responsible

Please select all that apply and provide relevant details.

Section 9 – Facilities to be used

Please ensure all details are completed for each facility, including places of storage and specific rooms that will be used for the project, where relevant. Certificate numbers can be obtained from the Facility Manager.

Note: The Facility Manager(s) of the facilities proposed in the project **must** be contacted prior to submission. They are required to sign the declaration confirming the feasibility of you conducting your research in their facility. The Facility Manager's declaration does not provide endorsement for approval of your application by the IBC.

Section 10 – Risk assessment and management

Please ensure all sections are completed and a description of the hazards, likelihood and consequences for the health and safety of people and the environment is provided. Information specific to the risks associated with GMOs can be found in the OGTR Risk Analysis Framework, 2013.

The WHS Unit provides training sessions that may be relevant to you including hazardous substance management. Additional training courses are provided at an organisational unit (OU) level. These courses should have been completed during your induction to UTAS, and a refresher course must be completed every 1 to 2 years.

Note: AS/NZS2243.3:2010 *Safety in laboratories – Microbiological safety and containment* may also be of assistance in considering your risk assessment, and can be accessed by searching for 'Safety in laboratories' in the SAI Global Database (which can be accessed via the University Library).

Note: If you are intending to transport the GMO(s) outside of a certified facility, please provide details of the transport mechanism and containers to be used for the transportation.

Note: Please include details of how the GMO(s) will be disposed of, and what specific steps you will take in the event of an unintentional release of the GMO(s). Note that no incineration facilities exist in Tasmania, and autoclaving or chemical treatment are the preferred disposal methods.

Section 11 – Persons undertaking the dealing

Please ensure all persons undertaking the dealing, including students, are included with the relevant details. The details of additional persons can be added as they become known during the project and should be noted in the annual report. Classes of persons may be added (e.g. Animal Services Staff) if appropriate for the proposed dealing.

Section 12 – Project Supervisor Declaration

Please ensure the Project Supervisor has read and understood the Declaration, including their responsibilities under the Gene Technology Act, and the potential consequences of breaches in legislation prior to the signing of the declaration.

Section 13 – Facility Manager Declaration

Please ensure that the Facility Manager(s) responsible for the facilities where the proposed dealings are to be conducted have read and confirmed the feasibility of conducting the proposed dealing in their facility.

Note: Confirmation and signoff from a Facility Manager does not represent an endorsement of the proposed dealing. This step ensures that the Facility Manager is aware of the potential research activities and confirms that their facility/facilities are appropriate for the work.

Section 14 – Head of School Declaration

Please ensure the Head of School has signed the application before submitting. Applications will not be considered by the IBC until a complete application including all relevant signatures has been received.

Section 15 – Comments for the University's IBC

Please include any additional information for UTAS's IBC in this section, which has not been previously covered in the application.

Section 16 – Checklist

Please check through all items and ensure they have been addressed prior to submission. Incomplete applications will be returned to the applicant.

Please submit completed applications to biorisk.management@utas.edu.au.