

**Overarching Principle and Intent**

The Biosafety and Radiation Safety Committee (BRSC) deals with a range of matters including those related to genetically modified organisms. The scope of the legislative and compliance matters include the Gene Technology Act and Regulations, as well as the Work Health and Safety legislation.

**Genetically Modified Organism Project Approval Procedure**

This procedure describes the Biosafety and Radiation Safety Committee (BRSC) approach to managing genetically modified organism (GMO) related applications (Exempt, NLRD, DNIR dealings), and related licence variations.

**Introduction**

Under the Office of the Gene Technology Regulator (OGTR) Guidelines for Accreditation of an Organisation, the BRSC provides advice to Chief Investigators regarding the identification and control of the risks associated with GMO dealings and complying with the prevailing legislative requirements.

**Objective of the Approval**

All dealings with GMOs must be reviewed by the BRSC 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.

**Scope**

This procedure covers the requirements for submitting GMO-related applications and requests for licence variations. The types of dealings considered are those described by the Gene Technology Regulator OGTR to be Exempt Dealings, Notifiable Low Risk Dealings (NLRD) and Dealing Not involving an Intentional Release (DNIR).

**Approval Process**

**New Exempt Dealing & NLRD Projects**

All GMO dealings that are considered to be Exempt Dealings or Notifiable Low Risk Dealings (NLRD) are described in the *Gene Technology Regulations 2001* ([Schedule 2](http://www.austlii.edu.au/au/legis/cth/consol_reg/gtr2001271/sch2.html) or [Schedule 3, Part 1 or 2](http://www.austlii.edu.au/au/legis/cth/consol_reg/gtr2001271/sch3.html)).

In considering an Exempt Dealing, the BRSC acts on the delegated authority of the OGTR. There is no requirement to inform the OGTR of applications involving Exempt Dealings.

In considering NLRD applications, the BRSC acts on behalf of the University in assessing an application and then informing the OGTR. Effectively, the BRSC acts on behalf of the OGTR.

1. The Chief Investigator must complete the [BRSC application](http://www.westernsydney.edu.au/__data/assets/word_doc/0006/58857/BRSC_Application_Form_Dec_2014.docx) form for all new Exempt Dealing and NLRD projects.

2. For NLRD applications, a [Record of Assessment (RoA)](http://www.westernsydney.edu.au/__data/assets/word_doc/0006/749085/BRSC_NLRD_Record_of_Assessment_Form_May_2015.docx) form must also be submitted.

3. Newly approved NLRD applications will be notified in the annual report to the OGTR. Notification of approved Exempt Dealings is not required.

**New DNIR Projects**

All GMO dealings that are considered to be Dealings Not Involving Intentional Release (DNIR) Dealings are described in the Gene Technology Regulations 2001 ([Schedule 3, Part 3](http://www.austlii.edu.au/au/legis/cth/consol_reg/gtr2001271/sch3.html)).

In considering DNIR applications, the BRSC assesses the application received on the BRSC application form. The DNIR Licence application is considered by the OGTR.

1. The Chief Investigator must complete the [BRSC application](http://www.westernsydney.edu.au/__data/assets/word_doc/0006/58857/BRSC_Application_Form_Dec_2014.docx) form as well as the [OGTR DNIR application](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/contained-1) form.

2. Upon approval of the BRSC application, the DNIR application will be forwarded by the BRSC Executive Officer to the OGTR for consideration.

3. Requests for additional information required by the OGTR will be forwarded to the BRSC Executive Officer and then the Chief Investigator. Responses from the Chief Investigator to the OGTR will be forwarded by BRSC Executive Officer.

4. Once the OGTR has approved the project application, a DNIR licence will be issued.

5. On receiving the DNIR licence, it will be forwarded by the BRSC Executive Officer to the Chief Investigator.

6. It is the responsibility of the Chief Investigator to ensure that they understand and comply with the licence requirements and any conditions that apply. In addition, the Chief Investigator is to ensure that any associated records that are generated as a result of the licence requirements or conditions are to be retained for future reference.

**Related Policies, Procedures & Forms:**

[Gene Technology Act 2000](https://www.legislation.gov.au/Details/C2011C00539)

[Gene Technology Regulations 2001](https://www.legislation.gov.au/Details/F2011C00732)

[OGTR Guidelines for the Transport, Storage and Disposal of GMOs](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/transport-guide-1)

[OGTR DNIR application form](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/contained-1)

[OGTR Operational Policies - Scope of variation of GMO licences](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/3156F3E571D6155BCA257DF9000D28E4/$File/Policy%20on%20scope%20for%20variation%20of%20GMO%20licences.pdf)

[OGTR Guidance for making Records of Assessment of NLRDs](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/nrld-record-guide-htm)

**Biosafety and Radiation Safety guidance documents available from REDI**

* GMO Dealings
* GMO Project Amendment Procedure
* Techniques and Organisms that are Not Gene Technology

Biosafety and Radiation Safety Team Contact: [Biosafetyradiation@westernsydney.edu.au](mailto:Biosafetyradiation@westernsydney.edu.au)

**Guidance on Data Storage and Retention Questions in the NEAF**

Copy of final RoA must be given to the CI (see Reg 13B)

Include directions if further information from CI is required?



