**Biosafety and Radiation Safety**

**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 Amendment Procedure**

**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 Amendment Process**

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 describes the process for amending previously approved GMO-related BRSC applications involving Exempt Dealings, Notifiable Low Risk Dealings (NLRD) or Do Not Intend to Release (DNIR). For amendments to DNIR projects, the BRSC will need to consider the amendment prior to an OGTR licence variation being submitted.

**Exempt Dealing – Amendments**

During the conduct of an approved Exempt Dealing project it may be necessary to amend the approved project application.

An amendment may include, but is not limited to, changes to the research team or facilities, extension of project expiry, changes to the cell line or microorganisms used or changes to the experimental procedure.

The Chief Investigator must obtain BRSC approval prior to introducing any changes to an approved application.

1. The Chief Investigator must complete the [BRSC Amendment Request](https://www.westernsydney.edu.au/__data/assets/word_doc/0005/749084/BRSC_Amendment_Request.docx) form. If the amendment warrants, the Chief Investigator may decide to highlight the changes in the previously approved application.

2. The completed Amendment Request form and amended application (if applicable) are to be forwarded to biosafetyradiation@westernsydney.edu.au for consideration by the BRSC.

3. If the project variation is not considered to alter the GMO dealing classification, alter the hazards or increase the risks associated with the project and is within the scope of project approval, the amendment will be considered by the BRSC. If not, a new application will need to be submitted.

**NLRD Dealings – Amendments**

During the conduct of an approved NLRD project it may be necessary to amend the approved project application. Depending on the nature of the amendment it may be possible for the BRSC to approve the amendment, otherwise a new application may need to be submitted.

In general terms, if any of the elements of [Regulation 13 (1)](http://www.austlii.edu.au/au/legis/cth/consol_reg/gtr2001271/s13.html) regarding the assessment of an NLRD project have changed this would prompt a new Record of Assessment (RoA). The new RoA would then need to be recorded in the annual report to the OGTR.

An amendment or variation to a licence may include, but is not limited to, changes to the research team or facilities, extension of project expiry, changes to the cell line or microorganisms used or changes to the experimental procedure.

The Chief Investigator must obtain BRSC approval prior to introducing any changes to an approved project.

1. The Chief Investigator must include any changes on the original project application form. The sections of the project application that have been added or varied must be highlighted for easy identification.

2. The completed updated project application and the [BRSC Amendment Request](https://www.westernsydney.edu.au/__data/assets/word_doc/0005/749084/BRSC_Amendment_Request.docx) form are to be forwarded to the BRSC.

3. If the project variation is not considered to alter the GMO dealing classification, alter the hazards or increase the risks associated with the project and is within the scope of project approval, the Amendment Request will be considered by the BRSC.

4. The Chief Investigator is to read and understand the conditions of approval (if applicable) and ensure that the members of the research team are also made aware.

5. Variations to previously approved NLRD applications that are required to be notified to the OGTR will be recorded in the annual report to the OGTR.

**DNIR Dealings – Amendments and Variations**

DNIR dealings involve approval by the BRSC and also the OGTR, who ultimately are responsible for the issuing of the DNIR licence.

In some cases, changes to a previously approved BRSC application may not impact on the scope of the DNIR licence. An example may be the addition of an exempt cell line to the project. If that is the case, a variation of licence request does not need to be sent to OGTR. [Refer OGTR Operational Policies - Scope of variation of GMO licences](https://www.ogtr.gov.au/sites/default/files/files/2021-06/policy_on_scope_for_variation_of_gmo_licences.pdf)

If any changes are required to an approved BRSC application, these must be approved by the BRSC prior to introducing any changes. In the situation that an approved BRSC application also has a related DNIR licence, the OGTR must approve the licence variation before any changes can be introduced.

1. Documentation to be forwarded to the BRSC for consideration must include:

1. Any changes on the previously approved application. The changes are to be highlighted for easy identification.
2. A completed [BRSC Amendment](https://www.westernsydney.edu.au/__data/assets/word_doc/0005/749084/BRSC_Amendment_Request.docx) Request and a copy of the proposed letter to the OGTR informing them of the requested variation(s) to the licence (if applicable). The Chief Investigator should refer to [OGTR Operational Policies - Scope of variation of GMO licences](https://www.ogtr.gov.au/sites/default/files/files/2021-06/policy_on_scope_for_variation_of_gmo_licences.pdf) for further details.

2. Based on the review of the submission by the BRSC:

- The amendment request may be approved with no need for a licence variation to be lodged with the OGTR.

- The amendment request may be conditionally approved by the BRSC, pending approval of the licence variation by the OGTR.

3. Licence variation requests will be forwarded to the OGTR by the BRSC Executive Officer.

4. OGTR requests for additional information will be forwarded to the Chief Investigator through the BRSC Executive Officer. In the event that the OGTR contact the Chief Investigator directly, the BRSC Executive Officer must be included in any emailed responses.

**Related Policies, Procedures & Forms:**

[Gene Technology Act 2000](https://www.legislation.gov.au/Details/C2016C00792)

[Gene Technology Regulations 2001](https://www.legislation.gov.au/Details/F2020C00957)

[OGTR Guidelines for the Transport, Storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos)

[OGTR DNIR application form](https://www.ogtr.gov.au/resources/publications/application-licence-dealings-not-involving-intentional-release-gmo-dnir)

[OGTR Operational Policies - Scope of variation of GMO licences](https://www.ogtr.gov.au/sites/default/files/files/2021-06/policy_on_scope_for_variation_of_gmo_licences.pdf)

[OGTR Guidance for making Records of Assessment of NLRDs](https://www.ogtr.gov.au/resources/publications/guidance-making-record-assessment-nlrd-and-responsibilities-those-undertaking-nlrds)

**Biosafety and Radiation Safety guidance documents available from Research Services**

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

Biosafety and Radiation Safety Team Contact: Biosafetyradiation@westernsydney.edu.au

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

BRSC Exec Officer includes in Annual Report to OGTR

Approved appears twice



