Griffith University Biosafety Committee

Registration of Biological Dealing(s) Information Guide

The purpose of the Biological Dealing (RBD) registration form is to inform the University Biosafety Committee (UBC) of projects or activities that may involve organisms, substances or other materials of biological origin that may be classified as moderate to high risk, but which may not have been explicitly assessed within a licensed dealing application. The types of dealings included are defined in this guide.

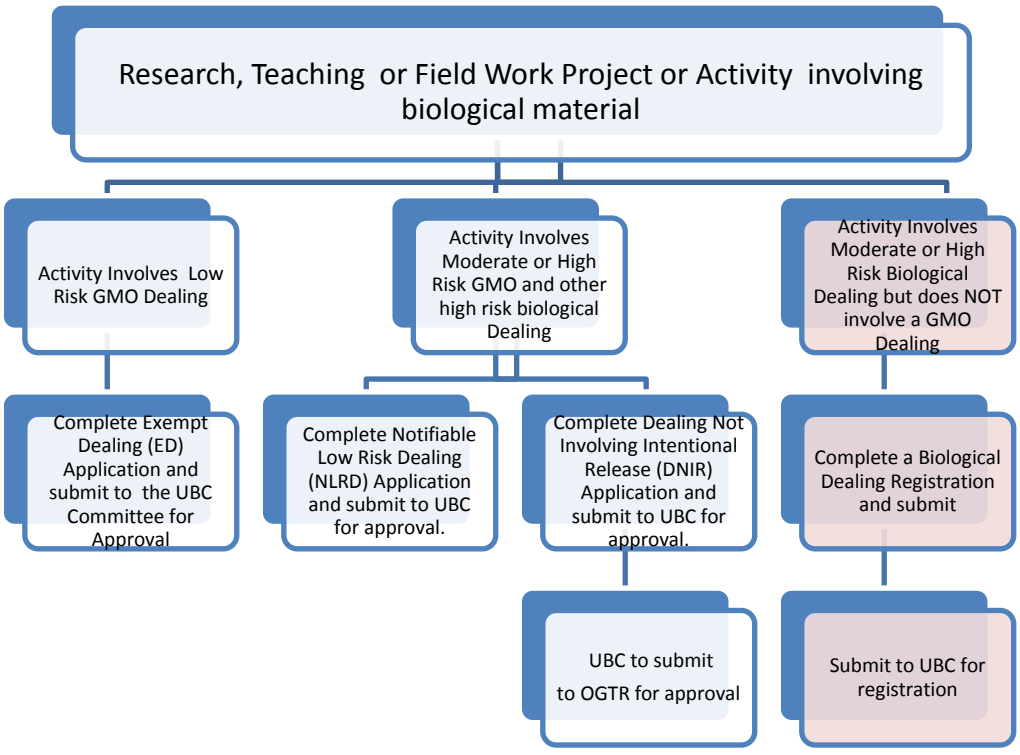
REGISTRATION PROCESS

Upon submission of the registration form, the UBC will review the information and make a record of the activity. The information will be used to inform the UBC to assist in the monitoring of biosafety and incident management.

UBC APPLICATION TYPES

- If the activity or project involves multiple numbers or types of high risk dealings they can be submitted on the same application.
- Storage of biological material is also considered to be a dealing.
- The RBD form should not be used for dealings involving genetically modified organisms (GMOs).
- In instances where a Biological Dealing has been assessed as part of GMO dealing application then a separate RBD application is not required.

The flow chart below outlines the type of UBC form required:



ACTIVITY/CONTACT DETAILS (SECTION 1)

Details of the person taking primary responsibility for overseeing the activity or project involving the biological material is required A list of key contacts handling the material should be included. The applicant must describe the project or activity. Include the project title or course code, if applicable.

TYPES OF BIOLOGICAL WORK (SECTION 2)

This form is relevant for all research, teaching or fieldwork activities that involve one or more of the following categories:

A. **Wild type microorganisms from risk group 3 or 4;**
Activities involving the use or storage of these organisms will be considered to be a dealing.

Organism risk group classifications are as listed in AS2243.3, Section 3 Library/SAI Global or any microorganism categorised as Dangerous Goods Class 6.2 (Infectious Substances) or those falling under the Dangerous Goods Regulations (IATA).

B. **Risk Group 2 microorganisms including bacteria, parasites, fungi, viruses and prions;**
Activities involving the use or storage of any risk group 2 organisms will be considered to be a dealing. Where microorganisms of risk group 2 (or higher) are cultured in volumes greater than 10 Litres, please note this under the material information in section 3 of the form.

C. **Potentially infectious animals, tissues or fluids including unscreened clinical specimens**;
Where an activity involves human or animal, tissues, fluids or other materials that are suspected of containing viable pathogenic risk group 2, 3 or 4 microorganisms the dealing must be registered. This includes tissue or body fluids that could contain zoonotic organisms or have not been screened for such (e.g. Bats).

D. **Activities involving poisonous or venomous animals or biological toxins;**
Where an activity or project involves the handling of poisonous animals, invertebrates, fish or other organism that produces venom or other toxin that has the potential to cause significant injury to humans the dealing must be registered. Examples include venomous snakes, spiders and cone shells.

Where an activity or project involves the handling or use of a biological toxin (or biotoxin), that has the potential and is likely to cause significant illness or death to humans then the dealing must also be registered. For example snake venom. The term biotoxin generally describes any toxic material that originated from a biological source such as venoms, but may also synthesised molecules. Activities involving endotoxins or toxoids do not need to be registered, unless they are being used in such a way or in sufficient quantity to present a significant risk to individuals or the community. For further clarification email the UBC or consult with the Griffith Biosafety Advisors to determine if registration is necessary for a particular circumstance.

E. **Biological material that appears on the Defence Strategic Goods List** (DSGL);
Some Biological materials are listed on the Defence Strategic Goods List. Activities involving biological materials appearing on the DSGL should be registered with UBC who will notify the Office of research for further guidance and permits. These materials may include microorganisms or toxins that potentially have military applications and therefore may present a security risk to Australia. Further information on the Defence Strategic Goods List is available at Griffith Office of Research - Strengthened Export Controls, http://www.defence.gov.au/deco/DSGL.asp or consult with the Griffith Biosafety Advisors.

F. **Biological material involving Security Sensitive Biological Material** (SSBA's).
The Department of Health classifies some microorganisms as Security Sensitive Biological Material. Activities involving biological materials classified as an SSBA must be registered with the UBC. A List of SSBA's is available at http://www.health.gov.au/ssba or consult with the Griffith Biosafety Advisors.

BIOLOGICAL MATERIAL DETAILS (SECTION 3)

Provide a list of material or organisms involved in the activity. Please indicate the material category as one of the following: Bacteria, Fungus, Virus, Prion, Protozoa, Plant, Invertebrate, Animal, Toxin, Clinical Specimen or Cell Line. Indicate the risk group and include name strain details if available. Please also include any useful comments in the notes section such as antibiotic resistance types or other factors that indicate virulence.

FACILITIES USED (SECTION 4)

Biologicals must be undertaken in an appropriate physical containment facility as stipulated by AS/NZS2243.3, the primary facility in which the dealing will be undertaken must be indicated, as well as where any material will be stored. Secondary or contingency locations should also be listed if applicable.

ASSESSMENT AND RISK MANAGEMENT (SECTION 5)

A risk assessment for the project or activity must be completed, but does not have to be submitted with the registration form. If the risk assessment is on Gsafe then the reference number can be included. In your risk assessments please ensure that hazards have been identified, assessed and appropriate controls considered and implemented. Please include details on infection control, waste disposal procedures, transport requirements and unintentional release plans. If the dealing involves Biotoxins, list stock concentrations as well as any information on lethal doses in vertebrate (LDL), as well as a safety data sheet (SDS), where available.

DECLARATION OF COMPLIANCE (SECTION 6)

The project/activity coordinator or supervisor must sign the registration form.