Research Office
Kolling Building, Level 13
Royal North Shore Hospital
St Leonards NSW 2065
Tel (02) 9926 4590

Health
Northern Sydney
Local Health District

Institutional Biosafety Committee

Exempt Dealings and Notifiable Low Risk Dealings (NLRD)

Information for applicants

Institutional Biosafety Committee

Instructions to Applicants

The Institutional Biosafety Committee (IBC) Instructions to Applicants provides useful links, information and a checklist to assist with completion and submissions of the GMO Application form. The information in this document is underpinned by the IBC GMO Application form, the Office of the Gene Technology Regulator (OGTR), and the Australian and New Zealand Standards (AS/NZS).

GMO Applications are the prime source of information available to the IBC and must be submitted and approved prior to commencement of the research. The Application must contain all the information necessary for assessment of the Application without the need for further written or oral explanation, or reference to additional documentation, including the Internet. All details in the Application must be current at the time of submission.

Accuracy of Information:

Download the latest GMO Application form from the NSLHD website and read the instructions carefully before submission to avoid delay in processing your application. Check carefully that all the information contained in the application is accurate before submission.

Review of Submitted proposals:

Initial review of the submitted GMO application form is carried out at the next meeting of the RNSH IBC provided the dealing is submitted prior to the submission deadline for that meeting. Submission after this date will involve delays in review and therefore delays in approval.

After initial review three outcomes are possible:

1. The IBC will find the dealing acceptable and grant FULL approval
2. The IBC will request further information of the applicant. This information will need to be returned to the Research Office for consideration at a subsequent full IBC meeting.
3. The IBC will request further information of the applicant. This information will need to be returned to the Research Office who will facilitate an out of session review by the IBC Executive.

If outcome 2 or 3 occurs then this requires submission of an amended application. Resubmission should be made with an appropriate cover letter addressing the committee's concerns and a copy of the application form amended in tracked changes.

Notifiable Low Risk Dealings:

Notifiable Low Risk Dealings (NLRDs) are described in the *Gene Technology Regulations 2001* (the Regulations), and are dealings with GMOs 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. NLRDs must be:

- conducted by persons with appropriate training and experience within a facility certified to either Physical Containment level 1 (PC1), PC2 or PC3;
- assessed by an Institutional Biosafety Committee (IBC) https://www.ogtr.gov.au/resources/publications/guidance-ibcs-regulatory-requirements-contained-research-gmos-containing-engineered-gene-drives
- transported, stored and disposed of in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos

Exempt dealings:

A dealing with a GMO is only an Exempt Dealing if it meets **all** of the following conditions:

- it does not involve an intentional release of the GMO into the environment.
  - it is mentioned in the amended changes to exempt dealings from July 2007 as Part 1 of Schedule 2, Gene Technology Regulations 2001 as amended 2007 https://www.legislation.gov.au/Details/F2007L01317
  - it does not involve genetic modification, other than a modification described in the categories below;
  - it is conducted in accordance with Australian Standard AS/NZS 2243.3:2002 (Safety in Laboratories: Microbiology) for Physical Containment Level 1

The Office of the Gene Technology Regulator:

The Office of the Gene Technology Regulator (OGTR) is a part of the Australian Government Department of Health and Ageing: http://www.ogtr.gov.au
Schedule 3, Parts 1 and 2 of the *Gene Technology Regulations 2001* which specifies the kinds of NLRDs suitable for PC1, PC2 and PC3 are at: (https://www.ogtr.gov.au/about-ogtr/legislative-documents)

Australian and New Zealand Standards:

AS/NZS 2243.3-2010 is the section of the Australian Biosafety Standards and Procedures where you will find specific information about approved laboratory procedures and decontamination strategies: you will need to refer to this document when you fill out your NRLD.

Section 3 classes different organisms according to their risks. Information on NLRD type is requested in NLRD Application Form.

Appendix F has lists of decontamination chemicals and the minimum necessary concentrations and contact times. Information on decontamination strategies, organism/s involved, decontaminant/s and contact time/s should be specified in the NLRD Application Form.

Institutional Biosafety Committee:

Institutional Biosafety Committees (IBCs) must prepare a record of assessment (RoA) of each proposed NLRD. A Copy of the RoA must be provided to the applicant who must retain this copy and be able to provide it to the OGTR upon request. The Research Office, on behalf of the IBC must also provide details of the RoA, to the OGTR as a part of each organisation's annual report.

Other helpful sources of biosafety information:

Chem Alert: Risk assessment data for compounds. Available on the USyd server, the link to log in is on the left of the page below. *This site has emergency information.*
http://sydney.edu.au/whs/guidelines/chemical/chemalert.shtml

Lists of minimal toxic concentrations: of common laboratory compounds:
http://hsis.safeworkaustralia.gov.au/ConsolidatedLists

The Canadian biosafety site: has complimentary information that may be helpful to you (Australian Standards take precedence of course):
http://www.phac-aspc.gc.ca/ep-mu/index-eng.php

LINKS

Exempt dealings:
https://www.ogtr.gov.au/resources/publications/guidance-notes-containment-exempt-dealings
Notifiable Low Risk Dealings (NLRDs):
https://www.ogtr.gov.au/what-weve-approved/notifiable-low-risk-dealings-nlrds
Transport, storage and disposal guidelines:
https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos

NOTE: This information sheet is intended as a guide only. For official information refer to the OGTR and relevant Australian standard sites.

APPENDIX 1: Researcher checklist for submission.

The role of the IBC is to provide on-site scrutiny of low-risk contained dealings with genetically modified organisms (GMOs), ensuring the work carried out at NSLHD is compliant with federal gene technology legislative requirements.

The IBC reports to the Office of Gene Technology (OGTR).

The focus of the OGTR is:	Therefore the OGTR(IBC) wants to know:
• to contain GMOs so they do not escape into the environment	○ What measures are you taking to prevent the GMO escapes?
• to minimise any risk of harm to people and the environment posed by GMOs	○ How is the GMO transported and stored? ○ How is the GMO handled and disposed of?
• What is the GMO you are using is and how it will be used?	○ Where does the GMO come from? And how was the GMO made? ○ What equipment will the GMO touch? How will this be decontaminated?

The OGTR/IBC does not need to know why you are doing the experiment or the scientific outcomes so this does not need to be included in the application.

The following checklist has been drafted to assist researchers completing their IBC application forms. The IBC does not require this checklist to be submitted however are happy to accept it to support your application.

Identify the GMO What is the GMO you are using? GMO name:	
How is it classified? Schedule no.: part no.: kind of dealing no.:	
Staff: Are all staff involved listed? Have you indicated who will train inexperienced staff?	 Yes/No Yes/No
Have you included details each persons (or class of persons) previous experience handling GMOs? Are they up to date with their PC2 training?	Yes/No Yes/No

Where did the GMO come from? Who makes the GMO? When imported, are Transport logs maintained? When being transported, is it clearly labelled and double contained?	 Supplier: Yes/No Yes/No
Have you reported the relevant animal ethics number?	Yes/No AEC No.
Decontamination Have you detailed decontamination strategies? Have you specified what decontaminant strategy you will use, what concentration of chemical (% w/v or v/v) and how long it will take?	 Yes/No Yes/No
Have you detailed spill clean-up strategies for small (<10mL) and large (>10 mL) spills	Yes/No
Have you outlined how staff will mitigate any risk posed by the GMO?	Yes/No
Signatures Kearns Animal house Any facilities that are not your lab.	 Yes/No/NA Yes/No/NA
If this GMO was previously approved, please provide the IBC reference number.	