Institutional Biosafety Committee
Research Office, Level 13 Kolling Building
Royal North Shore Hospital, Reserve Road
St Leonards, NSW, 2065
(T) 02 9926 4590
Email: NSLHD-Research@health.nsw.gov.au

GMO Application Form

Exempt Dealings and Notifiable Low Risk Dealings (NLRDs)

Notifying Organisation: Royal North Shore Hospital **Accreditation Number**: ACCR_080

Project Title:		
IBC Project Reference Number:		*Research Office Use Only*

Is this notification accompanied by an application for a declaration that certain information be treated as **Confidential Commercial Information (CCI)**?

Yes		**No**	

If the CCI is covered by previous CCI application(s), please provide the CCI application number(s) here:
_____

Has an application been submitted to the NSLHD Animal Ethics Committee (AEC) for this project?		
☐ Yes Please attach copy of the AEC approval letter or if not yet approved by the AEC please provide status update.	☐ No	

General Information

Research Involving Exempt Dealing: Research involving exempt dealings are not reportable to the OGTR. However, the proposed research must be issued with an IBC identification number before work can commence. Complete **parts 1, 2 and 5 of this form only**.

Research Involving Notifiable Low Risk Dealing (NLRDs): Any research involving a NLRD GMO requires approval from the Royal North Shore Institutional Biosafety Committee (IBC) and is reported to the national gene regulator (the OGTR). A written Record of Assessment from the IBC will be provided to the Project Chief Investigator once the NLRD project application has been approved. The Record of Assessment will also be provided to the OGTR and will be visible on the public record. Complete **parts 1, 3, 4 and 5 of this form.**

Research Involving both NLRD and Exempt Dealings: Where research involves both NLRD and Exempt Dealings please complete **all sections of this form**.

For further information please refer to the IBC Information sheet and submission checklist:
https://www.nslhd.health.nsw.gov.au/Research/ResearchOffice/Pages/Institutional-Biosafety.aspx
E-mail: NSLHD-Research@health.nsw.gov.au Phone: 9926 4590

Please submit a word and PDF version of this completed form via email to NSLHD-Research@health.nsw.gov.au

Please note: you should retain a copy of your completed notification for your own records.

Part 1: Personnel Details

1.1 Principal Investigator:

Name:	
Position:	
Relevant qualifications:	
Relevant GMO/PC2 experience:	
Business Contact Number:	
Mobile Contact Number:	
E-mail Address:	

CLASS of PERSONNEL	
Research Assistants ☐ Post Graduate Students ☐ Under Graduate Students ☐ Post Doc ☐ Other ☐ Please list:	Completed PC2 training: Y / N If no provide details of when and how staff will be trained:

Project Details

1.3 Please indicate Type of GMOs covered by this application

☐ Exempt (complete section 1 then go to Part 2)

☐ NLRD (complete section 1 then go to Part 3)

☐ Both (fill in the entire form)

1.4 Location: Please provide details of all laboratories and locations where the GMO will be used/stored.

FACILITY NAME *eg. lab group/division*	**FACILITY ADDRESS** *eg. room, level, building*	**TYPE** *eg.PC1[a] PC2*	**OGTR ID**	**EXPIRY DATE**
			CERT /	
			CERT /	
			CERT /	

			CERT /	

Part 2. Exempt Dealings

1. Classification of Exempt dealings - tick box(s) as appropriate.

	OGTR Item No	Description of dealing
☐		2. Any dealing with a genetically modified *Caenorhabditis elegans*, unless: (a) An advantage is conferred on the animal by the genetic modification; or (b) As a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.
☐		3. Any dealing with an animal into which genetically modified somatic cells have been introduced, if: (a) The somatic cells are not capable of giving rise to recombinant infectious agents; or (b) The animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
☐		4. A dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture *in each vessel containing the resultant culture.* (a) the donor DNA: (i) is not derived from micro-organisms implicated in, or with a history of causing disease in human beings, other animals, plants or fungi, (ii) it must be characterised and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; and (b) must not code for a toxin for vertebrates with an LD50 of less than 100 µg/kg; and (c) must not code for a toxin for vertebrates with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels; and (d) must not be uncharacterised DNA from a toxin-producing organism; and (e) must not include a viral sequence unless the donor nuclaeic acid: (i) is missing at least 1 gene essential for viral multiplication that: (A) is not available in the cell into which the nucleic acid is introduced; (B) will not become available during the dealing (ii) is incapable of correcting a defect in the host/vector system leading to production of replication incompetent virions; and (iii) must not confer an oncogenic modification
☐		5. Any dealing involving shot-gun cloning or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either: (a) a pathogen; or (b) a toxin-producing organism

2. Description of Exempt GMOs

Why do you consider the project should be classified as an Exempt GMO? List specifically how the project meets the relevant criteria for exemption you have selected in the table above (Part 3.1).

For example: This project is exempt as it uses a host and vector system mentioned in Schedule 2 Part 2. Host = animal or human cell cultures (MCF7 human breast cancer cells) and vector = non-conjugative plasmid (pGemT vector).

The Principal Investigator has read and understood the OGTR Guidelines for the Transport, Storage and Disposal of GMOs
YES
(Please provide Transport, Storage and Disposal Outline here) *Guidelines for the Transport, Storage and Disposal of GMOs | Office of the Gene Technology Regulator (ogtr.gov.au)*

3. Please explain how biological spills be prevented, contained and cleaned.

Include details of spills inside and outside of BSCII hoods/incubators and procedure for cleaning up small and large spills.

Exempt dealings – Go directly to declaration (Part 5)

Part 3.NLRDs

3.1 Please indicate dealings covered by this application

- ☐ Conduct experiments with GMOs
- ☐ Make, Develop, Produce or Manufacture GMOs
- ☐ Breed of GMOs
- ☐ Propagation of GMOs
- ☐ Use the GMO in the course of manufacture of a thing that is not a GMO
- ☐ Grow, Raise or Culture GMOs
- ☐ Import of GMOs
- ☐ Transport of GMOs
- ☐ Dispose of GMOs including decontamination (for solid and liquid waste) and spill (large and small) strategies
- ☐ Storage of GMOs

3.2 Please provide a short explanation of the purpose of your application and for each of the dealings covered above.
Include details of where each dealing will take place and decontamination strategy:

3.3 Please explain how biological spills will be prevented, contained and cleaned.
Include details of spills inside and outside of BSCII hoods/incubators and procedure for cleaning up small and large spills.

3.4 Please provide details of the proposed dealings, other than viruses, in the table below.
This table is intended to generate a concise, accurate record of all the GMOs to be generated or used and the purpose of the proposed dealings. The columns **Schedule, Part and Kind of Dealing** requires that you select one of the following categories which best describes the dealing with the GMO(s) – as per Schedule 3 Part 1 or Part 2 of the *Gene Technology Regulations 2001* (as amended by the *Gene Technology Amendment Regulations September 2011). Details of viral vectors, particles and packaging cell lines should be listed in Part 3 Question 3.*

Part 2 of Schedule 2 describes the host/vector systems for exempt dealings.
Part 1 of Schedule 3 describes the types of dealings with GMOs that are classified as NLRDs suitable for physical containment level 1.
Part 2 of Schedule 3 describes the types of dealings that are classified as NLRDs suitable for physical containment levels 2 and 3.

The current OGRT regulations are available via the OGTR website.

Common name of parent organism	Scientific name of parent organism	Vector(s) & method of transfer	Identity & function of nucleic acid & organism of origin (include what is known regarding pathogenic or oncogenic potential)	If the work involves animals indicate AEC approval no. And expiry date	Sched	Part	Kind of dealing

3.5 Does this work involve viral vectors? Yes (proceed to table)/no

Please provide details of the viral vectors in the table below.

This table is intended to generate a concise, accurate record of all viral vectors to be used in this protocol including (i) replication competent viruses, (ii) replication defective retroviruses (includes lentiviruses), and (iii) replication defective non-retroviruses. Please refer to the companies viral vector map for the following information. The columns **Schedule, Part and Kind of Dealing** requires that you select one of the following categories which best describes the dealing with the GMO(s). Please click here for further guidance on viral vectors. *Please remove example before submitting.*

Viral vector name	Parent organism	Accessory and virulence genes present (excluding gag, pol)	Self-inactivating	Dealing and characteristic	Sched	Part	Kind of dealing
Eg. Lentiviral vector(Replication defective retrovirus/lentivirus)	*Human immunodeficiency virus*	*No virulence or accessory genes present.*	*Yes. Deletion of the U3 portion of 3'LTR ensures self-inactivation*	*Expression of a fluorescent marker to human and mouse cell lines (In vitro)* *Does not confer oncogenic modification or immunomodulatory effect in humans.*	*3*	*2.1*	*I*

Part 5: Declaration

PART A

Laboratory Management Committee Representative for the proposed laboratory (add or remove as required)

Printed Name:		**Signature:**	
Job title:	Level Choose an item. Laboratory Management Committee Representative	**Date:**	
Printed name:		**Signature:**	
Job Title:	Level Choose an item. Laboratory Management Committee Representative	**Date:**	

Kearn's Facility Manager (if required)

Printed Name:		**Signature:**	
		Date:	

☐ I have a risk assessment in place that covers all aspects of the GMO dealings in this application. It has been approved by the WHS Committee and is attached to this application.

☐The PI or named investigators on the approved protocol will ensure all class of staff working will have up to date PC2 training and be trained in all aspects of GMO handling/decontamination/storage outlined in the approved protocol. **Principal Investigator name (please print) and signature:**	
Date:	