



For Office Use Only	
Protocol No	GT /

Notification of an Exempt Dealing COVER SHEET

Project Title: _____	
Project Supervisor: _____	
Faculty/Unit: _____	
Telephone No: _____	Fax No: _____
Starting Date: _____	Completion Date: _____
Room(s) where GMO will be used, including containment level: _____	
Room(s) where GMO is stored: _____	
Other Universities and/or facilities to be involved in the research: _____	

GTRC Declaration
The GTRC has evaluated this dealing and agrees that it is an exempt dealing as specified by Schedule 2 of the <i>Gene Technology Regulations 2001</i> and the <i>Gene Technology Amendment Regulations 2011</i> .

Signature of Project Supervisor: Date: _____
.....

Signature of Head of Unit: Date: _____
.....

Signature of Chair of GTRC:..... Date: _____
.....

LIST OF RESEARCHERS INVOLVED IN THE PROJECT

Please list the names of all staff and students who will be participating in the project, and give details of their training. All persons who will be working in a laboratory certified to use or create a GMO must complete and satisfactorily pass the GMO Quiz on eLearning. The person must also be provided with a local induction to the laboratory and be listed as an authorised user for the laboratory. If researchers have not completed the GMO Quiz, please provide contact details (name, student/staff number, unit, supervisor and email address) to the secretary of the GTRCMs [Penny Potter](#), and one of the following: [Ms Ellen Manning](#) (for Chemistry); [A/Professor Marie Ranson](#) (for Biological Sciences) or [Ms Linda Deitch](#) (for IHMRI).

It is highly recommended that researchers complete a biosafety training course, as well as an induction.

	Name	Position	Completed GMO Quiz?
Principal Investigator (Project Supervisor)	<hr/>	<hr/>	<hr/>
Co-Investigator(s)	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other Participants	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

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Gene Technology Review Committee

1 Project Summary - briefly describe the project, including the aims of the proposed dealing, method of producing GMOs and their use (this should be written in plain English).

2 Exemption Category – circle the item that applies

Part 1 Exempt dealings

Item	Description of dealing
2	A dealing with a genetically modified <i>Caenorhabditis elegans</i> , unless: <ul style="list-style-type: none"> (a) an <i>advantage</i> 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	A dealing with an animal into which genetically modified somatic cells have been introduced, if: <ul style="list-style-type: none"> (a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and (b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
3A	A dealing with an animal whose somatic cells have been genetically modified <i>in vivo</i> by a replication defective viral vector, if: <ul style="list-style-type: none"> (a) the <i>in vivo</i> modification occurred as part of a previous dealing; and (b) the replication defective viral vector is no longer in the animal; and (c) no germ line cells have been genetically modified; and (d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and (e) the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.
4	(1) Subject to subitem (2), a dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 25 litres of GMO culture in each vessel containing the resultant culture.

- (2) The donor nucleic acid:
- (a) must meet either of the following requirements:
- (i) it must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy:
- (A) human beings; or
- (B) animals; or
- (C) plants; or
- (D) fungi;
- (ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host or vector to cause harm;

Example

Donor nucleic acid would not comply with subparagraph (ii) if its characterisation shows that, in relation to the capacity of the host or vector to cause harm, it:

- (a) provides an advantage; or
- (b) adds a potential host species or mode of transmission; or
- (c) increases its virulence, pathogenicity or transmissibility; and
- (b) must not code for a toxin with an LD₅₀ of less than 100 µg/kg; and
- (c) must not code for a toxin 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 nucleic acid from a toxin-producing organism; and
- (e) must not include a viral sequence, unless the donor nucleic 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; and
- (B) will not become available during the dealing; and
- (ii) cannot restore replication competence to the vector.
- 5 A 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.

3 Circle the host/vector system that will be used

Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	<i>Escherichia coli</i> K12, <i>E. coli</i> B, <i>E. coli</i> C or <i>E. coli</i> Nissle 1917 or any derivative that does not contain:	1. Non-conjugative plasmids 2. Bacteriophage
		(a) generalised transducing phages; or	(a) lambda (b) lambdoid (c) Fd or F1 (eg M13)
		(b) genes able to complement the conjugation defect in a non-conjugative plasmid	3. None (non-vector systems)

<i>Bacillus</i> — specified species — asporogenic strains with a reversion frequency of less than 10^{-7} :	<ol style="list-style-type: none"> 1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include <i>B. cereus</i>, <i>B. anthracis</i> or any other pathogenic strain of <i>Bacillus</i> 3. None (non-vector systems)
(a) <i>B. amyloliquefaciens</i>	
(b) <i>B. licheniformis</i>	
(c) <i>B. pumilus</i>	
(d) <i>B. subtilis</i>	
(e) <i>B. thuringiensis</i>	
<i>Pseudomonas putida</i> — strain KT 2440	<ol style="list-style-type: none"> 1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2. None (non-vector systems)
<i>Streptomyces</i> — specified species:	<ol style="list-style-type: none"> 1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. None (non-vector systems)
(a) <i>S. aureofaciens</i>	
(b) <i>S. coelicolor</i>	
(c) <i>S. cyaneus</i>	
(d) <i>S. griseus</i>	
(e) <i>S. lividans</i>	
(f) <i>S. parvulus</i>	
(g) <i>S. rimosus</i>	
(h) <i>S. venezuelae</i>	
<i>Agrobacterium radiobacter</i>	<ol style="list-style-type: none"> 1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. None (non-vector systems)
<i>Agrobacterium rhizogenes</i> — disarmed strains	
<i>Agrobacterium tumefaciens</i> — disarmed strains	
<i>Lactobacillus</i>	<ol style="list-style-type: none"> 1. Non-conjugative plasmids
<i>Lactococcus lactis</i>	<ol style="list-style-type: none"> 2. None (non-vector systems)
<i>Oenococcus oeni</i> syn.	
<i>Leuconostoc oeni</i>	
<i>Pediococcus</i>	
<i>Photobacterium angustum</i>	
<i>Pseudoalteromonas tunicata</i>	
<i>Rhizobium</i> (including the genus <i>Allorhizobium</i>)	
<i>Sphingopyxis alaskensis</i> syn.	
<i>Sphingomonas alaskensis</i>	
<i>Streptococcus thermophilus</i>	
<i>Synechococcus</i> — specified strains:	
(a) PCC 7002	
(b) PCC 7942	
(c) WH 8102	
<i>Synechocystis</i> species — strain PCC 6803	
<i>Vibrio cholerae</i> CVD103-HgR	

2	Fungi	<p><i>Kluyveromyces lactis</i></p> <p><i>Neurospora crassa</i> — laboratory strains</p> <p><i>Pichia pastoris</i></p> <p><i>Saccharomyces cerevisiae</i></p> <p><i>Schizosaccharomyces pombe</i></p> <p><i>Trichoderma reesei</i></p> <p><i>Yarrowia lipolytica</i></p>	<ol style="list-style-type: none"> 1. All vectors 2. None (non-vector systems)
3	Slime moulds	<p><i>Dictyostelium</i> species</p>	<ol style="list-style-type: none"> 1. <i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. None (non-vector systems)
4	Tissue culture	<p>Any of the following if they cannot spontaneously generate a whole animal:</p> <p>(a) animal or human cell cultures (including packaging cell lines);</p> <p>(b) isolated cells, isolated tissues or isolated organs, whether animal or human;</p> <p>(c) early non-human mammalian embryos cultured <i>in vitro</i></p> <p>Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant:</p> <p>(a) plant cell cultures;</p> <p>(b) isolated plant tissues or organs</p>	<ol style="list-style-type: none"> 1. Non-conjugative plasmids 2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells 3. Baculovirus (<i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems) <ol style="list-style-type: none"> 1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in <i>Agrobacterium tumefaciens</i>, <i>Agrobacterium radiobacter</i> or <i>Agrobacterium rhizogenes</i> 2. Non-pathogenic viral vectors 3. None (non-vector systems)
