APPLICATION FOR AN EXEMPT DEALING

Please attach Risk Assessments, plasmid maps and / or manuals pertinent to the GMO for which you are making application to the IBC.

1. **Project Title**

2. **Project Supervisor**

School:

Building and Room No.:

Phone:

Email:

3. **Project Dates** (please note a project must not begin before the IBC has given approval)

Commencement Date:

Finishing Date:

4. **Exemption Category** (please mark applicable category with an x)

**refer to table at end of this form for the detailed description of each category.*

1-2	Dealing with a genetically modified *Caenorhabditis elegans*	
1-3	Dealing with an animal into which genetically modified somatic cells have been introduced	
1-3A	Dealing with an animal whose somatic cells have been genetically modified in vivo by a replication defective viral vector	

1-4	Dealing involving a host / vector system	☐
	HOST / VECTOR DETAILS Item: Class: Host: Vector:	
1-5	Dealing involving a shotgun cloning OR the preparation of a cDNA library, in a host / vector system	☐

4.1 Modified trait(s) – class and details

4.2 Details of recombinant DNA, including vector

including brief summary of procedures if relevant.

5. PC Level:

6. Facilities to be used

Facility Name:

Building No.

Room No.

Facility Manager:

Name:

Signature: Date:

Facility Manager (Animal Holding Facility if applicable)

Name:

Signature: Date:

7. Method of Waste Disposal:

8. Principal Investigator:

Name:

Signature Date:

9. IBC Approval:

Name:

Signature: Date:

*Categories of Dealings Exempt from Licensing under the Gene Technology Regulations 2001, effective from 1 September 2011

PART 1 EXEMPT DEALINGS

Item	Description of dealing
1-2	A 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.
1-3	A 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 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.
1-3A	A dealing with an animal whose somatic cells have been genetically modified *in vivo* by a replication defective viral vector, if a. the *in vivo* 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
1-4	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;
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 LD_{50} of less than 100 microg/kg; and
c. must not code for a toxin with an LD_{50} of 100 microg/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.

1-5 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

PART 2 HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

Item	Class	Host	Vector
2-1	Bacteria	*Escherichia coli* K12, *E. coli* B , *E. coli* C or *E. coli* Nissle 1917 — any derivative that does not contain: a. generalised transducing phages; or b. genes able to complement the conjugation defect in a non-conjugative plasmid	1. Non-conjugative plasmids 2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) 3. None (non-vector systems)
		Bacillus — specified species — asporogenic strains with a reversion frequency of less than 10^{-7}: a. *B. amyloliquefaciens* b. *B. licheniformis* c. *B. pumilus* d. *B. subtilis* e. *B. thuringiensis*	1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus* 3. None (non-vector systems)

Item	Class	Host	Vector
		Pseudomonas putida — strain KT 2440	1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 2. None (non-vector systems
		Streptomyces — specified species: a. *S. aureofaciens* b. *S. coelicolor* c. *S. cyaneus* d. *S. griseus* e. *S. lividans* f. *S. parvulus* g. *S. rimosus* h. *S. venezuelae*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. None (non-vector systems)
		Agrobacterium radiobacter *Agrobacterium rhizogenes* — disarmed strains *Agrobacterium tumefaciens* — disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. None (non-vector systems)
		Lactobacillus *Lactococcus lactis* *Oenococcus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicata* *Rhizobium* (including the genus *Allorhizobium*) *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Streptococcus thermophilus* *Synechococcus* — specified strains: (a) PCC 7002 (b) PCC 7942 (c) WH 8102 *Synechocystis* species — strain PCC 6803 *Vibrio cholerae* CVD103-HgR	1. Non-conjugative plasmids 2. None (non-vector systems)
2-2	Fungi	*Kluyveromyces lactis* *Neurospora crassa* — laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei* *Yarrowia lipolytica*	1. All vectors 2. None (non-vector systems)
2-3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. None (non-vector systems)

Item	Class	Host	Vector
2-4	Tissue culture	Any of the following if they cannot spontaneously generate a whole animal: a. animal or human cell cultures (including packaging cell lines); b. isolated cells, isolated tissues or isolated organs, whether animal or human; c. early non-human mammalian embryos cultured *in vitro*	1. Non-conjugative plasmids 2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells 3. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 4. None (non-vector systems)
		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: a. plant cell cultures; b. isolated plant tissues or organs	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens*, *Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. None (non-vector systems)