

# APPLICATION FOR GMO DEALING

Gene Technology Regulations 2001 effective 1 September 2011

University of Tasmania Institutional Biosafety Committee



This application form should be completed for all Exempt and Notifiable Low Risk category GMO dealings to be undertaken by University Personnel or to be undertaken by other personnel within University premises.

**Note: Please complete this form using Adobe Acrobat rather than Preview on Mac devices.**

Notifying Organisation Name: The University of Tasmania

Accreditation Number: ACCR 051

Completed forms should be submitted to: [biorisk.management@utas.edu.au](mailto:biorisk.management@utas.edu.au)

**NOTE: Confidentiality**

If you wish to make an application for a declaration that specifies information is Confidential Commercial Information (CCI) for the purposes of the Act, you must also complete the CCI application form available at [www.ogtr.gov.au](http://www.ogtr.gov.au) and place it at the end of this application.

|          |               |
|----------|---------------|
| <b>1</b> | Project title |
|          |               |

|  |   |
|--|---|
| <b>2</b>   | Type of dealing   |
| Refer to <a href="#">Schedule 2</a> and <a href="#">Schedule 3</a> of the <i>Gene Technology Regulations 2001</i> to determine the correct type(s) of dealing. Indicate all that apply.  |   |
| Exempt Dealing   | Requires completion of Tables A and D   |
| Notifiable Low Risk Dealing – PC1  | Requires completion of Table B. Table D also required for PC1.1(c) dealings                                 |
| Notifiable Low Risk Dealing – PC2  | Requires completion of Table C. Table D also required for PC2.1(d), (e), (f), (h), (i), (j) or (l) dealings |
| <b>NOTE: A dealing is <u>not</u> a Notifiable Low Risk Dealing if it:</b><br><i>a. Is also a dealing of a kind mentioned in <a href="#">Part 3 of Schedule 3</a>; or</i><br><i>b. Involves an intentional release of the GMO into the environment.</i><br><b>A dealing that is <u>not</u> an Exempt Dealing or Notifiable Low Risk Dealing must be authorised under an OGTR license. Contact the <a href="#">Biosafety and Biosecurity Officer</a> for more information.</b> |   |

|  |                                |
|--|--------------------------------|
| <b>3</b>   | Person responsible for dealing |
| Project supervisor   |                                |
| Email address  |                                |
| Telephone  |                                |
| School/Institute/College   |                                |
| Has the project supervisor previously submitted a GMO dealing application to this IBC?                           | Yes      No                    |
| If no, please attach a one-page resume outlining relevant experience and qualifications in relation to GMO work. |                                |
| Alternate Contact  |                                |
| Email address  |                                |
| Telephone  |                                |
| School/Institute   |                                |

| 4  | About the dealing |    |
|--|-------------------|----|
| Does this dealing replace an existing dealing?                             | Yes               | No |
| If yes, provide dealing ID number  |                   |    |
| Proposed commencement date   |                   |    |
| Expected completion date<br>(Note: maximum 5 years from commencement date) |                   |    |

| 5   | Activities involved in the dealing   |  |
|---|--|--|
| <p><b>Only dealings that are listed on an authorisation can be undertaken. Therefore, please 'un-check' from the list of dealings any that you specifically know will definitely <u>not</u> be undertaken.</b></p>  |  |  |
| <p><b>NOTE:</b> A dealing includes the possession, supply or use of the GMO, for the purpose of, or in the course of, a dealing mentioned in any of the paragraphs listed.</p>  | Conduct experiments with the GMO   |  |
|   | Make, develop, produce or manufacture the GMO  |  |
|   | Breed the GMO  |  |
|   | Propagate the GMO  |  |
|   | Grow, raise or culture the GMO   |  |
|   | Transport the GMO  |  |
|   | Dispose of the GMO   |  |
|   | Store the GMO  |  |
|   | Use the GMO in the course of manufacture of a thing* that is not the GMO.  |  |
|   | <p>A thing may be a substance (e.g. a protein) or an object in electronic or magnetic form.</p> <p><i>If yes, complete the following details:</i></p> <p>Is the thing* subject to regulation by other agencies (e.g. Food Standards Australia, Australian Pesticides and Veterinary Medicines Association, Therapeutic Goods Administration, Biosecurity Tasmania)?</p> <p style="text-align: center;">Yes            <b>Agency</b><br/>No</p> <p><i>*As defined in the Gene Technology Act 2000</i></p> |  |
| Import the GMO  |  |  |
| <p><i>If yes, complete the following details</i></p> <p>Does the material require an import permit from the Department of Agriculture and Water Resources or Biosecurity Tasmania? For further information, check the <a href="#">BICON</a> or <a href="#">TBIRD</a> system, or contact the <a href="#">Biosafety and Biosecurity Officer</a>.</p> <p style="text-align: center;">Yes            No</p> <p>Do you have a valid Import Permit or have you submitted an Import Permit application for the GMO?</p> <p style="text-align: center;">Yes            No</p> |  |  |

**Description of work (*a brief statement in lay terms*).**

Please include the aims of the proposed dealing, method of producing GMOs and how they will be used. Please ensure the information provided, including the description, accurately includes all aspects of the dealing.

If more than one type of dealing is included on this application, please ensure that the work associated with each dealing type is clearly identified and outlined.

Please ensure that details of storage and transport – including importation under a Department of Agriculture Biosecurity import permit – are included as these aspects of a dealing also require approval.

**Expected impact and benefits of the work (*a brief statement in lay terms*)**

| 7 Description of the Dealing – Host organism(s) and source(s) of genetic material |   |   |  |   |   |   |
|---|---|---|--|---|---|---|
| Common name of host organism  | Scientific name and strain of host organism                 | Vector(s) and method of transfer  | Exempt host/vector system?   | Identity and function of genetic material & organism of origin                                    | Organisms or tissues (if any) to be used with the GMO(s) and method of exposure | Dealing Type  |
| <i>e.g. Zebrafish, mouse, E.coli</i>  | <i>e.g. Danio rerio, Mus musculus, Escherichia coli K12</i> | <i>e.g. plasmid microinjected into embryos, standard non-conjugative plasmid expression vector by electroporation</i> | <i>Yes or No – refer <a href="#">Part 2, Schedule 2 of Gene Technology Regulations</a></i> | <i>e.g. expression of green fluorescent protein, expression of insulin gene from Homo sapiens</i> | <i>e.g. infect mouse tissue by microinjection</i>                               | <i>e.g. PC2(d) – refer to <a href="#">Schedule 2</a> and <a href="#">Schedule 3</a></i> |

**NOTE: IBC Assessors are from a range of University disciplines and require adequate detail to understand what your specific dealing(s) will involve.**

This section covers Part 1 of [Schedule 2 of the Gene Technology Regulations 2001](#) and describes the type of dealings with GMOs which are classified as Exempt Dealings.

A dealing is an Exempt Dealing if it:

- is a kind mentioned in this table; and
- does not involve a genetic modification other than a modification described; and
- does not involve an intentional release of the GMO into the environment; and
- does not involve a retroviral vector that is able to transduce human cells.

**NOTE:** Please ensure the host/vector system is selected in Table D if an Exempt Dealing under Item 4 or 5 is selected below

| Select all that apply | Item | Description of dealing   |
|-----------------------|------|--|
|                       | 2    | A dealing with a genetically modified <i>Caenorhabditis elegans</i> , unless: <ol style="list-style-type: none"> <li>(a) an advantage is conferred on the animal by the genetic modification; or</li> <li>(b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.</li> </ol>   |
|                       | 3    | A dealing with an animal into which genetically modified somatic cells have been introduced, if: <ol style="list-style-type: none"> <li>(a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and</li> <li>(b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.</li> </ol>   |
|                       | 3A   | A dealing with an animal whose somatic cells have been genetically modified <i>in vivo</i> by a replication defective viral vector, if: <ol style="list-style-type: none"> <li>(a) the <i>in vivo</i> modification occurred as part of a previous dealing; and</li> <li>(b) the replication defective viral vector is no longer in the animal; and</li> <li>(c) no germ line cells have been genetically modified; and</li> <li>(d) the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and</li> <li>(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.</li> </ol>   |
|                       | 4    | <ol style="list-style-type: none"> <li>(1) Subject to subitem (2) below, a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing no more than 25 litres of GMO culture in each vessel containing the resultant culture.</li> <li>(2) The donor nucleic acid:               <ol style="list-style-type: none"> <li>(a) must satisfy either of the following requirements:                   <ol style="list-style-type: none"> <li>(i) it must not be derived from organisms implicated in, or with a history of causing, disease in (A) human beings, (B) animals, (C) plants or (D) fungi; or</li> <li>(ii) it must be characterised and the information derived from its characterisation show that it is unlikely to increase the capacity of the host vector to cause harm;</li> </ol> </li> <li>(b) must not code for a toxin with an LD50 of less than 100 µg/kg; and</li> <li>(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</li> <li>(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and</li> <li>(e) if the donor nucleic acid includes a viral sequence - cannot give rise to infectious agents when introduced into any potential host species, without additional non-host genes or gene products that:                   <ol style="list-style-type: none"> <li>(i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and</li> <li>(ii) will not become available during the dealing; and</li> </ol> </li> <li>(f) If the donor nucleic acid includes a viral sequence - cannot restore replication competence to the vector.</li> </ol> </li> </ol> |
|                       | 5    | A dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1-6 of the table in Part 2 of Schedule 2, if the donor nucleic acid is not derived from either: <ol style="list-style-type: none"> <li>(a) a pathogen; or</li> <li>(b) a toxin-producing organism.</li> </ol>   |

|          |  |
|----------|--|
| <b>B</b> | <b>Notifiable Low Risk Dealing – PC1</b> |
|----------|--|

This section covers Part 1 of [Schedule 3 of the Gene Technology Regulations 2001](#). These dealings must be conducted in a certified PC1 (or higher) containment facility.

| Select all that apply | Item   | Description of dealing   |
|-----------------------|--------|--|
|                       | 1.1(a) | a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit or a genetically modified laboratory rat, unless: <ul style="list-style-type: none"> <li>(i) an advantage is conferred on the animal by the genetic modification; or</li> <li>(ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification;</li> </ul> |
|                       | 1.1(c) | a dealing involving virions of a replication defective vector derived from <i>Human adenovirus</i> or <i>Adeno associated virus</i> , either without a host or in a host mentioned in item 9 of Part 2 of Schedule 2, if the donor nucleic acid: <ul style="list-style-type: none"> <li>(i) cannot restore replication competence to the vector; and</li> <li>(ii) does not confer an oncogenic modification or immunomodulatory effect in humans.</li> </ul>  |

|          |  |
|----------|--|
| <b>C</b> | <b>Notifiable Low Risk Dealing – PC2</b> |
|----------|--|

This section covers Part 2 of [Schedule 3 of the Gene Technology Regulations 2001](#). These dealings must be conducted in a certified PC2 containment facility.

**NOTE:** There are no certified PC3 or PC4 facilities in Tasmania. Dealings involving [Risk Group 3 or 4 organisms](#) are not permitted under any circumstances.

| Select all that apply | Item    | Description of dealing  |
|-----------------------|---------|---|
|                       | 2.1(a)  | a dealing involving whole animals (including non-vertebrates) that: <ul style="list-style-type: none"> <li>(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and</li> <li>(ii) does not involve any of the following: <ul style="list-style-type: none"> <li>(A) a genetically modified laboratory guinea pig;</li> <li>(B) a genetically modified laboratory mouse;</li> <li>(C) a genetically modified laboratory rabbit;</li> <li>(D) a genetically modified laboratory rat;</li> <li>(E) a genetically modified <i>Caenorhabditis elegans</i>;</li> </ul> </li> </ul> |
|                       | 2.1(aa) | a dealing involving a genetically modified laboratory guinea pig, a genetically modified laboratory mouse, a genetically modified laboratory rabbit, a genetically modified laboratory rat, or a genetically modified <i>Caenorhabditis elegans</i> if: <ul style="list-style-type: none"> <li>(i) the genetic modification confers an advantage on the animal; and</li> <li>(ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;</li> </ul>   |
|                       | 2.1(b)  | a dealing involving a genetically modified plant  |
|                       | 2.1(c)  | a dealing involving a host/vector system that are not mentioned as a host/vector system in Part 2 of Schedule 2, if neither the host or vector has been implicated in, or had a history of causing, disease in otherwise healthy human beings, animals, plants or fungi;  |
|                       | 2.1(d)  | a dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if: <ul style="list-style-type: none"> <li>(i) the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy human beings, animals, plants or fungi; and</li> <li>(ii) the genetic modification is characterised;</li> <li>(iii) the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;</li> </ul>   |
|                       | 2.1(e)  | a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid: <ul style="list-style-type: none"> <li>(i) is characterised, and the characterisation shows that it may increase the capacity of the host/vector to cause harm; or</li> <li>(ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy human beings, animals, plants or fungi;</li> </ul>  |

|  |         |  |
|--|---------|--|
|  | 2.1(f)  | a dealing involving a host/vector system mentioned in Part 2 of Schedule 2 and producing more than 25 litres of GMO culture in each vessel containing the resultant culture, if:<br>(i) the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility; and<br>(ii) the donor nucleic acid satisfies the conditions set out in subitem 4 (2) of Part 1 of Schedule 2;  |
|  | 2.1(g)  | a dealing involving complementation of knocked-out genes, if the complementation is unlikely to increase the capacity of the GMO to cause harm compared to the capacity of the parent organism before the genes were knocked out;  |
|  | 2.1(h)  | a dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in Items 1-6 of Part 2 of Schedule 2, if the donor nucleic acid is derived from either:<br>(i) a pathogen; or<br>(ii) a toxin-producing organism;  |
|  | 2.1(i)  | a dealing involving virions of a replication defective viral vector unable to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector;   |
|  | 2.1 (j) | A dealing involving virions of a replication defective non-retroviral vector able to transduce human cells, other than a dealing mentioned in paragraph 1.1 (c), either without a host or into a host mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore competence to the vector;  |
|  | 2.1 (k) | A dealing involving virions of a replication defective non-retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if:<br>(i) the donor nucleic acid cannot restore replication competence to the vector; and<br>(ii) the donor nucleic acid does not:<br>(A) confer an oncogenic modification in humans; or<br>(B) confer an immunomodulatory effect in humans;  |
|  | 2.1 (l) | A dealing involving virions of a replication defective retroviral vector able to transduce human cells either without a host or into a host mentioned in Part 2 of Schedule 2, if:<br>(i) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble into a virion without these functions being supplied <i>in trans</i> ; and<br>(ii) viral genes needed for virion production in the packaging cell lines are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and<br>(iii) either:<br>(A) the retroviral vector includes a deletion in the Long Term Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or<br>(B) the packaging cell line and packaging plasmids express only viral genes <i>gagpol</i> , <i>rev</i> and an envelope protein gene, or a subset of these;  |
|  | 2.1 (m) | A dealing involving virions of a replication defective retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:<br>(i) the donor nucleic acids does not:<br>(A) confer an oncogenic modification or immunomodulatory effect in humans; and<br>(ii) all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied <i>in trans</i> ; and<br>(iii) viral genes needed for virion production in the packaging cell line are expressed from independent, unlinked loci with minimal sequence overlap with the vector to limit or prevent recombination; and<br>(iv) either:<br>(A) the retroviral vector includes a deletion in the Long Terminal Repeat sequence of DNA that prevents transcription of genomic RNA following integration into the host cell DNA; or<br>(B) the packaging cell line and packaging plasmids express only viral genes <i>gagpol</i> , <i>rev</i> and an envelope protein gene, or a subset of these. |

## D

## Details of Host/vector systems

This table covers the host/vector systems listed in Part 2 of [Schedule 2 of the Gene Technology Regulations 2001](#).

This section **must** be completed for the following application classes:

- Exempt Dealing applications under Items 4 or 5
- PC1.1(c)
- PC2.1(d), (e), (f), (h), (i), (j) or (l)

| Item   | Class    | Host (Select all that apply)  | Vector (Select all that apply)   |
|--|----------|---|--|
| 1  | Bacteria | <input type="checkbox"/> <i>Escherichia coli</i> K12, <i>E. coli</i> B or <i>E. coli</i> C or <i>E. coli</i> Nissle 1917 – any derivative that does not contain:<br>(a) generalised transducing phages; or<br>(b) genes able to complement the conjugation defect in a non-conjugative plasmid  | <input type="checkbox"/> 1. Non-conjugative plasmids<br>2. Bacteriophage<br><input type="checkbox"/> (a) lambda<br><input type="checkbox"/> (b) lambdoid<br><input type="checkbox"/> (c) Fd or F1 (eg M13)<br><input type="checkbox"/> 3. None (non-vector systems)  |
|  |          | <i>Bacillus</i> – specified species – asporogenic strains with a reversion frequency of less than 10 <sup>-7</sup> :<br><input type="checkbox"/> (a) <i>B. amyloliquefaciens</i><br><input type="checkbox"/> (b) <i>B. licheniformis</i><br><input type="checkbox"/> (c) <i>B. pumilus</i><br><input type="checkbox"/> (d) <i>B. subtilis</i><br><input type="checkbox"/> (e) <i>B. thuringiensis</i>   | <input type="checkbox"/> 1. Non-conjugative plasmids<br><input type="checkbox"/> 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><br><input type="checkbox"/> 3. None (non-vector systems)  |
|  |          | <input type="checkbox"/> <i>Pseudomonas putida</i> – strain KT 2440   | <input type="checkbox"/> 1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264<br><input type="checkbox"/> 2. None (non-vector systems)  |
|  |          | <i>Streptomyces</i> – specified species:<br><input type="checkbox"/> (a) <i>S. aureofaciens</i><br><input type="checkbox"/> (b) <i>S. coelicolor</i><br><input type="checkbox"/> (c) <i>S. cyaneus</i><br><input type="checkbox"/> (d) <i>S. griseus</i><br><input type="checkbox"/> (e) <i>S. lividans</i><br><input type="checkbox"/> (f) <i>S. parvulus</i><br><input type="checkbox"/> (g) <i>S. rimosus</i><br><input type="checkbox"/> (h) <i>S. venezuelae</i> | <input type="checkbox"/> 1. Non-conjugative plasmids<br>2. Certified plasmids:<br><input type="checkbox"/> SCP2<br><input type="checkbox"/> SLP1<br><input type="checkbox"/> SLP2<br><input type="checkbox"/> PIJ101 and derivatives<br><input type="checkbox"/> 3. Actinophage phi C31 and derivatives<br><input type="checkbox"/> 4. None (non-vector systems) |
|  |          | <input type="checkbox"/> <i>Agrobacterium radiobacter</i>   | <input type="checkbox"/> 1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors<br><input type="checkbox"/> 2. None (non-vector systems)  |
|  |          | <input type="checkbox"/> <i>Agrobacterium rhizogenes</i> – disarmed strains   |  |
|  |          | <input type="checkbox"/> <i>Agrobacterium tumefaciens</i> – disarmed strains  |  |
|  |          | <input type="checkbox"/> <i>Lactobacillus</i><br><input type="checkbox"/> <i>Lactococcus lactis</i>   | <input type="checkbox"/> 1. Non-conjugative plasmids<br><input type="checkbox"/> 2. None (non-vector systems)  |
|  |          | <input type="checkbox"/> <i>Oenococcus oeni</i> syn. <i>Leuconostoc oeni</i>  |  |
|  |          | <input type="checkbox"/> <i>Pediococcus</i>   |  |
|  |          | <input type="checkbox"/> <i>Photobacterium angustum</i>   |  |
|  |          | <input type="checkbox"/> <i>Pseudoalteromonas tunicata</i>  |  |
|  |          | <input type="checkbox"/> <i>Rhizobium</i> (including the genus <i>Allorhizobium</i> )   |  |
|  |          | <input type="checkbox"/> <i>Sphingopyxis alaskensis</i> syn. <i>Sphingomonas alaskensis</i>   |  |
| <input type="checkbox"/> <i>Streptococcus thermophilus</i> <i>Synechococcus</i> – specified strains:<br><input type="checkbox"/> PCC 7002<br><input type="checkbox"/> PCC 7942<br><input type="checkbox"/> WH 8102 |          |   |  |
| <input type="checkbox"/> <i>Synechocystis</i> species – PCC 6803   |          |   |  |
| <input type="checkbox"/> <i>Vibrio cholerae</i> CVD103-HgR   |          |   |  |

## D

## Details of Host/vector systems

This table covers the host/vector systems listed in Part 2 of [Schedule 2 of the Gene Technology Regulations 2001](#).

This section **must** be completed for the following application classes:

- Exempt Dealing applications under Items 4 or 5
- PC1.1(c)
- PC2.1(d), (e), (f), (h), (i), (j) or (l)

| Item | Class          | Host (Select all that apply)   | Vector (Select all that apply)  |
|------|----------------|--|---|
| 2    | Fungi          | <input type="checkbox"/> <i>Neurospora crassa</i> – lab strains  | <input type="checkbox"/> 1. All vectors<br><input type="checkbox"/> 2. None (non-vector systems)  |
|      |                | <input type="checkbox"/> <i>Pichia pastoris</i>  |   |
|      |                | <input type="checkbox"/> <i>Saccharomyces cerevisiae</i>   |   |
|      |                | <input type="checkbox"/> <i>Schizosaccharomyces pombe</i>  |   |
|      |                | <input type="checkbox"/> <i>Kluyveromyces lactis</i>   |   |
|      |                | <input type="checkbox"/> <i>Trichoderma reesei</i>   |   |
|      |                | <input type="checkbox"/> <i>Yarrowia lipolytica</i>  |   |
| 3    | Slime moulds   | <input type="checkbox"/> <i>Dictyostelium</i> species  | <input type="checkbox"/> 1. <i>Dictyostelium</i> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2<br><input type="checkbox"/> 2. None (non-vector systems)   |
| 4    | Tissue culture | <input type="checkbox"/> Animal or human cell cultures (including packaging cell lines)                | <input type="checkbox"/> 1. Plasmids<br><input type="checkbox"/> 2. Non-viral vectors, or defective viral vectors unable to transduce human cells<br><input type="checkbox"/> 3. <i>Baculovirus</i> ( <i>Autographa californica</i> nuclear polyhedrosis virus), polyhedrin minus<br><input type="checkbox"/> 4. None (non-vector systems)  |
|      |                | <input type="checkbox"/> Isolated cells, isolated tissues or isolated organs, whether animal or human; |   |
|      |                | <input type="checkbox"/> early non-human mammalian embryos cultured <i>in vitro</i>                    |   |
|      |                | <input type="checkbox"/> Plant cell cultures   | 1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in<br><input type="checkbox"/> <i>Agrobacterium tumefaciens</i> ,<br><input type="checkbox"/> <i>Agrobacterium radiobacter</i> or<br><input type="checkbox"/> <i>Agrobacterium rhizogenes</i><br><input type="checkbox"/> 2. Non-pathogenic viral vectors<br><input type="checkbox"/> 3. None (non-vector systems) |
|      |                | <input type="checkbox"/> isolated plant tissues or organs  |   |

| 8                     | Modified trait(s) and gene(s) responsible |         |
|-----------------------|---|---------|
| Select all that apply | Class of modified trait                   | Details |
|                       | Virus resistance                          |         |
|                       | Fungal resistance                         |         |
|                       | Bacterial resistance                      |         |
|                       | Disease resistance                        |         |
|                       | Pest resistance                           |         |
|                       | Herbicide tolerance                       |         |
|                       | Antibiotic resistance                     |         |
|                       | Pesticide resistance                      |         |
|                       | Abiotic stress resistance                 |         |
|                       | Altered agronomic characteristics         |         |
|                       | Altered horticultural characteristics     |         |
|                       | Altered nutritional characteristics       |         |
|                       | Altered physical product characteristics  |         |
|                       | Altered physiological characteristics     |         |
|                       | Altered pharmaceutical characteristics    |         |
|                       | Attenuation                               |         |
|                       | Antigen expression                        |         |
|                       | Protein expression                        |         |
|                       | Growth factor expression                  |         |
|                       | Altered biosensor characteristics         |         |
|                       | Altered bioremediation characteristics    |         |
|                       | Altered biocontrol characteristics        |         |
|                       | Reporter/marker gene expression           |         |
|                       | Immuno-modulatory protein expression      |         |
|                       | Other                                     |         |

All facilities to be used, including places of storage must be authorised. For PC2 NLRDs, storage of GMOs outside of a certified PC2 facility must be authorised by the IBC. Unauthorised storage of GMOs is an offence under the Act.

|   | Facility 1 | Facility 2 | Facility 3 | Facility 4 |
|---|------------|------------|------------|------------|
| OGTR Certification No.  |            |            |            |            |
| Room Name/Number(s)   |            |            |            |            |
| Building/Campus   |            |            |            |            |
| Type of facility  |            |            |            |            |
| Facility Contact  |            |            |            |            |
| Experiments/aspects of dealing to be performed in this facility |            |            |            |            |

**Will the dealing involve storage of GMOs outside of a facility listed above?**

GMOs may be stored outside a certified facility provided that:

1. Transport to storage outside the facility must be in accordance with the [OGTR Guidelines for the Transport, Storage and Disposal of GMOs](#).
2. GMOs or organisms containing GMOs may be stored outside the facility in a storage unit (freezer, fridge, controlled temperature room or other container). A biohazard symbol must be displayed on the storage unit. Access to the storage unit must be restricted or controlled to prevent unintentional release of GMOs into the environment (ie: The storage unit must be locked when not in use). GMOs or organisms containing GMOs being stored outside the facility must be double contained
3. The primary container must be sealed to prevent the escape or release of the GMOs and must be labelled. The primary container must be stored in an unbreakable secondary container. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.
4. Records must be kept of all NLRD category material in storage.

Yes      No

If yes, where?

**Do you propose to transport the GMO(s) outside a certified facility? If yes, how will the GMOs be transported?**

This includes transport of rodents between CFF and MSP. Include details of transportation method and container type.

**What are the possible hazard(s) to human health and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from the proposed genetic modification(s)?**

**What are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from an unintentional release of the GMOs into the environment?**

**How will the GMO(s) be disposed of?**

**In the event of an unintentional release of the GMO, what steps will you take to remedy the situation?**

*Eg. In the event that a GMO is unintentionally released into the environment, the Project Supervisor will be immediately contacted, and he/she will inform the animal welfare officer and the IBC. Every effort will be made to locate and retrieve the GMO.*

The IBC must assess whether the persons or categories of persons have appropriate training and experience to undertake the dealing. This includes persons beyond those conducting the research, such as persons involved in importation, transportation and disposal of GMOs.

|   |  |                                   |                        |
|---|--|-----------------------------------|------------------------|
| <p>Indicate the categories of persons that will be involved with the dealing. For each relevant category, list the name and staff/student ID for persons known at the time of application</p> <p><i>Details of additional persons can be added in each Annual Report as they become associated with the dealing(s).</i></p> | <input type="checkbox"/>                                       | Honours or undergraduate students | Name, student ID       |
|   | <input type="checkbox"/>                                       | Postgraduate students             | Name, student ID       |
|   | <input type="checkbox"/>                                       | Research staff                    | Name, staff ID         |
|   | <input type="checkbox"/>                                       | Other Persons                     | Name, staff/student ID |
| Do all personnel involved in the dealing have appropriate training and experience?  | <p style="text-align: center;">Yes                      No</p> |                                   |                        |

If yes, details of training must be provided to the Facility Manager prior to commencement of the dealing.

If no, what measures are in place to ensure all personnel are adequately trained before commencing the dealing?

**NOTE:** All personnel working in an OGTR certified facility must be trained in the OGTR requirements of the [Physical Containment Facility Guidelines](#), irrespective of whether they are working with GMOs. Personnel must indicate to the Facility Manager that they fully understand their training in the OGTR requirements by signing a record of their training.

| 12 Project Supervisor Declaration  |                                     |             |
|--|-------------------------------------|-------------|
| <p><b>Please initial each of the following statements to indicate that you understand your responsibilities when dealing with GMOs and then sign the application form.</b></p>   |                                     |             |
| I have read, considered and understand my responsibilities under the <a href="http://www.ogtr.gov.au/">Gene Technology Act 2000</a> and agree to undertake the GMO dealing outlined in this application in accordance with the relevant OGTR guidelines and regulations (including, but not limited to all disposal, transport and storage).   |                                     |             |
| I am aware of my responsibilities in relation to ensuring that any personnel conducting this work must have the appropriate training and experience in procedures and equipment used. All persons involved in this dealing will be directly supervised by myself or another person competent in this dealing until they demonstrate their ability to follow relevant operating procedures, guidelines and regulations. |                                     |             |
| I have considered and assessed the potential risks that the conduct of this dealing could pose to people and/or the environment and will ensure all persons involved in this dealing have been notified of these risks and are familiar with the appropriate actions and precautions which should be implemented to minimise these risks.  |                                     |             |
| Where a GMO is received from sources outside the institution responsible for the project, I will take steps to confirm its identity.   |                                     |             |
| I confirm documented procedures are in place to decontaminate any spills involving GMOs inside or outside the nominated facilities. In the event of an unintentional release of GMOs I am aware that I must put into place the appropriate responses to contain the release and I will inform the IBC as soon as practicable of any incidents, accidents or unintentional releases involving GMOs.                     |                                     |             |
| I am aware that breaches of the legislation are serious matters and that penalties could include loss of OGTR Accreditation status for the organisation, imprisonment and/or substantial fines.  |                                     |             |
| <b>Project Supervisor Name</b>   | <b>Project Supervisor Signature</b> | <b>Date</b> |
|  |                                     |             |

| 13 Facility Manager Declaration   |  |             |
|---|--|-------------|
| <p><b>As Facility Manager I have been informed of the nature of and risks involved with this GMO dealing and after consideration of them, I hereby confirm the feasibility of the work being performed in the listed facility in a safe and compliant manner.</b></p> <p><b>I will ensure that the appropriate safety procedures are followed and that personnel are appropriately inducted and trained prior to undertaking work in the listed facility. In the event of an unintentional release of GMOs, I am aware that I must put into place the appropriate responses to contain the release and I will inform the IBC as soon as practicable of any incidents, accidents or unintentional releases involving GMOs.</b></p> |  |             |
| <b>Facility Manager Name - Facility 1</b>   | <b>Facility Manager Signature – Facility 1</b> | <b>Date</b> |
|   |  |             |
| <b>Facility Manager Name - Facility 2</b>   | <b>Facility Manager Signature – Facility 2</b> | <b>Date</b> |
|   |  |             |
| <b>Facility Manager Name - Facility 3</b>   | <b>Facility Manager Signature – Facility 3</b> | <b>Date</b> |
|   |  |             |
| <b>Facility Manager Name - Facility 4</b>   | <b>Facility Manager Signature – Facility 4</b> | <b>Date</b> |
|   |  |             |

| 14 Head of School/Director of Institute Declaration   |                                |             |
|---|--------------------------------|-------------|
| <p><b>As the Senior Manager responsible for the research activities of the Project Supervisor, I have been informed of the nature of and risks involved with this GMO dealing and after consideration of them, I hereby consent to the proposed activities.</b></p> |                                |             |
| <b>Head/Director Name</b>   | <b>Head/Director Signature</b> | <b>Date</b> |
|   |                                |             |

|           |  |
|-----------|--|
| <b>15</b> | <b>Comments for the University's IBC</b> |
|           |  |

|   |                  |  |
|---|------------------|--|
| <b>16</b>   | <b>Checklist</b> |  |
| <b>Please confirm all of the items below have been completed prior to submission of this application</b>  |                  |  |
| I have completed all sections of the application  |                  |  |
| The project duration (Section 4) does not exceed 5 years  |                  |  |
| I have consulted <a href="#">Schedules 1-3</a> of the <i>Gene Technology Regulations 2001</i> to determine the appropriate category of my application |                  |  |
| If my project involves viral vectors, I have consulted the <a href="#">viral vector flow chart</a> to categorise the application                      |                  |  |
| If GMOs are to be imported, I hold (or have applied for) a relevant import permit(s)  |                  |  |
| All participants in the proposed activity have read the OGTR <a href="#">Transport, Storage and Disposal Guidelines</a>                               |                  |  |
| All participants have undertaken relevant inductions for the facilities listed on the application   |                  |  |
| I have discussed the proposed activities with the relevant Facility Manager(s) to confirm feasibility and space availability                          |                  |  |
| I have listed the correct facilities (including OGTR certification numbers) on the application form   |                  |  |
| The application has been signed by the applicant, Facility Manager(s) and Head of School/Institute  |                  |  |

|                     |  |  |
|---------------------|--|--|
| <b>IBC use only</b> | <b>IBC Project Identifier</b>            |  |
|                     | <b>Date of Receipt</b>                   |  |
|                     | <b>Date of IBC Approval</b>              |  |
|                     | <b>Date of Notification to Applicant</b> |  |