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| **GMO DEALING APPLICATION**  as per Gene Technology Regulations 2001 effective 8 October 2020 | UoA_mono_horz |
| INSTITUTIONAL BIOSAFETY COMMITTEE |  |

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| This application form must be completed and submitted to the University of Adelaide IBC for all Exempt, Notifiable Low Risk (NLRD) or Licenced (DNIR) GMO dealings undertaken by University personnel or undertaken by personnel from other institutions who are working in University premises.  **INSTRUCTIONS**  Complete the P*reliminary information*, *Person responsible for dealing* and *Project title* sections, then complete the relevant sections for the type of GMO dealings you propose to undertake:   * Part A for exempt dealings (dealings exempt from licencing) * Part B for notifiable low risk dealings (NLRDs) * Part C for licenced dealings (DNIRs)   Then complete Part D, obtain all required signatures and submit completed forms in **an electronic** format to: [ibc@adelaide.edu.au](mailto:ibc@adelaide.edu.au). A Word document with electronic signature is preferred. |

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| NOTE: Confidentiality  If anything in this application form is confidential commercial information, contact [ibc@adelaide.edu.au](mailto:ibc@adelaide.edu.au) to obtain a sensitive-marked version of this application form. |

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| IBC use | IBC Dealing ID |  |

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| Preliminary information | | |
| **Institution responsible for dealing** This will be the primary employing institution of the Project Supervisor |  | |
| **Institutional Biosafety Committee** | The University of Adelaide Institutional Biosafety Committee | |
| **Is this dealing reviewed/authorised by another IBC?** | Yes  No If yes, complete following details | |
| **Other IBC name** |  |
| **Dealing ID allocated by other IBC** |  |
| **Does this application replace another approved dealing?** | Yes  No If yes, complete following details | |
| **IBC Dealing Identifier number or**  **OGTR NLRD Identifier number** |  |
| **Category of the dealing being replaced**  leave blank if this application does not replace another dealing | Exempt  PC1 NLRD  PC2 NLRD  PC3 NLRD  DNIR |
| **For dealings involving animals, enter the Animal Ethics Committee approval or application number** *(if known)* |  | |

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| Person responsible for dealing | |
| **Project supervisor name** |  |
| **Project Supervisor’s University ID** |  |
| **Primary Employing Institution of Project Supervisor (if not the University of Adelaide)** |  |
| **Email address** |  |
| **Telephone** |  |
| **School** |  |
| **Has the project supervisor previously submitted a GMO dealing application to this IBC?** | Yes  No If no, please provide a brief one page resume as an attachment outlining relevant experience and qualifications in relation to GMO work. |

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| Project title For notifiable low risk dealings (NLRDs) and licenced dealings, this title will be published in the [OGTR GMO Record](https://www.ogtr.gov.au/gmo-dealings), along with the dealing commencement date, and dealing type(s). |
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PART A: Dealings exempt from licensing *(Exempt dealings)*

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| A(i) | Type of exempt dealing | |
| 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 in this table; and * does not involve an intentional release of the GMO into the environment; | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 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. |
|  | 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. |
|  | 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. |
|  | 4 | **NOTE: ALSO COMPLETE SECTION A(ii)**  (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; and  *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.*  (b) must not code for a toxin with an LD50 of less than 100 micrograms per kilogram; and  (c) must not code for a toxin with an LD50 of 100 micrograms per kilogram 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) 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:  (i) are not available in the host cell into which the nucleic acid is introduced as part of the dealing; and  (ii) will not become available during the dealing; and  (f) if the donor nucleic acid includes a viral sequence—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 items 1 to 6 of the table in Part 2 of this Schedule, if the donor nucleic acid is not derived from either:  (a) a pathogen; or  (b) a toxin‑producing organism. |

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| A(ii) | Exempt [4] hosts and vectors - only complete this section if exempt [4] dealing is selected in Part A(i) | | |
| For Exempt [4] dealings only - select all hosts and vectors that apply ***from the list below*** | | | |
| Item | Host Class | Host (select all that apply) | Vectors (select all that apply) |
| 1 | Bacteria | *Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917—any derivative that does not contain:   * 1. generalised transducing phages; or   2. genes able to complement the conjugation defect in a non‑conjugative plasmid | non‑conjugative plasmids;  lambda bacteriophage;  lambdoid bacteriophage;  Fd, F1 or M13 bacteriophage |
| 2 | Bacteria | *Bacillus—*asporogenic strains of the following species with a reversion frequency of less than 10–7:  (a) *B. amyloliquefaciens*;  (b) *B. licheniformis*;  (c) *B. pumilus*;  (d) *B. subtilis*;  (e) *B. thuringiensis* | non‑conjugative plasmids;  other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis*or any other pathogenic strain of *Bacillus* |
| 3 | Bacteria | Pseudomonas putida strain KT2440 | Non‑conjugative plasmids |
| 4 | Bacteria | The following *Streptomyces* 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* | non‑conjugative plasmids;  plasmids SCP2, SLP1, SLP2, pIJ101 and derivatives;  actinophage phi C31 and derivatives |
| 5 | Bacteria | Any of the following:  (a) *Agrobacterium radiobacter*;  (b) *Agrobacterium rhizogenes* (disarmed strains only);  (c) *Agrobacterium tumefaciens* (disarmed strains only) | Disarmed Ri or Ti plasmids |
| 6 | Bacteria | Any of the following:  (a) *Allorhizobium*species;  (b) *Corynebacterium glutamicum*;  (c) *Lactobacillus*species;  (d) *Lactococcus lactis*;  (e) *Oenococcus oeni*syn. *Leuconostoc oeni*;  (f) *Pediococcus* species;  (g) *Photobacterium angustum*;  (h) *Pseudoalteromonas tunicata*;  (i) *Rhizobium*species;  (j) *Sphingopyxis alaskensis*syn. *Sphingomonas alaskensis*;  (k) *Streptococcus thermophilus*;  (l) *Synechococcus* species strains PCC 7002, PCC 7942 and WH 8102;  (m) *Synechocystis*species strain PCC 6803;  (n) *Vibrio cholerae*CVD103‑HgR;  (o) *Zymomonas mobilis* | Non‑conjugative plasmids |
| 7 | Fungi | Any of the following:  (a) *Kluyveromyces lactis*;  (b) *Neurospora crassa*(laboratory strains);  (c) *Pichia pastoris*;  (d) *Saccharomyces cerevisiae*;  (e) *Schizosaccharomyces pombe*;  (f) *Trichoderma reesei*;  (g) *Yarrowia lipolytica* | All vectors |
| 8 | Slime moulds | Dictyostelium species | *Dictyostelium*shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 |
| 9 | 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* | plasmids;  replication defective viral vectors unable to transduce human cells;  polyhedrin minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV) |
| 10 |  | 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 | Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes*(disarmed strains only) or *Agrobacterium tumefaciens*(disarmed strains only);  non‑pathogenic viral vectors |

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| A(iii) | Description of the GMOs and dealings |
| **Description of work** Please consult the OGTR [Guidelines for the Transport, Storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos) for guidance.  For storage - consider whether GMOs may be sent for long term storage in a biobank at the completion of the experiments. | |
| **Briefly explain what the exempt GMOs are, and the aims of the work:**    **How will the GMOs be created or obtained (including import, if applicable)?**    **Describe the proposed experiments with the GMOs and any material derived from the GMOs:**  **How and where will GMOs, and material derived from GMOs, be stored?**    **How do you propose to transport GMOs between approved facilities?**    **Describe the method of destruction and/or disposal of GMOs:**    **Will GMOs be exported overseas, or transported to another organization not listed in this application?** | |

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| **Description of the GMO(s) –** *Use one row for each host/vector/nucleic acid combination* | | |
| **Scientific name of parent organism(s) being genetically modified** E.g. Escherichia coli K12 strain | **Method of genetic modification, including any vectors used** E.g. non-conjugative plasmid pUC19 transfer by electroporation | **Identity and function of nucleic acid & organism of origin**  Provide gene names, or gene family (e.g. cytokines) or gene function (e.g. ion transporters), and source organism E.g. Green fluorescent Protein (GFP) from Aequorea victoria |
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PART B – Notifiable Low Risk Dealings (NLRDs)

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| B(i) | Type of Notifiable Low Risk Dealing (NLRD) | |
| **Notifiable Low Risk Dealing – PC1**  The following kinds of notifiable low risk dealings must be conducted in OGTR certified physical containment level 1 (PC1) facilities. | | |
| **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:  (i) an advantage is conferred on the animal by the genetic modification; or  (ii) the animal is capable of secreting or producing an infectious agent as a result of the genetic modification; |
|  | 1.1(c) | A dealing involving virions of a replication defective vector derived from *Human adenovirus* or from *Adeno-associated virus*, either without a host or with a host mentioned in item 9 of Part 2 of Schedule 2, if the donor nucleic acid:  (i) cannot restore replication competence to the vector; and  (ii) does not confer an oncogenic modification or immunomodulatory effect in humans. |

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| **Notifiable Low Risk Dealing – PC2**  The following kinds of notifiable low risk dealings must be conducted in OGTR certified physical containment level 2 (PC2) facilities. | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 2.1(a) | a dealing involving whole animals (including non‑vertebrates) that:   1. involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and 2. does not involve any of the following:    1. a genetically modified laboratory guinea pig;    2. a genetically modified laboratory mouse;    3. a genetically modified laboratory rabbit;    4. a genetically modified laboratory rat;    5. a genetically modified *Caenorhabditis elegans*; |
|  | 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 *Caenorhabditis elegans*, if:   1. the genetic modification confers an advantage on the animal; and 2. the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification; |
|  | 2.1(b) | a dealing involving a genetically modified plant |
|  | 2.1(c) | a dealing involving a host/vector system not mentioned in paragraph 1.1 (c) or Part 2 of Schedule 2, if neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:   1. human beings; or 2. animals; or 3. plants; or 4. fungi; |
|  | 2.1(d) | a dealing involving a host/vector system not mentioned in Part 2 of Schedule 2, if:   1. the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy: 2. human beings; or 3. animals; or 4. plants; or 5. fungi; and 6. the genetic modification is characterised; and 7. the characterisation of the genetic modification shows that it is unlikely to increase the capacity of the host or vector to cause harm;   *Example: A genetic modification would not comply with subparagraph (iii) if, in relation to the capacity of the host or vector to cause harm, it:*   1. *provides an advantage; or* 2. *adds a potential host species or mode of transmission; or* 3. *increases its virulence, pathogenicity or transmissibility.* |
|  | 2.1(e) | ***\*\*Note: also select either checkbox (i) or (ii) below\*\****  a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:   1. **is characterised, and the characterisation shows that it may increase the capacity of the host or vector to cause harm; or** 2. **is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy:** 3. **human beings; or** 4. **animals; or** 5. **plants; or** 6. **fungi;** |
|  | 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:   1. the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility; and 2. 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;  *Example: A dealing would not comply with paragraph (g) if it involved complementation that, in relation to the parent organism:*   1. *provides an advantage; or* 2. *adds a potential host species or mode of transmission; or* 3. *increases its virulence, pathogenicity or transmissibility.* |
|  | 2.1(h) | ***\*\*Note: also select either checkbox (i) or (ii) below\*\****  a dealing involving shot‑gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in items 1 to 6 of the table in Part 2 of Schedule 2, if the donor nucleic acid is derived from either:   1. **a pathogen; or** 2. **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, either without a host or with a host mentioned in Part 2 of Schedule 2, if:   1. the donor nucleic acid cannot restore replication competence to the vector; and 2. the dealing is not a dealing mentioned in paragraph 1.1(c); |
|  | 2.1 (k) | a dealing involving virions of a replication defective non‑retroviral vector able to transduce human cells and a host not mentioned in Part 2 of Schedule 2, if:   * + 1. the donor nucleic acid cannot restore replication competence to the vector; and     2. the donor nucleic acid does not confer an oncogenic modification or immunomodulatory effect in humans; |
|  | 2.1 (l) | ***\*\*Note: also select either checkbox (A) or (B) below\*\****  a dealing involving virions of a replication defective retroviral vector able to transduce human cells, either without a host or with a host mentioned in Part 2 of Schedule 2, if:   1. all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied *in trans*; and 2. 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 3. either: 4. **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** 5. **the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these;** |
|  | 2.1 (m) | ***\*\*Note: also select either checkbox (A) or (B) below\*\****  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:   1. the donor nucleic acid does not confer an oncogenic modification or immunomodulatory effect in humans; and 2. all viral genes have been removed from the retroviral vector so that it cannot replicate or assemble new virions without these functions being supplied *in trans*; and 3. 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 4. either: 5. **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** 6. **the packaging cell line and packaging plasmids express only viral genes *gagpol*, *rev* and an envelope protein gene, or a subset of these.** |

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| **Notifiable Low Risk Dealing – PC3**  The following kinds of notifiable low risk dealings must be conducted in OGTR certified physical containment level 3 facilities.  For kinds of dealings that are not notifiable low risk dealings, refer to [Schedule 3 Part 3](#Check5) at the end of this form. | | |
| **Select all that apply** | **Item** | **Description of dealing** |
|  | 2.2 | A kind of dealing that   1. is a kind mentioned in Notifiable Low Risk Dealing – PC2 ; and 2. involves a micro-organism that [satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3](#Check3" \o "*A genetically modified micro-organism is taken to satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3 if the unmodified parent organism satisfies those criteria. This does not apply to NLRD PC2 replication defective viral vectors) |

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| B(ii) | Description of the NLRD GMOs and dealings |
| **Summary of the GMOs** Provide a brief summary of each NLRD GMO in this application and indicate the dealing type for each GMO. This information will be notified to the OGTR, but not published in the [GMO Record](https://www1.health.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1).  For example:  1) Mus musculus IL2 receptor gamma chain knockout (NLRD PC1 1.1(a))  2) Arabidopsis thaliana transformed with agrobacterium containing constructs for overexpression of ABC transporters (NLRD PC2 2.1(b))  3) Rattus norvegicus cell lines transduced with lentivirus containing the human hCG gene (NLRD PC2 2.1(L iii A). | |
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| **Description of the dealings to be conducted with the GMOs** | |
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| Please use the checkboxes toselect the dealings any that may be undertaken.  *NOTE: A dealing includes the possession, supply or use of the GMO, for the purposes of, or in the course of, a dealing mentioned in any of paragraphs listed.* | Conduct experiments with the GMO |
| Make, develop, produce or manufacture the GMO |
| Breed the GMO |
| Propagate the GMO |
| Use the GMO in the course of manufacture of a [thing](#Text83)\* that is not the GMO  If yes, complete following details Is the thing\* subject to regulation by other agencies (e.g. Food Standards Australia, Australian Pesticides and Veterinary Medicines Association, Therapeutic Goods Administration)?  Yes ⮚ Agency        No |
| Grow, raise or culture the GMO |
| Import the GMO (from overseas or interstate)  If yes, complete following details Is the import subject to Department of Agriculture (AQIS/DAFF) approval?  Yes ⮚ Import Permit ID        No |
| Transport the GMO |
| Dispose of the GMO |
| Store the GMO |

| **Description of work** Describe the following for each of the kinds of notifiable low risk dealings. If there are different kinds of dealings proposed, e.g. PC1 GM mice and PC2 GM microorganisms, make sure you answer the question for each type.  For storage - consider whether GMOs may be sent for long term storage in a biobank at the completion of the experiments.  Please consult the OGTR [Guidelines for the Transport, Storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos) for guidance. |
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| **Briefly explain what the NLRD GMOs are, and the aims of the work:**    **How will the GMOs will be created or obtained (including import, if applicable)?**    **Describe the proposed experiments with the GMOs and any material derived from the GMOs:**  **How and where will GMOs, and material derived from GMOs, be stored?**    **Will GMOs be stored outside of an OGTR certified facility?**    **How do you propose to transport GMOs between approved facilities?**    **Describe the method of destruction and/or disposal of GMOs:**    **Will GMOs be exported overseas, or transported to another organization not listed in this application?** |

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| **Description of the GMO(s) –** *Use one row for each host/vector/nucleic acid combination* | | |
| **Scientific name of parent organism(s)** The parent organism means the organism that you propose to genetically modify. It also includes intended host cells, e.g. tissue culture cells or host animal cells transduced by a vector. | **Method of genetic modification, including any vectors used** Describe the method of modification – e.g. knock-out, crossing of GM animals, CRISPR/Cas9 gene editing, prime editing. For dealings involving viral vectors please provide details of each of the plasmids to be used. | **Identity and function of nucleic acid & organism of origin**  Provide gene names, or gene family (e.g. cytokines) or gene function (e.g. ion transporters), and source organism |
| E.g. Mus musculus | E.g. microinjection of CRISPR/Cas9 construct into embryo | E.g. Cas9 from Streptococcus pyogenes  Green fluorescent Protein (GFP) from Aequorea victoria |
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| **Modified trait(s) and gene(s) responsible** | |
| **Class of modified trait (select all that apply)** | **Names of gene(s) responsible** |
| Abiotic stress resistance |  |
| Altered agronomic characteristics |  |
| Altered biocontrol characteristics |  |
| Altered bioremediation characteristics |  |
| Altered biosensor characteristics |  |
| Altered horticultural characteristics |  |
| Altered nutritional characteristics |  |
| Altered pharmaceutical characteristics |  |
| Altered physical product characteristics |  |
| Altered physiological characteristics |  |
| Antibiotic resistance |  |
| Antigen expression |  |
| Attenuation |  |
| Bacterial resistance |  |
| Disease resistance |  |
| Fungal resistance |  |
| Growth factor expression |  |
| Herbicide tolerance |  |
| Immuno-modulatory protein expression |  |
| Pest resistance |  |
| Pesticide resistance |  |
| Protein expression |  |
| Reporter/marker gene expression |  |
| Virus resistance |  |
| Other |  |

Part C – Licenced contained dealings

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| D(i) | Type of licenced contained dealing | | |
| **These dealings require a licence from the Gene Technology Regulator** | | | |
| **Select all that apply** | | **Item** | **Description of dealing** |
|  | | 3.1(a) | a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of nucleic acid encoding a toxin having an LD50 of less than 100 micrograms per kilogram; |
|  | | 3.1(b) | a dealing involving high level expression of toxin genes, even if the LD50 is 100 micrograms per kilogram or more; |
|  | | 3.1(c) | a dealing (other than a dealing mentioned in paragraph 2.1 (h)) involving cloning of uncharacterised nucleic acid from a toxin‑producing organism; |
|  | | 3.1(d) | a dealing involving virions of a replication defective viral vector and a host not mentioned in Part 2 of Schedule 2, if:  (i) the donor nucleic acid confers an oncogenic modification or immunomodulatory effect in humans; and  (ii) the dealing is not a dealing mentioned in paragraph 2.1(i); |
|  | | 3.1(e) | a dealing involving a replication competent virus or viral vector, other than a vector mentioned in Part 2 of Schedule 2, if the genetic modification confers an oncogenic modification or immunomodulatory effect in humans; |
|  | | 3.1(f) | a dealing involving, as host or vector, a micro‑organism, if:  (i) the micro‑organism has been implicated in, or has a history of causing, disease in otherwise healthy:  (A) human beings; or  (B) animals; or  (C) plants; or  (D) fungi; and  (ii) none of the following sub‑subparagraphs apply:  (A) the host/vector system is a system mentioned in Part 2 of Schedule 2;  (B) the genetic modification is characterised and its characterisation shows that it is unlikely to increase the capacity of the host or vector to cause harm;  (C) the dealing is a dealing mentioned in paragraph 2.1 (g);  Example: A genetic modification would not comply with sub‑subparagraph (B) if, 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. |
|  | | 3.1(g) | a dealing involving the introduction, into a micro‑organism,of nucleic acid encoding a pathogenic determinant,unless:  (i) the dealing is a dealing mentioned in paragraph 2.1 (g); or  (ii) the micro‑organism is a host mentioned in Part 2 of Schedule 2; |
|  | | 3.1(h) | a dealing involving the introduction into a micro‑organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products are likely to increase the capacity of the micro‑organisms to induce an autoimmune response; |
|  | | 3.1(i) | a dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with an increased capacity to cause harm compared to the capacity of the parent or donor organism;  *Example: A dealing would comply with paragraph (i) if it produces a novel replication competent virus that has a higher capacity to cause harm to any potential host species than the parent organism because the new virus has:*  *(a) an advantage; or*  *(b) a new potential host species or mode of transmissibility; or*  *(c) increased virulence, pathogenicity or transmissibility.* |
|  | | 3.1(j) | a dealing, other than a dealing mentioned in paragraph 2.1 (l) or (m), with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells; |
|  | | 3.1(k) | a dealing involving a genetically modified animal, plant or fungus that is capable of secreting or producing infectious agents as a result of the genetic modification; |
|  | | 3.1(l) | a dealing producing, in each vessel containing the resultant GMO culture, more than 25 litres of that culture, other than a dealing mentioned in paragraph 2.1 (f); |
|  | | 3.1(m) | a dealing that is inconsistent with a policy principle issued by the Ministerial Council; |
|  | | 3.1(n) | a dealing involving the intentional introduction of a GMO into a human being, unless the GMO:   * 1. is a human somatic cell; and   2. cannot secrete or produce infectious agents as a result of the genetic modification; and   3. if it was generated using viral vectors:  1. has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells; and 2. the testing did not detect a virus mentioned in sub‑subparagraph (A); and 3. the viral vector used to generate the GMO as part of a previous dealing is no longer present in the somatic cells; |
|  | | 3.1(o) | a dealing involving a genetically modified pathogenic organism, if the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification; |
|  | | 3.1(p) | a dealing involving a micro‑organism that [satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 4](#OLE_LINK2); |
|  | | 3.1(q) | a dealing involving a micro‑organism that [satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 3](#OLE_LINK2) and that is not undertaken:   1. in a facility that is certified by the Regulator to at least physical containment level 3 and that is appropriate for the dealing; or 2. in a facility that the Regulator has agreed in writing is a facility in which the dealing may be undertaken; |
|  | | 3.1(r) | a dealing involving a GMO capable of sexual reproduction, the sexual progeny of which are, as a result of the genetic modification, more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism); |
|  | | 3.1(s) | a dealing involving a viral vector that can modify an organism capable of sexual reproduction, so that the sexual progeny of the organism are more likely to inherit a particular nucleotide sequence or set of nucleotide sequences (when compared to inheritance from the unmodified parent organism). |

***Note: A modification that increases the likelihood of inheritance of a nucleotide sequence or sequences, as described in paragraphs (r) and (s), is generally known as an engineered gene drive.***

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| **Description of the GMO(s) –** *Use one row for each host/vector/nucleic acid combination* | | |
| **Scientific name of parent organism(s)** The parent organism means the organism that you propose to genetically modify. It also includes intended host cells, e.g. tissue culture cells or host animal cells transduced by a vector. | **Method of genetic modification, including any vectors used** Describe the method of modification – e.g. knock-out, crossing of GM animals, CRISPR/Cas9 gene editing, prime editing. For dealings involving viral vectors please provide details of each of the plasmids to be used. | **Identity and function of nucleic acid & organism of origin**  Provide gene names, or gene family (e.g. cytokines) or gene function (e.g. ion transporters), and source organism |
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| If any Licenced Dealings are selected above, the IBC will issue a Record of Assessment confirming the type of dealing and contact you to advise the next steps. |

Part D – All dealing types

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| D(i) | Risk assessment and management | |
| **Benefits of the work** (a brief statement in plain English) | | |
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| **Describe the risks the proposed GMO dealings pose to the health and safety of people and the environment.** | | |
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| **Describe the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (ie the risk) from an unintentional release of the GMO(s)** | | |
|  | | |
| **Please indicate the relevant Risk Group(s) (as per ASNZS 2243:3:2010) for all micro-organisms involved in this dealing.** Select all that apply.  University personnel can access the Australian standards online via The University of Adelaide Library | | No microorganisms involved in this dealing  Risk Group 1 micro-organisms involved in this dealing  Risk Group 2 micro-organisms involved in this dealing  Risk Group 3 micro-organisms involved in this dealing  Risk Group 4 micro-organisms involved in this dealing |

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| D(ii) | Personnel and Training | |
| The IBC must assess whether the persons or categories of persons have appropriate training and experience to undertake the dealing. This includes persons beyond the persons conducting the research, such as persons involved in importation, transportation and disposal of GMOs.  Indemnification of University personnel requires that the University of Adelaide IBC has a record of all persons undertaking the dealing**.** | | |
| **Indicate ALL categories of persons that will be involved with the dealing, and list the name and ID for persons known at the time of writing this application.**  Additional persons can be added later as they become known/involved with the dealing | | |
| **Classes of Persons** | | **Name(s) and UoA ID number** (aXXXXXXX) |
| Principal Investigator | |  |
| Research Staff | |  |
| Postgraduate Students | |  |
| Honours/undergraduate student | |  |
| Visitor (researcher from another organisation) | |  |
| Facility staff *(only uncheck if facility staff will not deal with GMOs)* | | *Not required* |
| Transport personnel *(e.g. couriers, only uncheck if GMOs will not be transported by an external contractor)* | | *Not required* |
| Waste collection service provider *(e.g. Veolia driver, SARDI greenhouse services, only uncheck if viable GMOs will not be disposed of)* | | *Not required* |

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| **Have all personnel named above read and understood the following training requirements for dealing with GMOs**  *It is the responsibility of the Principal Investigator to ensure that all listed personnel have read and understood all of the Guidelines that apply to the dealings they are proposing to undertake, or will engage external persons to undertake. For example, personnel should read and understand parts 1.2.1 & 1.2.3 of the TSD Guidelines if they will be transporting PC2 GM animal to another facility, or providing GMOs to a courier for transport.*  *Personnel commencing work on this dealing at a later date must be trained and the IBC notified prior to commencing work on the dealing.* | |
| [Guidelines for the Transport, storage and Disposal of GMOs](https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos)  *All sections relevant to the physical containment (PC) level and type of organisms in the application.* | Yes  No |
| [National Framework of Ethical Principles in Gene Technology](https://www.ogtr.gov.au/sites/default/files/files/2021-07/national_framework_of_ethical_principles.pdf)  *Part 5.1 Ethical principles in gene technology (Pages 10-11).* | Yes  No |

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| D(iii) | Facilities to be used | | | |
| All facilities to be used, including places of storage, must be listed in your application.  Storage of some PC1 and PC2 GMOs outside of a certified facility is permitted, but the location must be approved by the IBC. Unauthorised storage of GMOs is an offence under the Act.  NOTE: For dealings with Risk Group 2 GM microorganisms that may generate aerosols – the facility must contain a Class II biosafety cabinet. Please note use of a BSCII in the experiments/aspects box. | | | | |
|  | | **Facility 1** | **Facility 2** | **Facility 3** |
| **Organisation** | |  |  |  |
| **OGTR Certification No.** | |  |  |  |
| **Room Number(s)** | |  |  |  |
| **Building** | |  |  |  |
| **Class of Facility** | | Choose an item. | Choose an item. | Choose an item. |
| **Facility Contact** | |  |  |  |
| **Facility Contact Details** | | Email | Email | Email |
| **Experiments/aspects of dealing (including storage) in this facility** | |  |  |  |

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|  | **Facility 4** | **Facility 5** | **Facility 6** |
| **Certification holder (Organisation)** |  |  |  |
| **OGTR Certification No.** |  |  |  |
| **Room Number(s)** |  |  |  |
| **Building** |  |  |  |
| **Class of facility** | Choose an item. | Choose an item. | Choose an item. |
| **Facility Contact** |  |  |  |
| **Facility Contact Details** | Email | Email | Email |
| **Experiments/aspects of dealing (including storage) in this facility** |  |  |  |

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| **If any OGTR certified facilities (PC1 or PC2) are listed above, have all personnel listed in this application completed a Record of Training and provided a copy to the listed Facility Contact and the IBC?**  *See* [*https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/gene-technology/gmo-containment-facilities#facility-user-training*](https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/gene-technology/gmo-containment-facilities#facility-user-training) | Yes  No |

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| D(iv) | Comments for the University’s IBC |
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| D(v) | Project Supervisor Declaration | | | |
| **Please initial** (*do not mark with tick or cross*) each of the following statements to indicate that you understand your responsibilities when dealing with GMOs and then sign the application form. | | | | |
| I have read, considered and understand my responsibilities under the Gene Technology Act 2000 and agree to undertake the GMO dealing outlined in this application in accordance with the relevant Office of the Gene Technology Regulator guidelines and regulations (including, but not limited to all disposal, transport and storage). <http://www.ogtr.gov.au/> | | | |  |
| I am aware of my responsibilities in relation to ensuring that any personnel conducting this work are appropriately trained and are aware of and also follow the relevant guidelines and regulations. | | | |  |
| I have considered the potential risks that the conduct of this dealing could pose to people and/or the environment and will implement appropriate actions and precautions 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. | | | |  |
| 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. | | | |  |
| I confirm that all personnel named in this application have read and understood the requirements for transporting, storing and disposing of GMOs, and the behavioral requirements for working in OGTR certified facilities. | | | |  |
| Project Supervisor Name | | Project Supervisor Signature | Date | |

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| D(vi) | Facility Manager Declaration | | |
| 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 consent to the work being performed in the listed facility.  I will ensure that the appropriate safety procedures are followed and that personnel are appropriately 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.  **For OGTR certified facilities**  All personnel named in Part 8 of this application have provided me with a completed Record of Training. | | | |
| Facility 1 Facility Manager Name | | Facility 1 Facility Manager Signature | Date |
| Facility 2 Facility Manager Name | | Facility 2 Facility Manager Signature | Date |
| Facility 3 Facility Manager Name | | Facility 3 Facility Manager Signature | Date |
| Facility 4 Facility Manager Name | | Facility 4 Facility Manager Signature | Date |
| Facility 5 Facility Manager Name | | Facility 5 Facility Manager Signature | Date |
| Facility 6 Facility Manager Name | | Facility 6 Facility Manager Signature | Date |

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| D(vii) | Head of School Declaration | | |
| 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 work. | | | |
| Head of School Name | | Head of School Signature | Date |