IBC reg no:

………………. **INSTITUTIONAL BIOSAFETY COMMITEE**

 **APPLICATION FOR A NOTIFIABLE LOW RISK DEALING**

 **(NLRD) SUITABLE FOR PHYSICAL CONTAINMENT**

 **LEVEL 1 (PC1) OR LEVEL 2 (PC2)**

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| **1** | **Project Supervisor/Principal investigator**  |
| **Name and address of Principal Investigator submitting proposal.** Name of Principal Investigator: School/Centre: Telephone Number: Mobile Number: Email Address:**Name(s) of other Principal Investigators and/or Associate Investigators responsible for the project.** Name of Co-principal Investigator: School/Centre: Telephone Number: Mobile Number: Email Address: |
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| **2** | **Project Title** |
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| **3** | **Description of the project** |
|  *Briefly describe the project and the purpose of conducting these dealings. (Use plain English). Include enough information about the dealing in order to make classification as a PC1 or PC2 NLRD clear.* |

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| **4** | **Schedule 3 Part 2 - Notifiable low risk dealings suitable for physical containment level 1***(please tick the appropriate PC1 NLRD category)* |
| [ ]  | a) a dealing involving a genetically modified laboratory mouse 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: |
| [ ]  | c).  a dealing involving a replication defective vector derived from *Human adenovirus* or *Adeno associated virus* in a host mentioned in item 4 of Part 2 of Schedule 2, if the donor nucleic acid:     (i).  cannot restore replication competence to the vector; and    (ii). does not:        A.  confer an oncogenic modification in humans; or        B.  encode a protein with immunomodulatory activity in humans.  |

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| **5** | **Schedule 3 Part 2 - Notifiable low risk dealings suitable for physical containment level 2** *(please tick the appropriate PC2 NLRD category)**N*ote Because of subregulation 12 (1), a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 3. |
| [ ]  | a) a dealing involving whole animals (including non-vertebrates) that:  (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 (ii) 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*;
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| [ ]  | 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: (i) the genetic modification confers an advantage on the animal; and (ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification; |
| [ ]  | b) a dealing involving a genetically modified plant; |
| [ ]  | 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: i. human beings; orii. animals; oriii. plants; oriv. fungi; |
| [ ]  | d). a dealing involving a host and vector not mentioned as a host/vector system in Part 2 of Schedule 2, if: i. the host or 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; and

ii. the donor nucleic acid is characterised; andiii. the characterisation of the donor nucleic acid shows 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 (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.
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| [ ]  | e). a dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid: 1. i. encodes a pathogenic determinant; or
2. ii. is uncharacterised nucleic acid from an organism that 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;
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| [ ]   | 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: i. the dealing is undertaken in a facility that is certified by the Regulator as a  large scale facility; andii. the donor nucleic acid satisfies the conditions set out in subitem 4 (2) of Part 1  of Schedule 2; |
|  [ ]   |  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:     a. provides an advantage; or    b. adds a potential host species or mode of transmission; or    c. increases its virulence, pathogenicity or transmissibility. |
|  [ ]   | h). 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 Schedule 2, if the donor nucleic acid is derived from either: i. a pathogen; orii. a toxin-producing organism;  |
|  [ ]   | i). a dealing involving the introduction of a replication defective viral vector unable to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector; |
|  [ ]   | j). a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells, other than a dealing mentioned in paragraph 1.1 (c), into a host mentioned in Part 2 of Schedule 2, if the donor nucleic acid cannot restore replication competence to the vector; |
|  [ ]   | k). a dealing involving the introduction of a replication defective non-retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if: i. the donor nucleic acid cannot restore replication competence to the vector; andii. the donor nucleic acid does not:* + 1. confer an oncogenic modification in humans; or
		2. encode a protein with immunomodulatory activity in humans;
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|  [ ]   | l). a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host mentioned in Part 2 of Schedule 2, if: 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 in trans; andii. 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; andiii. either:1. 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
2. the packaging cell line and packaging plasmids express only viral genes gagpol, rev and an envelope protein gene, or a subset of these;
 |
|  [ ]   | m). a dealing involving the introduction of a replication defective retroviral vector able to transduce human cells into a host not mentioned in Part 2 of Schedule 2, if: i. the donor nucleic acid does not: * 1. confer an oncogenic modification in humans; or
	2. encode a protein with immunomodulatory activity in humans; and

ii. 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 *in trans*; and 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; andiv. either:* 1. 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
	2. 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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| **6** | **Describe the host organism and tissue/cell type to be genetically modified.** |
| *Please include details of the organism (animal, algae, fungi, bacteria, plant, protozoa etc.) including the species / cell line etc. as appropriate.* |

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| **7** | **What vectors or methods will be used for the transfer of DNA.**  |
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| **8** | **Modified trait(s) and gene(s) responsible)** |
| *Please describe the identity and function of the nucleic acid / gene to be transferred and organism of origin.* |

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| **9** | **Where will this work be conducted? Give building, room number and Campus.**  |
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| **10** | **What is the certified physical containment level of this facility?**  |
|  PC1 [ ] PC2 [ ] Other (please specify): |

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| **11** | **What is the type of facility?** |
|   Laboratory [ ] Animal House [ ] Plant House [ ] Other (please specify): |

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| **12** | **Do you have approval to use this facility?**(*attach written confirmation if not located at work)*  |
|   Yes [ ] No [ ]  |

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| **13** | **What are the possible hazard(s) or risk(s) to staff performing the proposed genetic modification** |
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| **14** | **What are the possible risk(s) resulting from an unintentional release into the environment and what would you do in the event of the unintentional release.** |
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| **15** | **Do you propose to transport GMOs outside the certified facility- if so give further details and confirm that all transport complies with OGTR guidelines.**  |
| *Give details of transport (eg. between facilities, to storage unit, for disposal, export to another institution, import from a supplier).* Does GMO transport comply with OGTR guidelines Yes [ ] No [ ]   |

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| **16** | **Do you propose to store the GMOs outside the certified facility- if so give further details and confirm that storage complies with OGTR guidelines.**  |
| *Give details of where the GMOs will be stored including container (eg fridge/freezer) and location (eg. room, building , campus)* Does GMO storage comply with OGTR guidelines Yes [ ] No [ ]   |

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| **17** | **Details of all personnel involved with the project.** |
| *for each person include full name, qualifications, relevant experience ( eg. use of gene manipulation and microbiological techniques) and role in the project**team.* |

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| **18** | **Please confirm that all staff and students involved in this project have been trained in the standard operating procedures related to this GMO dealing**  |
|  Yes [ ] No [ ]  Submit request for further training [ ] |

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| **19** | **Commencement date** |
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| **20** | Completion date |
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| **21** | **Signature of Principal Investigator submitting this proposal.** |
|    Signature: Date: |

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| **22** | IBC Declaration |
| The IBC has evaluated this dealing and agrees that it is a Notifiable Low Risk Dealing requiring PC1 or PC2 *(delete as appropriate)* containment as specified by Schedule 3 part 1 of the *Amended Gene Technology Regulations 2011* |
| Name of IBC Chair: |
| Signature of IBC Chair: *Date* / / |