Swinburne Biosafety Committee

Application for Notifiable Low Risk Dealings (NLRDs) suitable for Physical Containment level 2 (PC2)

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| DATE RECEIVED | SBC REFERENCE NUMBER |
| *Office use only* | *Office use only* |

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| 1 | Title of project |
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| 2 | Responsible Person Supervisor |
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| 3 | Type of NLRD Dealing (check the box that applies) – Schedule 3, Part 2, 2.1 |
|  | (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:  (A) a genetically modified laboratory guinea pig;  (B) a genetically modified laboratory mouse;  (C) a genetically modified laboratory rabbit;  (D) a genetically modified laboratory rat;  (E) a genetically modified *Caenorhabditis elegans*; |
|  | (aa) A dealing involving a genetically modified laboratory guinea pig, a genetically modified 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; or  (ii) animals; or  (iii) plants; or  (iv) 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:  (A) human beings; or  (B) animals; or  (C) plants; or  (D) fungi; and  (ii) the donor nucleic acid is characterised; and  (iii) the characterisation of the donor nucleic acid shows that it is unlikely to increase the capacity of the host or vector to cause harm; |
|  | (e) A dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the donor nucleic acid:  (i) encodes a pathogenic determinant; or  (ii) is uncharacterised nucleic acid from an organism that 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; |
|  | (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; and  (ii) 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; |
|  | (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; or  (ii) 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; and  (ii) the donor nucleic acid does not:  (A) confer an oncogenic modification in humans; or  (B) encode a protein with immunomodulatory activity in humans; |
|  | (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*; and  (ii) 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  (iii) either:  (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  (B) 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:  (A) confer an oncogenic modification in humans; or  (B) 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; and  (iv) either:  (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  (B) the packaging cell line and packaging plasmids express only viral genes g*agpol*, revand an envelope protein gene, or a subset of these. |

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| 4 | Table of GMOs – list all the GMOs to be generated and or used | | |
| **Scientific name of**  **unmodified organism** | | **Vectors and method of transfer** | **Gene Identity and Species of**  **Origin** |
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| 5 | **Modified trait(s) and gene(s) responsible** (*Eg fungal resistance, attenuation, protein expression,*  *disease resistance etc)*) | |
| **Class of modified trait** | | **Details** |
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| 6 | What are the possible hazard(s) or risk(s) to the staff performing the proposed genetic modification(s)? |
| *250 words max* | |

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| 7 | What are the possible hazard(s) or risk(s) from an unintentional release of the GMO(s) into the environment? |
| *250 words max* | |

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| 8 | What are the steps you will take in the event of an unintentional release of the GMO(s)? |
| *250 words max* | |

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| 9 | **Do you propose to transport the GMO(s) outside a certified facility?** (Include details about method of transportation) |
| *250 words max* | |

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| 10 | How will the GMO(s) be disposed of? |
| *250 words max* | |