

University of Tasmania
Institutional Biosafety Committee
Internal Mail Box 46

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| Exempt Dealing Notification Form | School: Discipline: | IBC reference No. <hr/> |
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|--------------------------|-------------|--------|
| (Name of Head of School) | (Signature) | (Date) |
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The objective of this form is to

- i) notify the IBC that you have commenced an “exempt” dealing involving a genetically modified organism, and
- ii) provide sufficient information that the IBC can reasonably be sure that the dealing is indeed exempt.

This form attempts to cover the whole range of manipulations covered under “exempt dealings”. These may include manipulations as diverse as tissue harvesting from transgenic mice, to recombinant protein expression in *E. coli*. Therefore you may need to modify some sections of the form to suit your circumstances, keeping in mind the objectives of the exercise.

The University of Tasmania IBC has also decided that in some circumstances, generic reporting for exempt dealings may be acceptable. As one example, where the project involves the creation of a genomic library and subsequent gene characterisation, the project may involve analysis of multiple genes, and the use of several different cloning vectors. Rather than complete a report for each combination of gene/vector/host, it would be acceptable in this instance to briefly outline the experimental plan and objectives in Section 7 (eg, create genomic library from rat liver DNA in bacteriophage vector Y, and subclone approximately 10 genes into various plasmid-based *E. coli* vectors for further analysis). Note that if you are investigating certain categories of genes, such as oncogenes or toxin genes, you can't do this under “exempt dealings” but must apply for a “Notifiable Low Risk Dealing” authorisation from the IBC **before** commencing work.

Finally, “exempt dealings” must be carried out in a PC1 facility. Links to references on the structural and procedural requirements of PC1 (equivalent to a typical teaching laboratory) may be found in the University's Microbiology Policy (http://www.admin.utas.edu.au/hr/ohs/pol_proc/index.html).

1 Project Supervisor**2 Project Title****3 Exemption Category (Please tick appropriate box)**

- 1 Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal:
- (a) by the deletion or inactivation of the gene concerned; or
- (b) for mice that also carry a selectable marker gene — by the selectable marker gene
- 2 Any dealing with a whole animal, if:
- (a) naked recombinant nucleic acid has been introduced into its somatic cells; and
- (b) the introduced nucleic acid is incapable of giving rise to infectious agents
- 3 Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells:
- (a) are capable of giving rise to recombinant infectious agents; or
- (b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.
- 4 Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if:
- (a) the donor DNA:
- (i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and
- (ii) is not an oncogene; and
- (iii) does not code for a toxin for vertebrates with an LD50 of less than 100 µg/kg; and
- (iv) does not code for a toxin for vertebrates with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels; and
- (v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or
- (b) the donor DNA includes a viral sequence or viral sequences, but:
- (i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and
- (ii) is incapable of complementing a defect in the host/vector system.
- 5 Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of this Schedule.

| 4 Host / Modified Organism (provide species name) | |
|----------------------------------------------------------|-----------------|
| <i>Type:</i> | <i>Species:</i> |
| Animal | |
| Protozoa | |
| Fungi | |
| Algae | |
| Bacteria | |
| Virus | |
| Plant | |

| 5 Vector system (if relevant) | |
|--------------------------------------|--------------------|
| <i>Vector type (eg, plasmid)</i> | <i>Vector name</i> |
| | |

| 6 Source and name of modified gene(s) | |
|----------------------------------------------|------------------------------|
| <i>Source of modified gene (species)</i> | <i>Name of modified gene</i> |
| | |

| 7 Nature of manipulation | |
|---------------------------------|--|
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| | |

| 8 Location and Containment Level of Facilities to be used |
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| <i>Please provide Room Numbers or Certification Numbers. For Exempt Dealings (PCI Containment), attach a completed and signed PCI checklist with the Application.</i> |
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| 9 Commencement date |
|----------------------------|
| |

| 10 Completion date |
|---------------------------|
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| 11 IBC Declaration |
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| The IBC has evaluated this dealing and agrees that it is an exempt dealing as specified by Schedule 2 of the <i>Gene Technology Regulations 2001</i> . |
| Name of IBC: |
| Name of IBC Chair: |
| Signature of IBC Chair: |
| <i>Date</i> / / |