|  |
| --- |
| **Application and Risk Assessment for Gene Technology1,2****NLRDs and Exempt Dealings***1Conducting of dealings with Genetically Modified Organisms under the Gene Technology Act 2000 and Gene Technology Regulations 2001. Regulation 13B(a) requires an IBC that has assessed a proposal as being an NLRD to make a record of its assessment, in a form approved by the Regulator, and specifies the information that this record must contain. The information requested within this application to be assessed by the LTIBC are in accordance with Regulation 13B(a)(i)-(x).* *2Notifiable Low Risk Dealings (NLRD’s) are listed in Schedule 3 of the Gene Technology Regulations 2001. It is a requirement under the Gene Technology Act 2000 that applications for NLRD’s be submitted to the LTIBC for consideration prior to commencement of GM dealings. In addition, La Trobe University requires submission of applications for any dealings that may be Exempt as listed in Schedule 2 of the Regulations.* |

Complete this form and associated Schedules then submit for assessment to: biosafety@latrobe.edu.au

|  |
| --- |
| **Section 1. Project Details** |

|  |  |
| --- | --- |
| **Project Title:** |       |

|  |  |  |
| --- | --- | --- |
| **Does this application replace an existing approval?** | **Is the project funded by an external agency?** | **Are any other approvals required for this project?** |
| [ ]  | **YES** | [ ]  | **NO** | [ ]  | **YES** | [ ]  | **NO** | [ ]  | **YES** | [ ]  | **NO** |
| *If YES, provide all relevant reference numbers*      | *If YES, provide all relevant reference numbers*      | *If YES, provide all relevant details*      |

**Principle/Chief Investigator** *person who will have overall responsibility for this program*

|  |  |
| --- | --- |
| **Title/Full Name** |       |
|  |  |  |  |
| **Position** |       | **Staff ID** |       |
|  |  |  |  |
| **Research Group and Department** |       | **Phone** |       |
|  |  |  |  |
| **Email** |       |
|  |  |  |  |
| **Role/Qualifications** |       |

**Primary Contact** *If someone other than the project Chief Investigator listed above*

|  |  |
| --- | --- |
| **Title/Full Name** |       |
|  |  |  |  |
| **Position** |       | **Staff ID** |       |
|  |  |  |  |
| **Research Group and Department** |       | **Phone** |       |
|  |  |  |  |
| **Email** |       |
|  |  |  |  |
| **Role/Qualifications** |       |

**Duration of Project Approval** *(For Research Office Use Only)*

*Note that the LTIBC can only approve an application for a maximum of 5 years*

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Commencement Date:** |       | **Project Conclusion Date:** |       |

**Project Summary**

|  |
| --- |
| *Provide a simple overview of the program of activity that involves Gene Technology* *(i.e. aim of the project, background, intended use/purpose of the GMO etc.)* |
|       |

|  |
| --- |
| **Section 2. Classification of Genetically Modified Organisms**  |

**Project Classification Summary** *Refer to Appendix below to complete:*

 *Note: more than one box can be checked*

|  |  |  |
| --- | --- | --- |
| [ ]  | Exempt Dealing | *List the classification(s) as determined from* ***the checkboxes below*** *(e.g. Schedule 2, Part 2, Item 1 and Item 4; Schedule 3, Part 2.1 (e), (h)).* |
|  |  |       |
| [ ]  | NLRD Suitable for PC1 |
|  |  |
| [ ]  | NLRD Suitable for PC2 |
|  |  |
| [ ]  | NLRD Suitable for PC3 |
|  |  |
| [ ]  | NLRD Suitable for PC1 and PC2 |

Check the box(es) that are applicable to each class of Dealings. List those that have been checked in Section 2 of the Application Form. If you need assistance in determining which are applicable, please contact the LTIBC biosafety@latrobe.edu.au.

*Refer to* [***Types of Dealings with GMOs classified as Exempt dealings – October 2019***](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/F0E09860680FCE94CA257CD00009FDA2/%24File/Types%20of%20Exempt%20Dealings%20-%20October%202019.pdf) *and* [***Types of Dealings with GMOs classified as Notifiable Low Risk Dealings (NLRDs) – October 2019***](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/B525FA0446AEA866CA257CD00009FE1D/%24File/Types%20of%20NLRDs%20-%20October%202019.pdf) *for further details.*

[ ]  **Schedule 2, Part 1, Exempt Dealings (PC1)**

[ ]  **Item 2**, a dealing with a genetically modified *Caenorhabditis elegans*

[ ]  **Item 3**, a dealing with an animal into which genetically modified somatic cells have been introduced

[ ]  **Item 3A**, a dealing with an animal whose somatic cells have been genetically modified in vivo by a replication

 defective viral vector

[ ]  **Item 4**, (1) Subject to sub-item (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

[ ]  **Item 5**, 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 this Schedule

[ ]  **Schedule 2, Part 2, Host/vector systems for exempt dealings (PC1)** *(refer to the complete schedule for details for strains)*

[ ]  **Item 1**, Bacteria- *Escherichia coli* K12, *E. coli B*, *E. coli C* or *E. coli Nissle* 1917

[ ]  **Item 2**, Bacteria- *Bacillus*—asporogenic strains with a reversion frequency of less than 10–7

[ ]  **Item 3**, Bacteria- *Pseudomonas putida* strain KT2440

[ ]  **Item 4**, Bacteria- *Streptomyces* species

[ ]  **Item 5**, Bacteria- *Agrobacterium* species

[ ]  **Item 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*

[ ]  **Item 7**, Fungi

[ ]  **Item 8**, Slime Moulds

[ ]  **Item 9**, Tissue Culture (animal or human cell culture or isolated cell/tissue/organs and early non-human

 embryos)- if they cannot spontaneously generate a whole animal

[ ]  **Item 10**, Tissue Culture (Plant cells and isolated tissues or organs)- if they are not intended, and are not

 likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant

[ ]  **Schedule 3, Part 1, Notifiable low risk dealings suitable for at least physical containment level 1 (PC1)**

[ ]  **1.1 Kinds of dealing suitable for at least PC1**

[ ]  **(a)** a GM laboratory guinea pig, mouse, rabbit or 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 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.

[ ]  **Schedule 3, Part 2, Notifiable low risk dealings suitable for at least physical containment level 2 (PC2)**

[ ]  **2.1 Kinds of dealing suitable for at least PC2**

[ ]  **(a)** **Whole animals (including non-vertebrates)** THAT (involves genetic modification of the genome of the

 oocyte or zygote or early embryo to produce a novel whole organism) AND (does not involve a GM

 laboratory guinea pig, mouse, rabbit, rat or *Caenorhabditis elegans*).

[ ]  **(aa)** **A GM laboratory guinea pig, mouse, rabbit, rat or *Caenorhabditis elegans*** IF (an advantage is

 conferred) AND (it does not result in the capacity to secrete or produce infections).

[ ]  **(b)** **A genetically modified plant**

[ ]  **(c)** **A host/vector system not mentioned in NLRD PC1 1.1(c) or Part 2 of Schedule 2** IF (neither is

 implicated in, or have a history of causing, disease).

[ ]  **(d)** **A host AND vector not mentioned as a host/vector system in Part 2 of Schedule 2** if (either HAS

 been implicated in, or has a history of causing, disease) AND (donor nucleic acid is characterised) AND

 (host or vector unlikely to gain increased capacity to cause harm).

[ ]  **(e)** **A host/vector system mentioned in Part 2 of Schedule 2** IF donor nucleic acid (encodes a pathogenic

 determinant) OR (is uncharacterised, from organism implicated in, or with a history of causing, disease).

[ ]  **(f)** **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 (it is undertaken in a certified large scale facility)

 AND (the donor nucleic acid satisfied specified conditions in subitem 4(2) of Part 1, Schedule 2.

[ ]  **(g)** **Complementation of knocked-out genes** IF (unlikely to increase GMO's capacity to cause harm

 compared to parent capacity)

[ ]  **(h)** **Shot-gun cloning or preparation of a cDNA library, in a host/vector system mentioned in item 1**

 **to 6 of Part 2, Schedule 2** IF the donor nucleic acid is derived from a pathogen OR toxin-producing organism

[ ]  **(i)** a dealing involving virions of **a replication defective viral vector** **that CANNOT enter intact human**

 **cells into a host NOT mentioned in Part 2 of Schedule 2** IF the donor nucleic acid cannot restore

 replication competence

[ ]  **(j)** a dealing involving virions of **a replication defective** **NON-RETROVIRAL vector that CAN enter intact**

 **human cells, other than NLRD PC1 1.1 (c),** either without a host or with **a host mentioned in Part 2 of**

 **Schedule 2** IF the donor nucleic acid cannot restore replication competence

[ ]  **(k)** a dealing involving virions of **a replication defective** **NON-RETROVIRAL vector that CAN enter intact**

 **human cells into a host NOT mentioned in Part 2 of Schedule 2** IF the donor nucleic acid cannot restore

replication competence **AND DOES NOT** confer an oncogenic modification in humans OR

 immunomodulatory effect in humans

 [ ]  **(l)** a dealing involving virions of a **replication defective RETROVIRAL vector that CAN enter intact**

 **human cells, either without a host or with a host mentioned in Part 2 of Schedule 2IF** (all viral genes

 have been removed) AND (viral genes needed for virion production meet specified conditions, to limit or

 prevent recombination) AND (the retroviral vector includes a specified deletion to prevent transcription after

 integration OR the packaging cell line and packaging plasmids meet specified conditions)

[ ]  **(m)** a dealing involving virions of a **replication defective RETROVIRAL vector that CAN enter intact**

 **human cells into a host NOT mentioned in Part 2 of Schedule 2** IF the donor nucleic acid DOES NOT

confer an oncogenic modification in humans OR immunomodulatory effect in humans in humans AND (all

 viral genes have been removed) AND (viral genes needed for virion production meet specified conditions, to

 limit or prevent recombination) AND (the retroviral vector includes a specified deletion to prevent transcription

 after integration OR the packaging cell line and packaging plasmids meet specified conditions)

[ ]  **2.2 Kinds of dealing suitable for at least PC3**

[ ]  **Schedule 3, Part 3, Notifiable low risk dealings suitable for at least physical containment level 3 (PC3)**

|  |
| --- |
| **Section 3. Types of GMOs** |

*List all the GMOs to be generated and or used*

|  |  |  |  |
| --- | --- | --- | --- |
| **Scientific name of the unmodified organism** | **Vectors and method of transfer** | **Gene identity and species of origin** | **Class of dealings** |
|       |      . |       |  |
|       |       |       |  |

|  |
| --- |
| **Section 4. Modified Trait(s) and Gene(s)** |

*List all the GMOs to be generated and or used*

|  |  |
| --- | --- |
| **Class of modified trait** | **Details** |
|       |       |

|  |
| --- |
| **Section 5. Types of GMO Dealings** |

|  |
| --- |
| *Identify all relevant dealings and provide the specific procedures for each relevant category. Indicate which classification of GMO (from Section 2 of this form) the dealing is applicable to. Aim to keep descriptions broad to avoid the need to submit new applications for future work.* |
| [ ]  | Conduct experiments with the GMO |  |       |
|  |  |  |  |
| [ ]  | Make, develop, produce or manufacture the GMO |  |       |
|  |  |  |  |
| [ ]  | Breed the GMO |  |       |
|  |  |  |  |
| [ ]  | Propagate the GMO |  |       |
|  |  |  |  |
| [ ]  | Use the GMO to manufacture something that is not the GMO |  |       |
|  |  |  |  |
| [ ]  | Grow, raise or culture the GMO |  |       |
|  |  |  |  |
| [ ]  | Import the GMO |  |       |
|  |  |  |  |
| [ ]  | Transport the GMO |  |       |
|  |  |  |  |
| [ ]  | Dispose of the GMO |  |       |
|  |  |  |  |
| [x]  | Possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the above categories |  | This box is checked if any category of dealing above is also checked |

|  |
| --- |
| **Section 6. Classes of Facilities** |

**Facilities in which the work will be conducted**

|  |  |
| --- | --- |
| *Notes:*  | *Must also include details of any non-LTU facilities to be considered by the LTIBC* |

| **Building Name** | **Room Number(s)** | **Containment Level** | **Facility Type** | **OGTR Certification Number** | **Certification Expiry Date** |
| --- | --- | --- | --- | --- | --- |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

|  |  |  |  |
| --- | --- | --- | --- |
| Storage outside of Physical Containment | [ ]  | **Required** | Discuss with the LTIBC. Storage will only be approved if conditions of storage are in accordance with the *OGTR Guidelines for Transport, Storage and Disposal of GMOs* |

**Class(es) of Facility Approved** *(For Research Office Use Only)*

|  |
| --- |
| This approval allows dealings in at least Physical Containment Level X (PCX) facilities as certified by the Office of the Gene Technology Regulator and approved by the LTIBC. The CI is to notify the Research Office of any changes/amendments to the list provided in this original application. |

|  |
| --- |
| **Section 7. Class(es) of Personnel** |

**Class(es) of Personnel who may work with the GMOs**

|  |  |
| --- | --- |
| *Notes:*  | *All personnel who intend to work with GMOs must complete the LTU Biosafety Training.*  |

|  |  |  |
| --- | --- | --- |
| [ ]  | Researchers (e.g. Post-Docs/Technicians) | *If OTHER, specifically indicate who:* |
|  |  |      . |
| [ ]  | LTU Students (e.g. Undergrad and Postgrad) |
|  |  |
| [ ]  | LARTF Personnel |
|  |  |
| [ ]  | Visitors (only those that will deal with a GMO) |
|  |  |
| [ ]  | Contractors (e.g. for waste disposal or transport) |
|  |  |
| [ ]  | Other |

**Do Personnel have the Appropriate Training?**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | YES | [ ]  | NO |
| *Notes:* | *Records of training and trained personnel applicable to this application should be kept within the Certified Facility* *If NO, then please provide an explanation/justification for LTIBC assessment* |
|       |

**Class(es) of Personnel Approved** *(For Research Office Use Only)*

|  |
| --- |
| This approval allows dealings by authorised and trained persons in the classes listed above. The CI is to provide the Research Office with a list of personnel associated with this approval. The CI is to maintain a current list of personnel and notify the Research Office of any changes/amendments to the list provided in this original application. |

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| --- |
| **Section 8. Risk Assessment and Risk Management** |

*Note, depending on the donor DNA, a DNIR licence may be required from the OGTR*

**Are any of the proposed organisms or classes of GMOs potentially harmful to, or have a history of causing disease in otherwise healthy organisms?**

|  |
| --- |
| *Identify which of the organisms or GMOs are potentially harmful* |
| [ ]  | Humans? |  | **Comments:**       |
|  |  |  |  |
| [ ]  | Animals? |  | **Comments:**      . |
|  |  |  |  |
| [ ]  | Plants? |  | **Comments:**       |
|  |  |  |  |
| [ ]  | Environment? |  | **Comments:**       |
|  |  |  |  |
| [ ]  | NO, none of the organisms or classes of GMOs are considered harmful to any of the above. |

**Will any viral vectors be used in the project?**

|  |
| --- |
| *If, YES, use the OGTR tables to assist with appropriate classification* |
| [ ]  | YES |  | [ ]  | NO | **Comments:**       |
|  |
| Are the viral vectors replication defective? |
| [ ]  | YES |  | [ ]  | NO | **Comments:**       |
|  |
| Can the vectors transduce/infect human cells? |
| [ ]  | YES |  | [ ]  | NO | **Comments:**       |

**Are any of the proposed donor DNA considered harmful to humans?**

|  |
| --- |
|  *If yes, add comments.* |
| [ ]  | The project will deal with donor DNA considered to be a **Pathogenic Determinant** |  |       |
|  |  |  |  |
| [ ]  | The project will deal with donor DNA considered to be **Oncogenic** in humans |  |       |
|  |  |  |  |
| [ ]  | The project will deal with donor DNA considered to be **Immunomodulatory** in humans |  |       |
|  |  |  |  |
| [ ]  | There an advantage conferred on the organism by the genetic modification |  |       |
|  |  |  |  |
| [ ]  | The modification increases virulence, pathogenicity or transmissibility |  |       |
|  |  |  |  |
| [ ]  | The GMO secretes or produces an infectious agent |  |       |
|  |  |  |  |
| [ ]  | The donor DNA is not characterised |  |       |
|  |  |  |  |
| [ ]  | The donor DNA is from a toxin producing organism(s) |  |       |
|  |  |  |  |
| [ ]  | NO, the donor DNA has been characterised, does not confer an advantage and is not considered harmful |

**Identify Potential Hazards or Risks to People**

|  |
| --- |
| *Note, list those applicable to the proposed organisms and GMOs (e.g. aerosols, exposure to allergens, infectious zoonotics, experimental agents, bites/scratches from animals).* |
| **Risk or Hazard** | **Proposed Controls** |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
| **Additional Comments:**       |

**Identify Potential Hazards or Risks to the Environment**

|  |
| --- |
| *Note, list those applicable to the proposed organisms and GMOs if unintentionally released into the environment (e.g. potential to survive or persist in the environment).* |
| **Risk or Hazard** | **Proposed Controls** |
|       |       |
| **Additional Comments:**       |

**Provide Details of the Action Management Plan Should an Unintended Release Occur**

|  |
| --- |
| *Provide details below. As a minimum, the plan must address the following:*1. *Relevant notifications (eg to IBC).*
2. *Noting the location(s) and extent of presence or escape.*
3. *Containment and recovery strategies (if applicable).*
4. *Methods for rendering the GMO(s) non-viable (if applicable).*
5. *Following instructions provided by representatives of the LTIBC and/or OGTR.*

*Note, that in the event of a suspected unintentional release, the LTIBC must be notified immediately.* |
|       |

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| **Section 9. Transport** |

**The transport, storage or disposal of GMOs must be undertaken in accordance with the *OGTR Guidelines for Transport, Storage and Disposal of GMOs*. This includes transport between approved facilities and institutions and the import and export of GMOs. Please keep in mind any future work you may want to undertake.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Do you intend to import GMOs into Australia?** | [ ]  | YES |  | [ ]  | NO |

If *Yes* – you need to ensure that you have the necessary import approvals (e.g. import permit) and that the conditions of use in that permit allow for GMOs and the activities/dealings that you require (e.g. the permit allows for *in vivo* activity if required not just *in vitro* work). Contact biosafety@latrobe.edu.au for assistance.

**Will any of the GMOs be transported between facilities and/or institutions?**

|  |
| --- |
| *If, YES, refer to the OGTR Guidelines for the Transport Storage and Disposal of GMOs and complete the acknowledgement below. Include in the comments any commercial transportation companies that might be used* |
| [ ]  | YES |  | [ ]  | NO | **Comments:**       |
|  |

**Transport of GMOs declaration**

|  |
| --- |
| When transporting GMOs, I, acknowledge that this must be undertaken in accordance with the *OGTR Guidelines for the Transport, Storage and Disposal of GMOs*. I understand and agree to be bound by these guidelines. I confirm that GMOs will not be transported unless: |
| [ ]  | personnel transporting GMOs are appropriately trained and have read the *OGTR Guidelines for the Transport, Storage and Disposal of GMOs* and they agree to comply with and be bound by all the requirements for transport. This includes any contractors used for transport. |
|  |  |
| [ ]  | the GMOs are appropriately contained (i.e. double contained). GMOs (e.g. micro-organisms and plants) to be transported must be wholly-contained within a sealed, unbreakable primary container. The Primary container must be packaged in a sealed, unbreakable secondary container. |
|  |  |
| [ ]  | the outermost container is appropriately labelled to include:1. Name, Address and Contact Details of the person responsible for the dealings.
2. A description to state that the container contains a GMO
3. A Biohazard label must be attached to any containers holding GMOs.
 |
|  |  |
| [ ]  | an Emergency Response Procedure is included in the transportation documentation |
|  |  |
| [ ]  | a documented and traceable accounting procedure is implemented ensuring that all GMOs are accounted for during and following transportation |
|  |  |
| [ ]  | access to all GMO material will remain restricted to authorised and trained persons only. This means persons that have completed the required biosafety training or approved reputable transportation companies |
|  |  |
| [ ]  | the external surfaces of the GMO transport containers will be decontaminated prior to transport, and the external and internal surfaces will be decontaminated (via thorough wiping of all surfaces) upon completion of transport. Decontamination will be undertaken with disinfectants appropriate to the GMO. |
|  |  |
| [ ]  | all packaging will be disposed of through the appropriate biological waste stream or decontaminated prior to disposal |
|  |  |
| [ ]  | Where relevant, other packaging and transport regulations will be complied with for the transport of GMOs |

|  |
| --- |
| **Section 10. Storage (if Applicable)** |

**Is this an application for storage of GMOs outside of an authorised physical containment facility?**

|  |
| --- |
| *If Yes – this application must include full details of the GMOs to be stored, where and how the GMOs will be stored and how access will be restricted to authorised personnel only. Complete the acknowledgement below.* |
| [ ]  | YES |  | [ ]  | NO | **Comments:**       |
|  |

**Storage of GMOs declaration (if applicable)**

|  |
| --- |
| When storing GMOs, I, acknowledge that this must be undertaken in accordance with the *OGTR Guidelines for the Transport, Storage and Disposal of GMOs*. I understand and agree to be bound by these guidelines. I confirm that an approval to store GMOs outside of authorised containment will be in accordance with the following conditions: |
| [ ]  | Whole, viable GM animals must not be stored outside of an authorised physical containment facility without permission, in writing, from the Regulator. This restriction does not apply to the sperm, fertilised eggs or embryos of GM animals. |
| [ ]  | Whole, viable GM plants must not be stored outside of an authorised physical containment facility without permission, in writing, from the Regulator. This restriction does not apply to the pollen, seeds, tubers, bulbs, corms or dormant stems of GM plants. |
| [ ]  | GMOs must not be stored in a site that is prone to flooding, storm surges or other natural disasters |
| [ ]  | GMOs, including organisms containing GMOs, being stored must be wholly contained inside a sealed, unbreakable primary container. |
| [ ]  | GMOs for which the minimum permitted physical containment level is PC2, must be packed inside a sealed, unbreakable secondary container. In the case of a small storage unit, such as a refrigerator, freezer, or cryogenic storage container, the storage unit is permitted to be the secondary container. |
| [ ]  | In the event of the escape, unintentional release, spill, leak or loss of GMOs from storage:* efforts must be implemented as soon as reasonably practicable to locate and/or retrieve the GMOs and return the GMOs to containment or render them non-viable; and
* the incident must be reported to the Regulator as soon as reasonably practicable.
 |
| [ ]  | GMOs must not be stored unless a supply of decontamination agents effective against the GMOs being stored is readily available for decontamination purposes. All containers of decontamination agents, including any solutions for decontaminating hands, must be labelled with the contents and, where necessary, the expiry date. Decontamination agents must not be used after their expiry date. |
| [ ]  | A person supplying the GMO for storage must label the material to be stored in a manner capable of notifying any other handler of the material that the item to be stored is, or contains a GMO. |
| [ ]  | The primary container must be labelled to clearly show the name or other identifier of the GMO being stored. |
| [ ]  | The storage unit, or any other secondary container, must be labelled to clearly show the name and contact details of the person responsible for the dealings, so that the person can be contacted should any GMOs be spilled or lost. |
| [ ]  | A biohazard label must be attached to the storage unit when storing any GM micro-organisms that satisfy the criteria for classification as a Risk Group 2 organism as defined in AS/NZS 2243.3. |
| [ ]  | Procedures must be in place to ensure that all GMOs stored can be accounted for. |
| [ ]  | A record(s) of GMOs being stored must be maintained and made available to the Regulator upon request. |
| [ ]  | The record(s) of GMOs being stored must allow the person storing the GMOs to find the exact location of where the GMO is being stored. |
| [ ]  | During the storage of GMOs outside of an authorised physical containment facility, access to the GMOs must be restricted, by any means that is effective, to only a person or class of persons mentioned in the LTIBC’s record of assessment as having the appropriate training and experience to deal with the GMOs |

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| **Section 11. Disposal** |

**Will GMOs be made non-viable before disposal?**

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| *List all methods (e.g. autoclaving, disinfection etc.)* |
|       |

**What method(s) will be used for disposal?**

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| --- |
| *Include the details of all methods (e.g. municipal landfill, incineration.)* |
|      . |

**Who will be involved in the disposal of GMOs?**

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| --- |
| *Also, if applicable, include the details of any centralised waste disposal within the School.* |
|      . |

**Will any Contractors be used for waste disposal?**

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| --- |
| *Provide the details of any contractors, including whether they have appropriate training for GMO disposal* |
|       |

**Will persons involved in disposal be appropriately trained?**

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| --- |
| *If Yes – indicate how they have been trained. If No, provide justification* |
| [ ]  | YES |  | [ ]  | NO | **Comments:**       |
|  |

**Disposal of GMOs declaration**

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| When disposing of GMOs, I, acknowledge that this must be undertaken in accordance with the *OGTR Guidelines for the Transport, Storage and Disposal of GMOs*. I understand and agree to be bound by these guidelines. I confirm that GMOs will not be disposed of unless: |
| [ ]  | personnel disposing of GMOs are appropriately trained and have read the *OGTR Guidelines for the Transport, Storage and Disposal of GMOs* and they agree to comply with and be bound by all the requirements for disposal. This includes any contractors used for disposal. |
|  |  |
| [ ]  | GMOs, or non-GM organisms containing GMOs, are rendered non-viable prior to disposal if the method of disposal is not also the method of decontamination (e.g. incineration). |
|  |  |
| [ ]  | Any wastes containing GMOs must be decontaminated prior to disposal if the method of disposal is not also the method of decontamination. |
|  |  |
| [ ]  | A person supplying the GMO for disposal must label the material in a manner capable of notifying any other handler of the material that the item to be disposed of is, or contains a GMO |
|  |  |
| [ ]  | Decontamination of GMOs must not be performed using defective equipment, expired chemical agents or any method that has not been validated as effective for the decontamination of the GMOs |
|  |  |
| [ ]  | access to all GMO waste prior to disposal, that has not been decontaminated will remain restricted to authorised and trained persons only. This means persons that have completed the required biosafety training or approved reputable waste contractors |

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| **Section 12. Principal Investigator Declaration** |

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| By submitting this application**,** we, the Principle Investigator and all Project Personnel, declare that we |
| [ ]  | have read the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001* (and subsequent amendments) and agree to comply with and be bound by all the requirements of the legislation regulating the conduct of gene technology research. I have considered the ethical principles in relation to this dealing and will act accordingly; |
|  |  |
| [ ]  | are aware of and abide by the Statement of Ethical Principles for Biotechnology in Victoria and the National Framework for the Development of Ethical Principals of Gene Technology; |
|  |  |
| [ ]  | abide by the terms and conditions set by the LTIBC; |
|  |  |
| [ ]  | will ensure that the qualifications and/or experience of all personnel involved with the project are appropriate to the procedures performed; |
|  |  |
| [ ]  | will ensure that appropriate permits from relevant State or Federal agencies will be obtained and that any imposed conditions will be observed; |
|  |  |
| [ ]  | will seek animal ethics and/or human ethics approval, if required; |
|  |  |
| [ ]  | have successfully completed the appropriate training prior to conducting any research and will ensure that all personnel that may work with the GMOs have or will be appropriately trained; |
|  |  |
| [ ]  | certify that the information contained in this application is true and accurate; |
|  |  |
| [ ]  | understand that the information contained in this application is given on the basis that it remains confidential in accordance with relevant La Trobe University policies; |
|  |  |
| [ ]  | will seek approval from the LTIBC for any modifications or amendments to the research prior to their implementation and understand that any amendment that varies the scope of the original proposal assessed and approved by the LTIBC may require the submission of a new application |
|  |  |
| By submitting this application, **I, the Principle Investigator**, declare that, I: |
|  |  |
| [ ]  | Have obtained agreement from all personnel and will retain evidence of this agreement. This evidence may consist of a hard-copy signed document or email from personnel agreeing to participate in and abide by the conditions described in this application. |

|  |  |  |  |  |  |
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|       |  |  |  | Date: |  |
| Name of Chief Investigator |  | Signed by Chief Investigator  |  |  |  |

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| **Section 13. Approvals–Record of Assessment** *(For Office Use Only)* |

Regulation 13B(a) requires an IBC that has assessed a proposal as being a NLRD to make a record of its assessment, in a form approved by the Regulator, and specifies the information that this record must contain.

The information contained within this application and assessed by the LTIBC are in accordance with Regulation 13B(a)(i)-(x).

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|  |  | *LTIBC Conditions/Comments* |
|  |  |  |  |
| [ ]  | APPROVED |       |
|  |  |
| [ ]  | APPROVED WITH CONDITIONS |
|  |  |
| [ ]  | NOT APPROVED |
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|  |  |
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| --- | --- | --- | --- | --- |
| LTIBC Approval Number: |       |  | Expiry Date: |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Date: |       |
| Signed by LTIBC Chair |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| IBC Name: | La Trobe University |  | IBC Number: | OGTR #310 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Accredited Organisation: | La Trobe University |  | Accreditation Number: | Accr-055 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| OGTR Submission Number: |       |  | Submission Date: |       |

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| **Section 14. OGTR Submission Template** *(For Office Use Only)* |

| **IBC\_Assessed** | **IBC\_NLRD\_Identifier** | **Assessment\_Date** | **IBC\_Name** | **Notifying\_Organisation\*** | **Proposing\_Organisation** | **Project\_Title\*** | **GMO\_Details** | **Dealing\_Type\*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Only submit NLRDs to the Gene Technology Regulator that have actually been assessed to be a NLRD.(The answer to this should be "****True****".)* | *Enter a unique identifier (this can include letters and numerals and other characters),eg. "COL 2011/43"Please do not enter extraneous information in this field such as project titles/purpose.* | *This must be a date only (no text) between 21 June 2001 and 30th June of the reporting period (future dates not permitted).Use any date format you wish - the cell will format the date automatically.* | *This is the IBC used by the organisation. e.g. ABCD Institutional Biosafety Committee.* | *Name of the organisation that submitted the NLRD proposal to the IBC. This should also be the organisation that notifies the Regulator.*  | *Name of the organisation(s) proposing to undertake the NLRD. This can be a number of organisations involved in undertaking the dealing.DETAILS ONLY REQUIRED FOR DEALINGS ASSESSED DURING AND AFTER THE 2018-2019 REPORTING PERIOD.* | *Brief project title, for listing on OGTR website (exclude name of the supervisor).DO NOT include any CCI information in the title.* | *Genus and species (where known) and for viruses, the family. If not known, describe the GMO as best you can. For multiple GMOs, please separate by a comma, or semi colon.* | *"[1 Sep 2011]" followed by the paragraph number(s) relating to the kinds of dealing relevant for each containment level as detailed in Schedule 3 of the Gene Technology Regulations e.g. [1 Sep 2011] PC1 - (a), PC2 - (a), (m) and (l), PC3* |
|       |       |       |       |       |       |       |       |       |