CONTENTS

1 BACKGROUND .................................................................................................................................................. 1
  Introduction ..................................................................................................................................................... 1

2 LEGAL AND OPERATIONAL FRAMEWORK ................................................................................................. 2

3 DEFINITIONS .................................................................................................................................................. 3
  Accreditation .................................................................................................................................................. 3
  Biohazard ...................................................................................................................................................... 3
  Certification .................................................................................................................................................. 3
  Dealing ......................................................................................................................................................... 3
  DIR .............................................................................................................................................................. 3
  DNIR ............................................................................................................................................................ 3
  Exempt Dealing ............................................................................................................................................. 4
  Gene Technology .......................................................................................................................................... 4
  IBC ............................................................................................................................................................... 4
  NLRD ........................................................................................................................................................... 4
  OGTR ............................................................................................................................................................ 4
  Organism ..................................................................................................................................................... 4
  PC ................................................................................................................................................................. 4

4 BIOSAFETY POLICY ...................................................................................................................................... 5

5 RESPONSIBILITIES – UNIVERSITY OF TASMANIA ...................................................................................... 6

6 INSTITUTIONAL BIOSAFETY COMMITTEE ................................................................................................ 7
  Role of the Committee ................................................................................................................................... 7
  Reporting Structure ...................................................................................................................................... 7
  Terms of Reference ...................................................................................................................................... 7
  Committee Membership ............................................................................................................................... 7
  Term of Office, Meetings and Quorum ........................................................................................................... 8
  Tenure and frequency of meetings is not specified. The Committee meets as required. ............................. 8
  Confidentiality and Security ........................................................................................................................... 8
  Conflict of Interest ...................................................................................................................................... 9
  Indemnification of Committee Members ......................................................................................................... 9
  Revocation of Membership ............................................................................................................................ 9
  Complaints Resolution .................................................................................................................................. 10
  Retention of Records .................................................................................................................................... 10
  Sharing of Expertise between Institutional Biosafety Committees ................................................................. 10

7 WORKING WITH BIOHAZARDOUS MATERIALS ....................................................................................... 11
  Microbiological Risk Groups ......................................................................................................................... 11
    Human and Animal Infectious Microorganisms ......................................................................................... 11
    Plant Infectious Microorganisms ................................................................................................................ 11
    Invertebrates Carrying Microorganisms .................................................................................................... 11
  Working with Human, Animal or Plant Cells or Tissues ................................................................................ 12

8 CONTAINMENT FACILITIES FOR MICROBIOLOGICAL WORK ............................................................. 13
  Physical Containment Levels .......................................................................................................................... 13
    Physical Containment Level 1 (PC1) ............................................................................................................ 13
    Physical Containment Level 2 (PC2) ............................................................................................................ 13
    Physical Containment Level 3 (PC3) ............................................................................................................ 13
    Physical Containment Level 4 (PC4) ............................................................................................................ 13

9 WORKING WITH GMOs .............................................................................................................................. 15
  What is a GMO? ............................................................................................................................................ 15
What is Gene Technology? ........................................................................................................... 16
What is a Dealing? .......................................................................................................................... 16
What is an Exempt Dealing? ........................................................................................................... 17
What is a Host/Vector System? ..................................................................................................... 17
What is a Notifiable Low Risk Dealing? ......................................................................................... 18
Deals that are NOT Notifiable Low Risk Dealings ................................................................. 18
Deals with Viral Vectors ........................................................................................................... 18

10 CONTAINMENT FACILITIES FOR GMO WORK .................................................................. 19
OGTR Containment Levels ........................................................................................................... 19
Certification of Containment Facilities ....................................................................................... 19

11 IBC APPROVAL FOR BIOHAZARDOUS OR INFECTIOUS MATERIAL ............................... 20
IBC Approval Procedures ............................................................................................................ 20

12 GMO LICENCES ....................................................................................................................... 21
Licence Legislation ....................................................................................................................... 21

13 IBC APPROVAL FOR GM WORK ............................................................................................ 22
IBC Approval Procedures ............................................................................................................ 22
Minor modifications to approved dealings .................................................................................. 22

14 IMPORTATION OF BIOLOGICAL MATERIALS ................................................................. 23
Permits ........................................................................................................................................ 23
Notification ............................................................................................................................... 23

15 TRAINING IN BIOSAFETY .................................................................................................... 24
Induction and Training ................................................................................................................ 24
Records of Training ..................................................................................................................... 24
Immunisation Requirements ....................................................................................................... 24
Access to PC2 Facilities ............................................................................................................. 24

16 AUDITING OF BIOHAZARD FACILITIES ............................................................................ 25
Internal Auditing ......................................................................................................................... 25

17 REPORTING ............................................................................................................................. 26
Reporting to the OGTR ................................................................................................................ 26
Reporting to the Institution ......................................................................................................... 26

18 CLEANING AND WASTE DISPOSAL ............................................................................... 27
Cleaning of PC Facilities ............................................................................................................. 27
Waste Disposal .......................................................................................................................... 27

19 STORAGE OF BIOHAZARDOUS MATERIALS AND GMOs ................................................. 28
Microbiological Materials .......................................................................................................... 28
Risk Group 1 ................................................................................................................................. 28
Risk Group 2 ................................................................................................................................ 28
GMO materials - Exempt & NLRD ............................................................................................ 28
Dealings Not Involving or Involving Intentional Release (DNIR or DIR) ..................................... 28

20 TRANSPORT OF BIOHAZARDOUS MATERIALS AND GMOS ........................................ 29
Within the Facility ....................................................................................................................... 29
Within the Organisation ............................................................................................................ 29
Between Organisations ........................................................................................................... 29

21 BIOHAZARD EMERGENCY PLAN ....................................................................................... 30
Containment Failure .................................................................................................................. 30
First Aid Procedures .................................................................................................................. 30
Biohazard Spills ........................................................................................................................ 30
Spills inside a biological safety cabinet .................................................................................... 30
Spills outside a safety cabinet but in a room, lab or plant house ................................................................. 30
GMO Spills .......................................................................................................................................................... 31
Spill of Material Subject to Quarantine ............................................................................................................ 31

22 REVIEW OF BIO-SAFETY MANUAL ................................................................................................................. 32

APPENDICES ....................................................................................................................................................... 33

Appendix 1 – Extract from NHMRC Immunisation Handbook........................................................................... 33
Appendix 2 – List of Exempt Dealings .................................................................................................................. 34
Appendix 3 – Host/Vector Systems for Exempt Dealings (Table 5) ................................................................. 36
Appendix 4 – Kinds of Dealings suitable for at least NLRD-PC1 (Tables 6 and 7) ............................................. 37
Appendix 5 – Dealings Requiring a Licence (as per Schedule 3 Part 3 of the Act) (Table 8) .................... 39
Appendix 6 – Viral Vector Flow Chart .................................................................................................................. 41
Appendix 7 - OGTR Policy on Scope for Variations of GMO Licences .......................................................... 44
Appendix 8 – PC2 Facility Induction Checklist ................................................................................................ 45
1 BACKGROUND

Introduction

In accordance with the requirements of the Work Health and Safety Act 2012, the University of Tasmania is required to exercise a duty of care towards staff, students and visitors. General principles guiding safe work at the University are provided in the University’s Work Health & Safety policy at:

Work Health & Safety

The Office of the Gene Technology Regulator (OGTR) has specific requirements in relation to practices and procedures involving Genetically Modified Organisms (GMOs). The University of Tasmania is an OGTR-accredited organisation.

The OGTR focus is on the containment of GMOs and animals, plants and microbes that contain GMOs, through a registration and licensing system. Transport and storage of GMOs are also an OGTR consideration. Further information is available at:

Office of the Gene Technology Regulator (OGTR)

This Manual summarises the operation of the University of Tasmania Biosafety management system and provides links to other relevant information and resources.


2 LEGAL AND OPERATIONAL FRAMEWORK


The management system requirements of WorkSafe Tasmania, Workplace Safety Australia, Safe Work Australia, Work Health and Safety Act 2012 and the OGTR are based on principles as found in the Standards ISO 9000 (Quality Assurance Systems) and ISO 14000 (Environment Management Systems).
3 DEFINITIONS

Accreditation

Organisations may be OGTR-accredited under Section 92 of the Gene Technology Act 2000. In order to gain accreditation, the organisation must show that it is able to establish and maintain, or have access to, an Institutional Biosafety Committee able to assess, approve and supervise Dealings.

Biohazard

Any material of biological origin that has the capacity to be detrimental to other biological organisms is deemed a biohazard. A biohazard may include:

- Microorganisms (including bacteria, parasites, fungi, viruses and prions) infectious to humans, animals and plants.
- Organisms or microorganisms capable of producing toxins detrimental to humans, animals and plants.
- Biological material of human, animal or plant origin transfected with infectious or toxin-producing microorganisms.
- Biological material of human, animal or plant origin naturally containing infectious or toxin-producing microorganisms.
- Any object or material contaminated with infectious or bio-toxic material, including sharp objects.

Certification

OGTR-accredited organisations may apply under Part 7 Division 2 of the Gene Technology Act 2000 to have facilities certified to specified Physical Containment (PC) levels. All Dealings, apart from Exempt Dealings, must be carried out in appropriate certified facilities.

Dealing

- Any experiments or activities involving making, developing, producing, manufacturing, breeding, propagating, growing, raising, culturing, importing or exporting a GMO.
- The use of a GMO in manufacturing a product that is not a GMO.
- Storage, transport or disposal of a GMO.

DIR

A Dealing involving an Intentional Release (OGTR classification) - a Dealing that includes the intentional release of a GMO into the environment. Each DIR requires an individual licence, specific to the work, from the OGTR.

DNIR

A Dealing NOT involving an Intentional Release (OGTR classification) - a Dealing that does not includes the intentional release of a GMO into the environment. Each DNIR requires an individual licence, specific to the work,

1 Only toxins of a biological nature are included in this Biosafety Manual.
Exempt Dealings are classified as Dealings under the Act, but they do not require a licence specific to the work and do not need to be reported to the OGTR.

Gene Technology

- Any technique used for the modification of genes or other genetic material.
- Genetically Modified Organism (GMO)
- An organism that has been modified by gene technology.

IBC

Institutional Biosafety Committee

NLRD

A Notifiable Low Risk Dealing (OGTR classification) - a Dealing that must be undertaken in an OGTR-certified PC facility, does not require an individual licence specific to the work but does need to be reported to the OGTR by the accredited organisation.

OGTR

Office of the Gene Technology Regulator

Organism

A biological entity that is viable, capable of reproduction or capable of transforming genetic material.

PC

Physical Containment - specialised containment facilities incorporating structural and behavioural measures to prevent contamination of personnel or the environment.
4 BIOSAFETY POLICY

Biosafety covers the proper use of biologically hazardous material. Biological hazards include any biological or pathogenic agent, substance or material (living or non-living) that may pose a threat to the health and safety of the researcher, participants, community or environment, or needs special precautions to be taken in their use or storage. University of Tasmania (hereafter referred to as the University) has a duty of care to all staff, students, volunteers, contractors and visitors. The University aims to meet all requirements of the Work Health and Safety Act 2012, the Gene Technology Act, 2000, and all other relevant legislation.

In order to meet that aim, the University provides human, physical and financial resources to support Biosafety work and uses specialist expertise as required. An Institutional Biosafety Committee (IBC) has been established to ensure that activities involving biohazards are planned and executed in such a way that every reasonable precaution is taken to protect the health and safety of each employee, the public, and environment, and to prevent damage to property. This IBC operates under the Gene Technology Regulations (GTR) administered by the Office of the Gene Technology Regulator (OGTR). Some material may be approved by OGTR but may also require permission through Biosecurity Tasmania.

The University also aims to ensure that applications to conduct or participate in research utilising GMOs and biohazardous materials are examined in detail prior to such approval and that safety guidelines laid down for particular research projects are adhered to in the conduct of that research.
5 RESPONSIBILITIES – UNIVERSITY OF TASMANIA

The Vice-Chancellor (University of Tasmania) has the ultimate responsibility for meeting the requirements of the Work Health and Safety Act 2012, Gene Technology Act, 2000, and associated Regulations and Standards.

The University’s Office of the Deputy Vice-Chancellor (Research) is responsible for ensuring that Biosafety is managed safely at the University and in accordance with all legislative requirements, and that resources are available to meet those requirements.

The Human Resources Work Health and Safety Unit has overall responsibility for the health, safety and welfare of University staff, students and volunteers, as well as for contractors and visitors to the University.

The Pro Vice Chancellors are responsible for ensuring allocation of resources to enable compliance with legislative requirements and University policies and procedures within each Division.

The Directors/Deans/Heads of Schools/Institutes/Centres have specific delegated responsibility for ensuring that University requirements are met within the sectors under their leadership.

Supervisors must ensure that:

- Approval for Biosafety work is obtained from the Institutional Biosafety Committee prior to commencement of any project involving biohazards or GMOs
- Staff under their supervision are consulted when new Biosafety work is planned
- OGTR rules are posted in OGTR-certified areas
- Personnel working with biohazards are familiar with the University Biosafety Manual and the Policy and Procedures therein and:
  - adhere to the requirements of the Biosafety Manual,
  - have received training in all aspects of biosafety work,
  - have received specific training with regards to working with GMOs, if indicated.

All persons undertaking biosafety work have an obligation to ensure that:

- Their activities do not risk their own safety
- They do not expose other personnel to risk
- They comply with all requirements detailed in the University Biosafety Manual and the Policy and Procedures therein
6 INSTITUTIONAL BIOSAFETY COMMITTEE

Role of the Committee
The role of the Institutional Biosafety Committee (IBC) is to oversee research and teaching activity involving genetically-modified organisms and Risk Group 2 biohazardous material, to assist the University in fulfilling its duty of care and meet the aims of the Biosafety Policy.

Reporting Structure
The Institutional Biosafety Committee (IBC) is a sub-committee of the WHS Committee. The IBC reports directly to the Office of the Deputy Vice-Chancellor (Research).

Terms of Reference
The terms of reference for the University of Tasmania Institutional Biosafety Committee are:

To be the primary body responsible for promoting Work Health and Safety, minimising accidental injury and incidents, maximising exemplary work practices and ensuring a safe and healthy working environment when dealing with biological material.

To be the primary source of advice to the Work Health and Safety Committee, the Vice-Chancellor and Council on all biological health and safety matters.

To ensure all practices involving biological materials are conducted in accordance with legislation, codes of practice and licensing requirements.

To undertake the assessment, review and approval of all University activities involving the use of; biological hazards, Genetically-modified Organisms and pathogenic organisms (including assessing the qualifications and experience of those involved).

To inspect physical containment facilities such as laboratories against the requirements of the Office of the Gene Technology Regulator (OGTR) at least once per year.

Tenure and frequency of meetings is not specified. The Committee meets as required.

To ensure that biological and physical containment facilities at all levels meet, and continue to meet, the safety requirements set down in the “Handbook on the Regulation of Gene Technology in Australia” produced by the OGTR and/or Standards Australia AS/NZS 2243.3: 2010 “Safety in Laboratories: Part 3: Microbiological safety and containment”.

To maintain a register of experiments and activities and those involved in using University containment facilities.

To communicate changes in Gene Technology Regulations and Australia/New Zealand Standards of Safety in Laboratories (AS2243.3) or similar guidelines.

Committee Membership
The composition of the Committee is such that it can competently carry out its duties.

All members are invited to join the Committee by the DVCRI and have equal voting rights.

The Committee should include at least the following members:
• Two molecular biologists with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of gene technology.

• One virologist and/or microbiologist with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of microorganisms.

• One researcher currently using gene technology in his/her research.

• A representative of the University Work Health and Safety Unit.

• A representative of Commercial Services and Development.

• A representative of the Animal Ethics Committee.

• An independent member (i.e. a person with no personal, pecuniary or research association with the University).

• A Chairperson will be appointed by the Office of the Deputy Vice-Chancellor (Research) [DVCR] from the membership of the Committee.

• A Deputy Chairperson should be nominated by the Chair and elected by and from the Committee membership.

• Any other person or persons may be recruited by the Committee to assist in its function or to provide special expertise.

**Term of Office, Meetings and Quorum**

Tenure and frequency of meetings is not specified. The Committee meets as required.

**Confidentiality and Security**

Maintaining confidentiality and security is essential to protecting the approval process as well as privacy, innovation, the integrity of research and the reputation and safety of individuals and Institutions.

Members of the IBC must sign a Confidentiality Agreement that protects information, conversations, deliberations or decisions from being disclosed outside of the Committee itself.

Any visitors, guests or observers present at IBC meetings must also sign Confidentiality Agreements.

Information may be sought by IBC members from contacts outside the IBC with regards to specific issues, but applicants must not be identified nor information divulged which could identify projects or applicants or which could be regarded as socially, scientifically or commercially sensitive. Those contacts must also be informed of the sensitive nature of such an enquiry and the corresponding confidentiality restrictions and be asked to be mindful of such, to exercise absolute discretion and not to discuss the nature of any conversations or information gained with other persons except in conjunction with IBC business or purposes.

Current institutional Confidentiality Agreements signed by IBC members cover in situations where expert advice was sought and provided by a member of another IBC. If the IBC deemed this not sufficient, then a standard one-way Confidentiality Agreement would be requested to be signed by the person providing assistance.

It is up to members to seek advice from the Chair if they are unsure of how to balance their responsibilities with regards to confidentiality and security.

University of Tasmania Information Technology Services (ITS) policies, procedures and guidelines must be adhered to:
• When using ITS facilities or equipment.
• When accessing University of Tasmania webpages or shared sites.

Should any confidential information (or any storage device containing confidential information) pertaining to the IBC be lost or stolen, the Chair must be notified immediately.

Conflict of Interest

A member of the IBC will not take part in the assessment/approval of a project/activity where the member is involved in that project/activity.

Any conflicts of interest must be declared prior to out-of-session assessment of applications and minuted at the subsequent full Committee meeting that ratifies the assessment outcome.

Indemnification of Committee Members

The University shall indemnify individual members who serve on the IBC for any costs arising as the result of legal action against individual members, as a result of work that they undertake as a committee member.

Revocation of Membership

In certain circumstances, the Committee may resolve to recommend to the Office of the [DVCRI] that a member be removed from the Committee. This may occur where the member:

• Has a real or apparent conflict of interest with the interests of the Committee.
• Behaves in a way that brings the Committee into disrepute.
• Impedes the Committee from fulfilling its Terms of Reference.
• Engages in misconduct.
• Incurs a criminal record.
• Incurs termination of employment due to misconduct.
• Has a poor attendance record (i.e. misses three meetings in a row without leave of absence, without good cause or without notifying the Chair).
• Fails to meet confidentiality requirements.
• Consistently fails to review applications and documents distributed for review by the Committee.
• Uses information for purposes other than those intended.
• Behaves in a manner that impairs the effectiveness of the Committee.
• Demonstrates mental or physical incompetence.

Prior to making a resolution to recommend removal, the Chair will meet with the member to outline the basis for the recommendation and will provide the member with reasonable opportunity, not exceeding two weeks, to be heard or to make a written submission in response. Following receipt of the member’s response, the Committee may:

• Resolve to recommend that the member be removed from the Committee.
- Resolve to retain the member.

Where the Committee resolves that a member be removed, the Chair of the Committee will take this recommendation to the Office of the [DVCR]. The granting of such a request is at the discretion of the Office of the [DVCR]. Should it be granted the member’s membership will cease immediately on notification by the Office of the [DVCR] to this effect.

- The Office of the [DVCR] may prohibit a member from being on property under his or her control (thus preventing that member from attending IBC meetings) whilst a resolution to recommend removal is considered, or in the case that criminal charges or allegations of misconduct are being investigated.

- A member may submit a complaint or grievance about any step in this process.

Complaints Resolution

Where complaints are made against the decisions of the IBC, the Chairperson will refer the matter to the Office of the [DVCR] for resolution.

Retention of Records

The IBC will keep/maintain records of all approvals for:

Microbiological work, Risk Group 2 and higher

All genetic manipulation work that is classified by the IBC as:

- Exempt Dealings
- Notifiable Low Risk Dealings (NLRD)
- Dealings Not Involving Intentional Release (DNIR)
- Dealings Involving Intentional Release (DIR)
- Stored GMOs If not part of an approved Dealing
- Stored microbiological materials that fall within the scope of this manual

Sharing of Expertise between Institutional Biosafety Committees

For specific applications that are outside of the expertise of the IBC assistance can be sought from members of alternative IBCs. Requests for such external advice may be sought directly by the IBC Chair approaching another IBC Chair as required.

A standard one-way Confidentiality Agreement may need to be signed by the person providing advice where institutional Confidentiality Agreements signed by IBC members do not adequately cover this arrangement.
7 WORKING WITH BIOHAZARDOUS MATERIALS

Microbiological Risk Groups

In Australia and New Zealand, the following classifications of micro-organisms are used\(^2\), which are based on the pathogenicity of the agent, the mode of transmission and the availability of preventive measures and treatment.

Human and Animal Infectious Microorganisms

Risk Group 1 (low individual and community risk) – a microorganism that is unlikely to cause disease in humans or animals.

Risk Group 2 (moderate individual risk, limited community risk) – a microorganism that can cause human or animal disease, but is unlikely to be a significant risk to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventive measures are available, and the risk of spread is limited.

Risk Group 3 (high individual risk, limited to moderate community risk) – a microorganism that usually causes serious human or animal disease and may present a significant risk to laboratory workers. It could present a risk if spread in the community or the environment, but there are usually effective preventive measures or treatment available.

Risk Group 4 (high individual and community risk) – a microorganism that usually produces life-threatening human or animal disease, represents a significant risk to laboratory workers and is readily transmissible from one individual to another. Effective treatment and preventive measures are not usually available.

Plant Infectious Microorganisms

Plant Risk Group 1 - a microorganism that is unlikely to be a risk to plants, industry, a community or region and is already present and widely distributed.

Plant Risk Group 2 - a microorganism that is a low to moderate risk to plants, industry, a community or region and is already present but not widely distributed.

Plant Risk Group 3 - a microorganism that is a significant risk to plants, industry, a community or region and is exotic but with a limited ability to disperse without the assistance of a vector.

Plant Risk Group 4 - a microorganism that is a highly significant risk to plants, industry, a community or region and is exotic and readily spread naturally without the assistance of a vector.

Invertebrates Carrying Microorganisms

Invertebrate Risk Group 1 - microorganisms carried by invertebrates where the microorganisms are unlikely to be a risk to humans or to the environment and are already present and widely distributed.

Invertebrate Risk Group 2 - microorganisms carried by invertebrates where the microorganisms are a low to moderate risk to humans or to the environment and are already present but not widely distributed. They have a limited ability to disperse because of low persistence of the microorganism outside the host. They are carried by invertebrates that are unlikely to be able to disperse or can be readily controlled.

Invertebrate Risk Group 3 - microorganisms carried by invertebrates where the microorganisms are a significant risk to humans or to the environment and are exotic and have the ability to disperse with or without the aid of a vector.

\(^2\) AS/NZS 2243.3:2010, Section 3
They are carried by invertebrates that are able to disperse.

Invertebrate Risk Group 4 - microorganisms carried by invertebrates where the microorganisms are a highly significant risk to humans or to the environment and are exotic and readily able to disperse with or without the aid of a vector. They may be carried by invertebrates that are difficult to detect visually.

Working with Human, Animal or Plant Cells or Tissues

Human, animal or plant standard cell lines (e.g. bought from a commercial supplier) are considered to be in Risk Group 1, unless otherwise indicated by the supplier.

Human or animal clinical or diagnostic specimens (i.e. a specimen that has been obtained purely for the purpose of diagnosing or monitoring a disease or condition) are considered to be in Risk Group 2, unless a higher Risk Group is indicated by the source or clinical history of the samples.

Work with human, animal or plant cells or tissues has the potential to be hazardous, dependent on the source of the material and the likelihood that it contains micro-organisms or biotoxins. PC1 laboratories can be adequate for working with this material if good microbiological practices are followed, but a documented Risk Assessment should be carried out prior to use to determine what PC level is appropriate.

Preparation of primary cells from human or animal organs or tissues should be done in PC2 containment.

All cells and tissues must be decontaminated prior to disposal.

Facilities within the University are not currently equipped to work with Risk Groups 3 and 4 microorganisms.

For examples of microbiological organisms in each of the Risk Groups, refer to Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment”. The Standard may be accessed through the SAI Global public database, Standards Online, via the University library.

---

See Appendix 1
8 CONTAINMENT FACILITIES FOR MICROBIOLOGICAL WORK

Physical Containment Levels

There are four physical containment levels corresponding to Risk Groups 1 – 4, as defined in Section 8 (above). All work performed in a laboratory or facility of a specific containment level must follow the procedures set out for that level of containment, but it is important to note that the laboratory must comply with the Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3” but does not necessarily require certification. The Standard may be accessed through the SAI Global public database, Standards Online, via the University library.

Animals and plants inoculated with organisms from the above Risk Groups must be housed in containment facilities appropriate to the physical containment level.

A summary of each Containment Level is provided below. Comprehensive information about the requirements for each Level is detailed in Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment”.

Physical Containment Level 1 (PC1)

This level of facility with its practices and equipment is appropriate for general and teaching laboratories. A Physical Containment Level 1 laboratory is suitable for work with microorganisms where the hazard levels are low, and where laboratory personnel can be adequately protected by standard laboratory practice. The organisms used are not known to cause disease in healthy adults (i.e. organisms are in Risk Group 1).

Work may be carried out on the open bench. Specimens that have been inactivated or fixed may be carried out in PC1 facilities.

Physical Containment Level 2 (PC2)

This level of facility with its practices and equipment is applicable to clinical, diagnostic, teaching and other premises where work is carried out with microorganisms or material likely to contain microorganisms, which may be present in the community, where the microorganism may be associated with animal, plant or human disease of moderate severity, (i.e. Risk Group 2 microorganisms).

With good microbiological techniques, work with these agents may be carried out on the open bench. If there is a significant risk from the production of aerosols, a biological safety cabinet should be used.

Physical Containment Level 3 (PC3)

This level of facility with its practices and equipment is applicable to clinical, diagnostic and other premises where work is carried out with indigenous or exotic microorganisms, and where there is a risk of serious infection to humans, animals or plants. Work with Risk Group 3 microorganisms must be carried out in Physical Containment Level 3 facilities.

A Physical Containment Level 3 laboratory provides safeguards to minimize the risk of infection to individuals, the community and the environment. **PC3 facilities are not available within the University at present.**

Physical Containment Level 4 (PC4)
This level of facility with its practices and equipment is applicable to work with highly infectious microorganisms, including Risk Group 4 microorganisms that pose a high individual risk of life-threatening disease and may be readily spread to the community. **PC4 facilities are not available within the University at present.**
9 WORKING WITH GMOS

All work involving GMOs comes under the control of the OGTR as set out in the Gene Technology Act 2000 and Gene Technology Regulations 2001 (updated September 2011).

The requirements of the OGTR are detailed on the OGTR website at www.ogtr.gov.au

Limited extracts from the site are reproduced below but researchers wishing to work with a GMO (designated by the OGTR as a ‘dealing’) should access the site and consult the Gene Technology Act 2000 and the Gene Technology Regulations 2001.

All work involving GMOs must be approved by the IBC; any work involving a DNIR or DIR must also be licenced by the OGTR.

What is a GMO?

A GMO is an organism that has been modified by the use of gene technology.

Organisms that are not classed by the OGTR as GMOs are shown in Table 1.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of organism</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species)</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells</td>
<td>IF: the introduced nucleic acid is incapable of giving rise to infectious agents</td>
</tr>
<tr>
<td>3</td>
<td>Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell</td>
<td>IF: the donor species is also the host species AND the vector DNA does not contain any heterologous DNA</td>
</tr>
<tr>
<td>6</td>
<td>An organism that results from an exchange of DNA</td>
<td>IF: such exchange can occur by naturally occurring processes AND the donor species and the host species are micro-organisms that satisfy the criteria in AS/NZS 2243.3:2010 (Safety in laboratories, Part 3) for classification as Risk Group 1 AND are known to exchange nucleic acid by a natural physiological process AND the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange</td>
</tr>
<tr>
<td>7</td>
<td>An organism that results from an exchange of DNA between the donor species and the host species</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 1: Organisms that are not GMOs (from Schedule 1 of the Act)
What is Gene Technology?

Gene technology is any technique used for the modification of genes or other genetic material.

Techniques that are not classed by the OGTR as gene technology are shown in Table 2.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of technique</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Somatic cell nuclear transfer</td>
<td>IF: the transfer does not involve genetically modified material</td>
</tr>
<tr>
<td>2</td>
<td>Electromagnetic radiation induced mutagenesis</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Particle radiation induced mutagenesis</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Chemical induced mutagenesis</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>Fusion of animal cells, or human cells</td>
<td>IF: the fused cells are unable to form a viable whole animal or human</td>
</tr>
<tr>
<td>6</td>
<td>Protoplast fusion, including fusion of plant protoplasts</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Embryo rescue</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>In vitro fertilisation</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>Zygote implantation</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>A natural process Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis</td>
<td>IF: the process does not involve genetically modified material</td>
</tr>
</tbody>
</table>

Table 2: Techniques that are not gene technology (from Schedule 1A of the Act)

What is a Dealing?

A Dealing includes any of the activities listed in Table 3:

The term 'dealings', in relation to a genetically modified organism (GMO) is defined in the Gene Technology Act 2000 (the Act).

'Deal with', in relation to a GMO, means the following:

- 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 that is not the GMO
- grow, raise or culture the GMO
- import the GMO
- transport the GMO
- dispose of the GMO
- possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs in Tables 4-8.

Table 3: OGTR definition of Dealings
What is an Exempt Dealing?

Exempt Dealings are classified as Dealings under the Act but do not require a licence specific to the work. Exempt dealings must be approved by the IBC but do not need to be reported to the OGTR.

There is no prescribed PC facility requirement for Exempts dealings, but the OGTR strongly suggests that all Exempt Dealings be carried out under PC1 conditions at minimum, a view that is supported by the IBC.

Activities described as Exempt Dealings are shown in Table 4 in Appendix 2.

What is a Host/Vector System?

The OGTR specifies which host/vector systems may be used for Exempt Dealings.

A vector system is the means by which donor nucleic acid is introduced into a host cell.

The host is the type of cell into which donor nucleic acid is introduced.

Vector systems can include plasmids, non-conjugative plasmids, bacteriophages or viruses.

- Non-conjugative plasmid means a plasmid that is not self-transmissible, and includes, but is not limited to, non-conjugative forms of the following plasmids:
  - Bacterial artificial chromosomes (BACs)
  - Cosmids
  - P1 artificial chromosomes (PACs)
  - Yeast artificial chromosomes (YACs)

Donor nucleic acid may also be introduced into the host using a non-vector system, which means a system by which donor nucleic acid is or was introduced (for example, by electroporation or particle bombardment) into a host cell:

- In the absence of a nucleic acid-based vector
- Using a nucleic acid-based vector in the course of a previous dealing and the vector is:
  - no longer present
  - Present but cannot be remobilised from a host cell

Approved host/vector systems are detailed in Table 5 in Appendix 3.
What is a Notifiable Low Risk Dealing?

Notifiable Low Risk Dealings (NLRDs) are classified as Dealings under the Act but do not require a licence specific to the work. NLRDs must be approved by the IBC and need to be reported to the OGTR by the accredited organisation; the OGTR will assign its own identification numbers to reported NLRDs; this information, including the name of the accredited organisation and the title of the Dealing, is made publicly available on the OGTR website.

There are prescribed PC facility requirements for NLRDs (PC1 or PC2 only).

Classifications of NLRDs are shown in Tables 6 and 7 in Appendix 4.

Dealings that are NOT Notifiable Low Risk Dealings

A Dealing that is not an Exempt Dealing or a Notifiable Low Risk Dealing can only be undertaken by a person who is licensed, under the Act, for the Dealing.

A person may only apply for a license after seeking approval for the project from the IBC.

Dealings NOT involving an intentional release of GMOs into the environment (DNIRs) are dealings with GMOs in contained facilities that do not meet the criteria for classification as Exempt Dealings or Notifiable Low Risk Dealings. These dealings must be licensed by the Gene Technology Regulator (the Regulator).

Dealings with a GMO licensed as a DNIR must not involve release into the environment.

The contained facilities used for conducting DNIRs must be certified and typically range from Physical Containment Level 2 (PC2) to Physical Containment Level 4 (PC4). The appropriate level of containment is determined by the Risk Group classification of the wild type (non-genetically modified parent) organism as outlined in the Australian/New Zealand Standard (AS/NZS 2243.3:2010) AND the risk(s) identified for dealings with the specific GMO.

The kinds of dealings with GMOs that are classified as DNIRs are described in Schedule 3, Part 3 of the Gene Technology Regulations 2001 (the Regulations) and are higher risk dealings than NLRDs.

In general, DNIRs consist of dealings with GM pathogenic organisms, or GM organisms containing higher risk genes from pathogens or genes that encode toxins or confer an oncogenic modification or immuno-modulatory function.

Dealings involving an Intentional Release of GMOs into the Australian environment (DIRs) are dealings with GMOs outside contained facilities. These can range from small-scale field trials (limited and controlled releases) of GMOs to general/commercial release of GMOs.

Dealings considered to carry a higher risk than those categorised as NLRDs, which may be undertaken only under a licence from the OGTR, are shown in Table 8 in Appendix 5.

Dealings with Viral Vectors

Dealings with viral vectors can be classified in the DNIR, NLRD, and exempt categories, therefore guidance on the correct classification of contained dealings with viral vectors has been developed – see the flow chart in Appendix 6.
10 CONTAINMENT FACILITIES FOR GMO WORK

OGTR Containment Levels

Four levels of containment facilities are defined for working with GMOs. These are PC1 to PC4 and these classifications harmonise with the Physical Containment classifications for microbiological work (Section 9). That is, for any one containment level, similar risk factors are associated with either microbiological work or work with GMOs. However, work with GMOs may need to be undertaken in OGTR-certified facilities. The OGTR has strict rules for working with GMOs and the Certification of containment facilities.

Certification of Containment Facilities

The Gene Technology Act requires NLRD PC1, NLRD PC2, DNIR and DIR Dealings to be conducted within an OGTR-certified facility.

The University currently has both Physical Containment Level 1 & Level 2 OGTR-certified animal, aquatic and laboratory facilities.

To be granted Certification, a facility must meet each of the requirements specific for that classification of certification.

Facilities are certified for a 5-year period. At the conclusion of this time a request for recertification can be submitted. Certified laboratories will have signage on the door specifying the certification and the approval period.

Certified facilities are inspected annually.

Personnel using OGTR-certified facilities must be trained in the requirements of that facility, and the training must be documented.

OGTR-certified facilities may be audited / inspected by the OGTR at any time.

For OGTR-certification of PC1 and PC2 animal, aquatic and laboratory facilities, both the Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment” and OGTR “Guidelines for Certification of a Physical Containment (TYPE) Facility” requirements must be adhered to. The Standard may be accessed through the SAI Global public database, Standards Online, via the University library. OGTR Guidelines for each type of facility may be downloaded from the OGTR website:

OGTR Certification Guidelines for PC Facilities
11 IBC APPROVAL FOR BIOHAZARDOUS OR INFECTIOUS MATERIAL

IBC Approval Procedures

Work specified as Risk Group 1 (refer Section 9) does not require approval from the IBC. However, PC1 procedures must be followed when working with these organisms.

All work specified as Risk Group 2 (Section 9) must be approved by the IBC and must be carried out in a PC2 microbiological facility. Procedures required for a PC2 microbiological facility, as set out in Australian Standard 2243.3:2010 “Safety in Laboratories: Part 3: Microbiological safety and containment” must be followed. Microbiological facilities are not certified but are audited by the IBC (refer to Section 7).

IBC approval must be obtained for Storage of all microbiological organisms of Risk Group 2 (if not part of an approved project)

The IBC must be notified of the importation or acquisition of all microbiological organisms of Risk Group 2 (if not part of an approved project)

To obtain approval from the IBC:

- Complete the Dealing with GMO application form for the proposed project, acquisition or storage.
- Submit the completed form to the IBC via Mail Box 46.
- Applications will be checked by the Chair then distributed to the Committee members. Applications are assessed and approved “out of session”.
- The application forms and information for obtaining IBC approval is available for download from the IBC web page: Biosafety

There are currently no facilities within the University equipped for working with risk groups 3 and 4 microorganisms.
12 GMO LICENCES

Licence Legislation

A GMO licence is a legal instrument issued by the Gene Technology Regulator (the Regulator) under the Gene Technology Act 2000 (the Act) that sets down the conditions under which specified dealings with genetically modified organisms (GMOs) must be undertaken. Licences may be issued for Dealings Not involving Intentional Releases (DNIRs), Dealings involving Intentional Releases (DIRs) or Inadvertent Dealings.

A person who deals with a GMO without a licence is guilty of an offence, punishable under Section 32 of the Act if;

- the person deals with a GMO, knowing that it is a GMO; and
- the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact; and
- the dealing with the GMO is not specified in an Emergency Dealing Determination, and the person knows or is reckless as to that fact; and
- the dealing is not a Notifiable Low Risk Dealing, and the person knows or is reckless as to that fact; and
- the dealing is not an Exempt Dealing, and the person knows or is reckless as to that fact; and
- the dealing is not included on the GMO Register, and the person knows or is reckless as to that fact.
13 IBC APPROVAL FOR GM WORK

IBC Approval Procedures

IBC approval must be obtained for:

- All procedures involving GMOs
- Storage of all GMOs (if not part of an approved Dealing)

The IBC must be notified of:

- The importation or acquisition of all GMOs (if not part of an approved Dealing)

**NOTE: The University of Tasmania is currently not accredited by the OGTR for any GMO work at PC3 or PC4 level.**

To obtain approval from the IBC:

- Complete the Dealing with GMO application form for the proposed project, acquisition or storage.
- Submit the completed form to the IBC via Mail Box 46.
- Applications will be checked by the Chair then distributed to the Committee members. Applications are assessed and approved “out of session”.
- The application forms and information for obtaining IBC approval is available for download from the IBC webpage: [Biosafety](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/forms)

Applications for a License from the OGTR for a Dealing Not involving Intentional Release (DNIR) or a Dealing involving Intentional Release (DIR) must first be approved by the IBC. To obtain IBC approval, submit completed DNIR or DIR form, downloaded from:


For assistance with OGTR applications, contact the Chair of the IBC (contact details are on the IBC webpage, as above).

A number of forms and guidelines are also available on the OGTR website in relation to assisting with preparing applications, for notification and reporting to the Gene Technology Regulator, as well as technical and procedural guidelines under the Gene Technology Act 2000 in relation to GMOs:


Failure to comply with appropriate PC operating procedures and/or licensing conditions will lead to revocation of approval by the IBC and/or revocation of licence by the OGTR.

Minor modifications to approved dealings

The OGTR allows the minor modifications to be made to Licensed Dealings; these can be found in Appendix 8. The IBC allow the same minor modifications to be made to approved Exempt and NLR Dealings, with the exception that NLRDs can only be approved for a maximum of 5 years. To apply for approval of a minor modification use the application form on the IBC website: [Biosafety](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/guidelines-1)
14 IMPORTATION OF BIOLOGICAL MATERIALS

Permits

Imported biological materials pose a potential quarantine risk, particularly if they are used in animal experimentation. Imported biological materials should be considered as potentially infectious, and handled and disposed of accordingly.

Biosecurity in Australia is the responsibility of the Federal Department of Agriculture and Water Resources. This department has quite specific and strict regulations and requirements regarding the use of imported biological materials. These regulations take into account assessments of the risks associated with the types of materials. Items are usually assessed as unrestricted, restricted or prohibited. Persons wanting to use restricted materials are required to obtain a permit for importation and use of the materials. All imports under import permits must abide by the conditions listed on the permit.

For further information about DAFF import permits and application forms, refer to the Department of Agriculture and Water Resources webpages at: Biosecurity

Notification

The IBC must be notified of all GMOs imported via import permit, or GMOs brought into the University of Tasmania or acquired by staff/students by other means, that fall within the scope of this manual.
15 TRAINING IN BIOSAFETY

Induction and Training

Biosafety induction into PC facilities is the responsibility of the person nominated as ‘Responsible Person’ for that facility:

- For contractors or visitors
- For staff, students and volunteers

The approved Project Supervisor is responsible for biosafety induction and ongoing training to the required PC level for all project personnel. A checklist for laboratory induction (which specifies appropriate levels of induction for not only researchers but also contractors and others who only enter facilities infrequently) appears in Appendix 7.

Records of Training

Records of biosafety training, including training in OGTR requirements, must be kept by the person nominated as the “Responsible Person” for the facility where the work is carried out. These will be required to be produced during the annual audit of the area.

Immunisation Requirements

Where laboratory personnel are working with infectious or potentially infectious microorganisms immunisation may be recommended (especially if pregnant, considering pregnancy, immune-compromised or immune-suppressed). Appendix 1 shows an extract of the NHMRC Immunisation Handbook showing recommended vaccinations for persons at increased risk of certain occupationally acquired vaccine-preventable diseases.

Access to PC2 Facilities

Routine access to Animal Facilities is only provided to persons that have undergone the Induction and Training required by the Facility Management.

Routine access to PC facilities is only provided to persons that have:

- Undertaken General Laboratory Safety Induction
- Undertaken PC Facility Induction (Appendix 7)
- Been issued with the required personal protective equipment
- Been authorised as a laboratory user by the Facility Management

Where access to PC facilities is required for the purposes of maintenance or cleaning, this will only be provided to persons that have:

- Undertaken the Cleaner/Maintenance Induction (Appendix 7)
- Demonstrated that they have any required personal protective equipment

PC2 facilities shall be kept locked at all times. Only authorised persons shall be provided with key card access to the laboratory.
Working safely is a condition of access to PC facilities, and repeated failure to observe safe working practices and procedures will result in the withdrawal of access privileges.

16 AUDITING OF BIOHAZARD FACILITIES

Internal Auditing

Internal auditing will take place in two forms:

The IBC will perform an arranged audit of all OGTR-certified PC1 and PC2 facilities at the University of Tasmania on an annual basis. The IBC will perform an arranged audit of all microbiological facilities using Risk Group 2 organisms for compliance with PC2 microbiological procedures on an annual basis.

The Chair of the IBC (or delegate) will request reports from Project Supervisors annually identifying the status of current exempt, NLRDs, DNIRs and DIRs.

The IBC may also conduct un-announced inspections/audits of facilities and procedures.

The IBC may investigate any occurrence involving a spill or unintentional release of microorganisms or GMOs.

The IBC will also undertake investigation where there is a notification of a breach of the OGTR legislation.
17 REPORTING

Reporting to the OGTR

The IBC has the responsibility for reporting to the OGTR:

The membership of the IBC

Details of current NLRD, DNIR and DIR projects

Details of certified containment laboratories, animal facilities and plant facilities

The preparation and submission of an annual report as an accredited organisation

Reporting to the Institution

The IBC has the responsibility for reporting to the Office of the Deputy Vice-Chancellor (Research):

Activities of the IBC, by way of Institutional Annual Report

Copy of the annual report submitted to OGTR
18 CLEANING AND WASTE DISPOSAL

Cleaning of PC Facilities

All facilities must be kept clean and tidy at all times. Workbenches should be cleared and surfaces decontaminated at the end of each day.

Items for sterilisation should be collected regularly and decontaminated by a suitable approved method i.e. autoclave. Treated waste should be disposed of on a regular basis.

Walls should be cleaned periodically or when visibly dirty by washing with a detergent solution. Open shelves should be periodically cleaned of dust to reduce the risk of contamination of work areas.

Only trained personnel shall be permitted to clean facilities. Floors should be cleaned outside normal working hours, preferably by wet mopping with a detergent solution. Sweeping, dry mopping and vacuuming should be avoided as these procedures produce airborne dust.

Waste Disposal

All waste must be segregated at the point of generation into:

General waste – non-infectious material, paper, plastics, paper products.

Sharps – syringes, needles, broken glass, scalpel blades. These must be collected in a puncture-resistant container.

Infectious waste – includes microbiologically contaminated materials such as culture bottles, used gloves, tissue samples. These must be collected into a sturdy bin or plastic bag and must be treated by autoclave before removal from the certified facility.

Microbiological Waste - waste containing live organisms from a PC2 microbiological facility must be treated by either steam sterilisation* or chemical disinfectant treatment**, e.g. 0.5-1% sodium hypochlorite solution (for liquid waste). After treatment, waste can then be disposed by the treated waste stream (solid) or by the sewer system (liquid).

* Where steam sterilisation is used, the temperature cycle must be monitored and the steam steriliser tested on a monthly basis. Refer to Australian Standard 2243.3:2010 Safety in Laboratories: Part 3: Microbiological Aspects and Containment Facilities.

** Refer to Australian Standard 2243.3: 2010 Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, for a full listing of chemical disinfectants.
19 STORAGE OF BIOHAZARDOUS MATERIALS AND GMOS

Microbiological Materials

Risk Group 1

Microbiological samples must be clearly labelled and stored in leak-proof containers.

Risk Group 2

Microbiological samples must be clearly labelled and stored in a leak-proof container within a second unbreakable container.

Secondary containers must be in a secured area to prevent access by unauthorised persons.

GMO materials - Exempt & NLRD

Only GMOs with IBC approval may be stored within any facilities coming under the jurisdiction of the University of Tasmania IBC.

All GMOs must be stored in sealed unbreakable primary containers and then in a secondary container that is labelled with a biohazard symbol, description of contents, date of storage and the contact details for the person responsible for the contents.

Secondary containers must be locked when not in use or located in a secure area that prevents access to the container by persons not authorised to access the contents.

Dealings Not Involving or Involving Intentional Release (DNIR or DIR)

For all completed projects, a storage form must be filled out and submitted to the IBC. The form can be downloaded from:


All the GMOs must be stored in sealed unbreakable primary containers.

Primary containers must be stored in a secondary container that is labelled with a biohazard symbol description of contents, date of storage and the contact details for the person responsible for the contents.

Secondary containers must be locked when not in use or located in a secure area that prevents access to the container by persons not authorised to access the contents.

NOTE: Storage of GMOs classified as DNIR or DIR must be licensed by the OGTR and any licensing conditions must be met.
20 TRANSPORT OF BIOHAZARDOUS MATERIALS AND GMOS

Within the Facility

No special conditions are required for transporting materials within a facility, i.e. within the walls that constitute the Physical Containment.

Within the Organisation

Precautions must be taken to ensure the biohazard materials and GMOs do not contaminate the environment. The material should be transported in a sealed unbreakable container, appropriately labelled. Where the material is PC2 (microbiological or GMO), a secondary sealed outer container must also be used.

Between Organisations

Stringent procedures have been developed for safe transport of biological, hazardous and dangerous materials by air, rail and road. For full details, refer to Australian Standard 2243.3: 2010 Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, Section 13 and references therein.

Conditions for transporting GMOs are available from the OGTR website:


For materials that are not commercially available a Materials Transfer Agreement is also required and must be fully executed prior to transfer.
21 BIOHAZARD EMERGENCY PLAN

Containment Failure
Where there has been a failure to contain biohazardous material or GMOs within a Room/Laboratory/Plant house/Animal facility:
Immediately notify the Project Supervisor.
Immediately notify the Chair or Executive Officer of the IBC.
Immediately notify the nominated Responsible Person for the facility.
Immediately notify Security, University of Tasmania, advising the nature of the incident.
Complete an online Incident Report form within 24 hours: Incident Form

First Aid Procedures
In case of accidental personal contamination/exposure to any Risk Group 2 biohazardous material or GMO:
Immediately notify the Project Supervisor.
Immediately notify the Chair or Executive Officer of the IBC.
Immediately notify the nominated Responsible Person for the facility.
Seek medical help if required.
Complete an online Incident Report form within 24 hours: Incident Form

Biohazard Spills
Spills inside a biological safety cabinet
Leave the cabinet ON to retain aerosols. Put on gloves.
Place absorbent material wetted with disinfectant over the spill and leave for about 10 minutes.
Remove the absorbent material and dispose of in correct manner.
Wipe the floor of the cabinet and any other contaminated surfaces with disinfectant.
For large spills, or any highly infectious material, decontaminate the cabinet with gaseous sterilant.
Spills outside a safety cabinet but in a room, lab or plant house
Low-risk microbiological material
Put on gloves. Cover spill with absorbent material wetted with disinfectant.
After about 10 minutes, Treat and dispose of all contaminated material.
Wipe the area with fresh disinfectant.

High-risk microbiological material
Do not breathe the aerosol!
Evacuate the area and close the doors for at least 30 minutes.
Advise others working in the area, including the nominated responsible person for the facility.

Remove and dispose of contaminated clothing.

Assemble several personnel to clean up spill.

Put on clean protective apparel, including mask and gloves.

Place absorbent material wetted with disinfectant over the spill and leave for 10 minutes.

Treat and dispose of all contaminated material.

Wipe over area with fresh disinfectant.

Discard protective apparel and gloves.

GMO Spills

Follow the procedure for high-risk microbiological material.

Spill of Material Subject to Quarantine

For quarantine related spills in the facility the following procedure must be followed.

Spill Management Instructions

- Put on relevant gloves, mask and plastic apron as required.
- Cover area of spill with absorbent material commencing at the exterior of the spill to contain any fluid. Once the spill is surrounded with absorbent material cover the remainder of the spill.
- Allow absorbent material sufficient time to completely absorb and congeal the spill.
- Remove any broken glass associated with the spill using tongs. Place this broken glass into a suitably sized plastic container.
- Using an approved dustpan and brush/scrapper pick up the absorbed spill and any remaining spill material(s) and place into an autoclave bag.
- Wipe area with absorbent cloths to remove any residual contaminant. Place used absorbent cloths into autoclave bag.
- Wash the spill area with a DAFF Biosecurity approved broad-spectrum disinfectant (i.e. Decon 90).
- Discard all single use items into autoclave bag, seal and autoclave in accordance with section 6.2 Waste Disposal.

Note: The reusable equipment, such as brooms, dustpans, and double lined bins will remain within the facility. The applicable method of cleaning of this equipment (via disinfectant, sterilisation, or other AQIS approved method) and the spillage area will be undertaken with an AQIS approved broad-spectrum disinfectant.

Note: Report all use of spill materials to the Research Laboratory Manager (#7147) or Technical Officer (#4659) so that replacement spill materials can be obtained.

Researchers will immediately report to DAWR Biosecurity and the chair of the Safety Committee any major spillage or loss of quarantine material. This includes any loss of quarantine material outside the confines of the premise, any spill which cannot be readily cleaned up within 15 minutes, or which may be accessed by the general public. Information that will be reported to include the volume spilled, the spill clean-up method (including the treatment and/or destruction of material used to clean up the spill), type of material and the details of all staff involved.
Department of Agriculture and Water Resources
Biosecurity:  1800 900 900

22 REVIEW OF BIO-SAFETY MANUAL

This manual shall be reviewed regularly by the IBC.
APPENDICES

Appendix 1 – Extract from NHMRC Immunisation Handbook

From Table 3.3.7: Recommended vaccinations for persons at increased risk of certain occupationally acquired vaccine-preventable diseases

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Workers (HCW)</td>
<td></td>
</tr>
</tbody>
</table>
| All HCW | Hepatitis B  
Influenza  
MMR (if non-immune)‡  
Pertussis (dTPa)  
Varicella (if non-immune) |
| HCW who work in remote Indigenous communities or with Indigenous children in NT, Qld, SA and WA, and other specified healthcare workers in some jurisdictions | Vaccines listed for ‘All HCW’, plus hepatitis A |
| HCW who may be at high risk of exposure to drug-resistant cases of tuberculosis (dependent on state or territory guidelines) | Vaccines listed for ‘All HCW’, plus consider BCG |

**Persons who work with children**

All persons working with children, including:
- staff and students working in early childhood education and care  
- correctional staff working where infants/children cohabit with mothers  
- school teachers (including student teachers)  
- outside school hours carers  
- child counselling services workers  
- youth services workers

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
</table>
| Influenza  
MMR (if non-immune)  
Pertussis (dTPa)  
Varicella (if non-immune) |

Staff working in early childhood education and care  

Vaccines listed for ‘Persons who work with children’, plus Hepatitis A

**Laboratory Personnel**

Laboratory personnel handling veterinary specimens or working with Q fever organism (*Coxiella burnetii*)

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q fever</td>
</tr>
</tbody>
</table>

Laboratory personnel handling either bat tissues or lyssaviruses (including rabies virus and Australian bat lyssavirus)

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabies</td>
</tr>
</tbody>
</table>

Laboratory personnel routinely working with these organisms:

- *Bacillus anthracis*  
- Vaccinia poxviruses  
- Poliomyelitis virus  
- *Salmonella enterica* subspecies enterica serovar Typhi (S. Typhi)  
- Yellow fever virus  
- *Neisseria meningitidis*  
- Japanese encephalitis virus  
- Seasonal Influenza Virus*

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
</table>
| Anthrax  
Smallpox  
Poliomyelitis (IPV)  
Typhoid  
Yellow fever  
Quadrivalent meningococcal conjugate vaccine (4vMenCV)  
Japanese encephalitis  
Influenza |

**Persons who work with animals**

Veterinarians

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
</table>
| Influenza  
Q fever  
Rabies |

Wildlife and zoo workers who have contact with at-risk animals, including kangaroos and bandicoots

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q fever</td>
</tr>
</tbody>
</table>

Persons who come into regular contact with bats (both ‘flying foxes’ and microbats), bat handlers, bat scientists, wildlife officers, zoo curators

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabies</td>
</tr>
</tbody>
</table>

Poultry workers and others handling poultry

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
</tr>
</tbody>
</table>

**Other persons exposed to human tissue, blood, body fluids or sewage**

Workers who have regular contact with human tissue, blood or body fluids and/or used needles or syringes

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
</tr>
</tbody>
</table>

Plumbers or other workers in regular contact with untreated sewage

<table>
<thead>
<tr>
<th>Vaccine</th>
</tr>
</thead>
</table>
| Hepatitis A  
Tetanus (dT or dTPa) |

*University of Tasmania addition
### Appendix 2 – List of Exempt Dealings

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of dealing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>A dealing with a genetically modified <em>Caenorhabditis elegans</em>, unless: an <em>advantage</em> is conferred on the animal by the genetic modification; or as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.</td>
</tr>
<tr>
<td>3</td>
<td>A dealing with an animal into which genetically modified somatic cells have been introduced, if: the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.</td>
</tr>
<tr>
<td>3A</td>
<td>A dealing with an animal whose somatic cells have been genetically modified <em>in vivo</em> by a replication defective viral vector, if the <em>in vivo</em> modification occurred as part of a previous dealing; and the replication defective viral vector is no longer in the animal; and no germ line cells have been genetically modified; and the somatic cells cannot give rise to infectious agents as a result of the genetic modification; and the animal is not infected with a virus that can recombine with the genetically modified nucleic acid in the somatic cells of the animal.</td>
</tr>
<tr>
<td>4</td>
<td>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. The donor nucleic acid: must meet either of the following requirements: 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; 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. 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; and must not code for a toxin with an LD$<em>{50}$ of less than 100 microg/kg; and must not code for a toxin with an LD$</em>{50}$ of 100 microg/kg or more, if the intention is to express the toxin at high levels; and must not be uncharacterised nucleic acid from a toxin-producing organism; and</td>
</tr>
</tbody>
</table>
must not include a viral sequence, unless the donor nucleic acid:

is missing at least 1 gene essential for viral multiplication that

(A) is not available in the cell into which the nucleic acid is introduced; and

(B) will not become available during the dealing; and

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 item 1 of Part 2 of this Schedule, if the donor nucleic acid is not derived from either:

| a pathogen; or
| a toxin-producing organism |

Table 4: List of Exempt Dealings (from Schedule 2 Part 1 of the Act)
## Table 5: Host/Vector Systems for Exempt Dealings (as per Schedule 2 Part 2 of the Act)

<table>
<thead>
<tr>
<th>Item</th>
<th>Class</th>
<th>Host</th>
<th>Vector</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bacteria</td>
<td><em>Escherichia coli</em> K12, <em>E. coli</em> B, <em>E. coli</em> C or <em>E. coli</em> Nissle 1917 — any derivative that does not contain:</td>
<td>1. Non-conjugative plasmids &lt;br&gt; 2. Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13) &lt;br&gt; 3. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>1</em>. generalised transducing phages; or <em>2</em>. genes able to complement the conjugation defect in a non-conjugative plasmid</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Bacillus</em> — specified species — asporogenic strains with a reversion frequency of less than 10⁻¹:</td>
<td>1. Non-conjugative plasmids &lt;br&gt; 2. Plasmids and phages whose host range does not include <em>B. cereus</em>, <em>B. anthracis</em> or any other pathogenic strain of <em>Bacillus</em> &lt;br&gt; 3. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. <em>B. amyloliquefaciens</em> &lt;br&gt;b. <em>B. licheniformis</em> &lt;br&gt;c. <em>B. pumilus</em> &lt;br&gt;d. <em>B. subtilis</em> &lt;br&gt;e. <em>B. thuringiensis</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Pseudomonas putida</em> — strain KT 2440</td>
<td>1. Non-conjugative plasmids including certified plasmids: pKT 262, pKT 263, pKT 264 &lt;br&gt; 2. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. <em>S. aureofaciens</em> &lt;br&gt;b. <em>S. coelicolor</em> &lt;br&gt;c. <em>S. cyaneus</em> &lt;br&gt;d. <em>S. griseus</em> &lt;br&gt;e. <em>S. lividans</em> &lt;br&gt;f. <em>S. parvulus</em> &lt;br&gt;g. <em>S. rimosus</em> &lt;br&gt;h. <em>S. venezuelae</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Agrobacterium radiobacter</em> &lt;br&gt;<em>Agrobacterium rhizogenes</em> — disarmed strains &lt;br&gt;<em>Agrobacterium tumefaciens</em> — disarmed strains</td>
<td>1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors &lt;br&gt; 2. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Lactobacillus</em> &lt;br&gt;<em>Lactococcus lactis</em> &lt;br&gt;<em>Oenococcus oeni</em> syn. <em>Leuconostoc oeni</em> &lt;br&gt;<em>Pediococcus</em> &lt;br&gt;<em>Photobacterium angustum</em> &lt;br&gt;<em>Pseudalteromonas</em> tunicata &lt;br&gt;<em>Rhizobium</em> (including the genus <em>Allovirhizobium</em>) &lt;br&gt;<em>Sphingopyxis</em> alaskensis syn. <em>Sphingomonas alaskensis</em> &lt;br&gt;<em>Streptococcus thermophilus</em> &lt;br&gt;<em>Synechococcus</em> — specified strains: &lt;br&gt;(a) PCC 7002 &lt;br&gt;(b) PCC 7942 &lt;br&gt;(c) WH 8102 &lt;br&gt;<em>Synechocystis</em> species — strain PCC 6803 &lt;br&gt;<em>Vibrio cholerae</em> CVD103-HgR</td>
<td>1. Non-conjugative plasmids &lt;br&gt; 2. None (non-vector systems)</td>
</tr>
<tr>
<td>2</td>
<td>Fungi</td>
<td><em>Kluyveromyces lactis</em> &lt;br&gt;<em>Neurospora crassa</em> — laboratory strains &lt;br&gt;<em>Pichia pastoris</em> &lt;br&gt;<em>Saccharomyces cerevisiae</em> &lt;br&gt;<em>Schizosaccharomyces pombe</em> &lt;br&gt;<em>Trichoderma reesei</em> &lt;br&gt;<em>Yarrowia lipolytica</em></td>
<td>1. All vectors &lt;br&gt; 2. None (non-vector systems)</td>
</tr>
<tr>
<td>3</td>
<td>Slime moulds</td>
<td><em>Dictyostelium</em> species</td>
<td>1. <em>Dictyostelium</em> shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 &lt;br&gt; 2. None (non-vector systems)</td>
</tr>
<tr>
<td>4</td>
<td>Tissue culture</td>
<td>Any of the following if they cannot spontaneously generate a whole animal:</td>
<td>1. Non-conjugative plasmids &lt;br&gt; 2. Non-viral vectors, or replication defective viral vectors unable to transduce human cells &lt;br&gt; 3. Baculovirus (<em>Autographa californica</em> nuclear polyhedrosis virus), polyhedrin minus &lt;br&gt; 4. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. animal or human cell cultures (including packaging cell lines); &lt;br&gt;b. isolated cells, isolated tissues or isolated organs, whether animal or human; &lt;br&gt;c. early non-human mammalian embryos cultured in vitro</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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:</td>
<td>1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in <em>Agrobacterium tumefaciens</em>, <em>Agrobacterium radiobacter</em> or <em>Agrobacterium rhizogenes</em> &lt;br&gt; 2. Non-pathogenic viral vectors &lt;br&gt; 3. None (non-vector systems)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. plant cell cultures; &lt;br&gt;b. isolated plant tissues or organs</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4 – Kinds of Dealings suitable for at least NLRD-PC1 (Tables 6 and 7).

<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1a</td>
<td>A Dealing involving:</td>
<td>UNLESS:</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory guinea pig OR</td>
<td>i. an advantage is conferred on the animal by the genetic modification OR</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory mouse OR</td>
<td>ii. the animal is capable of secreting or producing an infectious agent as a result of the genetic modification</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory rabbit OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory rat</td>
<td></td>
</tr>
<tr>
<td>1.1c</td>
<td>A Dealing involving:</td>
<td>IF THE DONOR NUCLEIC ACID:</td>
</tr>
<tr>
<td></td>
<td>a replication-defective vector derived from Human adenovirus or Adeno-associated virus in a host mentioned in Item 4 of Table 5</td>
<td>i. cannot restore replication competence to the vector AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii. does not:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. confer an oncogenic modification in humans OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. encode a protein with immunomodulatory activity in humans</td>
</tr>
</tbody>
</table>

Table 6: Kinds of Dealings suitable for at least NLRD-PC1* (from Schedule 3 Part 1 of the Act)

* Unless the Dealing also involves any items from Table 8, which require individual licences, specific to the work, from the OGTR

<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1a</td>
<td>A Dealing involving whole animals (including non-vertebrates)</td>
<td>THAT DOES NOT involve</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a genetically-modified laboratory guinea pig OR a genetically-modified laboratory mouse OR a genetically-modified laboratory rabbit OR a genetically-modified laboratory rat OR genetically-modified Caenorhabditis elegans</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AND IT DOES involve</td>
</tr>
<tr>
<td></td>
<td></td>
<td>genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism</td>
</tr>
<tr>
<td>2.1aa</td>
<td>A Dealing involving</td>
<td>IF:</td>
</tr>
<tr>
<td></td>
<td>a genetically-modified laboratory guinea pig OR a genetically-modified laboratory mouse OR a genetically-modified laboratory rabbit OR a genetically-modified laboratory rat OR genetically-modified Caenorhabditis elegans</td>
<td>the genetic modification confers an advantage on the animal AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification</td>
</tr>
<tr>
<td>2.1b</td>
<td>A Dealing involving a genetically-modified plant</td>
<td>AS LONG AS neither host nor vector has been implicated in, or has a history of causing, disease in otherwise healthy:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>human beings OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>animals OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>plants OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>fungi</td>
</tr>
<tr>
<td>2.1c</td>
<td>A Dealing involving a host/vector system not mentioned in Table 5 or in Item 1.1(c) of Table 6</td>
<td>IF:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the host or vector has been implicated in, or has a history of causing, disease in otherwise healthy:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>human beings OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>animals OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>plants OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>fungi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the donor nucleic acid is characterised</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the characterisation of the donor nucleic acid shows that it is unlikely to increase the capacity of the host or vector to cause harm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Example: Donor nucleic acid would increase the capacity of the host or vector to cause harm, if it:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a) provides an advantage or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) adds a potential host species or mode of transmission or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) increases its virulence, pathogenicity or transmissibility</td>
</tr>
<tr>
<td>2.1d</td>
<td>A Dealing involving a host and vector not mentioned in Table 5</td>
<td>IF THE DONOR NUCLEIC ACID:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>encodes a pathogenic determinant OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in otherwise healthy:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. human beings OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. animals OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. plants OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. fungi</td>
</tr>
<tr>
<td>2.1e</td>
<td>A Dealing involving a host/vector system mentioned in Table 5</td>
<td></td>
</tr>
</tbody>
</table>

University of Tasmania  Biosafety Manual Version 1.0 22/08/2014  Page 37
<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1f.</td>
<td>A Dealing involving a host/vector system mentioned in Table 5 AND producing more than 25 litres of GMO culture in each vessel containing the resultant culture</td>
<td>IF: the dealing is undertaken in a facility that is certified by the Regulator as a large scale facility AND the donor nucleic acid satisfies the conditions set out in Item 4 of Table 4</td>
</tr>
<tr>
<td>2.1g.</td>
<td>A Dealing involving complementation of knocked-out genes</td>
<td>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 2.1g 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</td>
</tr>
<tr>
<td>2.1h.</td>
<td>A Dealing involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in Item 1 of Table 5</td>
<td>IF THE DONOR NUCLEIC ACID: is derived from either: a pathogen OR a toxin-producing organism</td>
</tr>
<tr>
<td>2.1i.</td>
<td>A Dealing involving the introduction of a replication-defective viral vector unable to transduce human cells into a host not mentioned in Table 5</td>
<td>IF: the donor nucleic acid cannot restore replication competence to the vector</td>
</tr>
<tr>
<td>2.1j.</td>
<td>A Dealing involving the introduction of a replication-defective non-retroviral vector able to transduce human cells, other than a dealing mentioned in Item 1.1 (c) of Table 6, into a host mentioned in Table 5</td>
<td>IF: the donor nucleic acid cannot restore replication competence to the vector AND the donor nucleic acid does not: confer an oncogenic modification in humans OR encode a protein with immunomodulatory activity in humans</td>
</tr>
<tr>
<td>2.1k.</td>
<td>A Dealing involving the introduction of a replication-defective retroviral vector able to transduce human cells into a host not mentioned in Table 5</td>
<td>IF: 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 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 either: 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 the packaging cell line and packaging plasmids express only viral genes gagpol, rev and an envelope protein gene, or a subset of these</td>
</tr>
<tr>
<td>2.1l.</td>
<td>A Dealing involving the introduction of a replication-defective retroviral vector able to transduce human cells into a host not mentioned in Table 5</td>
<td>IF: the donor nucleic acid does not: confer an oncogenic modification in humans OR encode a protein with immunomodulatory activity in humans AND 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 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 either: 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 the packaging cell line and packaging plasmids express only viral genes gagpol, rev and an envelope protein gene, or a subset of these</td>
</tr>
</tbody>
</table>

Table 7: Kinds of Dealings suitable for at least NLRD-PC2* (from Schedule 3 Part 2.1 of the Act) *Unless the Dealing also involves any items from Table 8, which require individual licences specific to the work from the OGTR
Appendix 5 – Dealings Requiring a Licence (as per Schedule 3 Part 3 of the Act) (Table 8)

Note 1 The following list qualifies the list in Parts 1 and 2, and is not an exhaustive list of dealings that are not Notifiable Low Risk Dealings.

Note 2 A Dealing that is not a Notifiable Low Risk Dealing, or an Exempt Dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see Act, section 32).

<table>
<thead>
<tr>
<th>Item</th>
<th>Dealing</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>(a) A dealing involving cloning of nucleic acid encoding a toxin having an LD$_{50}$ of less than 100 µg/kg</td>
<td>Other than a dealing mentioned in paragraph 2.1 (h) of Table 7</td>
</tr>
<tr>
<td></td>
<td>(b) A dealing involving high level expression of toxin genes, even if the LD$_{50}$ is 100 µg/kg or more</td>
<td>Other than a dealing mentioned in paragraph 2.1 (h) of Table 7</td>
</tr>
<tr>
<td></td>
<td>(c) A dealing involving cloning of uncharacterised nucleic acid from a toxin-producing organism</td>
<td>Other than a dealing mentioned in paragraph 2.1 (h) of Table 7</td>
</tr>
</tbody>
</table>
|      | (d) A dealing involving the introduction of a replication defective viral vector                                                                                                                    | INTO A HOST not mentioned in Table 5, other than a dealing mentioned in paragraph 2.1 (i) of Table 7, IF THE DONOR NUCLEIC ACID:  
|      |                                                                                                                                           | (i) confers an oncogenic modification in humans OR (ii) encodes a protein with immunomodulatory activity in humans                               |
|      | (e) A dealing involving the introduction of a replication competent virus or viral vector                                                                                                             | Other than a vector mentioned in Table 5, IF THE DONOR NUCLEIC ACID:  
|      |                                                                                                                                           | (i) confers an oncogenic modification in humans OR (ii) encodes a protein with immunomodulatory activity in humans                               |
|      | (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 Table 5  
|      |                                                                                                                                           | (B) the donor nucleic acid is characterised and its character shows that it is unlikely to increase the capacity of the host or vector to cause harm  
|      |                                                                                                                                           | (C) the dealing is mentioned in paragraph 2.1 (g) of Table 7  
|      | Example                                                                                                                                   | Donor nucleic acid would not comply with sub-subparagraph (B) if, in relation to 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 increases its virulence, pathogenicity or transmissibility. |
|      | (g) A dealing involving the introduction, into a micro-organism, of nucleic acid encoding pathogenic determinant                                                                               | UNLESS:  
|      |                                                                                                                                           | (i) the dealing is a dealing mentioned in paragraph 2.1 (g) of Table 7 OR (ii) the micro-organism is a host mentioned in Table 5 |
|      | (h) A dealing involving the introduction, into a micro-organism, genes whose expressed products are likely to increase the capacity of the micro-organism to induce an autoimmune response | Other than a host mentioned in Table 5                                                                                                                                                                 |
|      | (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 | 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. |
| (j) | A dealing with a replication defective retroviral vector (including a lentiviral vector) able to transduce human cells | Other than a dealing mentioned in paragraph 2.1 (i) or (m) of Table 7 |
| (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 | |
| (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) of Table 7 |
| (m) | A dealing that is inconsistent with a policy principle issued by the Ministerial Council | |

| (n) | A dealing involving the intentional introduction of a GMO into a human being | UNLESS the GMO: |
|     |                                                                          | (i) is a human somatic cell AND |
|     |                                                                          | (ii) cannot secrete or produce infectious agents as a result of the genetic modification AND |
|     |                                                                          | (iii) if it was generated using viral vectors: |
|     |                                                                          | (A) has been tested for the presence of viruses likely to recombine with the genetically modified nucleic acid in the somatic cells AND |
|     |                                                                          | (B) the testing did not detect a virus mentioned in sub-subparagraph (A) AND |
|     |                                                                          | (C) the viral vector used to generate the GMO as part of a previous dealing is no longer present in the somatic cells |

| (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 |

| (p) | A dealing involving a micro-organism that satisfies the criteria in AS/NZS 2234.3:2010 for classification as Risk Group 4 | |

**Table 8 – Dealings requiring a DNIR or DIR Licence (as per Schedule 3 Part 3 of the Act)**
Appendix 6 – Viral Vector Flow Chart

parent virus meets criteria for Risk Group 4 microorganism in AS/NZS 2243.3:2010

No

genetic modification impairs treatment of disease caused by virus / viral vector

No

virus / viral vector is being introduced into a human

No

genetic modification may produce a novel replication competent virus

No

genetic modification may induce an autoimmune response

No

genetic modification may result in the production of a toxin

No

Go to virus characteristics

Yes

DNIR 3.1 (p)

Yes

DNIR 3.1 (o)

Yes

DNIR 3.1 (n)

Yes

DNIR 3.1 (i)

Yes

DNIR 3.1 (h)

Yes

DNIR 3.1 (a), (b) or (c)

* Effective from 1 September 2011, incorporating amendments up to the Gene Technology Amendment Regulations 2011 (No. 1). This table provides guidance only and does not constitute legal advice. Users must refer to the complete applicable conditions and exclusions in the Gene Technology Regulations 2001, as amended.

Website: www.octr.gov.au, Telephone: 1800 181 030 Updated August 2011
Virus characteristics

- If the vector is a replication competent virus, go to 1 – Replication competent viruses.
- If not, check if genetic modification restores replication competence.
  - If yes, go to Replication competent viruses.
  - If no, check if the vector is a retrovirus (including lentivirus).
  - If yes, go to Replication defective retroviruses.
  - If no, go to Replication defective non-retroviruses.
Replication defective non-retroviruses

- Vector can transduce human cells: No → *in vitro* dealings only → No → NLRD 2.1 (i)
- Yes → Modification involves a pathogenic determinant: No → NLRD 2.1 (f) >25L per vessel, Yes → NLRD 2.1 (e)

- *In vitro* dealings only: No → May confer an oncogenic modification or have an immunomodulatory effect in humans → No → NLRD 2.1 (k), Yes → DNIR 3.1 (d)

- May confer an oncogenic modification or have an immunomodulatory effect in humans: No → Human adenovirus or Adeno associated virus → No → NLRD 2.1 (j), Yes → NLRD 2.1 (j)
- Yes → NLRD 1.1 (c)
Appendix 7 - OGTR Policy on Scope for Variations of GMO Licences

Section 71 of the Gene Technology Act 2000 (the Act) provides for the Gene Technology Regulator (the Regulator) to vary the conditions of licences authorising dealings with genetically modified organisms (GMOs), either on the Regulator’s initiative or on application from the licence holder. The tables below provide guidance to licence holders/applicants on the OGTR’s policy for determining whether or not applications to extend the authority of GMO licences (for either intentional release or contained dealings) will be considered as variations or would warrant new GMO licence applications. The tables each identify three categories of proposed changes: those that are likely to be considered as variations; those likely to require a new licence application; and those that do not clearly fall into either of these categories and therefore require more specific consideration. This policy is a guide only and is based on the OGTR’s interpretation of the relevant provisions of the Act. The Regulator will not apply the policy inflexibly and will have regard to the merits of each individual application. The Regulator will apply the risk assessment process used in current risk assessment and risk management plans (RARMPs), based on the Risk Analysis Framework, to identify any additional risks that were not previously identified in the RARMP prepared for the licence. Licence applicants and licence holders who are concerned about the application of the policy in particular circumstances are encouraged to contact the Office for further advice and information. No conclusions can be drawn about whether a particular application for variation will be approved as this will be assessed on a case by case basis.

The Act requires that the Regulator must not vary a licence:

for dealings not involving an intentional release of GMOs (DNIR) so as to authorise dealings involving intentional release (subsection 71(2));

for dealings involving intentional release (DIR) under ‘limited and controlled’ conditions (s50A) unless the variation would also meet the conditions for a ‘limited and controlled’ release (subsection 71(2A)); or

if satisfied that the RARMP prepared in respect of the original application for the licence did not cover the risks posed by the dealings to be authorised by the varied licence (section 71(2B)).

The Regulator must also be satisfied that any risks posed by the dealings authorised under the varied licence are able to be managed so as to protect the health and safety of people and the environment (section 71 (4)).

The Regulator may request further information from a licence holder in regard to a variation application, and may take any other appropriate action. For example the Regulator may consult the Gene Technology Technical Advisory Committee or a local council where an intentional release is proposed to occur.

**Categories of proposed changes to licences authorising Dealings Not involving Intentional Release of a GMO (DNIR licences)**

<table>
<thead>
<tr>
<th>Unlikely to give rise to additional risks, and therefore likely to be considered as a variation to a licence</th>
<th>Case specific</th>
<th>May give rise to additional risks, and therefore likely to require a new DNIR application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addition of related gene or related parent organism</td>
<td>Addition of new genes unrelated to original introduced genes but within the purpose described in the original licence application</td>
<td>Addition of a GMO unrelated to original dealing</td>
</tr>
<tr>
<td>Changes to transport of GMOs (including import)</td>
<td>Add a new dealing for a related purpose to that of the original dealings</td>
<td></td>
</tr>
<tr>
<td>Minor changes to management protocols (e.g. change of decontamination method)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change facility (at same type and level or greater)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension of period of the licence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New project supervisor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 8 – PC2 Facility Induction Checklist

I Level A Induction - Introduction and Orientation
(Contractors and cleaners require Level A induction only)

Tours of labs and facilities:

- Floor orientation – card/keys/egress/security/toilets
- Building evacuation
- Eyewash/Safety showers
- First Aid – location of kits/trained personnel
- Explanation of PC and why we do induction (Biological Hazards/OGTR)
- No eating/drinking or wearing headphones in labs
- Food refrigerator access outside facility
- Don’t place paper/books/tools on benches
- Wearing of PPE – glasses/shoes (where to find them)
- When finished in area remove glasses and wash hands
- Consult technical staff if any questions/issues/unsure

II Level B Induction
(People using facilities occasionally require Level A and Level B induction only)

- Allocation/laundering of gown (if necessary)
- WHS induction MUST BE COMPLETED before work commences:
  - Risk assessments/SWP's for new chemicals/equipment/tasks
  - Biological/chemical/GMO spills procedures
  - Fire Extinguishers and blankets
- Tour of appropriate areas:
  - Research Labs/Tissue Culture areas
  - Booking of equipment (Booked)
  - Autoclave area/prep/wash-up
  - Hot Room/Cold Room/Freezer Room (if applicable)

III Level C Induction
(Lab based Students [Undergrad, Honours and Postgrad], volunteers and new staff require all levels of induction)

WHS:

- The following online courses MUST BE COMPLETED before work commences:
  - Work Health and Safety Integrated Training
  - UTAS Staff and Students Workers Health and Safety Course
  - PC2 Laboratory Induction

- The following training MUST BE COMPLETED before work commences:
Working with hazardous chemicals in the workplace
Risk management for workers
Chemical spills management
Environmental awareness
Training in safe and appropriate use of equipment/facilities
Chemical storage cabinets
Understanding of how to work in PC2:
- Working safely with organisms
- Safe use of Bunsen burners
- Class 2 Biosafety cabinet (BSC)
- Fume hood
- Bench centrifuge
- Balances
- Hot plate stirrers
- Water baths
- Pipettors
- Incubators
- Other (Specify)

General House Keeping:
- End of day clean-up
- Procedures for cleaning work area – daily, weekly
- Disposal of waste:
  - Solvents
  - Biohazardous waste
  - Sharps
  - Quarantine waste

Ordering:
- Order forms – including risk assessment requirements

Storage:
- Correct labelling of solutions, cultures and GMOs
- Storage of solutions, cultures and GMOs
- Storage of chemicals and reagents
- Corrosives and flammables
- Labelling and location of cultures
- Storage of GMOs

Media Preparation and Autoclaving:
- Preparation of media
- Access and use of autoclave
- Clean material for autoclaving
- Collection of material after autoclaving
- Transport of GMOs

This record is to confirm that I have gone through an induction process to allow me to work in the PC2 laboratory, performing tasks consistent with my training.

Name: ____________________________________________

Supervisor or Person Responsible: ________________________________

School or Institution affiliation: ________________________________

Position: ____________________________________________

Date of Induction: ___________________________________________