Regulated and Hazardous Biological Materials Policy

Responsible Officer

Deputy Vice-Chancellor (Research)

Approved by

Vice-Chancellor

Approved and commenced

August 2019

Review by

August 2022

Relevant Legislation, Ordinance, Rule and/or Governance Level Principle

- Gene Technology Act 2000 (Cwth)
- Gene Technology Regulations 2001 (Cwth)
- Gene Technology Amendment Regulations 2011 and 2019 (Cwth)
- Gene Technology (Licence Charges) Act 2000 (Cwth)
- Gene Technology (Tasmania) Act 2012 (Tas)
- Gene Technology Regulations 2003 (Tas)
- Genetically Modified Organisms Control Act 2004 (Tas)
- Biosecurity Act 2015 (Cwth)
- Biosecurity Regulations 2016 (Cwth)
- Biosecurity Act 2019 (Tas, draft)
- National Health Security Act 2007 (Cwth)
- National Health Security Regulations 2008 (Cwth)

Responsible Organisational Unit

Research Division

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1 Objective

The objective of this Policy is to outline responsibilities and obligations associated with Dealings involving gene technology, Regulated Biological Materials and Hazardous Biological Materials to ensure risks are identified and managed appropriately.

2 Scope

This Policy applies to teaching and research activities at facilities owned or managed by the University of Tasmania (“the University”). These activities may be performed by staff, students, visiting fellows and scholars, and persons holding discretionary titles of the University (“Staff and Students”).

Compliance with legislation is out of scope of this Policy, and is covered by the Legal Compliance Policy.

Records and Information collected in relation to this Policy will be managed and retained by a delegate of the Responsible Officer in accordance with University Records Management Policy, Procedures and Guidelines.

3 Responsibilities and Obligations

In order to identify and manage risks to human health, the natural environment and Australia’s agricultural production, the framework of actions listed in this section must be applied to implement best practices for the appropriate containment of Regulated and Hazardous Biological Materials.

The University is required to:

- Sustain the resources and procedures necessary to enable effective oversight of Dealings. This includes resourcing and convening an Institutional Biosafety Committee (IBC).
- Hold appropriate facility certifications to conduct activities with Regulated Biological Materials. This includes Department of Agriculture (DA) Approved Arrangements, Physical Containment certifications (OGTR) and Approved Quarantine Places (Biosecurity Tasmania).
- Employ a Biological Safety Officer as defined under Section 1.5.10 of AS2243.3:2019 Safety in Laboratories – Microbiological Safety and Containment.
- Employ or nominate a staff member (the “Facility Manager”) to be accountable for each facility where Dealings are performed.
- Maintain a register of all current Exempt Dealings, Notifiable Low Risk Dealings (NLRDs) and Licensed Dealings conducted by the University.
- Provide access to training and continuing education to members of the IBC on relevant legislation and developing topics relating to Regulated or Hazardous Biological Materials.
- Ensure that facilities provided to staff and students conducting Dealings are constructed and/or furnished to a standard which meets regulated containment requirements appropriate to the Dealings.
The Institutional Biosafety Committee is required to:

- Comply with the conditions of accreditation as set out in the instrument of accreditation issued by the OGTR.
- Assess and monitor Dealings to ensure they are conducted in accordance with legislation, regulations, Australian Standards, codes of practice, University procedures and licencing requirements. This includes reviewing risk assessments where appropriate and ensuring staff and students conducting the research are adequately experienced and qualified.
- Inspect, or facilitate inspections of, all certified University facilities annually and keep records of these inspections.
- Provide guidance and training to Facility Managers, staff and students when completing applications for relevant permits, licences, authorisations and certifications for Dealings.
- Develop, implement and maintain usage procedures, guidelines and training materials relating to Regulated or Hazardous Biological Materials.
- Notify relevant authorities promptly of the occurrence or suspected occurrence of Biosecurity Events or breaches of legislative or regulatory compliance by the University.

The Biological Safety Officer is required to:

- Act as the primary contact between the University and relevant governing or advisory bodies (including the OGTR, DA, Biosecurity Tasmania and the Association of Biosafety for Australia and New Zealand (ABSANZ)).
- Manage the University’s Biosecurity Industry Participant account with DA, including facilitating submission of import permit applications, compliance agreements and facility certification applications.
- Act as the IBC secretariat and provide strategic and operational support to the committee via Ex Officio membership.
- Maintain effective communication with the University’s ethics committees to provide advice on issues pertaining to Regulated or Hazardous Biological Materials.
- Maintain information resources for staff and students relating to Regulated or Hazardous Biological Materials. This includes assisting the IBC with development and implementation of user groups, procedures, guidelines and training materials.
- Prepare and disseminate Annual Reports to the OGTR, the University Research Committee (URC), and official communiques to relevant authorities as required.
- Guide and assist Facility Managers to rectify any Corrective Action Requests or non-conformances issued by regulatory authorities.

Facility Managers are required to:

- Provide training and induction to users of their facility and ensure training materials are reviewed and updated regularly.
- Manage and maintain their facility/facilities to ensure regulated containment
requirements appropriate for the Dealings conducted within the facility are implemented.

- Report any issues including breaches of containment, non-compliances, or condition which renders their facility unsuitable for use to the IBC and Biological Safety Officer immediately.

- Follow direction and guidance issued by the Biological Safety Officer to rectify any Corrective Action Requests or non-conformances issued by regulatory authorities in a timely manner.

- Maintain a working knowledge of guidelines, regulations and policies relating to activities occurring in their facility with assistance from the Biological Safety Officer.

- Facilitate effective communication between academics responsible for research activities and staff and students conducting Dealings within their facility.

- Review risk assessments completed by staff and students conducting Dealings within their facility to ensure hazards are controlled.

Staff and Students are required to:

- Obtain approval from the IBC, DA, Biosecurity Tasmania or any other relevant regulatory body prior to conducting any Dealings with Regulated Biological Materials.

- Complete a risk assessment meeting the guidelines of Section 2.1.2 of AS2243.3:2019 Safety in Laboratories – Microbiological Safety and Containment prior to conducting any Dealings with Regulated or Hazardous Biological Materials. Dealings may only be undertaken after the risk assessment has been approved by the Facility Manager or the IBC.

- Seek guidance from the IBC or Biological Safety Officer on any matters relating to Regulated or Hazardous Biological Materials where necessary.

- Ensure they are adequately trained and qualified to undertake the activities related to any Dealing they intend to conduct.

- Comply with any related University policy, including the Legislative Compliance Policy, procedure or guideline, and any direction or condition of any certification, licence, agreement or permit issued to them. This includes reporting the occurrence or suspected occurrence of biosecurity events or breaches of legislative or regulatory compliance that they may become aware of to the IBC, Biological Safety Officer and Facility Manager promptly.

- Conduct Dealings only within appropriate facilities.

- Follow any direction or condition issued by the IBC, Biological Safety Officer or relevant Facility Manager.

- Submit annual reports to the IBC regarding facilities, NLRDs and licence compliance regarding any relevant Dealings undertaken or proposed.

4 Definitions and Acronyms

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<thead>
<tr>
<th>Term/Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ABSANZ</td>
<td>Association of Biosafety for Australia and New Zealand</td>
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<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Approved Arrangement</td>
<td>A biosecurity containment facility for which an approval is in force under paragraph 406(1)(a) of the <em>Biosecurity Act 2015</em>.</td>
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<td>Approved Quarantine Place</td>
<td>A place, or part of a place, that has been approved by Biosecurity Tasmania as meeting containment standards suitable for storage and use of plant material under biosecurity control.</td>
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<td>Biohazard</td>
<td>A potential microbiological source of harm (AS2243.3:2019)</td>
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<td>Biological Safety Officer</td>
<td>A person who is competent in the assessment and control of biological hazards and has responsibility and authority for oversight of the control of biological hazards (AS2243.3:2019)</td>
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<tr>
<td>Biosafety</td>
<td>Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release (AS2243.3:2019)</td>
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<tr>
<td>Biosecurity</td>
<td>Principles and preventative measures undertaken to reduce the risk of the introduction, spread and establishment of diseases, pests or invasive species which may adversely affect the natural environment, agricultural production or human society.</td>
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<td>Biosecurity Event</td>
<td>The detection or uncontained presence of a disease, pest or invasive species (<em>Biosecurity Act 2019</em> (Tas))</td>
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<td>Biosecurity Industry</td>
<td>A person or organisation who is the holder of the approval of an Approved Arrangement with DAWR under the <em>Biosecurity Act 2015</em>.</td>
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<td>Biosecurity Material</td>
<td>Any material which may pose a risk to Australia or Tasmania’s natural environment, agricultural production or human society, and is regulated by DAWR or Biosecurity Tasmania. This includes any carrier of such material.</td>
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<td>Biosecurity Matter</td>
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<td>Corrective Action Request</td>
<td>Notification provided by a regulatory authority to the manager of a certified facility regarding the detection of a regulatory non-conformity and advice for action to rectify the non-conformity.</td>
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<td>DA</td>
<td>Department of Agriculture; responsible for enacting the <em>Biosecurity Act 2015</em> and subordinate regulations.</td>
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<td>Dealing</td>
<td>In relation to a Hazardous or Regulated Biological Material, means the following:</td>
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<td>a) conduct experiments with the material;</td>
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<td>b) make, develop, produce or manufacture the material;</td>
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<td>c) breed the material;</td>
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<td>d) propagate the material;</td>
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<td>e) use the material in the course of manufacture of a thing that is not the material;</td>
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<td>f) grow, raise or culture the material;</td>
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<td>g) import the material;</td>
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<td>h) transport the material;</td>
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<td>i) dispose of the material;</td>
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<td>and includes the possession, supply or use of the material for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i). (<em>Gene Technology Act 2000</em>).</td>
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Regulated and Hazardous Biological Materials Policy

Facility Manager
A staff member accountable for a facility where Dealings are performed.

Gene Technology
Techniques and activities concerned with the expression of genes, selection of organisms based on genetic variation, artificial modification of genes and transfer of genes to new host organisms.

GMOs
Genetically Modified Organisms [as defined in Section 10.1 of the Gene Technology Act 2000 (Cwth) and Schedule 1B of the Gene Technology Amendment Regulations 2019 (Cwth)]

Hazardous Biological Material
Hazardous non-regulated biological agents categorised into a risk grouping according to AS2243.3:2019. This may include organic toxins, bacteria, parasites, fungi, viruses, plant pathogens, invertebrates and aquatic organism pathogens capable of causing disease.

IBC
Institutional Biosafety Committee

Licenced Dealing
A Dealing Not Involving Intentional Release (DNIR) or a Dealing Involving Intentional Release (DIR). DNIRs involve a higher level of risk than an NLRD, but do not permit intentional release of a GMO into the environment. DIRs pose a higher level of risk than an NLRD and involve intentional release of GMOs into the Australian environment. Licenced Dealings require direct scrutiny by the OGTR.

NLRD
Notifiable Low Risk Dealings. A dealing with a GMO which is not considered to pose risks that require direct scrutiny by the OGTR.

OGTR
Office of the Gene Technology Regulator

Regulated Biological Material
Any material which may be genetically-modified, subject to regulation by an Act of Parliament or subordinate regulation (including Biosecurity Material) or an SSBA

SSBA
Security Sensitive Biological Agent as listed in Part 3 of the National Health Security Act 2007.

TSD
Guidelines for the Transport, Storage and Disposal of GMOs as enforced by the OGTR

University
All references to “the University” refer to the University of Tasmania

URC
University Research Committee

Supporting Documentation
- Australian Standard 2243.3 Safety in Laboratories – Microbiological Safety and Containment.
- Legal Compliance Policy, University of Tasmania

Versioning

<table>
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<tr>
<th>Former Version(s)</th>
<th>Version 1 – Gene Technology Policy; approved May 2012; Minor amendments approved July 2013.</th>
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