

Biosafety and Biosecurity Policy

Section 1 - Purpose

(1) The purpose of this Policy is to establish and maintain the safety framework for research and teaching involving Microorganisms and biohazardous materials. The implementation of this Policy will facilitate compliance with relevant legislation, promote high-quality research and teaching, and minimise risks to human and animal health, and the environment.

Background

(2) Macquarie University (the University) is dedicated to managing its Biohazards in a responsible manner while maintaining its research, teaching and service missions. The University is committed to ensuring that individuals using Microorganisms and other biohazardous materials are suitably trained and supervised.

(3) All research at the University is governed by the [Macquarie University Code for the Responsible Conduct of Research](#). The [AS/NZS 2243.3:2022](#) Microbiological safety and containment standard is also applicable to all research, teaching and services involving Microorganisms and biohazardous materials. Further Acts, regulations and guidelines become applicable when dealings involve the use of Genetically Modified Organisms (GMOs), Security Sensitive Biological Agents (SSBAs) or biological materials requiring biosafety containment. The list below highlights the legislation applicable to each of these dealings:

- a. GMOs – [Gene Technology Act 2000](#), [Gene Technology Amendment Act 2015](#), and [Gene Technology Regulations 2001](#).
- b. SSBAs – [National Health Security Act 2007](#), [National Health Security Regulations 2018](#) and the SSBA Regulatory Scheme.
- c. Biological Materials Requiring Biosafety Containment – [Biosecurity Act 2015](#).

Scope

(4) This Policy covers research, teaching and services involving Biohazards, GMOs, SSBAs and biological materials requiring biosafety containment. This Policy applies to all Macquarie University employees, students, researchers, service providers, contract employees and University Controlled Entities conducting any activity related to biohazardous materials on University premises or outside the geographical boundaries of the University (field research and teaching).

Section 2 - Policy

Accreditation

(5) The University will:

- a. maintain [Office of the Gene Technology Regulator](#) (OGTR) accreditation;
- b. maintain internal processes to effectively monitor work involving Biohazards and GMOs at the University; and
- c. maintain an appropriately constituted Institutional Biosafety Committee (IBC) that is provided with the resources

required for institutional monitoring.

Certification

(6) The University will:

- a. ensure it maintains certification of OGTR and quarantine approved premises (as defined as an Approved Arrangement site under the [Biosecurity Act 2015](#));
- b. inspect these facilities at least annually to ensure they remain compliant with current standards; and
- c. restrict access to certified facilities to those persons who are inducted, adequately trained and have approval to enter.

Institutional Biosafety Committee

(7) The University will:

- a. maintain an IBC as required by legislation, with an agreed Terms of Reference and operating procedures;
- b. provide the IBC with resources and powers to fulfil its Terms of Reference and operate as set out in the relevant legislation and guidelines;
- c. employ a Biosafety Officer to assist the IBC in monitoring and reporting; and
- d. respond effectively to recommendations from the IBC to ensure that all biohazardous activity within the University remains in accordance with the relevant legislation, regulations, standards, guidelines and codes.

Biosafety Awareness

(8) The University will:

- a. ensure relevant personnel are adequately trained to enable them to be considered an accredited person under the [Biosecurity Act 2015](#);
- b. ensure that any research, teaching or services using biological materials are only undertaken after a risk assessment has been performed; and
- c. ensure any dealings with GMOs, use of agents classified as Risk Group 2 and above, SSBA or agents requiring containment or approval under the [Biosecurity Act 2015](#), have been approved by the IBC.

Review and Reporting

(9) The University will:

- a. require all persons involved in dealings with GMOs, using agents or animals containing agents classified as Risk Group 2 and above, SSBA or agents requiring containment or approval under the [Biosecurity Act 2015](#), to submit research applications, risk assessments, teaching protocols, progress reports and final reports to the IBC;
- b. ensure dealings with GMOs, the use of agents classified as Risk Group 2 and above, SSBA or agents requiring containment or approval under the [Biosecurity Act 2015](#), are not commenced without the prior approval of the IBC;
- c. ensure the IBC reviews all applications, risk assessments and reports in respect of any dealings with GMOs, use of agents classified as Risk Group 2 and above, SSBA or agents requiring containment or approval under the [Biosecurity Act 2015](#), so that they may assess the risks associated with the biological dealing being undertaken and ensure these risks have been adequately controlled;
- d. enable the IBC to conduct monitoring inspections, at least annually, of the University's PC2 and BC2 facilities in which Biohazards and/or GMOs are handled to ensure compliance with the relevant legislation, regulations,

standards, guidelines and codes;

- e. require the IBC to report at least annually to the Deputy Vice-Chancellor (Research);
- f. require the IBC to report at least annually to the OGTR in accordance with the [Guidelines for Accreditation of Organisations 2012](#) and the Explanatory Information on the Guidelines for Accreditation of Organisations v 1.4 issued by the OGTR;
- g. maintain transparent operating procedures to manage and report any adverse events or complaints that may arise during the conduct of activity using Microorganisms or biohazardous materials, in accordance with the [Macquarie University Code for the Responsible Conduct of Research](#) and the IBC Terms of Reference and operating procedures; and
- h. treat seriously, monitor, pursue and address any breaches.

Section 3 - Procedures

(10) Nil.

Section 4 - Guidelines

(11) Nil.

Section 5 - Definitions

(12) The following definitions apply for the purpose of this Policy:

- a. Biohazard – biological agents that pose a hazard to the health of humans and other living organisms or the environment. Biohazards can include pathogenic micro-organisms, viruses, toxins (from biological sources), spores, fungi and bioactive substances. Biohazards can also be considered to include biological vectors or transmitters of disease. Outside the health arena, biohazards can cause social and economic disruption, property damage and environmental degradation.
- b. GMO – Genetically Modified Organism (as defined in Part 2 of the [Gene Technology Act 2000](#)).
- c. IBC – Institutional Biosafety Committee.
- d. Microorganism – an organism too small to be seen without the aid of a microscope e.g. virus, bacteria, protozoa, and some algae and fungi.
- e. OGTR – Office of the Gene Technology Regulator which acts under the [Gene Technology Act 2000](#) and [Gene Technology Regulations 2001](#).
- f. Risk Group - a numerical classification of infectious microorganisms as defined in the [AS/NZS 2243.3:2022](#).
- g. SSBA – Security Sensitive Biological Agent.

(13) A reference to a legislative provision, legislation (including subordinate legislation), regulation or an Australian standard is to that provision, legislation, regulation or standard as amended, re-enacted or replaced.

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Responsible Executive	Sakkie Pretorius Deputy Vice-Chancellor (Research) +61 2 9850 8645
Responsible Officer	Ross McLennan Pro Vice-Chancellor, Research Services +61 2 9850 7737
Enquiries Contact	Ross McLennan Pro Vice-Chancellor, Research Services +61 2 9850 7737