Biosafety Policy

Section 1 - Summary

(1) This Policy aims:

a. To provide a framework for the safety and security of all University Staff, students, contractors, volunteers and visitors when dealing with or coming into contact with potentially hazardous biological material; and,
b. To reinforce the University's commitment and capacity to managing the risk of unintentional release of, or human or animal exposure to:
    i. biological hazards;
    ii. genetically modified organisms;
    iii. biological material that is controlled, regulated or prohibited; and
    iv. biological material of security concern.

(2) The implementation of this Policy will comply with relevant legislation, promote high quality research and teaching and minimize risks to human and animal health and the environment.

Section 2 - HESF/ASQA/ESOS Alignment

(3) HESF: Standards 2.3 Wellbeing and Safety; 4.1 Research; 4.2 Research Training; 5.2 Academic and Research Integrity.

Section 3 - Scope

(4) This Policy applies across the University and to all University Staff, students, contractors, volunteers and visitors who:

a. may handle or are potentially exposed to biological hazards, genetically modified organisms (GMOs) and security sensitive biological agents (SSBAs);
b. work in or need to service facilities where biohazardous materials are used (including clinics, biological teaching and research laboratories, plant, insect and animal and aquatic laboratories); and / or,
c. supervise personnel who handle biological hazards or work in laboratories.

(5) This Policy does not apply to:

a. the use of biological material that is not hazardous (e.g. plant and animal materials used in the preparation of food for human consumption; and biologicals used in standard clinical practice).

Section 4 - Definitions

(6) Biohazard: A biohazard is a potential source of harm caused by biological risk group agents or toxins. Biohazards, which may provoke infection, allergy or toxicity in humans, animals or plants include:

a. biological risk group agents (i.e. microorganisms; viruses, fungi & bacteria) as classified in AS 2243.3: Safety in Laboratories-Part 3 Microbiological Safety and Containment;
b. material that might be reasonably expected to contain biological risk group agents including:
    i. Human and animal tissues, bodily fluids and excreta
    ii. Plants
    iii. Insects
    iv. aquatic organisms;
c. biological toxins and poisons;
d. prions (proteinacious infectious particles); and/or,
e. emerging new biohazards not captured within the above definition.

(7) Biological agents: Any living organism that may cause harm to humans, animals or the environment. This includes pathogens; biological toxins; material of human or animal origin such as blood, body fluids, tissues, cells, cell lines, live animals; whole plants; plant material; environmental, food and other types of samples that have a potential for containing biological agents including pathogens; any other material of biological origin; and biological molecules such as DNA, RNA extracted from any of the samples listed above.

(8) Biological Physical Containment: A system of confining microorganisms or other entities within a defined space.

(9) Biosafety: Containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents or toxins, or their accidental release into the environment.

(10) Dealing: A "dealing" with biologically hazardous material is defined as:

a. conducting experiments with;
b. making, developing, collecting, producing or manufacturing;
c. breeding;
d. propagating;
e. using in the course of manufacturing of something that is not a biosafety or biosecurity concern;
f. growing, raising or culturing;
g. importing or exporting;
h. transporting;
i. disposing of;

and includes:

j. the possession, supply or use of for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (i).

(11) Defence and Strategic Goods List (DSGL): goods and technology of biosecurity concern that may not be exported from Australia unless a permit has been granted.

(12) Genetically modified organism (GMO): An organism that has been modified by gene technology (a)*; or, an organism that has inherited traits from an organism, where the traits occurred in the initial organism because of

gene technology; or, anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms; but does not include:

a. a human being, if the human being is covered by paragraph (a)* only because the human being has undergone somatic cell gene therapy *; or,
b. an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

* The TGA will continue to monitor the conduct of human gene therapy especially if the work involves a live or viable GMO which may present possible occupational health and safety or environmental risks.

(13) The Therapeutic Goods Administration (TGA): Part of the Australian Government Department of Health and Aged Care, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

(14) Security Sensitive Biological Agent (SSBA): A biological agent outlined and regulated by the National Health Security Act.

Section 5 - Policy Statement

(15) All staff and students working with biohazards at Victoria University (VU) must be aware of, and comply with, the requirements of all relevant legislation or regulations governing dealings with biohazards. A list of regulatory requirements can be found on the Compliance SharePoint Site.

(16) All those involved in activities with biologicals must ensure that biohazards are identified, together with planned actions to eliminate or, if this is not possible, mitigate the risks. The steps taken to identify biohazards and to eliminate risks must be recorded to establish credible data which enables measurement and improvement.

(17) All staff are expected to take an active role in creating safe work places and work practices by complying with University policies and procedures, taking responsibility for their own actions, and not putting themselves or others at risk.

Part A - Compliance

(18) VU expects all those working with biologicals to:

a. Ensure compliance with relevant legislation, regulations and University policies and procedures found in the VU Policy Library;
b. Ensure that all biosafety compliance requirements imposed by funding bodies who fund research are fulfilled;
c. Promote an organisational culture that adopts and implements biosafety and biosecurity compliance;
d. Ensure the management and reporting of emergencies and incidents via the Senior Manager, Research Infrastructure & Biosafety to the relevant regulatory body/bodies are strictly observed (this is additional to the Health and Safety - OHS Incident Reporting and Investigation Procedure);
e. Ensure that all biological-associated permits, licenses and accreditations are obtained via the Senior Manager, Research Infrastructure & Biosafety before work commences; and
f. Advise the Institutional Biosafety Committee (IBC) about any issues that impact on compliance.

Part B - Communication and Training

(19) Where appropriate, VU will:

a. ensure biosafety is part of the organisational planning process;
b. ensure resourcing available to ensure biosafety standards;
c. implement processes that require appropriate approval and monitoring of all dealings with biological hazards including reporting acquisitions, maintenance of biological inventories and project approval;
d. facilitate forums for consultation and communication on biosafety matters; and,
e. create and provide appropriate biosafety induction, instruction, training and supervision.

Part C - Quality, Standards & Risk Management

(20) VU will seek to ensure that:

a. industry best practice for controlling identified hazards are taken into account and, as far as reasonably practicable, introduced into the planning and delivery of University activity;
b. work with biohazards is conducted in facilities that meet the relevant structural requirements in order to reduce the risk of unintentional infection or release of the agents;
c. work conducted in containment facilities meets the relevant engineering requirements along with behavioural and administrative requirements;
d. internal certification and inspection process for laboratories are implemented;
e. measurable objectives and targets to ensure continued improvements are established with the aim of:
    i. reducing and preventing Incidents;
    ii. reducing Non-Compliance;
f. effective process for resolving biosafety issues and managing risks are maintained; and
g. appropriate reporting and recording mechanisms for incidents, emergencies and near-misses are established.

Section 6 - Procedures

(21) Biosafety - Dealings Involving Risk Group Agents

(22) Biosafety - Certification of Biocontainment Facilities Procedure

(23) Biosafety - Dealings Involving Genetically Modified Organisms Procedure

(24) Biosafety - Importing and Exporting Biological Material Procedure

(25) Biosafety - Non-Compliance & Adverse Incidents Procedure

(26) Biosafety - Packaging and Transport of Biological Materials Procedure

(27) Biosafety - Labelling, Storage and Transport of Genetically Modified Organisms Procedure

Section 7 - Supporting Documents and Information

(28) Compliance SharePoint Site

(29) VU Policy Library

(30) Health and Safety - OHS Incident Reporting and Investigation Procedure

(31) AS/NZS 2243.3 Microbiological Safety and Containment. Access to current document is restricted by limited VU

Licence

(32) Biosecurity Act 2015

(33) Gene Technology Act 2000

(34) Gene Technology Regulations 2001 (Cth)

(35) Defence and Strategic Goods List 2024 (Cth)

(36) Therapeutic Goods Authority

(37) National Health Security Regulations 2018 (Cth)

(38) National Health Security Act 2007 (Cth)

Status and Details

Status	Current
Effective Date	6th April 2023
Review Date	6th April 2026
Approval Authority	Deputy Vice-Chancellor, Research & Impact
Approval Date	6th April 2023
Expiry Date	Not Applicable
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