Biorisk Management Policy (MPFXXX)
DRAFT – 17 December 2024

1. Objectives

1.1. This policy outlines the University's commitment to the responsible use of Regulated Biological Materials (RBM) through its Biorisk Management Program.

1.2. The Biorisk Management Program reflects the commitment to the safe, secure and compliant use of RBMs by controlling the risk of accidental exposure and unintended or unauthorised use or release of RBMs, to avoid harm to people, animals and the environment through:

(a) provision and maintenance of appropriate containment facilities, equipment, training and institutional accreditations;
(b) governing, monitoring and assessing the use of RBMs at the University;
(c) processes that prevent and detect non-compliance;
(d) risk assessment, mitigation and authorisation, supported by expert advice on compliant practices and safe-handling;
(e) management of incidents; and
(f) fostering a culture that encourages proactive management of biorisk.

2. Scope

2.1. This policy applies to activities and facilities involving or containing RBMs including:

(a) biological agents and related potentially infectious material (PIM);
(b) genetically modified organisms (GMOs);
(c) material conditionally imported into Australia (biosecurity material); and
(d) biological agents identified as Dual Use in applicable Australian or international legislation, including Security Sensitive Biological Agents (Dual Use Biological Agents).

2.2. This policy applies to:

(a) all staff, graduate researchers, honoraries, students, contractors, visitors, volunteers of the University; and
(b) non-University personnel carrying out activities at locations under the management or control of the University,

where such personnel:

(c) handle, procure or generate RBMs;
(d) access Containment Facilities; or
(e) are members of the Institutional Biosafety Committee (**IBC**) or any of its sub-committees.

3. Authority

3.1. This policy is made under the *University of Melbourne Act 2009* (Vic) and the Vice-Chancellor Regulation and supports compliance with the:

(a) Australian Code for the Responsible Conduct of Research
(b) AS/NZS 2243.3-2022 Safety in laboratories Part 3: Microbiological safety and containment
(c) Biosecurity Act 2015 (Cth)
(d) Gene Technology Act 2000 (Cth)
(e) National Health Security Act 2007 (Cth)

4. Policy

4.1. The University of Melbourne is committed to responsible and compliant use of RBMs. All personnel must comply with applicable laws, regulations, codes, standards, this policy and its Ancillary Requirements.

4.2. The University's Biorisk Management Program, under the oversight of the Deputy Vice-Chancellor (Research), implements its commitment to the compliant, safe and secure use of RBMs by controlling the risk of:

(a) unintended or unauthorised release, access or accidental exposure;

(b) harm to people, animals and the environment; and
(c) non-compliance

in accordance with the procedural principles, roles, responsibilities and Ancillary Requirements prescribed under this policy.

4.3. The Deputy Vice-Chancellor (Research) will establish:
(a) an Institutional Biosafety Committee (**IBC**) (and any relevant sub-committees) to internally regulate IBC-Regulated Activities through review, oversight and monitoring; and
(b) such other reporting, governance and oversight bodies or responsibilities as deemed necessary or desirable to ensure proper University oversight of the Biorisk Management Program, and these will be documented in Ancillary Requirements.

4.4. The University adopts a compliance approach to managing biological risk, in accordance with the broader institutional risk management framework. Specific risks associated with biohazards are identified, assessed, and controls are defined, authorised, implemented and monitored in accordance with this policy and Ancillary Requirements.

4.5. All personnel working with RBMs at the University will:
(a) exercise caution, follow authorised University biorisk management requirements, SOPs and implement all authorised risk mitigation controls, including use of personal protective clothing and equipment;
(b) where appropriate, seek advice from the Office of Research Ethics and Integrity (**OREI**) in relation to risk controls and regulatory requirements;
(c) conduct RBM activities only in appropriately certified spaces;
(d) obtain authorisation, through successful completion of relevant reviews, assessments, checks and required training, to safely and securely work with RBM;
(e) meet the conditions of any approval, certification, permit or licence issued by the IBC or external regulatory body;
(f) remain current with training and safety practices;
(g) keep an inventory of RBMs held and register the acquisition of Biological Agents with OREI;
(h) report RBM and Containment Facility incidents and near misses to OREI;
(i) cooperate with any internal or external audit or inspection activity, and promptly action any corrective actions issued.

5. Procedural principles

Implementing the Biorisk Management Program

5.1. The University governs activities involving RBM via an integrated program of oversight and management, which provides control and monitoring for projects, personnel and facilities that use hazardous biological materials. The Deputy Vice-Chancellor (Research) will determine detailed roles and responsibilities relating to the Biorisk Management Program in accordance with this policy, and these will be maintained and recorded by the OREI, and published on the University's website as Ancillary Requirements.

5.2. The Biorisk Management Program encompasses the following principal elements:
(a) risk identification and management, including the provision of expert advice on risk mitigation controls;
(b) processes for authorisation of personnel accessing RBMs, including reliability checks, education and training, skills development and competency assessment;
(c) processes and governance to review, approve, oversee, monitor and report on all RBM activity;
(d) maintenance of a central RBM register;
(e) development and use of appropriate and consistent Containment Facility safety practices;
(f) physical containment of RBMs through the operation, monitoring and regulatory oversight of appropriately certified facilities;
(g) a culture of continual improvement and proactive compliance;
(h) education, training and expert advice;
(i) incident management, reporting, assessment and review;

(j) internal audit and inspection of facilities, high risk biological agents and projects, external audits of facilities, and external or management-initiated program audits; and

these elements are further described in Ancillary Requirements, authorised by the DVCR and maintained and published by OREI, that further describe the elements and requirements of the Biorisk Management Program.

Institutional Biosafety Committee

5.3. The University's IBC will:

(a) work diligently to discharge its functions in a timely and professional manner, and in accordance with regulations and its Terms of Reference;
(b) manage and escalate complaints, concerns and issues to the Director, OREI in appropriate cases;
(c) operate in accordance with the principles of procedural fairness.

5.4. Institutional Biosafety Committee Chairs and members will adhere to the Terms of Reference (including the behaviours described in the Terms of Reference), this policy and terms of appointment in the discharge of its duties.

5.5. Deans will make staff available to serve on the IBC in proportion to the number of applications submitted for review, taking into account the specific expertise required by the committee.

5.6. Personnel must ensure that any IBC-Regulated Activities are submitted to the IBC secretariat in the OREI (or such other applicable IBC as described in the Ancillary Requirements) for review and authorisation prior to commencing such IBC-Regulated Activity.

Facilities

5.7. The Deputy Vice-Chancellor (Research) will determine requirements and guidance for working with RBMs in facilities, including:

(a) appropriate IBC governance, oversight, certification holder and monitoring arrangements for University and certain non-University facilities;
(b) an internal facility certification program for any facility using RBMs that are not externally-certified;
(c) requirements in relation to externally-certified facilities;
(d) facility maintenance requirements; and

that these requirements will be recorded and maintained by OREI, and published on the University's website as Ancillary Requirements.

5.8. The Deputy Vice-Chancellor (Research) will oversee a program of annual inspections of certified facilities carried out by OREI on behalf of the IBC in order to maintain appropriate certifications, and may determine other performance monitoring activities to be conducted and these requirements will be recorded and maintained by OREI, and published on the University's website as Ancillary Requirements.

Training

5.9. The Deputy Vice-Chancellor (Research) will determine mandatory training and authorisation requirements for personnel in accordance with regulatory requirements, and these requirements will be maintained and recorded by OREI, and published on the University's website as Ancillary Requirements.

Importation

5.10. The Deputy Vice-Chancellor (Research) will determine requirements for the importation of RBM in accordance with regulatory requirements, and these requirements will be maintained and recorded by OREI, and published on the University's website as Ancillary Requirements.

Preventative and contingency measures

5.11. Personnel must immediately report to OREI all incidents or near-misses involving RBMs and Containment Facilities, as further described in the Ancillary Requirements, in addition to relevant Health and Safety reporting in the case of accidents.

5.12. In accordance with the principles of the Risk Management Policy, in the event of a critical incident, the University's response will prioritise, in this order:
(a) human life, safety and wellbeing;
(b) animal life, safety and wellbeing;
(c) environmental protection;
(d) maintenance of core operations; and
(e) protection of property interests.

5.13. Stop Work orders may be issued under circumstances likely to cause significant damage, to the health and safety of people, animals or to the environment.

5.14. The Deputy Vice-Chancellor (Research) may determine other preventative and contingency measures, including incident management measures, and these will be recorded and maintained by OREI, and published on the University's website as Ancillary Requirements.

Inventories

5.15. Personnel will keep an inventory of RBMs held and report:
(a) the acquisition of RG3 Biological Agents to OREI immediately; and
(b) any changes to RG2 Biological Agent inventories to OREI on an annual basis.

1. Roles and Responsibilities

Role/Decision/Action	***Responsibility***	***Conditions and limitations***
Deputy Vice-Chancellor (Research)	Responsible for, and oversees, the Biorisk Management Program, and supports its implementation, delegates authority and determines scope of the Program and its roles and responsibilities. Establishes and oversees the IBC. Determines IBC Terms of Reference. Appoints and dismisses the IBC Chair. Acts as the CEO for purposes of the *Gene Technology Act.* Determines governance and reporting of the Biorisk Management Program to ensure appropriate oversight.	
Director, OREI by delegation from DVC-R	Administers processes to support the functions of the IBC relating to assessment and monitoring of IBC-regulated Activities and containment facility certification and oversight. Acts as point of contact for external regulators, including Approved Arrangements Manager. Procures and monitors mandatory training artefacts. Maintains inventory of RBMs. On behalf of the Deputy Vice-Chancellor (Research),	Processes to support IBC assessment and monitoring of: • Gene Technology dealings • Risk Group 3 activities • SSBAs • DURC (USA) agents and/or activities • Certified facilities under the Gene Technology Act • Approved Arrangement sites under the Biosecurity Act • Internally-certified Microbiological Containment Facilities

	appoints appropriately qualified staff, including: (a) an Institutional Biological Safety Officer (BSO); (b) a Responsible Officer and Deputy Responsible Officer, under the SSBA Standards.	Role responsibilities of the Institutional Biological Safety Officer are described in BRM Program Role Responsibilities [BRM-PR002] [Link] Role responsibilities of the Responsible Officer and Deputy Responsible Officer are described in The University of Melbourne SSBA Manual [Link] Role responsibilities of Approved Arrangements Manager are described in BRM Program Role Responsibilities [BRM-PR002][Link]
Institutional Biosafety Committee (IBC)	Internal regulator of IBC-regulated Activities. Assessment and oversight of IBC-regulated activities involving RBMs and Containment Facilities in accordance with the TORs. [hyperlink]	• Gene Technology dealings • Risk Group 3 activities • SSBAs • DURC (USA) agents and/or activities • Certified facilities under the Gene Technology Act • Approved Arrangement sites under the Biosecurity Act • Internally-certified Microbiological Containment Facilities
Facility Manager	Administers processes to ensure the compliant operation of the Containment Facility. Controls authorised facility access and access to RBMs. Maintains records relating to facility maintenance.	
Deans	Establish and implement local Faculty processes, to ensure personnel and facilities act and operate in accordance with this Policy and Ancillary Requirements, that risks are assessed and authorised, and that mandatory training is completed.	
Personnel	Complete mandatory training and hold appropriate authorisations in accordance with this Policy and Ancillary Requirements. Obtain and / or comply with all required approvals and authorisations for working with RBMs under this policy, including seeking review of any activity within the scope of the IBC-Regulated Activities.	

	Keep an inventory of RBMs held and report these to OREI in accordance with Ancillary Requirements. Report incidents as described in this policy and in accordance with Ancillary Requirements.	
Director, OH&S	Administers processes for assessing and reporting risk, hazards and OHS related incidents involving regulated biological materials.	
Executive Director, Business Services	Procures and maintains facilities and equipment that meet the requirements in the relevant standards, guidelines and/or conditions for the containment, handling, storage, and treatment specific to the type of RBM or activities being undertaken.	

2. Definitions

Activities means all dealings involving regulated biological materials such as acquiring, importing, transporting, generating, handling, storage, treatment and disposal.

Ancillary Requirements means the detailed activities, requirements, guidance, roles and responsibilities authorised by the Deputy Vice-Chancellor (Research) under this policy and maintained and published by Office of Research Ethics and Integrity.

Biohazard means a potential microbiological source of harm.

Biological Agent means a bacteria, parasite, fungi, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, toxicity or otherwise create a hazard to humans, animals or plants.

Biorisk Management Program means the program of controls outlined in this Policy and Ancillary Requirements.

Containment Facilities means facilities or locations where RBMs are used, propagated, generated or stored (including teaching, diagnostic, reference and research laboratories, plant, invertebrate, animal and aquatic containment facilities);

Dual Use Biological Agent means DUBA means high-consequence biological agents listed in the Australian Defence and Strategic Goods List (DSGL) or in the US Government Policy for Oversight of DURC and Pathogens with Enhanced Pandemic Potential (May 2024) and includes Security Sensitive Biological Agents (SSBAs).

GMOs means organisms defined as such under the Gene Technology Act;

IBC-Regulated Activities means:

(a) Gene Technology dealings;
(b) Risk Group 3 activities;

(c) Dual Use Biological Agent activities (includes SSBAs); and
(d) such other RBM Activities described in the IBC's Terms of Reference as falling within the IBC's internal regulatory functions.

Infectious microorganism means a microorganism capable of invading a susceptible host and multiplying in it, which may or may not cause a disease.

Institutional Biosafety Committee (IBC) means the University's internal regulatory committee established pursuant to section 4.3 of this policy.

Personnel means all people who use or interact with regulated biological materials, access facilities under the management or control of the University, or undertake projects requiring approval by the University's Biosafety Committees. It includes all personnel in the scope of this policy under section 2.2.

Potentially infectious material means PIM means:

a) blood, tissues, cell lines or body fluids sourced from a living organism that might reasonably be expected to contain infectious microorganisms or prions
b) environmental material reasonably expected to contain infectious microorganisms such as samples from a disease outbreak (e.g. food, water, soil or plant materials);

Prion means a proteinaceous infectious particle that lacks nucleic acids, which can cause scrapie and other related neurodegenerative diseases of humans and animals.

Regulated Biological Material means a biological agent governed by a regulatory scheme or recognised set of guidelines or standards. This includes:

(a) infectious microorganisms;
(b) potentially infectious materials such as:
  (i) blood, tissues, cell lines or body fluids sourced from a living organism that might reasonably be expected to contain infectious microorganisms or prions
  (ii) environmental material reasonably expected to contain infectious microorganisms such as samples from a disease outbreak (e.g. food, water, soil or plant materials);
(c) genetically modified organisms, including viable organisms that have been modified by gene technology, or that have inherited particular traits from an initial organism that occurred because of gene technology;
(d) imported materials under biosecurity control due to biosecurity risk (based on the probability of a disease or pest being introduced to Australia that may cause harm); and
(e) Dual Use Biological Agents (including SSBAs).

RBM register means the University's official lists of RBMs held, or in use at University certified facilities or by University personnel. The Register is maintained by OREI**.**

Security Sensitive Biological Agents (SSBA) means biological agents that could be developed or retained in types and quantities that could allow them to be used as weapons. All biological agents that are considered to be SSBA are included in the List of SSBAs established under the *National Health Security Act 2007.*

POLICY APPROVER
Deputy Vice-Chancellor (Research)

POLICY STEWARD
Pro Vice-Chancellor (Research Infrastructure)

REVIEW
This policy is due to be reviewed by March 2028.

VERSION HISTORY

Version	Approved By	Approval Date	Effective Date	Sections Modified
1	[Position title of policy approver]			N/A