Biosafety - Dealings Involving Risk Group Agents Procedure

Section 1 - Purpose / Objectives

(1) The objective of the procedure is to:

a. protect staff, students, contractors, visitors, community and environment from Biologicals that are a biosafety or biosecurity concern, and are stored or handled within the laboratory and clinical facilities at the University;
b. reduce the risk of unintentional release of, or exposure to Biological Risk Group Agents, prions and toxins;
c. comply with all legal requirements and meet the relevant Australian Standards, Codes and Regulations applicable to biologicals, Biological Risk Group Agents, prions and toxins that will be handled or possessed at the University;
d. inform all employees and relevant third parties and communicate individual obligations with regard to biosafety;
e. continually improve biosafety management at the University.

(2) This procedure outlines the requirements, responsibilities and general guidelines relating to safe handling, containment, storage, transport and disposal of microorganisms, prions, biological toxins or samples that might reasonably contain hazardous biological agents, or be considered a biosecurity risk. It is intended to provide management and laboratory work groups with guidelines to promote microbiological safety and prevent unintended spread of microorganisms.

(3) This procedure provides guidelines on laboratory safety that recognises the special hazards associated with Biological Risk Group Agents and ensures that all work areas employing such agents comply with the Australian New Zealand Standards, Safety in Laboratories, Part 3: Microbiological Safety and Containment (AS/NZS 2243.3).

(4) This procedure provides the training framework for:

a. work groups conducting teaching and/or research using material that potentially contains Biological Risk Group Agents; and
b. visitors, contractors, and support personnel that need access to the containment laboratories but do not handle the Biological Risk Group Agents in the laboratory.

(5) This procedure does not address dealings with genetically modified organisms (GMOs). Procedures relating to dealings with GMOs are detailed in the Dealings Involving Genetically Modified Organisms Procedure .

Section 2 - Scope / Application

(6) This procedure applies to all work areas of the University where potentially hazardous biological agents or samples that might reasonably contain hazardous biological agents are used, stored, handled, transported and disposed of.

Section 3 - Definitions

(7) Biosafety: The containment principles, technologies and practices that are implemented to prevent the unintentional exposure to Biological Risk Group Agents, prions and toxins, or their accidental release.

(8) Biological Risk Group Agents: are hazardous biological agents such as bacterium, protozoa, fungus, unicellular algae, virus able to cause disease in an otherwise healthy host (including human, animal or plant hosts). Tables 3.1 to 3.11 in the Australian New Zealand Standards, Safety in Laboratories, Part 3: Microbiological Safety and Containment (AS/NZS 2243.3) Classifies Risk Group 2, 3 & 4 Agents .

(9) Institutional Biosafety Committee (IBC): Governance Committee of the University. The IBC provides advice, resources and facilities as are necessary for safe laboratory practices.

(10) OGTR Certified Facility: A laboratory, animal house, plant house, insectary or aquarium that has been shown to meet the requirements of the Office of the Gene Technology Regulator (OGTR) for the containment of genetically modified organisms. OGTR certifications exist for all levels of physical containment (PC 1 to PC 4).

(11) Physical containment level 1 (PC1): A PC1 laboratory or facility is suitable for work with microorganisms that have been designated Risk Group 1. In addition, samples originally designated Risk Group 2 that have subsequently been fixed or inactivated may be handled in PC1 facilities.

(12) Physical containment level 2 (PC2): A PC2 laboratory or facility is suitable for work with biohazardous material that have been designated Risk Group 2 or below.

(13) Risk Assessment: A process of estimating the potential of a hazard to give rise to an adverse event. The estimation is based on a combination of the likelihood of the hazard occurring and the consequences if the hazard occurs. Control measures are identified to limit the risk.

(14) Risk Group 1: Risk Group 1 microorganisms and other biological agents are of low risk to the individual or workgroup and community, are unlikely to cause human, animal or plant diseases and are already present and widely distributed in the environment.

(15) Risk Group 2: Risk Group 2 microorganisms and other biological agents are of moderate risk to the individual or workgroup, limited risk to the community, may cause infection to humans, animals, plants, invertebrates or the environment, yet effective treatment is available. Risk Group 2 microorganisms are already present but not widely distributed in the environment.

(16) Risk Group 3: Risk Group 3 microorganisms and other biological agents are of high individual risk, moderate community risk and usually cause serious infection to humans, animals, plants, invertebrates or the environment. Effective treatment is available.

(17) Risk Group 4: Risk Group 4 microorganisms and other biological agents are of high individual and community risk, and usually cause life-threatening human or animal disease that may be readily transmissible between individuals. Effective treatment and preventative measures are not usually available.

(18) Security Sensitive Biological Agents: Security Sensitive Biological Agents (SSBA) are harmful biological agents such as viruses, bacteria, fungi and toxins that have the potential to cause significant damage to human health, the environment and the Australian economy. Details of the SSBA Regulatory Scheme, including a list of SSBAs can be found at http://www.health.gov.au/SSBA . The scheme is built around a tiered List of SSBAs and requires all entities and facilities handling SSBAs to comply with the National Health Security Act, the National Health Security Regulations and the SSBA Standards.

(19) Laboratory Work Group (or Work Area): A work group for the purposes of this procedure is a person or people who share physical space and may be exposed to infectious agents that are being used in that physical space. The physical space in which work with infectious agents is conducted is the work area. A work area may be a laboratory, animal house, plant house or other suitable containment facility.

Section 4 - Policy Statement

(20) See Biosafety Policy.

Section 5 - Procedures

Part A - Roles and Responsibilities

(21) Key responsibilities and accountabilities are outlined in the Biosafety Governance Procedure (pending) .

Part B - Procedures

General Procedures for all Biological Risk Group Agents

Biological Risk Group Agent Notification

(22) All biological material needs to be assigned a Biological Risk Group classification as defined in AS 2243.3.

(23) All Biological Risk Group Agents must be approved and listed on one of the VU Biological Agents Approved Lists before being brought on site.

(24) Staff & students must:

a. report new acquisitions that may potentially contain Biological Risk Group agents on the Biological Risk Agent Notification Form to the Manager, Research Infrastructure and Biosafety. If the goods are already on the approved list and all conditions of use are met, a Biological Risk Agent Notification Form is not required.
b. ensure the form is complete and all declarations signed by the appropriate person.

(25) The Manager, Research Infrastructure and Biosafety shall:

a. maintain the VU Biological Agents Approved Lists and establish guidelines for their use, storage and handling
b. check the notification for completeness
c. register the notification on the database
d. acknowledge the receipt of the notification and inform the applicant that the product can be obtained.

Biological Inventory

(26) A list of all samples that potentially contain Biological Risk Group Agents used or stored at VU shall be maintained by each laboratory work group. The Staff member responsible for the laboratory work group is responsible for their laboratory work group inventory and upon request must provide the inventory to the Laboratory Support Staff that manage the laboratories where the biologicals are used or stored.

(27) The Technical Lab Support Staff shall collate the biological inventories of all laboratory work groups in the labs they are responsible for. The Laboratory Support Staff must annually audit biological inventories on behalf of the College.

(28) Colleges must ensure that samples that potentially contain Biological Risk Group Agents used in their laboratories are registered.

(29) The Manager, Research Infrastructure and Biosafety inspects and audits inventories and submits inspection results to the IBC for review.

(30) The IBC assesses and reviews compliance.

Risk Assessments

(31) VU has the one Risk Assessment process that is managed by OHS. The OHS Risk Assessment Form can be downloaded from the OHS website.

(32) A Risk Assessment must be conducted on all procedures where Biological Risk Group Agents are present, including work with human, plant and animal cells. The Risk Assessment must be conducted by the laboratory work group to estimate potential hazards and outline measures to minimize risk. A Risk Assessment should also determine if the work needs to be conducted with additional precautions, or at a higher level of physical containment.

(33) Risk Assessments must only be approved on the basis of adequate storage, handling and disposal of the biological agents, and on completion of biohazard training.

(34) Upon request the Manager, Research Infrastructure and Biosafety reviews Risk Assessments. OHS also refers Risk Assessments for advice as appropriate.

(35) If the Risk Assessment score is high (or the project involves GMOs), project approval by the IBC is required and a Standard Operating Procedure must be completed by the researcher and submitted with the application. A SOP example template can be downloaded from Biosafety Website.

IBC Project Approval

(36) IBC project approval is required for all high risk projects as outlined below.

(37) IBC project approval is not required for Risk Group 1 Agents (low risk).

(38) IBC project approval not required for Risk Group 2 Agents (low risk), unless:

a. Risk Group 2 agents are cultured in large volumes (> 25 Litres)
b. Risk Group 2 agents require special precautions associated with their use as highlighted in AS 2243.3.
c. they are to be used in humans or animals (NB: Human Research Ethics Application or an Animal Research Ethics Application must also be completed).

(39) IBC project approval is required for the following high risk projects:

a. Genetically Modified Organisms (i.e. genetically modified - microorganism, animals and plants)
b. Prions
c. Risk Group 3 or 4 biological agents
d. Procedures that might give rise to Risk Group 3-4 microorganisms
e. Infectious / potentially infectious animals and plants (e.g. bats)
f. Poisonous or venomous animals and plants (e.g. snakes, spiders, mushrooms)
g. Biological agents and toxins on the Defence Strategic Goods List
h. Security Sensitive Biological Material
i. Goods that require the use of a Quarantine Approved Premises

j. Emerging new biohazards not captured within the above definition.

(40) If project approval is required, a Biohazard Material Project Application Form must be completed by the staff member in charge of the project and submitted to the IBC for approval. The staff member in charge of the project must forward the following documents to the IBC Executive Officer:

a. one (1) original application signed and authorised by all relevant parties (including all attachments)
b. an electronic application must be emailed to the IBC Executive Officer, original only, scanned copies will not be accepted
c. applications will not be processed without the appropriate authorisation. All Electronic and hard copies of IBC Forms that require IBC approval must be submitted prior to the IBC agenda cut-off date to be considered at the following committee meeting.

(41) Applications to the IBC must be clear and written in lay language in order to allow thorough assessment. Failure to submit a well written application will result in the IBC requesting the application to be re-submitted.

(42) The Manager, Research Infrastructure and Biosafety is available to pre-review project applications, pre-review is strongly recommended. Applications for pre-review must be submitted to the Manager, Research Infrastructure and Biosafety at least 10 working days before the IBC agenda cut-off date.

(43) If project approval is required, work cannot commence without prior written approval from the IBC. The IBC Secretary will email the notification to the staff member in charge of the project within 14 working days of the meeting.

(44) High Risk Biological projects must be reviewed annually and a final report must be submitted at the end of the project using the IBC Annual Progress Report/Final Report Form . Applications for storage of Biologicals or GMOs must be made before expiry of the current IBC project approval.

(45) All project amendments must be approved by the IBC before work can continue. Prior to submitting a request to amend an existing application, the staff member responsible for the project must contact the IBC Executive Officer to obtain the most recent approved version of the project and complete the IBC Amendment Form or IBC Add/Delete a Co-investigator Form as applicable. Failure to do so will result in the IBC not considering the request.

(46) IBC project approval from other organisations for work at VU is not transferable.

(47) VU researchers and teachers using High Risk Biologicals in work conducted at external organisations are required to inform the VU IBC.

(48) High Risk Projects expire after five years. By law extensions are not possible for GMO projects. For all other projects a formal request for extension must be submitted.

Project Post Approval Requirements

(49) Research or teaching activity begins with the approval of the application. After approval the staff member responsible for the project must ensure:

a. everyone named on the application has access to the final approved version and understands their responsibilities in relation to the project
b. work is carried out only by persons named on the application
c. everyone named on the application have completed the relevant Biosafety training and local laboratory inductions
d. project-specific training has been undertaken and a record of attainment of competency maintained

e. work is carried out in accordance with the application and any cited SOPs or Guidelines
f. VU OHS Risk assessment process has been completed.

Training

(50) All personnel, visitors and contractors are bound by their employing organizations IBC training requirements.

(51) Level One: Organisation Wide Procedures

a. A working knowledge of current legislation, the role of the IBC, behavioural requirements for working in the laboratory and the approval process for dealings is required for all personnel working in the Internally Certified Containment Laboratory. This training is provided by the Manager, Research Infrastructure and Biosafety on behalf of the IBC. Training records are kept by Office for Research. All personnel must complete the relevant online biosafety training course(s) and the associated competency assessment.

(52) Level Two: Laboratory-Specific Procedures

a. All personnel are inducted into the lab by the Laboratory Support Staff. Laboratory induction is also compulsory for all visitors and contractors (including environmental services, engineering, security, IT and administrative personnel) that enter the laboratory.
b. Induction includes: High risk areas (e.g. Tissue Culture & Animal House) have specific induction process where personnel are trained by an authorised trainer to use the facility.
c. The facility specific training record is maintained by the Technical Laboratory Support Staff, and may be requested by the IBC or the associated regulator at any time.

(53) Level Three: Project-Specific Procedures

a. It is the responsibility of the relevant project supervisor/subject coordinator to ensure that all their staff/students are aware and compliant with the relevant Biosafety and Biosecurity regulations in relation to their particular project/activity.
b. It is the responsibility of the relevant project supervisor/subject coordinator to organize project-specific training and maintain a record of competency assessment.

Non-Compliance and Adverse Incident reporting

(54) Please see Non-Compliance and Adverse Incidents Procedure .

(55) All incidents must be reported via the OHS portal.

(56) All biohazardous adverse incidents (and near misses) or non-compliant (or suspected non-compliant) incidents involving regulated biologicals must be immediately reported to the IBC by calling the IBC Emergency Phone (0481 001 329). Types of incidents include: non contained spills of GMOs or potentially hazardous biological material, all laboratory acquired infections, breach of containment and escape of transgenic animals.

(57) The IBC will formally investigate and seek a written explanation of the incident from the staff member responsible for the project, or other relevant persons, on the incident using the IBC Incident Form .

Risk Group 1 Agents

(58) A Biological Risk Agent Notification Form must be completed and approved, if the agent is not already on the laboratories approved agents list.

(59) The OHS Risk Assessment Form must be completed and approved prior to the commencement of a project.

(60) A Biological Risk Agent Inventory Table must be maintained.

(61) Project approval is not required for Risk Group 1 Agents.

(62) Storage, handling, transport or disposal of Risk Group 1 agents shall be conducted in accordance with the Australian New Zealand Standards, Safety in Laboratories, Part 3: Microbiological Safety and Containment (AS/NZS 2243.3) .

(63) Work with Risk Group 1 agents (that are not part of an approved OGTR dealing with a genetically modified organism) must be conducted in an Internally Certified PC1 Laboratory, as described in the Internal Certification of Containment Laboratories Procedure .

Risk Group 2 Agents

(64) A Biological Risk Agent Notification Form must be completed and approved, if the agent is not already on the laboratories approved agents list.

(65) The OHS Risk Assessment Form must be completed and approved prior to the commencement of a project.

(66) A Biological Risk Agent Inventory Table must be maintained for the life of the project.

(67) Institutional Biosafety Committee approval of projects employing Risk Group 2 agents is not generally required, unless a risk assessment score is high. Depending on the risk classification a Biohazard Material Project Approval Form must be submitted

(68) All Risk Group 2 agents that are transmissible by the respiratory route or involve microbiological procedures that are likely to produce aerosols must be performed in a Class II Biosafety cabinet.

(69) Storage, handling, transport or disposal of Risk Group 2 agents shall be conducted in accordance with the Australian New Zealand Standards, Safety in Laboratories, Part 3: Microbiological Safety and Containment (AS/NZS 2243.3).

(70) Work with Risk Group 2 Agents (that is not part of an approved OGTR dealing with a genetically modified organism) must be conducted in Internally Certified Physical Containment Level 2 (PC 2) facilities, as described in the Internal Certification of Containment Laboratories Procedure .

(71) All work with human blood, blood products and tissues (including human and animal cells) that cannot be considered to have been treated in such a way to render any infectious agents present in the sample unable to cause infection must be conducted in facilities that meet the requirements for Physical Containment Level 2 (PC2) laboratories. This applies to both screened and unscreened samples.

(72) Where it is expected that a sample (for example blood, soil, human or animal cells or tissues, wastewater effluent) may contain an infectious agent that could be categorized as Risk Group 2, the sample shall be handled as though it is a culture of a Risk Group 2 infectious agent/s.

Risk Group 3 and 4 Agents

(73) Victoria University does not have facilities that are appropriate for conducting work with Risk Group 3 and Risk Group 4 Agents. As a result, work with Risk Group 3 and 4 agents must not be conducted in Victoria University managed facilities without the prior approval from the Vice-Chancellor or nominated representative (PVC (Research & Research Training)) on the advice from the Institutional Biosafety Committee.

(74) Victoria University personnel must not work with Risk Group 3 and 4 agents at non-VU facilities without the prior approval from the Vice-Chancellor or nominated representative (PVC (Research & Research Training)) on the advice

from the Institutional Biosafety Committee.

(75) The decision to allow University personnel to work with such agents will be based on:

a. The provision of training in risk assessment and risk management procedures for handling such agents
b. The provision of evidence that demonstrates that the staff member or student is competent in all procedures in which the agent is used
c. The provision of documents that demonstrate that the facility in which the work is being conducted meets the requirements for Physical Containment Level 3 and above as outlined in the AS/NZS 2243.3
d. The acquisition of the relevant license and permits by the Office for Research.

Security Sensitive Biological Agents & Goods Listed on the Defence Strategic Goods List

(76) Victoria University does not have facilities that are appropriate for conducting work with Biological Risk Group Agents that are on the Security Sensitive Biological Agents list or Defence Strategic Goods List.

(77) Biological Risk Group Agents that are on the Security Sensitive Biological Agents list or Defence Strategic Goods List must not be used by Victoria University personnel at Victoria University facilities without the prior approval from the Vice-Chancellor or nominated representative (PVC (Research & Research Training)) on the advice from the Institutional Biosafety Committee.

(78) Victoria University personnel must not work with Security Sensitive Biological Agents or Defence Strategic Goods List Agents at facilities not managed by Victoria University without the prior approval from the Vice-Chancellor or nominated representative (PVC (Research & Research Training)) on the advice from the Institutional Biosafety Committee.

(79) The decision to allow University personnel to work with Security Sensitive Biological Agents and goods on the Defence Strategic Goods List will be based on the following criteria:

a. The provision of training in risk assessment and risk management procedures in place for handling such agents
b. The provision of evidence that demonstrates that the staff member or student is competent in all procedures in which the agent is used
c. The provision of documents that demonstrate that the facility in which the work is being conducted meets the requirements of the Regulatory Scheme
d. The acquisition of the relevant license and permits by the Office for Research.

Other approval required

(80) For work with humans or animals, animal ethics and/or human ethics approval must be granted before work can commence.

(81) If Risk Group Agents are to be imported and exported the Import, Export, Transport and Packaging of Biological Material Procedure must be followed.

(82) If Risk Group Agents are genetically modified, the Dealings Involving Genetically Modified Organisms Procedure must be followed.

(83) If the biological is considered a Biosecurity risk in Victoria, your work may be prohibited, controlled or restricted. The classification and general control of noxious weeds and pest animals in Victoria is determined under the Catchment and Land Protection Act. Contact the Manager, Research Infrastructure and Biosafety to obtain the relevant permits before commencing work.

Section 6 - Guidelines

(84) Nil

Section 7 - Templates

(85) Nil

Section 8 - References

(86) International/National/State Acts, Regulations and Standards

a. Australian New Zealand Standards, Safety in Laboratories Part 3: Microbiological aspects and Containment Facilities (AS/NZS 2243.3)
b. Catchment and Land Protection Act
c. Security Sensitive Biological Agents
d. Defence Strategic Goods List Agents

Section 9 - Support Documents

(87) All supporting documents can be found on the Biosafety website or by contacting the Manager, Research Infrastructure and Biosafety (ibc@vu.edu.au).

(88) The following procedures have been referenced in this document:

a. IBC P002 Internal Certification of Containment Facilities Procedure
b. IBC P003 Dealings Involving Genetically Modified Organisms Procedure
c. IBC P004 Import, Export, Transport & Packaging of Biological Material Procedure
d. IBC P005 Non-Compliance and Adverse Incidents Procedure
e. IBC P006 Biosafety Governance Procedure

(89) The following forms have been referenced in this document:

a. IBC F004 Biological Risk Agent Notification Form
b. IBC F005 Biohazard Material Project Application Form
c. IBC F003 IBC Annual Progress Report/Final Report Form
d. IBC F002 Amendment Form
e. IBC F001 IBC Add/Delete a Co-investigator Form
f. IBC F006 Incident Form
g. OHS Risk Assessment Form

(90) The following resources have been referenced in this document

a. IBC D004 Biological Risk Agent Inventory Table
b. IBC D008 - D010 VU Biological Agents Approved Lists

Status and Details

Status	Historic
Effective Date	9th September 2016
Review Date	31st October 2020
Approval Authority	Vice-Chancellor
Approval Date	25th August 2016
Expiry Date	20th July 2022
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