Biosafety - Dealings Involving Risk Group Agents Procedure

Section 1 - Summary

(1) This Procedure:

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

(2) This Procedure does not address dealings with Genetically Modified Organisms (GMOs). Procedures relating to dealings with GMOs are detailed in the Biosafety - Dealings Involving Genetically Modified Organisms Procedure.

Section 2 - Scope

(3) 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 - Policy/Regulation

(4) Biosafety Policy

Section 4 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
Deputy Vice-Chancellor, Research & Impact (DVCRI)	Responsible to the Vice-Chancellor for VU's Institutional Biosafety Committee (IBC) and its implementation of requirements as specified by regulatory bodies in relation to the handling of Biological Risk Group Agents.

Roles	Responsibilities
Executive Director, Research Services	Responsible to the DVC-RI to ensure that the Senior Manager, Research Infrastructure & Biosafety, advises and reports on the regulatory and legislative requirements the handling of Biological Risk Group Agents, and is adequately supported to develop, implement, monitor, and review associated procedures and guidelines.
Senior Manager, Research Infrastructure & Biosafety	Authorised to advise on and report to the IBC on legislative requirements for the handling of Biological Risk Group Agents.
Directors, Executive Deans and Heads of Department	Ensure that all staff and students receive appropriate information and training necessary for them to handle Biological Risk Group Agents in accordance with all legislative requirements.
Manager, Technical Services	Ensure that designated research spaces are adequately supported so that Biological Risk Group Agents can be handled in a compliant and safe manner. Ensure that Technical Managers have resources to develop and implement training and procedures necessary to ensure that all handling of Biological Risk Group Agents is in accordance with all legislative requirements.
Technical Managers	Ensure that all end-users of biocontainment facilities are adequately trained and competent, and that there are procedures in place to ensure that all Biological Risk Group Agents are handled in accordance with regulatory and legislative requirements.
Project Supervisor / Subject Coordinator (including Primary/Chief Investigators, Academic Supervisors, Research Supervisors and Unit Conveners)	Responsible for the health and safety of the undergraduate and postgraduate students they supervise, in addition to volunteers and staff employed under them. Ensure that students and staff are aware of and abide by VU's procedures for the handling of Biological Risk Group Agents.
Staff, Students, Volunteers and External Users of University Facilities working with Biological Risk Group Agents	Ensure that they follow safety guidelines and abide by VU's Procedures for handling of Biological Risk Group Agents, as set out by VU and their respective facility manager and Project Supervisor/ Subject Coordinator. Ensure that their actions do not put themselves, or any other individual at risk.
Senior Officer, Animal Ethics & Biosafety	Act as the IBC Secretary and as such are responsible for receiving and sending communications between Project Supervisor/ Subject Coordinator, end-users, facility managers and the IBC.

Part B - General Procedures for all Biological Risk Group Agents

Biological Risk Group Agent Notification

(5) All biological material needs to be assigned a Biological Risk Group classification as defined in the current AS/NZS 2243.3:2022.

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

(7) Staff and students must:

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

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(8) The Senior Manager, Research Infrastructure & Biosafety, or delegate, shall:

a. maintain the VU Biological Agents Approved List 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

(9) 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 must maintain up-to-date biological inventory. Upon request, they must provide this inventory to the Technical Manager and any laboratory support personnel overseeing the facilities where the biologicals are used or stored.

(10) Technical Managers shall collate the biological inventories of all laboratory work groups in the facilities for which they are responsible and, in conjunction with other laboratory personnel must annually audit biological inventories on behalf of the Institute/College.

(11) Institutes/Colleges must ensure that samples that potentially contain Biological Risk Group Agents that are used/stored in their facilities are registered.

(12) The Senior Manager, Research Infrastructure & Biosafety shall periodically inspect and audit inventories and provide findings to the IBC for review.

(13) The IBC shall assess and review compliance.

Risk Assessments

(14) 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 minimise 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.

(15) Risk Assessments must only be approved on the basis of adequate storage, handling and disposal of the biological agents, and on completion of Biosafety Training modules.

(16) Upon request the Senior Manager, Research Infrastructure & Biosafety reviews Risk Assessments. OHS also refers to Risk Assessments for advice as appropriate.

(17) If the Risk Assessment score is high (or the project involves GMOs), project approval by the IBC is required and a Standard Operating Procedure (SOP) must be completed by the researcher and submitted with the application.

Part C - IBC Project Approval

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

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

(20) 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/NZS 2243.3.
c. they are to be used in humans or animals (NB: an application must be made to the relevant Ethics Committee).

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

a. Genetically Modified Organisms (GMOs) (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 biological agents;
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 and Strategic Goods List 2024 (Cth);
h. Security Sensitive Biological Agents;
i. Goods that require the use of Approved Arrangements under the Department of Agriculture, Fisheries and Forestry;
j. Emerging new biohazards not captured within the above definition.

(22) If project approval is required, a Biohazardous Material Project Application Form must be completed by the staff member in charge of the project (eg: Primary/Chief Investigator) and submitted to the IBC for approval. The staff member in charge of the project must forward the following documents to the Senior Officer, Animal Ethics & Biosafety:

a. one original application form, signed and authorised by all relevant parties (including all attachments)
b. the original electronic copy of the application. NB: scanned copies will not be accepted
c. applications will not be processed without the appropriate authorisation.

(23) 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.

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

(25) If project approval is required, work cannot commence without prior written approval from the IBC. The Senior Officer, Animal Ethics & Biosafety will email the notification to the staff member in charge of the project within 14 working days of the meeting.

(26) 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 Risk Group Agents or GMOs must be made before expiry of the current IBC project approval.

(27) 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 Senior Officer, Animal Ethics & Biosafety 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.

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

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

(30) 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.

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Project Post Approval Requirements

(31) Research or teaching activity with Risk Group Agents 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. evidence that all staff/students named on the application have completed the relevant Biosafety Training and local facility inductions;
d. evidence that project-specific training has been undertaken and a record of attainment of competency maintained;
e. declaration that work will be carried out in accordance with the application and any cited SOPs or Guidelines;
f. evidence that the VU Risk Management Procedure and risk assessment process has been completed.

Part D - Training

(32) All staff, students, visitors, external users of University facilities, and contractors are bound by their employing organisations IBC training requirements.

(33) Level One: Organisation Wide Procedures

a. Biosafety Training provides a working knowledge of current legislation, the role of the IBC, behavioural requirements for working in containment facilities, and the approval process for dealings with biological agents. This training is required for all personnel working in the internally certified containment facilities. This training is developed by the Senior Manager, Research Infrastructure & Biosafety on behalf of the IBC. Training records are maintained on the staff/student record and by Research Services. All personnel must complete the relevant online biosafety training course(s) and the associated competency assessment.

(34) Level Two: Facility-Specific Procedures

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

(35) Level Three: Project-Specific Procedures

a. It is the responsibility of the relevant project supervisor/subject coordinator to ensure that all staff/students engaged on the project are aware of and compliant with the relevant Biosafety regulations in relation to their particular project/activity.
b. It is the responsibility of the relevant project supervisor/subject coordinator to organise project-specific training and maintain a record of competency assessment.
c. The project-specific training records may be requested by the IBC or an associated regulator at any time.

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Part E - Non-Compliance and Adverse Incident reporting

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

(37) All incidents must be reported via the OHS Incident Reporting System (as per the Health and Safety - OHS Incident Reporting and Investigation Procedure) and the IBC Incident Report Form to the IBC.

(38) 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, Risk Group Agents or potentially hazardous biological material, all laboratory acquired infections, breach of containment and escape of transgenic animals.

(39) Depending on the circumstances, 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, via the IBC Incident Report Form.

Part F - Risk Group 1 Agents

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

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

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

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

(44) Storage, handling, transport or disposal of Risk Group 1 agents shall be conducted in accordance with the AS/NZS 2243.3 and the Biosafety - Packaging and Transport of Biological Materials Procedure.

(45) Work with Risk Group 1 Agents (that are not part of an approved OGTR dealing with a GMO) must be conducted in a PC1 Laboratory, as described in the Biosafety - Certification of Biocontainment Facilities Procedure.

Part G - Risk Group 2 Agents

(46) A Biological Risk Group Agent Notification Form must be completed and approved, if the agent is not already on the VU Biological Agents Approved List.

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

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

(49) IBC 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 Biohazardous Material Project Application Form must be submitted to the IBC.

(50) 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 (VSCII). All users of a BSCII must complete Biosafety Cabinet Training.

(51) Storage, handling, transport or disposal of Risk Group 2 agents shall be conducted in accordance with AS/NZS 2243.3 and the Biosafety - Packaging and Transport of Biological Materials Procedure.

(52) Work with Risk Group 2 Agents (that is not part of an approved OGTR dealing with a GMO) must be conducted in Internally Certified PC 2 facilities, as described in the Biosafety - Certification of Biocontainment Facilities Procedure.

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(53) All work with human blood, blood products and tissues (including human and animal cells) which 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 handled as Risk Group 2 material. In clinical settings, this includes appropriate PPE and utilising biocontainment equipment (e.g. BSCII, sealed centrifuge) for any activities that potentiate the production of aerosols. This applies to both screened and unscreened samples.

(54) Where it is expected that a sample (e.g. blood, soil, human or animal cells/tissues, wastewater effluent) may contain an infectious agent that could be categorised as Risk Group 2, the sample shall be handled as though it is a Risk Group 2 Agent.

Part H - Risk Group 3 and 4 Agents

(55) VU 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 VU managed facilities without the prior approval from the Vice-Chancellor or nominated representative (e.g. Deputy Vice-Chancellor, Research & Impact) on advice from the IBC.

(56) University staff 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 (e.g. Deputy Vice-Chancellor, Research & Impact) on advice from the IBC.

(57) 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/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 3/4, as outlined in AS/NZS 2243.3;
d. the acquisition of the relevant license and permits by Research Services.

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

(58) 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. The SSBA Regulatory 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 2007 (Cth), the National Health Security Regulations 2018 (Cth) and the SSBA Standards.

(59) The Defence and Strategic Goods List 2024 (Cth) (DSGL) is the list that specifies the goods, software or technology that is regulated when exported, supplied, brokered or published. A permit is required when exporting, supplying, brokering or publishing DSGL items, unless there is an exemption.

(60) VU does not have facilities that are appropriate for conducting work with Biological Risk Group Agents that are on the SSBA list or DSGL.

(61) Biological Risk Group Agents that are on the SSBA list or DSGL must not be used by University personnel at VU facilities without prior approval from the Vice-Chancellor, or nominated representative (e.g Deputy Vice-Chancellor, Research & Impact), on advice from the IBC.

(62) VU personnel must not work with SSBA or goods on the DSGL at facilities not managed by the University without

the prior approval from the Vice-Chancellor or nominated representative (e.g. Deputy Vice-Chancellor, Research & Impact) on the advice from the IBC.

(63) The decision to allow University personnel to work with SSBA and goods on the DSGL 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/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 Research Services.

Part J - Other approval required

(64) For work with animals or humans, approval must be granted from the Animal Ethics Committee or Human Research Ethics Committee prior to commencing any research or teaching activities.

(65) If Risk Group Agents are to be imported and exported the Biosafety - Packaging and Transport of Biological Materials Procedure and the Biosafety - Importing and Exporting Biological Material Procedure must be followed.

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

(67) If the Risk Group Agent is considered a biosecurity risk in Victoria, the 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 1994 (Vic). Contact the Senior Manager, Research Infrastructure & Biosafety for assistance in obtaining the relevant permits before commencing work.

Section 5 - HESF/ASQA/ESOS Alignment

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

Section 6 - Definitions

(69) 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.

(70) Biological Risk Group Agents

(71) Institutional Biosafety Committee (IBC): Governance Committee of the University, established in accordance with written guidelines issued by the OGTR under the Gene Technology Act. The IBC provides advice, resources and facilities as are necessary for safe laboratory practices.

(72) 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 (GMOs). OGTR certifications exist for all levels of physical containment (PC 1 to PC 4).

(73) Physical containment level 1 (PC1)

(74) Physical containment level 2 (PC2)

(75) 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.

(76) Risk Group 1 (RG1): 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.

(77) Risk Group 2 (RG2): 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. RG2 microorganisms are already present but not widely distributed in the environment.

(78) Risk Group 3 (RG3): 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.

(79) Risk Group 4 (RG4): 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.

(80) Laboratory Work Group (or Work Area): A work group 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.

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Glossary Terms and Definitions

"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). AS/NZS 2243.3 Tables 3.1 to 3.11 classifies Risk Group 2, 3 & 4 Agents.

"Physical containment level 1 (PC1)" - A PC1 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.

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

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