

Infectious Agent Project Approval Procedure (MPF1153)

GOVERNING POLICY

This procedure is made under the [Infectious Agent Project Approval Policy](#).

SCOPE

This procedure applies to all areas of the University where hazardous infectious agents or biological material (including diagnostic samples), that might reasonably be expected to contain these agents, is stored, used, handled, transported or disposed.

PROCEDURE

1. Work with Risk Group 3 agents

1.1. Work groups must complete the [Use of a Risk Group 3 Agent Project Application Form](#) which is available on the Office for Research Ethics and Integrity website. This form must be forwarded to the Biosecurity and Biosafety Officer or Gene Technology and Biosafety Officer for consideration by the Gene Technology and Biosafety Committee.

1.2. Work groups will only acquire and commence projects involving Risk Group 3 agents for which the Gene Technology and Biosafety Committee has provided written approval.

2. Work with Risk Group 4 agents

2.1. The Gene Technology and Biosafety Committee will make recommendations to the Deputy Vice-Chancellor (Research) about whether to allow University personnel to work with Risk Group 4 agents in facilities controlled by other organisations. These recommendations will be based on the provision of evidence that:

- the organisation can train personnel in the risk assessment and risk management procedures applicable to handling such agents
- demonstrates that the staff member or student is competent in all procedures in which the agent is used
- demonstrates that a comprehensive health monitoring management system is in place as outlined in AS/NZS 2243.3
- demonstrates that the facility in which the work is being conducted meets the requirements for Physical Containment Level 4 (PC4) as outlined in AS/NZS 2243.3.

2.2. University personnel will only acquire and commence work with Risk Group 4 agents for which the Deputy Vice-Chancellor (Research) has provided written approval.

2.3. University personnel wishing to begin work with Risk Group 4 agents should contact the [Office for Research Ethics and Integrity](#) for advice on how to proceed.

RELATED DOCUMENTS

- Australian/New Zealand Standards, 2243.3: Safety in Laboratories Part 3: Microbiological safety and containment (available through [University Library](#))
- [Containment Facility Internal Certification Policy](#)
- [Containment Facility Internal Certification Procedure](#)
- [Infectious Agent Reporting Policy](#)

- [Infectious Agent Reporting Procedure](#)
- [Use of a Risk Group 3 Agent Project Application Form](#)

DEFINITIONS

Term	Definition
biological material	Any material such as tissue (including organs and bone), cell lines or body fluids sourced from a living organism. Samples (for example, unscreened human blood or blood products) are included in this definition.
hazardous infectious agent	A bacterium, fungus, virus or other agent able to cause disease in an otherwise healthy host (for example, human, animal or plant).
infectious agent	An infectious agent is a bacterium, fungus, virus or other agent that is able to invade and replicate in a host organism (for example, human, animal or plant) and which may or may not cause a disease.
project	Any work conducted by University personnel including research, diagnostic or clinical testing and epidemiological identification that fits within the scope described for this procedure.
Risk Groups 1, 2, 3 and 4 (Human and animal infectious microorganisms)	Risk groups, as defined in AS/NZS 2243.3, divide microorganisms that are infectious for humans and animals into categories for Australasia based on their pathogenicity, the mode of transmission, the host range of the agent and the availability of effective prevention and treatment. Risk Group 1 agents have the lowest individual and community risk and include microorganisms that are unlikely to cause human or animal disease. Risk Group 2 agents may cause disease in healthy hosts, but are difficult to transmit (limited community risk), don't usually cause serious or life-threatening illness and are readily treated or prevented. Risk Group 3 agents are those that usually cause serious disease and may present a serious risk to laboratory workers. Risk group 3 agents also present a limited to moderate community risk if spread in the environment, but there are usually effective measures for treatment and/or prevention. Risk Group 4 agents are those that present significant individual and community risks and usually produce life-threatening disease, are readily transmissible and effective prevention and/or treatment are not usually available.
Risk Groups 1, 2, 3 and 4 (Plant infectious microorganisms)	Risk groups, as defined in AS/NZS 2243.3, divide microorganisms that are infectious for plants into categories for Australasia primarily based on their containment to avoid risk to the environment. The economic or ecological impact, the ease of spread, the host range of the agent and the use in the facility (in vitro or in vivo) are considered when determining the risk group for these pathogens. Risk Group 1 agents are unlikely to be a risk to plants, industry, a community or region and are already present and widely distributed. Risk Group 2 agents have a low to moderate risk to plants, industry, a community or region and is present but not widely distributed. Risk Group 3 agents are those that present a significant risk to plants, industry, a community or region, are exotic but with a limited ability to spread without a vector. Risk Group 4 agents are those that present a highly significant risk to plants, industry, a community or region, are exotic and readily spread naturally without a vector.
work group	A work group for the purposes of this procedure is a person or people who share physical space and may be exposed to hazardous infectious agents that are being used in that physical space. Examples of work groups include all members of a laboratory, those working in clinical settings, diagnostic and reference laboratories, and pathology laboratories.

RESPONSIBLE OFFICER

The Director, Office for Research Ethics and Integrity is responsible for the development, compliance monitoring and review of this procedure and any associated guidelines.

IMPLEMENTATION OFFICER

The Biosecurity and Biosafety Officer, Office for Research Ethics and Integrity is responsible for the promulgation and implementation of this procedure in accordance with the scope outlined above. Enquiries about interpretation of this procedure should be directed to the implementation officer.

REVIEW

This procedure is to be reviewed by 30 November 2015.

VERSION HISTORY

Version	Approved By	Approval Date	Effective Date	Sections Modified
1	Senior Vice-Principal	1 Aug 2013	1 Aug 2013	N/A