

# Infectious Agent Project Approval Policy (MPF1246)

## RELEVANT LEGISLATION

Government legislation:

- [Occupational Health and Safety Act 2004](#) (Vic)
- [University of Melbourne Act 2009](#) (Vic)

University legislation:

- [Statute 1.7 – University Governance](#)

## SCOPE

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

## POLICY

### 1. Suitability of research involving infectious agents

1.1. University personnel may only conduct work involving Risk Group 2 agents and biological material reasonably expected to contain these in containment facilities that meet Physical Containment Level 2 (PC2) requirements based on AS/NZS 2243.3 (refer to the [Containment Facility Internal Certification Policy](#) and the [Containment Facility Internal Certification Procedure](#) for further information).

1.2. University personnel may only conduct work with Risk Group 3 agents in containment facilities that meet Physical Containment Level 3 (PC3) requirements as outlined in AS/NZS 2243.3 (refer to the [Containment Facility Internal Certification Policy](#) and the [Containment Facility Internal Certification Procedure](#) for further information).

1.3. The University will ensure that appropriate risk assessment and risk management strategies are in place for work with high-risk (Risk Group 3 and 4) infectious agents.

1.4. Work with Risk Group 4 agents poses a high level of risk to human health and/or the environment. The University of Melbourne does not have facilities that are appropriate for conducting work with such agents. Subject to section 2.2, University personnel may conduct work with Risk Group 4 agents in appropriate facilities controlled by other organisations.

### 2. Approval of projects

2.1. The Gene Technology and Biosafety Committee must provide written approval for University personnel to handle, store or dispose of Risk Group 3 agents.

2.2. The Deputy Vice-Chancellor (Research), on advice from the Gene Technology and Biosafety Committee, must provide written approval for University personnel to work with Risk Group 4 agents in appropriate facilities controlled by other organisations.

2.3. The following projects do not require approval under this policy:

- any project or work that involves Risk Group 2 agents or biological material reasonably expected to contain these and that is conducted in containment facilities certified by Gene Technology and Biosafety Committee (GTBC)
- any project or dealing that is approved under the Gene Technology Regulatory Scheme and that is conducted in containment facilities certified by the Office of the Gene Technology Regulator (OGTR) or approved by the Department of Agriculture, Fisheries and Forestry (DAFF).

## SCHEDULES

- [Schedule A – Projects that require approval under this policy](#)

## 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 Project Approval Procedure](#)
- [Infectious Agent Reporting Policy](#)
- [Infectious Agent Reporting Procedure](#)

## DEFINITIONS

Term	Definition
<b>biological material</b>	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.
<b>hazardous infectious agent</b>	A bacterium, fungus, virus or other agent able to cause disease in an otherwise healthy host (for example, human, animal or plant).
<b>infectious agent</b>	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.
<b>project</b>	Any work conducted by University personnel including research, diagnostic or clinical testing and epidemiological identification that fits within the scope described for this policy.
<b>Risk Groups 1, 2, 3 and 4 (Human and animal infectious microorganisms)</b>	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.
<b>Risk Groups 1, 2,</b>	Risk groups, as defined in AS/NZS 2243.3, divide microorganisms that are infectious

<b>3 and 4 (Plant infectious microorganisms)</b>	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.
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**RESPONSIBLE OFFICER**

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

**IMPLEMENTATION OFFICER**

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

**REVIEW**

This policy 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