Biorisk Management Procedure

Version	Approved by	Approval date	Effective date	Next full review
1.0	Director, UNSW Risk. & Sa(k)8.0.Tc.0.T()-4.1.(o)-5...TJ./TT2.1.Tf.0.Tc.0.Tw.4.012.0.Td.()Tj EMC../P.<</MCID 27 >>BDC /I			

implements (AA) and Dealings to apply good practice controls and to

manage the containment of all biological materials that present a potential biorisk, while also complying with the requirements of all relevant legislation, Australian Standards and regulatory requirements. This Procedure will assist workers and students to continuously improve their biosafety processes and ability to use biological materials in a safe, effective manner.

Effective management of biorisk can be achieved by implementing a 4-step biorisk management process as described in the Risk Management Procedure HS329 (refer to section 3.4):

1. Identify hazards: gather information, i

1.2. Assess the risks

In the second step the aim is to assess the risks associated with the proposed work. A risk assessment of how agents of biological origin will be used in an activity must be completed prior to commencing work. This enables mitigation of the hazards inherently related to the proposed work, the actions required to negate harm to our people, and identify the level and type of physical containment facility required. The assessment should include considerations as described in AS/NZS2243.3 Safety in Laboratories – Microbiological Safety and Containment. After identification of the biological hazard(s) any relevant legislation for the biological hazard must be identified. All microorganisms need to be assigned a risk group (1 – 4) using AS/NZS 2243.3 as the primary assessment tool. Unless otherwise stated, references to particular risk groups (e.g., Risk Group 1) are to human, terrestrial animal, plant, invertebrate and aquatic organism risk groups, as defined in AS/NZSS 2243.3.

Factors that can be considered in relation to the risk from infectious microorganisms include:

(a) the potential economic and ecological impact

(b) the infectious microorganism's presence in Australia or New Zealand

(c) ease of spread

(d) use in the facility, in vitro or in vivo

(e) the host range.

Projects involving biological agents that are identified as Risk Group 3 must be assessed by the UNSW Gene Technology Research Committee. Projects involving any Sensitive Security Biological Agents (SSBAs) must consult the UNSW Biosafety Coordinator and Research Ethics and Compliance Support (RECS) before proceeding as these agents are strictly controlled by legislation. No organism should be imported until all

- Ensuring containment facilities are appropriate for all teaching and research activities involving biohazards and that facilities are registered and/or certified as required.
- Ensuring that registers of biological hazards and containment facilities are maintained, regularly reviewed, and a copy sent annually to the UNSW Biosafety Coordinator.
- Appointing a local Biosafety expert for the School.
- Ensuring that training needs are identified, all persons are appropriately tp9ta-8 (i)3.1 (7n)-9 (ed,S(y)-8 (afut)-1.1 (

Biosafety Advisor/Officer /Coordinator	A Competent individual who is designated to provide advice, guidance and assurance on biorisk management. The BSA/BSO shall report directly to Senior Management and have delegated authority to prohibit work in the event that it is considered necessary to do so. The role should be independent of those responsible for implementing the programme of work. (ISO 35001:2019)
Biorisk	Biorisk is the effect of uncertainty expressed by the combination of the consequences of an event (including changes of circumstances) and the associated “likelihood” of occurrence where biological material is the source of harm
Biosecurity	The measures taken to minimise the risk of infectious diseases caused by viruses, bacteria or other microorganisms, insects & pests, entering, emerging, establishing or spreading in Australia, potentially harming the Australian population, our food security and economy.
DIR	Dealing Involving Intentional Release. A dealing with a GMO which involves the intentional release of the GMO to

IBC	Institutional Biosafety Committee The IBC is the University's primary body responsible for ensuring all practices involving biological material adhere to the Australian and International Standards. This includes AS2243.3 Safety in Laboratories – Microbiological Safety and Containment and ISO 35001, Biorisk Management and other codes of practice, and licensing requirements.

Appendix A . Definition of Biological Risk

In order to ensure that the research is carried out safely and according to best practice, the following definitions will apply to research materials and processes that come under a Faculty/Division IBC TOR and would fall into one of three risk levels. The definitions do not include reagents and kits which may be purchased to support the research, and that may or may not require an Import Permit (IP).

Low Risk biological agents and processes – managed by Chief Investigator/Supervisor

- Materials that are not described in AS/NZS2243.3 lists of risk group agents, and:
- Are naturally occurring, ubiquitous, environmental materials e.g., soil and water samples from naturally occurring local environments, or derivatives (e.g. commercially available and collaborator-provided cultures of such materials), that may or may not require an import permit, and
- Are not Genetically Modified, as described under the Gene Technology Legislation as Exempt, NLRD, DNIR or DIR,
- Any aquatic or terrestrial vertebrate, invertebrate, plants (include aquatic or terrestrial mammals, birds, fish, reptiles, insects, plants, snails and such) studied in-situ and does not include handling,
- Any commercially available plants used from nursery stock,
- Any commercially available, research-bred and acquired, non-GMO research animals (e.g. mice, rats, rabbits, sheep), that do not require an import permit, are brought onto campus and where the research involves observation only (e.g. diet & behaviour studies).

Minor Risk biological agents and processes – managed by Chief Investigator/Supervisor

- Materials described as Risk Group 1 in AS/NZS2243.3 lists of risk group agents, and
- Materials that require a PC1 facility,
- Material that is described under the Gene Technology Legislation as an Exempt Dealing, that have had the classification of the dealings assessed and confirmed as being Exempt by the UNSW GTRC,
- Materials that require an import permit but do not require an Approved Arrangement under the Biosecurity Legislation (e.g. cell lines),
- Any aquatic or terrestrial vertebrate, invertebrate, plants (include aquatic or terrestrial mammals, birds, fish, reptiles, insects, plants, snails and such) if brought onto campus, or the in-situ studies include handling,
- Any animal or plant material collected in the field such that the background level of microbial flora can be considered ubiquitous and where the scope of the study does not aim at identifying microorganisms derived from the samples and samples are not processed to culture cells or tissues,
- Any commercially research-bred and acquired, non-GMO and does not require an import permit, research animal e.g. mice, rats, rabbits, sheep, where the research involves the inclusion of non-GMO Risk Group 1 or Exempt dealings,
- A risk assessment shall be conducted on all microorganisms to determine the risk group, if the work needs to be conducted with additional precautions or in a higher level of physical containment. The risk assessment should include a review of recent literature to support the risk grouping and the level of physical containment. The UNSW Biosafety Coordinator and the local IBC can be consulted for further guidance.

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- x Materials described under the Gene Technology Legislation as Risk Group 2 and 3 and Notifiable Low Risk Dealings (NLRD2).
- x These materials and processes are assessed by the GTRC.

Very High Risk biological agents and processes – managed Materials described under the Gene Technology Legislation as

regarding the continuation of any member. The Dean/Divisional Head nominates a Deputy Chair from the IBC membership. The Deputy Chair will act in the Chair's absence or where the Chair has a conflict of interest. All members are appropriately indemnified by the University to fulfil their role on the IBC.

A Secretary will be appointed to support the IBC and their role includes assessing applications for completeness prior to acceptance on the agenda and notifying applicants of the outcomes of the review. The Secretary will be the first point of contact for investigators that need to contact the Committee.

The Faculty/Division IBC is composed of the following membership:

1. The Chair and Deputy Chair must be a voting member, appointed by the Dean, employed by the University, and a staff member within the organisation who possesses the skills to manage the

4. If a sufficient number of members with relevant qualifications and experience are not available, the final recommendation for a proposal is postponed until the views of additional members have been sought, or until the next meeting of the Faculty/Division IBC.

Members are selected onto the Faculty/Division IBC to their relevant expertise and as such, must be present at meetings of the Faculty/Division IBC where their expertise is required in respect of assessments of particular proposed dealings. If members cannot attend meetings where their expertise is required, they will notify the IBC Secretary as soon as possible. Although membership to the Faculty/Division IBC is voluntary, members are deemed to have vacated office if they are absent without leave for three consecutive meetings and have not notified the IBC Secretary.