Biorisk Management Procedure

Version	Approved by	Approval date	Effective date	Next full review
1.0	Director, UNSW Risk & Safety Management	28 June 2022	28 June 2022	June 2025

Procedure Statement		
Purpose	This Procedure describes the actions and processes required for adherence to the *Biosafety Policy* and its relevant legislative and regulatory requirements.	
Scope	This Procedure applies to all workers at UNSW and affiliated centres and institutes in Australia and overseas who may handle or are potentially exposed to biological materials that have associated hazards. This Procedure is a structured approach to protect and to prevent exposure to any biohazardous material.	
Are Local Documents on this subject permitted?	☐ Yes, however Local Documents must be consistent with this University-wide Document	☐ No
Procedure Processes and Actions		

Contents

1. Biorisk Management 1
   1.1. Identify hazards 2
   1.2. Assess the risks 3
   1.2.1 Risk Assessment Team 3
   1.3. Control the risks 3
   1.4. Review control measures 4
2. Faculty/Division IBC 4
3. Biosecurity (Approved Arrangements (AA) and Genetically Modified Organisms (GMOs)) 4
4. Responsibilities 4

Appendix A – Definition of Biological Risk 9

Appendix B. Faculty/Division IBC Terms of Reference 10

1. Biorisk Management

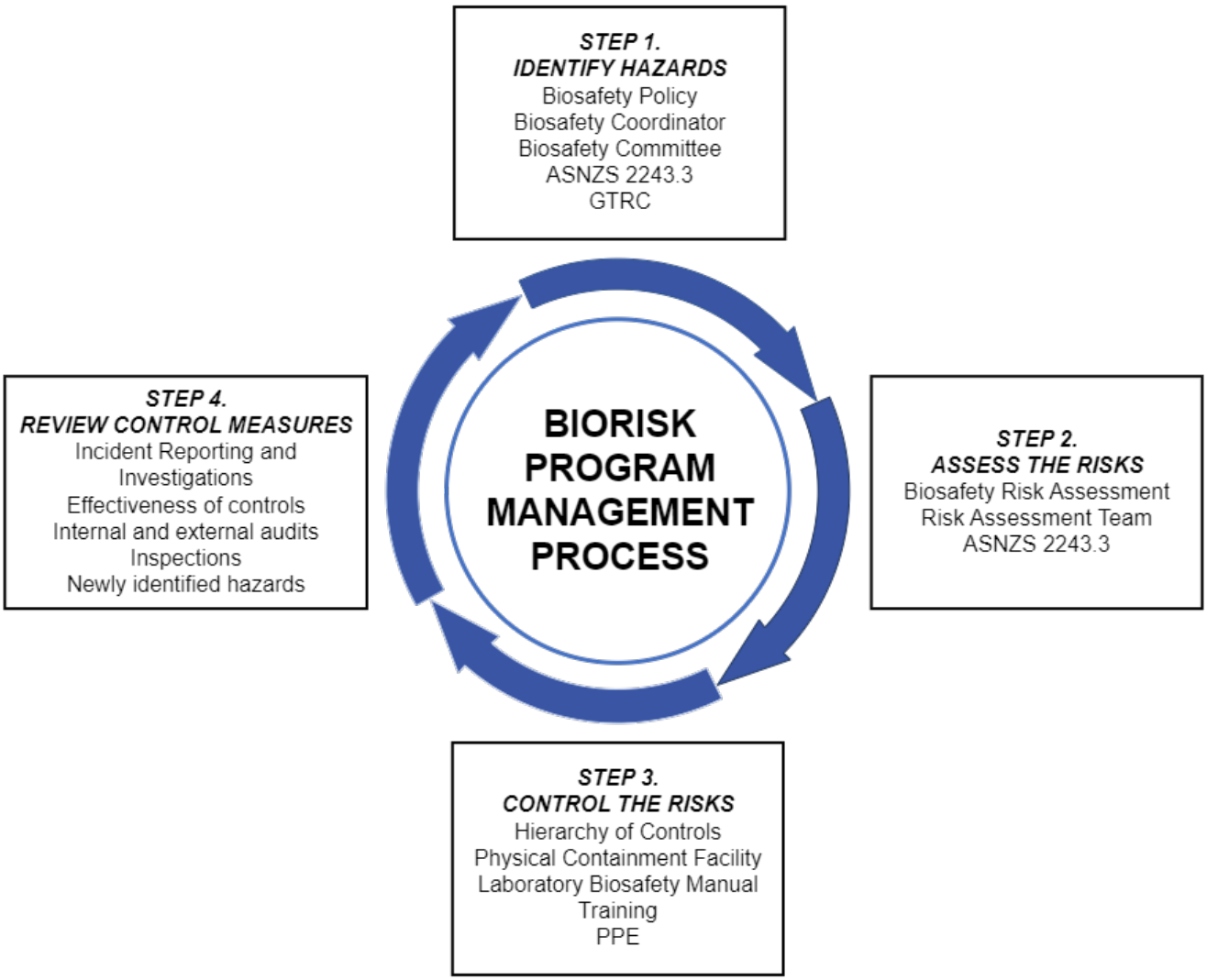
Biorisk management means implementing coordinated activities to apply good practice controls and to manage the containment of all biological materials that present a potential biorisk, while also complying with the requirements of all relevant legislation, Australian Standards and regulatory requirements. 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, identify the hazards associated with any biological material and the proposed work. Identify the relevant governing legislation.
2. *Assess risks*: evaluate the risks, decide who may be harmed by assessing the risks associated with the hazards of the material and the proposed work.

3. *Control risks*: develop a risk control strategy, select and implement risk control measures. Identify all the relevant controls, record all findings and implement all the identified relevant controls using the hierarchy of controls.
4. *Review control measures*: regularly review the risk management documentation, the effectiveness of implemented control measures as well as incidents and newly identified hazards.

The four steps of the process should be carried out for all biological work. The Figure below gives an example of the four steps that are required for an effective biorisk management process.



Risk assessment is the fundamental process that supports a broader biorisk management program. Effective biorisk management integrates and cooperates with UNSW's existing safety and quality management and leadership structures to promote evidence-based, continuous improvement, and an organisation-wide biosafety culture. As such, risk assessment is an important responsibility of all members of the laboratory, and of stakeholders outside the laboratory.

1.1. Identify hazards

The aim of the first step is to gather information, identifying the hazards that may cause risk of harm to people and the environment. In this step, required approval and relevant legislation must be identified. The UNSW *Biosafety Policy*, and the *Risk Management Procedure HS329* and any other UNSW documents relating to work with biological materials should be consulted during the planning stage. Once identified, the relevant legislation will determine any additional controls that may be required to be implemented, including requirements for an Import Permit (IP). When a hazard associated with a biological material has been identified it must be recorded on the Laboratory/Facility Microorganism/Biological/ Biohazard Register and the HS Hazard Register.

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 permissions and approvals have been granted.

Further guidance is provided on the Safety website.

1.2.1 Risk Assessment Team

A risk assessment team may be formed to undertake a risk assessment of biological work. All persons involved in the project should take part in the risk assessment process. The roles and responsibilities of all team members must be clearly defined before starting the assessment, although additional people may be consulted as needed. The members of the risk assessment team should have demonstrated skill in working with the biological agents being handled or similar biological agents and understand all the hazards associated with the protocols, processes and procedures to be carried out in the laboratory and within the scope of the work being assessed. The team members must be familiar with the layout and condition of the laboratory facility as well as the equipment to be used in the procedure. The team members must have completed all relevant training and have demonstrated an understanding of the *Risk Management Procedure HS329*. The risk assessment team should know the competency and experience of laboratory personnel who will be doing the laboratory work. Personnel on the risk assessment team may include, but are not limited to, principal investigators, laboratory and quality managers, students and biosafety experts. Careful selection of team members to contribute to the laboratory risk assessment process can directly support the establishment and maintenance of an improved biosafety risk culture by facilitating leadership and organisational involvement, ownership and understanding of biosafety responsibilities. In situations where the number of personnel is limited, it may not be possible to gather a team of people qualified to carry out the risk assessment, but as a minimum it should involve any person that will be involved or undertake the activity and their supervisor.

It is important to note that the involvement of the laboratory and/or organisational leadership in the risk assessment process, whether by direct participation in the risk assessment team or by communication with the team, is essential to establish organisational support for and sustainability of a biosafety management program. Supervisors will review and approve the risk assessment and ensure all control measures are in place prior to work commencing.

1.3. Control the risks

A strategy to control the identified risks must be developed: risk control measures must be selected and implemented. Risk control measures must be selected based on the hierarchy of controls outlined in UNSW *Risk Management Procedure* HS329 (refer to section 3.4.3) and must include the recommended mitigations identified in the risk assessment process. Every effort should be made to reduce the risk by either elimination of certain hazardous materials, substitution with lower risk group biohazards, and/or reducing the volume of the biohazards.

When working with biological agents in a laboratory, animal house or any other facility, a physical containment facility is required, as identified in the risk assessment step. While the containment level is based on the risk group of the biological agent if it is a microorganism, it also provides a basis for the safe handling and containment of other hazardous biological materials, as well as other controls that may need to be implemented. Access to physical containment facilities must be restricted to authorised people. The level of physical containment that is identified will dictate the facility's structural requirements, containment equipment, PPE requirements and administrative controls that are necessary to work safely with the designated risk group. All physical containment facilities must be registered with the Safety Unit. There may be specific controls identified in legislation that need to be implemented and the risk assessment may identify additional control equipment or processes that might also be needed. If it is unclear which level of physical containment is required, contact the UNSW Biosafety Coordinator for assistance.

As required in ASNZS 2243.3, UNSW will maintain a register of all biological materials. All biological materials at UNSW must be registered on the UNSW Biological Material Register. On delivery, purchased biological goods need to be checked to ensure that the correct order has been received before being entered on the UNSW Biological Material Register and being made available for use.

1.4. Review control measures

Risk assessment and implemented control measures must be regularly reviewed and in particular if new hazards are identified, if there have been changes to the relevant legislation or if there have been changes in the workplace that may impact the controls as outlined in UNSW *Risk Management Procedure* HS329 (refer to section 3.4.4). To undertake a review, start at step 1 (identify hazards) again and continue through the rest of the biorisk management process. Any updates and changes identified during the review must be effectively communicated to all users.

2. Faculty/Division Institutional Biosafety Committee (IBC)

Each Faculty/Division where biological work and processes are being conducted and deemed of "significant" risk category (Appendix A), will establish a local Institutional Biosafety Committee (IBC) in accordance with the Terms of Reference in Appendix B. The local IBC will report to the relevant Dean/Divisional Head and the local L2 Safety Committee. The objective of the Faculty/Division IBC is to protect and to prevent exposure to significant risk category biohazardous materials by verifying that:

1. the range of identified risks posed by, or as result of work with biohazardous materials is appropriate
2. the controls are commensurate to the risks.

In doing so, the Faculty/Division IBC will assure UNSW and UNSW Council of the biosafety competence of those undertaking these tasks.

3. Biosecurity (Approved Arrangements (AA) and Genetically Modified Organisms (GMOs))

Approved Arrangements (AA) are managed by RECS. Genetically Modified Organisms (GMOs) applications are managed and assessed by the GTRC.

4. Responsibilities

University Senior Leadership Team (SLT) is responsible for:

- Providing and maintaining the resources, systems and procedures necessary to enable effective oversight of biological and biohazardous work. This includes resourcing and convening Faculty/Division IBCs.
- Employing a UNSW Biosafety Coordinator as defined under Section 1.5.10 of AS2243.3 and ISO 35001.
- Providing access to training and continuing education to members of the IBC on relevant legislation and developing topics relating to biosafety, biosecurity and gene technology.
- Ensuring that facilities provided to staff and students conducting biological work are compliant with the relevant legislative requirements and relevant Australian Standards.

The Head of School is responsible for:

- Ensuring research or teaching using biological agents that fall under the "significant risk" definition is reviewed and assessed by the Faculty/Division IBC prior to commencing.

- 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 trained and that training records are kept.

The Supervisor/Principal Investigator (PI)/Chief Investigator (CI) is responsible for:

- Establishing and implementing systems to meet the objectives in this Procedure. This responsibility extends to all aspects of biological research involving all individuals who enter or work in the PI's/CI's containment facility or collaborate in carrying out the PI's/CI's research or teaching.
- Implementing and maintaining a register of all biological hazards within their control.
- Having comprehensive, appropriate and approved, risk assessments and safe work procedures that enable work to be undertaken safely.
- Registering all physical containment facilities with the Safety Unit.
- Assessing the risk of exposure of workers and students to biological hazards and ensuring that the identified controls are implemented and maintained.
- Obtaining and recording all legislative approvals, licenses and certificates that are required.
- Ensuring that departing workers make their workspace safe and reassign responsibility for the control of any remaining biological, chemical and plant hazards to others before they leave.
- Ensure provision of adequate training is available and that anyone involved in the proposed work is adequately trained and qualified to undertake the activities related to any work they intend to conduct.

UNSW Biosafety Coordinator

The UNSW Biosafety Coordinator is a specialist, competent adviser to UNSW, Senior Management and Heads of School/Institute on matters relating to safe handling of biological materials. Duties will include:

- Provide advice on local rules and procedures, risk assessment, appropriate facilities for the work, appropriate control measures and approval/notification procedures.
- Provide advice on design and biosafety oversight during facility refurbishments and the design and construction of new facilities.
- Assist supervisors in identifying training needs within the University, School or Institute, in particular to ensure the competence of workers to carry out the work safely.
- Be the main point of contact for advice on biosafety.
- Investigate the circumstances of any accidents or untoward incidents involving biological agents, in liaison with the Safety Team and ensure that appropriate action is taken.
- Maintain current biosafety training materials.

Facility/Laboratory Managers

- Provide induction to users of their facility and ensure training materials are reviewed and updated regularly.
- Identify competent people who can train others in the use of equipment and research techniques.
- Manage and maintain their facility/facilities to ensure regulated containment requirements appropriate for the dealings conducted within the facility are implemented.
- Ensure any issues including breaches of containment, non-compliances, or condition which renders their facility unsuitable for use are reported to the IBC and UNSW Biosafety Coordinator immediately.
- Follow direction and guidance issued by the UNSW Biosafety Coordinator to implement any corrective actions or rectify non-conformances issued by regulatory authorities in a timely manner.
- Maintain a working knowledge of regulations, policies and guidelines relating to activities occurring in their facility with assistance from the UNSW Biosafety Coordinator.
- Facilitate effective communication between academics responsible for research activities and staff and students conducting dealings within their facility.
- Review risk assessments completed by staff and students conducting dealings within their facility to ensure hazards are controlled.

Staff and Students

- Obtain approval from the IBC prior to conducting any "significant risk" biological work or processes, as well as obtain approval from Department of Agriculture, Water and Environment, or any other relevant regulatory body as required.

- Complete a risk assessment meeting the guidelines of Section 2.1.2 of AS2243.3 prior to conducting any dealings.
- Seek guidance from the IBC, UNSW Biosafety Coordinator, Supervisor/Principal Investigator/Chief Investigator, Laboratory Manager on any matters relating to biosafety, biosecurity or gene technology where necessary.
- Complete all training that has been identified as required for their role and the work to be undertaken.
- Comply with any related University policy, including the *Legislative Compliance Policy*, procedure or guideline, and any direction or condition of any certification, licence, agreement or permit issued to them.
- Follow any direction or condition issued by the IBC, UNSW Biosafety Coordinator, Supervisor/Principal Investigator/Chief Investigator, Laboratory Manager.

Accountabilities	
Responsible Officer	Director, UNSW Risk and Safety Management
Contact Officer	Senior Manager, Safety and Injury Management
Supporting Information	
Legislative Compliance	*Biosecurity Act 2015* (Cth) *Gene Technology Act 2000* (Cth) *National Health Security Act 2007* (Cth)
Parent Document (Policy)	Biosafety Policy
Supporting Documents	UNSW Biosafety website: Biological | Safety (unsw.edu.au) Central Biosafety Training Biohazardous Material Register Biosecurity Management Regulated Biological Materials Research Procedure Risk determination of human biological material - Guideline (HS651) Classification of microorganisms by risk group (HS076) Animal Research HS risk identification guideline (HS066) HSMS Review Procedure (HS319) Health Monitoring Guideline (HS091) Hazard and Risk Register (Workplace) (in SafeSys) Laboratory Hazardous Waste Disposal Guideline (HS321) Biosafety Legislation (HS430) Risk Management Procedure (HS329) UNSW RECS
Related Documents	Legislative Compliance Policy
Superseded Documents	HS323 Biosafety Procedure, v2.7
File Number	2022/035513
Definitions and Acronyms	
Approved Arrangement	A biosecurity containment facility for which an approval is in force under paragraph 406(1)(a) of the *Biosecurity Act 2015* (Cth)
Biological/Biohazardous material	A biological hazard is a potential source of harm caused by biological risk group agents or toxins. Biohazards, which may provoke infection, allergy or toxicity in humans, animals or plants are classified in ASNZS 2243.3:
Biosafety	The application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated.

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 the environment. DIRs require licencing and direct scrutiny from the OGTR
DNIR	Dealing Not Involving Intentional Release. A dealing with a GMO which is conducted in an OGTR-certified containment facility, is of higher risk than an NLRD and requires licencing and direct scrutiny from the OGTR.
Gene Technology	Any technique for the modification of genes or other genetic material, but *does not* include: a. sexual reproduction; b. homologous recombination; c. mutations that occur naturally or through damage by radiation or chemicals; or d. any other technique specified in the regulations for the purposes of this paragraph
Genetically Modified Organism (GMO)	A Genetically Modified Organism is an organism which has;- a. been modified by gene technology; b. a mutation that involved the introduction of foreign nucleic acids; c inherited particular traits from an organism (the *initial organism*), being traits that occurred in the initial organism because of gene technology; or d. anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms; but *does not* include: e. a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or f. an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.
GTRC	Gene Technology Research Committee The GTRC is the University's primary body responsible for ensuring all practices involving gene technology, biosecurity-regulated materials and biologically-hazardous materials of Risk Group 3 and above are conducted in accordance with the governing legislation including the Gene Technology Act 2000, Gene Technology Regulations 2001 and ASNZS 2243.3.
Import Permit	A permit issued by the Department of Agriculture (BICON) for the import of conditionally prohibited materials to Australia.

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.
NLRD	Notifiable Low Risk Dealing. A dealing with a GMO which does not require direct scrutiny from the OGTR but must be assessed by an Institutional Biosafety Committee (or equiv). All NLRDs must be conducted in a certified containment facility.
OGTR	Office of the Gene Technology Regulator (DoH)
Physical Containment (PC) Facility	A physical containment facility (PC facility) is a facility that involves the combination of building, engineering, equipment and practises to handle microorganisms safely and to protect users and the environment as described in AS/NZ 2243.3
PC1-4	Physical Containment level 1 to level 4 (lowest containment level through to highest) • As described in AS/NZS 2243.3, for handling material that may contain microorganisms of the corresponding Risk Group level. • As described by the OGTR to explain the categories of organisms and types of dealings intended to be contained in each facility type. These levels are intended to harmonise as closely as possible with the Risk Group levels
PPE	Personal Protective Equipment
Risk Group	Risk Groups are classifications for microorganisms that are infectious for humans, animals and plants, based on pathogenicity, host range, mode of transmission, plus availability of effective preventative measures and effective treatment. Risk groups are designated from 1 (the lowest risk) to 4 (the highest risk).
SSBA	Security Sensitive Biological Agents as defined by the DoH the SSBA Regulatory Scheme builds on Australia's obligations under the Biological and Toxins Weapons Convention and UN Security Council Resolution 1540.

Revision History

Version	Approved by	Approval date	Effective date	Sections modified
1.0	Director, UNSW Risk & Safety Management	28 June 2022	28 June 2022	New procedure

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.

Significant Risk biological agents and processes – managed by IBC

- Materials described as Risk Group 2 in AS/NZS2243.3 lists of risk group agents, and
- Materials that require a PC2 facility,
- Imported and/or transferred biological materials that require a Biocontainment (BC) 1 or 2 Approved Arrangement under the Biosecurity Legislation *(Reagents and research kits are included where indicated in accompanying information),
- Any aquatic or terrestrial vertebrate, invertebrate, plants (include aquatic or terrestrial mammals, birds, fish, reptiles, insects, plants, snails and such) brought onto campus and the research involves an invasive procedure, including euthanasia,
- 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 invasive procedures such as research involving non-GMO Risk Group 2 and or surgical procedures.

High Risk biological agents and processes – managed by GTRC

- Materials described as Risk Group 3 in AS/NZS2243.3 lists of risk group agents, and
- Materials that require a PC3 facility.

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

Very High Risk biological agents and processes – managed by GTRC

- Materials described under the Gene Technology Legislation as Dealings Not Intending release (DNIR), and Dealings Intending Release (DIR). These materials and processes are reviewed by the GTRC and assessed and approved by the OGTR.
- Materials that are identified as Security Sensitive Biological Agents (SSBA) on the Department of Health List of SSBAs. Applicants must consult the UNSW Biosafety Coordinator and RECS before proceeding.

Appendix B. Faculty/Division IBC Terms of Reference

The Faculty/Division IBC will:

1. Review and assess research, teaching or other activity submissions associated with biological work and processes of 'significant' risk (Appendix A) prior to the work being undertaken. This includes:
   1.1. consideration of the actual and potential risks to the health and safety of people and the environment
   1.2. assessing that the people undertaking the work have the appropriate experience, skills, training and competence
   1.3. ensuring the appropriate level of containment of laboratory facilities (where relevant)
   1.4. assurance that all certifications and registrations have been identified and will be in place before work begins.
2. Verify that a comprehensive range of biosafety risks have been identified relevant to the proposed activities and that the suite of controls provide adequate assurance to ensure the elimination or mitigation of the stated risks in accordance with the relevant legislation.
3. Confirm that adequate resources including human, training, equipment, and facilities are available for the given project schedule. If these are deemed not to be adequate or available, provide recommendations and conditions that must be satisfied prior the work commencing.
4. Where the project is being undertaken in a shared working environment, confirm that adequate controls have been identified.
5. Maintain a register of all import permits of the Faculty/Division.
6. Review submissions where the risk category is not clear, or as requested by the Faculty/Division.
7. Undertake inspections as indicated by the annual schedule.
8. Identify trends and common performance issues arising from the review of submissions.
9. Participate in investigations as required.
10. Not review the "high risk" and "very high risk" categories as defined in Appendix A.
11. Deal with alleged non-compliance and grievances via Committee decisions, including referral to the UNSW Conduct & Integrity Office (research.integrity@unsw.edu.au) for allegations involving possible breaches of the Australian Code for the Responsible Conduct of Research for review in accordance with the UNSW Research Code of Conduct.
12. Participate in the process of certification or registration by external agencies and inspection of containment facilities by the University and external agencies.

Membership of the committee

The Faculty/Division IBC comprises a minimum of six people and has the collective expertise to competently assess and provide advice on the work undertaken by the University and its affiliated organisations. Roles and responsibilities may be combined in the same person where appropriate.

Committee members, including the Chair, are appointed by the Dean/Divisional Head for a period of three years, with the possibility for renewal for another three years. Members will be advised in writing of their appointment to the Committee and its conditions. Any individual's membership of the Committee may be withdrawn by the Faculty/Division at any time during the proposed period of appointment. Such a decision will be advised in writing by the Dean or Divisional Head. Membership may also be withdrawn in the instances where members are unable to attend two consecutive meetings and do not provide justification to the Committee for their non-attendance. The Committee may make recommendations to the Dean/Divisional Head

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 business of the Committee, including the ability to resolve conflicts. The Deputy Chair shall be appointed by the Dean to receive delegation of all Chair duties in the absence of the Chair.
2. At least two persons who have relevant scientific expertise and experience for the scope of the IBC. This may include microbiologist, virologist, gene technologist, marine ecologist, plant ecologist, animal researcher as appropriate. Members must be appointed to equip the IBC with technical and scientific expertise to assess the risks and hazards associated with proposed biological work and processes.
3. A biosafety expert who is a biosafety or safety professional and is an expert in biosafety practices and legislative and regulatory compliance.
4. A biocontainment facilities expert who is an engineer (or equivalent) with expertise in testing biological safety facilities and equipment.
5. The IBC may also consist of non-voting members whose skills are considered to enhance the capacity of the IBC to undertake its work. From time to time, it is necessary for the IBC to rely on the advice of an expert (i.e., not a voting member of the IBC) to address a specific, short-term skills deficit in the IBC. These non-voting members are co-opted at the discretion of the Committee.

Quorum for meetings

1. The decisions by the Faculty/Division IBC are made by consensus as recommendations to the Dean/Divisional Head, where quorum consists of at least 50% of members present. Out of session decisions are ratified at the next quorate meeting.
2. If the quorum does not contain the collective technical and scientific expertise to assess the projects, the Committee may invite additional non-voting experts to report to the Committee.
3. Attendance of quorate meetings may be facilitated by video-linking, teleconferencing or other remote linking technology of some members in circumstances where face-to-face attendance is not possible. Such remote members may authorise the Chair to record their support of any proposals or other decision outcomes.

Executive committee

1. The Committee may establish an Executive Committee at any time from the available members which must include the Chair and at least one other voting member.
2. The Executive Committee may consider 'out of session' business, such as approve amendments to projects which have been granted conditional approval by the Committee and initiate urgent action required in response to reports of incidents, adverse events or emergencies.

Conflict of interest

The following arrangements are in place to deal with conflicts or potential conflicts of:

1. Members declare to the Presiding Member or Deputy, at the earliest opportunity, any potential conflict of interest in any matter that is presented to the Faculty/Division IBC for assessment.
2. All declarations of conflict of interest are recorded in the minutes of the meeting at which the declaration is made.
3. The member who has declared a conflict of interest is excluded from the deliberations and assessment of the matter by the Faculty/Division IBC.

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.

Meetings will be held at dates and times to be determined by the Committee with the aim to meet at least four times per year to facilitate regular consideration of Committee matters. The submission dates for items that need to be reviewed by the committee will be set at regular intervals at the end of each calendar year for the ensuing 12 months. If circumstances or the nature of business is urgent or extraordinary, the Chair may call additional meetings provided that at least 7 days' notice is given to Committee members.

Revision of Terms of Reference

The Faculty/Division IBC Terms of Reference will be reviewed every two years or as necessary in response to changes in legislation, University policy or concerns expressed by members of the Committee. Changes and amendments to these model Terms of Reference will require the endorsement of the IBC and approval of the Director, Risk and Safety.