Biosafety and Biosecurity Procedure

Section 1 - Preamble

(1) This Procedure is effective from 25 July 2024.

Section 2 - Purpose

(2) This Procedure sets out how the University ensures the safe use of regulated biological materials (RBMs) for research or teaching activities, in accordance with legislative requirements.

Section 3 - Scope

(3) This Procedure applies to Deakin staff, students and associates who use RBMs for research and teaching activities, regardless of where the work is carried out, and to non-Deakin personnel who are either listed on a Deakin Biological Work Safety Assessment, Laboratory Biosafety Committee (LBC) Application or have a legitimate need to access Deakin-controlled biological containment facilities.

Section 4 - Policy

(4) This Procedure is pursuant to the Research Conduct Policy.

Section 5 - Procedure

(5) The University is committed to meeting its responsibilities under the relevant legislation with respect to the safe handling, containment, and security of RBMs by:

a. oversight of activities by a properly constituted institutional biosafety committee (IBC)
b. assessing applications for proposed work with RBMs to ensure risks posed to the health and safety of people and the environment have been identified and managed to an acceptable level before work commences
c. communicating compliance expectations and requirements to staff, students and non-Deakin personnel through the provision of education, training and advice
d. ensuring that only personnel who are appropriately trained and, where required, deemed to be 'Fit and Proper' are approved to be authorised persons, able to handle RBMs or access biological containment facilities unsupervised
e. monitoring compliance with standards, guidelines, internal and external approvals, including the inspection of certified biological containment facilities
f. reviewing outcomes of incidents and/or audit findings to ensure appropriate corrective action has been taken in accordance with the Risk Management Policy and reporting occurs internally in accordance with the Compliance Management Policy as well as to external regulators as required
g. submitting an annual report to the Office of the Gene Technology Regulator to outline the University's

management of dealings involving Genetically Modified Organisms (GMOs)

h. maintaining appropriate records including IBC deliberations, a register of RBMs, approved procedures, projects, facilities and authorised personnel.

Laboratory Biosafety Committee

(6) Deakin will maintain a Biosafety Committee called the Laboratory Biosafety Committee (LBC) responsible for ensuring, on behalf of the University, that all activities relating to the use of RBMs are conducted in accordance with relevant legislation and Australian Standards.

(7) The LBC will conduct business in accordance with the LBC terms of reference.

Specialist, Biosafety and Biosecurity

(8) The Specialist, Biosafety and Biosecurity is authorised to report on biosafety and biosecurity matters and ensures that notifiable events and dealings are reported to regulators within legislated timeframes.

(9) The Specialist, Biosafety and Biosecurity fulfils the requirements of a Biological Safety Officer as defined in AS/NZS2243.3:2022 and is responsible for Approved Arrangements under the Biosecurity Act 2015 (Cth).

(10) The Specialist, Biosafety and Biosecurity is authorised to intervene (and if necessary, suspend work) on matters or activities that have the potential to adversely affect the health and safety of people or the environment and to ensure that work with RBMs proceeds in compliance with applicable legislation and LBC decisions.

Related roles and responsibilities

(11) The Deputy Vice-Chancellor Research and Innovation will submit an annual report to the Office of the Gene Technology Regulator to demonstrate that Deakin is meeting its obligations and responsibilities under Gene technology legislation and the Guidelines for Accreditation of Organisations.

(12) Heads of Academic Units (or equivalent) are responsible for ensuring that biosafety and biosecurity requirements regulated by the LBC are implemented within their Academic Units and to monitor implementation of this Procedure.

(13) Each Academic Unit that conducts work with RBMs should appoint a local area Biosafety Officer who is authorised to advise and report on biosafety and biosecurity matters. This person may be the Laboratory Manager or equivalent.

(14) The Laboratory Manager (or equivalent role with overall responsibility for operation of the biological containment laboratory or facility), in conjunction with the local area Biosafety Officer is the co-ordinator of acquisition, registration, usage and disposal of RBMs and ensures records are kept in relation to these activities.

(15) The Laboratory Manager is responsible for:

a. ensuring safe procedures are documented, and reviewed regularly
b. implementing initial and continuing training programs specific to the facility
c. controlling ongoing access and use of the facility in accordance with the Property Management Policy
d. ensuring unauthorised personnel are supervised and facility-related maintenance and cleaning is carried out in accordance with safe procedures.

Researcher Responsibility

(16) Staff and students who use RBMs for research or teaching, are responsible for being aware of and complying with relevant legislation, regulations, codes of practice, Australian Standards, LBC approved biosafety and biosecurity guidelines or procedural documents to achieve the highest standards of practice.

(17) Researchers are responsible for obtaining all relevant internal or external approvals (including permits or licences) prior to commencement of work with RBMs (including GMO dealings), and ensure they meet the conditions of any approvals.

(18) Researchers who are not directly involved in conducting research using RBMs but intend to be authors on a publication that requires LBC approval, must be satisfied that approval has been obtained and the research was conducted according to the applicable legislation and Deakin-specific requirements.

Biosafety and Biosecurity Education and Training

(19) All staff, students and non-Deakin personnel listed on a Deakin LBC application, Biological Work Safety Assessment or who have a need to access a biological containment facility unsupervised, must first be approved as an Authorised Person by undertaking education and training, and competency assessment, in accordance with Deakin's Biosafety Training requirements (See Deakin Biosafety and Biosecurity induction and training).

Biosecurity Fit and Proper Person Test

(20) Personnel conducting Biosecurity Activities including the use of biosecurity-controlled materials or considered to be a 'relevant associate' of a biosecurity containment facility must complete a 'Biosecurity Fit and Proper Person Test' before being determined to be an Authorised Person approved to conduct Biosecurity Activities.

Biological Work Safety Assessments

(21) Personnel who intend to use RBMs for research or teaching purposes must complete a Work Safety Assessment: Biological Hazards form to identify and manage potential risks posed to the health and safety of people and the environment as well as the identification of any relevant approvals required prior to performing the proposed work (See Research and work safety assessments page)

(22) The Work Safety Assessment: Biological Hazards form must be reviewed and approved by the local Biosafety Officer and Area Manager (this can be the same person).

(23) All work involving RBMs or material likely to contain these (including Risk Group 2 Biological Agents) must be submitted for review and further approval by the Specialist, Biosafety and Biosecurity.

(24) Advice from the LBC must be sought prior to the acquisition or handling (receipt, use or storage) of security sensitive, high risk biological agents or RBMs reasonably likely to contain these.

(25) Work with RBMs must not commence prior to the receipt of written approval.

Importation of Biological Material

(26) Personnel who intend to bring or transport biological materials into Australia, must seek advice from the Specialist, Biosafety and Biosecurity regarding the import conditions and whether a Biosecurity Import Permit is required, prior to importing the goods into Australia.

GMO project applications

(27) Staff and students must obtain approval from the LBC or an alternative appropriately constituted IBC before undertaking a dealing involving GMOs or the use of gene technology, by submitting the relevant application form (see Biosafety and biosecurity forms, guidelines and legislation).

(28) Staff and students must first determine the type or class of dealing as Exempt, Notifiable Low Risk or Licenced Dealings (which include Dealings Not involving Intentional Release – DNIR or Dealings involving Intentional Release – DIR).

a. Exempt Dealings pose a very low risk but cannot involve the release of a GMO into the environment. Exempt Dealings are described in Schedule 2 of the Gene Technology Regulations 2001
b. Notifiable Low Risk Dealings (NLRDs) must only be conducted within the types of certified containment facilities specified in an approved application and according to the relevant Guidelines for the certification of physical containment facilities. NLRDs are described in Schedule 3 of the Gene Technology Regulations 2001
c. Licenced Dealings are initially assessed by the LBC, and then undergo further review and approval by the Office of the Gene Technology Regulator. Work can only be conducted once a project-specific licence outlining the conditions of approval has been issued and acknowledged by all investigators listed in the licence.

(29) The LBC will confirm the classification of the 'Dealing' and determine if the risks associated with the project have been identified and managed. Work must not commence on a project prior to receiving written approval by Deakin's LBC.

(30) All Deakin project applications to work with GMOs must identify a Principal Investigator who is a paid member of staff at the University and has the ultimate responsibility for the safe and compliant use of the RBMs described in the project and for monitoring procedures.

(31) The role of a Principal Investigator does not relieve the individual responsibility of each listed investigator who works with RBMs approved in the project application.

External projects using RBMs at another institution within Australia

(32) Staff and students who are listed on a project approved by an LBC at another institution within Australia, must submit a Notification of involvement in external project involving dealings with GMOs form and provide a copy of the IBC application approved by the other institution for noting by the LBC.

Amendments to an approved LBC project

(33) Requests for amendments to an approved LBC project must be submitted via ResearchPoint and approved prior to being implemented.

GMO Project Reporting

(34) Principal Investigators must submit a Progress Report using the relevant form on request by the Deakin LBC. The LBC will review the report and decide whether the project may be continued, suspended, modified or discontinued.

(35) Principal Investigators must submit a Final Report using the relevant form to the Deakin LBC:

a. within two months of completing the project or
b. at the end of the approval period or
c. prior to the departure of the Principal Investigator from Deakin.

Biological Materials Reporting

(36) Investigators must maintain records of RBMs used according to the Research Data Management Procedure and report any inventory changes to the local area Laboratory Manager (or equivalent).

(37) The Laboratory Manager (or equivalent) maintains an inventory of RBMs for their area of responsibility and provides and reports to Deakin Biosafety annually or on request.

(38) Research Ethics and Integrity maintains a central register of RBMs in use by University staff and students to manage compliance and provide relevant advice.

External projects using RBMs at another institution in a country other than Australia

(39) Projects conducted in countries other than Australia must comply with applicable international standards, guidelines as well as any country specific legislation.

(40) Staff and students should discuss a proposal to use RBMs in another country with the Specialist, Biosafety and Biosecurity, to assist with compliance with international standards, guidelines and codes of practice.

External Institutions that use Deakin's Laboratory and Biosafety Committee

(41) External institutions may request to use Deakin's Laboratory and Biosafety Committee for the review of their projects that use GMOs. Requests from an external institution to use Deakin's LBC will only be considered if:

a. approved by the Deputy Vice-Chancellor Research and Innovation or nominee
b. the external institution is an accredited organisation that holds or intends to obtain a certification for the Biological Containment Facility where they intend to conduct GMO Dealings.

(42) Where approval is granted to use Deakin's LBC, a formal agreement between the external institution and Deakin must be developed in consultation with Deakin's LBC and include (but not limited to) terms addressing matters described in the Guidelines for Accreditation of Organisations.

Reporting of non-compliances concerning the use of RBMs

(43) Incidents concerning the non-compliant use of RBMs will be managed in accordance with the process for allegations of non-compliance to LBC Approvals or Biosafety and Biosecurity Regulatory requirements (See Research Code Breach and Serious Research Code Breach website).

Section 6 - Definitions

(44) For the purpose of this Procedure:

a. Academic Unit: a School, Department, the National Indigenous Knowledges Education Research Innovation Institute or an Institute that reports directly to the Deputy Vice-Chancellor Research and Innovation.
b. Accredited organisation: An organisation accredited by the Gene Technology Regulator under Section 92 of the Gene Technology Act 2000.
c. Approved Arrangement: is an arrangement for which an approval is in force that provides for the University to carry out specified activities (biosecurity activities) to manage biosecurity risks associated with specified goods, premises or other things.
d. Associates: include contractors, consultants, volunteers, visiting appointees and visitors to the University. Note that a 'relevant associate' in the context of Biosecurity legislation refers to personnel identified by the University to be in a position to control or influence the compliant conduct of biosecurity activities.
e. Authorised Person: A person who has successfully completed training approved by the LBC and where relevant, a Fit and Proper Person Test, that deems them able to be approved to conduct work with RBMs and/or access Deakin Biological Containment Facilities unsupervised.
f. Biological Safety Officer: as defined by the Australian/New Zealand Standard 2243.3 (current version) Safety in laboratories, Part 3: Microbiological safety and containment shall be appointed and contactable to provide advice and guidance on microbiological safety.
g. Biological Containment Facilities (includes Laboratories): places designed, built and operated for the purpose of containing hazardous biological materials to prevent unintentional exposure, or their accidental release. In addition to meeting Australian Standards requirements, specialised facilities require additional certifications

including OGTR-Certified Physical Containment Facilities and Biosecurity Containment Facilities approved by the Department of Agriculture, Fisheries and Forestry (also referred to as Approved Arrangement Sites).

h. Biosecurity Activities: activities to manage biosecurity risks associated with specified goods (under 'biosecurity control'), premises or other things as determined by the Department of Agriculture, Fisheries and Forestry.
i. Conditions: risk management obligations essential to meeting the requirements of an approval.
j. Dealing: In relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of (a) to (i).
k. 'Fit and Proper' Person: has passed a test which determines whether a person is of a trustworthy nature and demonstrates the personal integrity to work with goods subject to Biosecurity control, this test is defined in section 530 of the Biosecurity Act 2015 (Cth).
l. Gene Technology: Work involving the manipulation of genetic material governed by legislative requirements set by the Office of the Gene Technology Regulator (OGTR).
m. Laboratory Biosafety Committee (LBC): a committee constituted in accordance with the terms of reference and the requirements of a Biosafety Committee under the Australian/New Zealand Standard 2243.3 (current version) Safety in laboratories, Part 3: Microbiological safety and containment and an Institutional Biosafety Committee under the Gene Technology Act 2000 (Cth).
n. Non-compliance: an occurrence of non-compliance with laws, regulations, standards, codes and other licensing or contractual obligations. An unintentional or deliberate act or omission, which leads to the University and/or staff member(s) failing to meet their compliance obligations.
o. Principal Investigator: A Deakin staff member who is competent with respect to the safe handling of RBMs used in a project and who has the ultimate responsibility for meeting project or any related approval conditions and will:
    i. ensure that all people involved in the project understand and accept their roles and responsibilities
    ii. ensure that procedures and resources are in place so that all people associated with the project can meet their responsibilities, including their education, training and supervision, as appropriate
    iii. be competent with respect to the RBMs used in the project
    iv. obtain all applicable permits, and approvals associated with the project.
p. Regulated Biological Materials: includes but is not limited to hazardous biological agents (microorganisms, prions or biological toxins and materials reasonably likely to contain these: blood, tissues, cell lines, body fluids sourced from living organisms; animals; plants; environmental or outbreak related samples such as food, water and soil), Genetically Modified Organisms, imported material under biosecurity control and Security Sensitive Biological Agents.
q. Research: the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
r. Teaching activity: any action or group of actions undertaken with the aim of achieving a scientific purpose, where the scientific purpose is imparting or demonstrating knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements.

Status and Details

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