Regulated Biological Materials Research Procedure

Version	Approved by	Approval date	Effective date	Next full review
4.0	Deputy Vice-Chancellor Research & Enterprise	19 April 2024	19 April 2024	April 2027

Procedure Statement		
Purpose	To describe the responsibilities and authorities governing regulated biological materials in accordance with the requirements of the *Gene Technology Act 2000* (Cth) (henceforth referred to as the *Act*) and the *Gene Technology Regulations 2001* (Cth) (the *Regulations*), the AS/NZS 2243.3 Safety in Laboratories Part 3 Microbiological Safety and Containment Standard (the *Standard*) and other relevant codes and legislation.	
Scope	This Procedure applies to all staff and research trainees at UNSW and affiliated centres and institutes involved in research involving regulated biological materials in Australia and overseas.	
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. Preamble

The use of regulated biological materials (RBMs) in research is subject to oversight by State and Federal regulators, with the objective to protect the health and safety of people and the environment and managing the risks whilst utilising the exciting opportunities RBMs can hold for health and scientific research. This Procedure outlines the mechanisms by which UNSW manages the use of RBMs, including genetically modified organisms as defined by the Gene Technology Regulations 2001 and Risk Group 3

microorganisms as defined in the AS/NZS 2243.3 Safety in Laboratories Part 3 Microbiological Safety and Containment Standard.

2. Regulatory Environment

UNSW is an Accredited Institution with the regulators in accordance with the requirements of the *Act* and *Regulations* as well as the *Standard*. The Vice-Chancellor, as Head of the Establishment, has delegated the Deputy Vice-Chancellor Research & Enterprise and Pro Vice-Chancellor (Research) with the support of the UNSW Gene Technology Research Committee (UNSW GTRC) and Research Ethics and Compliance Support (RECS) to oversee the use of RBMs in research at UNSW according to its terms of reference and according to the requirements of the Act and Regulations as well as the Standard.

All research involving the use of RBMs is reviewed by the GTRC and approved by the DVCRE or PVC(R) and, where required, by the relevant regulator, prior to the commencement of the research. The GTRC is also tasked with overseeing the certification of facilities for holding GMOs above the level of Exempt Dealings and for PC3 facilities, and with the subsequent monitoring of those facilities to ensure compliance with certification and other requirements. Any proposed changes to approved GTRC protocols and facilities are reviewed by the GTRC and approved by the DVCRE or PVC(R) and, where required, by the relevant regulator.

Research involving higher-order invertebrate or vertebrate animals requires additional review by the UNSW Animal Care & Ethics Committees (ACECs) and approval by the DVCRE or PVC(R). Additional permit requirements apply to the import or export of RBMs or animals.

3. Principles of Regulated Biological Materials Research at UNSW

The University recognises the risk criteria in dealings with RBMs outlined in the *Act* and *Regulations* as well as the *Standard* and the potential harmful consequences to people and the environment posed by research involving RBMs. Harm to the health and safety of people includes, for example, toxicity, allergenicity, disease or injury. Harm to the environment can involve toxicity to other organisms, loss of biodiversity or disruption or adverse effects on the biotic environment through selective advantage of GMOs, or degradation of the abiotic environment.

The framework for research involving RBMs at UNSW is based on the potential levels of harm to people and the environment and considers the appropriate levels of containment and safety procedures in the use of the parent organism and modifications. The University also recognises that our knowledge of true risks is constrained by rapidly developing technology and that some risks may be perceived rather than real. Appropriate levels of risk in research involving RBMs are determined on an on-going basis by the DVCRE or PVC(R) in consultation with the GTRC and based on the evolving requirements of the *Act* and *Regulations* as well as the *Standard.*

4. University Gene Technology Research Committee

The UNSW GTRC shall act in relation to:

- UNSW and its affiliated organisations including those for which Affiliation Agreements are in force in respect of RBM matters and the role of the UNSW GTRC; and
- All research, teaching or other activity that involves RBMs as defined in this Procedure.

In addition to the responsibilities accorded under the *Act*, *Regulations*, *Standard*, Guidelines and the Affiliation Agreements, the UNSW GTRC shall provide advice to the Vice-Chancellor of UNSW (or delegated officer) in relation to any biological hazard generated during, or relevant to, teaching, research or other activity involving RBMs within UNSW or its affiliated organisations.

4.1. Terms of Reference

Under its terms of reference, the UNSW GTRC is charged with the following responsibilities:

1 Assess and review, in accordance with the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001*, proposed dealings involving the use of genetically modified organisms as Notifiable Low Risk Dealing (NLRD) or a dealing requiring licensing by the Regulator. The assessment and review of dealings involving GMOs includes: (i) consideration of the actual and potential risks to the health and safety of people and the environment; (ii) the competence of the personnel using GMOs and that the people using GMOs have appropriate experience skills and training to work with GMOs; and (iii) ensuring there is appropriate level of containment of the laboratory facilities used in working with GMOs.

2 In respect of proposed dealings requiring licensing by the Regulator, the GTRC will provide its assessment of the dealing on the OGTR licence application form and assist with the submission of the application to the Regulator and communicate the outcome to the project supervisors.

3 Inspect and recommend for certification to the Regulator, physical containment facilities before they are used for work involving GMOs.

4 Conduct annual inspections of PC3 facilities and all OGTR-certified facilities at and above level PC2 and oversee the follow-up of corrective actions.

5 Receive reports of incidents, including spills and unintentional release of RBMs, recommend actions for improvement or remediation, and report the incidents to regulatory authorities as required.

6 Assess and review work involving Risk Group 3 microorganisms as defined in the AS/NZS 2243.3 Safety in Laboratories Part 3: Microbiological Safety and Containment Standard. The review ensures (i) availability of sufficient resources (space and training) in PC3 facilities to support the work; (ii) identification of potential risks of harm to people in the laboratory, the community and the environment in case of unintentional release; and (iii) processes and procedures are in place to minimise such harm.

7 Provide advice to the Vice-Chancellor of UNSW (or delegated officer) in relation to any biological hazard generated during, or relevant to, teaching, research or other activity involving GMOs and Risk Group 3 microorganisms within UNSW or its affiliated organisations.

8 Comply with the *Research Code of Conduct* to manage complaints and allegations of research involving RBMs which may involve deviations from the Code.

9 Report to the Regulator in accordance with the obligations and responsibilities under the *Act*, *Regulations* and *Guidelines for Accreditation of Organisations* issued by the Regulator.

10 Report on a regular basis to the DVCRE or PVC(R) and annually to University Council on its activities and compliance with its terms of reference.

4.2. Membership

The UNSW GTRC 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 Presiding Member, are appointed by the DVCRE or PVC(R) for a period of three years, with the possibility for renewal for another three years. The DVCRE or PVC(R) can terminate membership at any time. The Committee may make recommendations to the DVCRE or PVC(R) regarding the continuation of any member. The DVCRE or PVC(R) nominates a Deputy Presiding Member from the GTRC membership. The Deputy Presiding Member will act in Presiding Member's absence or where the Presiding Member has a conflict of interest.

All members are appropriately indemnified by the University to fulfil their role on the GTRC.

4.3. Composition

The UNSW GTRC is composed of the following membership:

- The Presiding Member.
- At least four persons who have a combined expertise in the research disciplines overseen by the GTRC. These disciplines may include molecular biology, microbiology, genetics, virology, immunology, oncology, biochemistry, epidemiology, plant biotechnology or bio-containment/ biosafety engineering, and infection control.
- At least one lay person external to the University and not involved in research using RBMs to reflect the views of the wider community.
- One representative of UNSW Health & Safety as the Biosafety Coordinator.

4.4. Conflict of Interest

The following arrangements are in place to deal with conflicts or potential conflicts of interest in accordance with the *Act*, *Regulation* and *Standard*:

- 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 UNSW GTRC for assessment.

- All declarations of conflict of interest are recorded in the minutes of the meeting at which the declaration is made.
- The member who has declared a conflict of interest is excluded from the deliberations and assessment of the matter by the UNSW GTRC.
- If there are insufficient members in attendance with relevant qualifications and experience, the final recommendation for a proposal is postponed until the views of additional members have been sought or until the next meeting of the UNSW GTRC.

4.5. Attendance at Meetings

Members are appointed to the UNSW GTRC due to their relevant expertise and as such, must be present at meetings of the UNSW GTRC 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 GTRC Coordinator within RECS as soon as possible.

Although membership to the UNSW GTRC is voluntary, members are deemed to have vacated office if they are absent without leave for three consecutive meetings. The UNSW GTRC records absences and apologies are lodged by a member who is unable to attend a meeting. The UNSW GTRC may consider granting leave of absence when a member has missed two consecutive meetings and seeks leave (in writing) to miss a third meeting giving reasons for each absence. Leave of absence may be granted for one or more meetings at the discretion of the Presiding Member of the UNSW GTRC. The Presiding Member will report this to the DVCRE or PVC(R).

The UNSW GTRC may co-opt and invite non-members to meetings to provide expert advice outside the scope of knowledge of the Committee. Such invitees will not vote in any decisions of the UNSW GTRC.

4.6. Quorum and Decision-Making Process

The recommendations to the DVCRE or PVC(R) made by the UNSW GTRC are achieved through consensus at quorate meetings, where quorum consists of at least 50% of members present. Out of session decisions are ratified at the next quorate meeting.

5. Institutional Biosafety Coordinator

As an *ex officio* member of the UNSW GTRC, the UNSW Biosafety Coordinator advises the GTRC and the University's researchers on health and safety regulations as relevant to RBMs and their containment. The Biosafety Coordinator provides specialist strategic advice to the GTRC on how to minimise risks of research involving RBMs to human health and the environment and is a point of contact in emergencies where there is danger to humans or the environment.

The Biosafety Coordinator ensures that University health and safety processes are recognised and followed as part of research involving RBMs and integrated with GTRC processes. The UNSW Biosafety Coordinator works with the GTRC to provide gene technology and Risk Group 3 microorganism training as required by the *Act*, *Regulations* and the *Standard* and ensures that this training is integrated with the general biosafety training program.

6. Facility Certification and Inspection

Researchers are responsible to ensure that, as a minimum, all Exempt gene technology dealings are conducted in PC1-compliant facilities. Facilities for proposed NLRD, DNIR and DIR gene technology dealings require certification by the Regulator. The GTRC is responsible for inspecting and recommending facilities to the Regulator for certification.

Upon successful certification, the GTRC conducts annual inspections and communicates with the Regulator about any proposed structural changes to certified facilities. Any items identified by the GTRC deemed non-compliant with certification conditions must be addressed by the Head of the facility within a specified time frame and the Regulator is notified as required. The DVCRE or PVC(R) may suspend gene technology research at any time should the facility be found non-compliant with certification conditions.

Research involving the use of Risk Group 3 microorganisms must be conducted in a PC3 laboratory. The GTRC will inspect all PC3 facilities at least annually and seek evidence of complete and up to date registers of all Risk Group 3 microorganisms and all relevant import and export permits.

7. External and Multi-centre Regulated Biological Material Research

UNSW researchers do not need to seek review by the UNSW GTRC if the research is conducted elsewhere and an external GTRC or equivalent biosafety committee accredited by the Regulator or by the appropriate

overseas authority provides the review, approval and monitoring of the research according to the *Act* and *Regulations* as well as the *Standard* or equivalent legislation overseas. However, evidence of the external review and approval must be provided by the lead UNSW researcher to UNSW prior to the commencement of the research or participation in an external project as specified on the UNSW Research Ethics & Compliance Support website/ SharePoint site.

Projects across multiple institutions need to be approved by the responsible GTRC or equivalent biosafety committee, where each committee is responsible for approving and monitoring the research at its institution. Participating committees may share documentation to raise awareness of all aspects of the research and potential implications of cumulative risks to humans or the environment.

The University reserves the right to place conditions on involvement or refuse involvement in external projects by its researchers should approved proposals not conform with the requirements of the *Act* and *Regulations or the Standard*, other relevant legislation or potentially expose the University to undue risk.

8. Monitoring of Research and Adverse Events

Research involving RBMs approved by UNSW is monitored by the University and its delegated bodies through mechanisms described in the *Act* and *Regulations* as well as the *Standard*, including annual and final reports for each approved project, internal and external audits of compliance with the approved protocol, and site visits and interviews with investigators and laboratory staff. The University may suspend or withdraw approval for research involving RBMs where it is reasonable to believe that continuation of the research project may compromise compliance with legislation.

Chief investigators are required to monitor research according to the approved protocol and report unexpected adverse events to the RECS Coordinator for GTRC as soon as possible (within 24h of the incident/adverse event) in accordance with the emergency instructions detailed on the UNSW Research Ethics & Compliance Support website/SharePoint site. This includes any unintentional release of RBMs. The Chief Investigators are to inform the UNSW Biosafety Coordinator as soon as possible (within 24h of the incident/adverse event) where there is possible risk to human safety involved. Such incidents must be reported online via SALUS. The RECS Coordinator will notify the GTRC of incidents, adverse events and the Committee may request additional monitoring, other actions as deemed appropriate.

Issues identified during monitoring or adverse event reporting which may possibly involve breaches of the UNSW *Research Code of Conduct* are handled in accordance with the *Complaints Management and Investigations Policy and Procedure.*

9. Complaints and Grievances

UNSW has established a complaints and grievances mechanism for UNSW staff, students and persons external to the university. Complaints about the conduct of research involving RBMs by UNSW staff, students and visitors should be directed to Director of Research Ethics and Compliance Support (RECS) (genetechnology@unsw.edu.au). The Conduct & Integrity Office (research.integrity@unsw.edu.au) are informed of allegations involving possible breaches of the *Australian Code for the Responsible Conduct of Research* to be reviewed in accordance with the UNSW *Research Code of Conduct*.

Grievances about compliance review and processes by UNSW staff and students should be addressed to the Director of RECS (genetechnology@unsw.edu.au).

10. Additional Operating Guidelines

Operating guidelines in support of this Procedure, such as rulings on record keeping, containment, competency and standard operating procedures for working with genetically modified organisms and Risk Group 3 microorganisms are approved by the DVCRE or PVC(R) and displayed in their most current form on the Research Ethics & Compliance Support website/ SharePoint site.

Accountabilities	
Responsible Officer	Director, Research Ethics and Compliance Support
Contact Officer	RECS Coordinator, Gene Technology Research: genetechnology@unsw.edu.au
Supporting Information	
Legislative Compliance	This Procedure supports the University's compliance with the following legislation: • *Gene Technology Act 2000* (Cth) • *Gene Technology Regulations 2001* (Cth) • AS/NZS 2243.3 Safety in Laboratories Part 3 Microbiological Safety and Containment Standard
Supporting Documents	Nil
Related Documents	• Australian Code for the Responsible Conduct of Research 2018 • National Framework of Ethical Principles in Gene Technology 2012 • Research Code of Conduct • Animal Research Ethics Procedure • Complaints Management and Investigations Policy and Procedure. • Biorisk Management Procedure • SALUS
Superseded Documents	Gene Technology Research Procedure v3.0
File Number	2019/14166
Definitions and Acronyms	
Advantage	In relation to an organism that is genetically modified, means a superior ability in its modified form, relative to the unmodified parent organism, to survive, reproduce or otherwise contribute to the gene pool.
Dealing	Includes (a) conducting experiments with, (b) make, develop, produce or manufacture, (c) breed, and (d) propagate a GMO, (e) use a GMO in the course of manufacture of a thing that is not a GMO, and (f) grow, raise or culture, (g) import, (h) transport and (i) dispose of a GMO; this includes the possession, storage, supply or use of a GMO for the purposes of, or in the course of, a dealing.
Exempt dealing	Is a category of dealings with GMOs that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs). The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment. Exempt dealings are described in Parts 1 & 2 of Schedule 2 of the *Gene Technology Regulations 2001 (Cth)*.
Gene technology	Any technique for the modification of genes or other genetic material, excluding (a) sexual reproduction, (b) homologous recombination and (c) any other technique specified in the *Regulations*.
Genetically modified organism (GMO)	Includes (a) an organism that has been modified by gene technology, (b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology, or (c) anything declared by the *Regulations* to be a GMO, or that belongs to a class of things declared by the *Regulations* to be GMOs.
Notifiable Low Risk Dealing (NLRD)	A dealing with GMOs that has been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions on containment, transportation, storage and disposal are met. NLRDs are described in Parts 1 & 2 of Schedule 3 of the *Gene Technology Regulations 2001(Cth)*.

Oncogenic modification	A genetic modification capable of contributing to tumour formation, including modifications that cause at least one of the following: (a) defects in DNA proofreading and repair, (b) defects in chromosome maintenance, (c) defects in cell cycle checkpoint mechanisms, (d) uncontrolled cell proliferation, (e) resistance to apoptosis, and/or (f) cellular immortalisation.
Physical containment (PC) facility	A facility certified by the Regulator to a specific containment level (PC1-PC4) to protect the health and safety of people and the environment.
Physical containment (PC) level	Followed by a numeral, is a specified containment level (PC1-PC4) under guidelines made by the Regulator, under section 90 of the *Act*, for the certification of facilities.
Regulator	The Office of the Gene Technology Regulator (OGTR).
Regulated biological materials	Means biological materials governed by a regulatory scheme or recognised set of guidelines or standards and includes for the purpose of this Procedure (i) genetically modified organisms as defined by the Gene Technology Regulations 2001 and (ii) Risk Group 3 microorganisms as defined in the AS/NZS 2243.3 Safety in Laboratories Part 3 Microbiological Safety and Containment Standard.
Risk Group 3 microorganisms	As defined in the AS/NZS 2243.3 Safety in Laboratories Part 3 Microbiological Safety and Containment Standard: A microorganism that usually causes serious human or animal disease and may present significant risk to laboratory workers. It could present a limited to moderate risk if spread in the community or the environment, but there are usually effective preventive measures or treatment available.

Revision History

Version	Approved by	Approval date	Effective date	Sections modified
1.0	Vice-President and Deputy Vice-Chancellor Research	31 July 2015	1 August 2015	New Procedure which superseded HS330 Gene Technology Procedure v3.2
2.0	Deputy Vice-Chancellor Research	2 May 2019	2 May 2019	Full review
3.0	Deputy Vice-Chancellor Research & Enterprise	30 March 2021	30 March 2021	Full review
4.0	Deputy Vice-Chancellor Research & Enterprise	19 April 2024	19 April 2024	Full review