Institutional Biosafety Committee Terms of Reference

Section 1 - Establishment

Purpose

(1) The Institutional Biosafety Committee (the Committee) advises Macquarie University (the University) and any external stakeholders on the identification and management of the risks associated with:

a. dealings with Genetically Modified Organisms (GMO's);
b. the use of agents classified as Risk Group 1 and higher;
c. working with Security Sensitive Biological Agents (SSBAs); and
d. the use of agents requiring containment or approval under the Biosecurity Act 2015.

Background

(2) The Committee has been established to conform to the requirements of the Gene Technology Act 2000 (the Act) and the Gene Technology Regulations 2001 (the Regulations). The University is an accredited organisation under the Act.

(3) As a condition of accreditation and in accordance with the Guidelines for Accreditation of Organisations 2012 (the Guidelines) the University must maintain a properly constituted and resourced Committee, whose members are able to provide professional and unfettered advice on risks associated with the gene technology work of the University.

Authority

(4) The Committee has authority delegated by Council as detailed in the Delegations of Authority Register section 7, under the Research Ethics subsection.

Section 2 - Membership

(5) As part of the accreditation requirements set out by the Office of the Gene Technology Regulator (OGTR), the Committee must comprise members with appropriate technical knowledge, independence and indemnification (from legal liabilities, claims, and lawsuits arising from their official duties and decisions within the Committee review process).

(6) The membership of the Committee consists of:

a. a Chair nominated by the Deputy Vice-Chancellor (Research) and approved by the Vice-Chancellor;
b. a Deputy Chair nominated by the Deputy Vice-Chancellor (Research) and approved by the Vice-Chancellor;
c. an independent external member appointed by the Deputy Vice-Chancellor (Research);
d. a Biosafety and Biosecurity Officer;
e. a health and safety representative from the University appointed by the Deputy Vice-Chancellor (Research);

and

f. up to 10 additional members co-opted by resolution of the Committee to address gaps in expertise.

(7) The Deputy Vice-Chancellor (Research) will appoint a secretary and provide sufficient resources for the Committee's effective and efficient functioning.

Term of Office

(8) Membership of the Committee is three (3) years unless otherwise specified.

(9) When a member's term expires, the Committee may recommend reappointment for the approval of the relevant authority.

Role of Chair

(10) The role of the Chair is to:

a. provide leadership and direction in conducting the Committee's business;
b. convene and chair Committee meetings;
c. liaise with the Office of the Gene Technology Regulator (OGTR) to obtain advice; and
d. provide education to Committee members and assist in the interpretation and dissemination of OGTR documents, the Guidelines and other Regulations.

(11) The Chair will nominate another member of the Committee to act as Chair when they and the Deputy Chair will be absent, or when both identify a conflict of interest.

Section 3 - Functions and Responsibilities

Committee Responsibilities

(12) The Committee will review and assess written proposals submitted by University staff, students and its affiliates to conduct dealings with GMOs and work involving High Risk Microorganisms.

(13) When reviewing submissions, the Committee must:

a. consider the actual and potential risks to humans and the environment;
b. evaluate the expertise of the investigators;
c. assess the adequacy of containment plans;
d. determine whether additional expertise should be consulted to assess a proposal; and
e. determine whether the health surveillance of researchers, laboratory staff and students is necessary.

(14) The Committee will:

a. maintain a register of approved dealings with:
    i. GMOs, SSBAs, and work involving Risk Group 1 and higher microorganisms;
    ii. agents requiring containment or approval under the Biosecurity Act 2015; and
    iii. certified facilities and where training is undertaken;
b. monitor dealings with GMOs and work involving High Risk Microorganisms (Risk Group 2 and above microorganisms, SSBAs and agents requiring containment or approval under the Biosecurity Act 2015) by undertaking regular inspections to ensure compliance with the Act and Regulations, National Health Security

Act 2007, AS/NZS 2243.3:2022 and the Biosecurity Act 2015;

c. provide regular education and training to researchers, students, visitors and personnel conducting dealings with GMOs, SSBAs, Risk Group 1 and above microorganisms and agents requiring containment or approval under the Biosecurity Act 2015;
d. inspect all certified facilities at least annually to ensure compliance with Office of the Gene Technology Regulator (OGTR) Guidelines and Department of Agriculture, Fisheries and Forestry (DAFF) requirements;
e. report to the Vice-Chancellor through the Deputy Vice-Chancellor (Research) at least once per year; and
f. submit an annual report to the OGTR in accordance with the Guidelines.

(15) The Committee may:

a. monitor work involving Risk Group 1 Microorganisms by undertaking inspections from time to time to ensure compliance with AS/NZS 2243.3:2022; and
b. impose new conditions for compliance if new methodologies emerge or if risk evaluation indicates new processes are required.

(16) The Committee is responsible for the approval and submission of all applications for certification of Office of the Gene Technology Regulator (OGTR) facilities and approved arrangement sites.

Member Responsibilities

(17) Members of the Committee will be required to sign a confidentiality agreement upon appointment and will treat and keep confidential all information and documents related to business considered.

Meetings

(18) The Committee will meet at least three times a year.

(19) The Chair may also invite individuals with specialist knowledge and expertise to attend Committee meetings as required.

Quorum

(20) The quorum of a Committee meeting is the majority of members holding office at the time.

(21) A decision of the Committee requires the presence of a quorum.

Conflicts of Interest

(22) Committee members must declare any conflict of interest prior to the matter being discussed.

(23) The Office of the Gene Technology Regulator (OGTR) considers a conflict of interest as:

a. a direct financial interest;
b. any indirect interest, for examples a financial benefit accruing to a close relative or partner of the member;
c. non-financial interest, for example a person may have an interest in a matter a result of an affiliation or membership of an interest group or organisation;
d. any interest that could be viewed as a possible conflict of interest; or
e. a combination of the above interests.

(24) On declaration of a conflict of interest, the member will absent themselves from the meeting for the duration of the discussion and decision of the matter in which they are conflicted.

(25) For applications and other matters considered by the Committee via circular resolution, if a member declares a conflict of interest they will be excluded from the review process by the secretary.

(26) Committee members must adhere to the Conflict of Interest Standards, and the Conflict of Interest Policy, as set out in the Macquarie University Code for the Responsible Conduct of Research.

Decisions

(27) Decisions of the Committee are made by a majority of members present being in favour of a resolution.

(28) Decisions may be made by the Committee via circular resolution.

Agendas and Minutes

(29) Agendas and associated documentation will be distributed electronically to members at least seven working days prior to a meeting.

(30) Minutes are to be prepared for each Committee meeting by the secretary. The draft minutes of each Committee meeting are to be reviewed by the Chair and circulated by the secretary to all members as soon as practicable.

(31) When business arising between meetings requires an urgent decision, this business may be considered by the Committee via a circular resolution and using the University's online review system.

(32) Committee records are subject to the Regulations and the State Records Act 1998 and must be retained in accordance with the University's Records and Information Management Policy. The secretary of the Committee is responsible for ensuring appropriate records management under the direction of the Chair.

Circular Resolution

(33) A circular resolution is a resolution passed without a meeting, by members of the Committee signing or approving via a verified email account/University system and returning the resolution stating whether or not they are in favour of the resolution.

(34) Circular resolutions must be circulated to all unconflicted members of the Committee and resolutions for approval cannot be amended after being circulated.

(35) Members must respond in writing stating that they 'Approve' or are 'Against' the resolution recommended in the circular resolution by the specified date. The Chair may allow more time for response where it may not be practicable to contact all members within this period.

(36) If a Committee member votes against the resolution, that Committee member may then request the Chair to convene a meeting. The Chair must convene a meeting as soon as practicable after the request for a meeting has been received by the secretary. The circular resolution will lapse if a meeting has been requested under this clause.

(37) If a member has not responded to the circular resolution in the manner required or within the time allowed for response, that member will be taken to have abstained from voting.

(38) A resolution is passed when the secretary receives the last response within the time allowed for response and an absolute majority of Committee members have approved the resolution.

(39) Passed circular resolutions will be retained as an official record by the secretary.

(40) Where a circular resolution has been passed, it will be noted by the Committee at its next meeting.

Complaints

(41) Complaints against Committee decisions should be directed to the Chair in writing.

(42) If a complaint is not resolved, it may be forwarded to the Director, Research Ethics and Integrity for investigation. The Director, Research Ethics and Integrity may report the matter to the Deputy Vice-Chancellor (Research).

(43) Complaints against Committee members should be directed in writing to the Director, Research Ethics and Integrity. The Director, Research Ethics and Integrity will investigate the matter and may provide a report to the Deputy Vice-Chancellor (Research).

(44) If a Committee member has a complaint about the conduct of the Committee or another member, the member should forward their complaint in writing to the Director, Research Ethics and Integrity. The Director, Research Ethics and Integrity will investigate the matter and may provide a report to the Deputy Vice-Chancellor (Research).

(45) Allegations of misconduct must be dealt with in accordance with the Macquarie University Code for the Responsible Conduct of Research.

(46) Where a complaint alleges serious misconduct that falls outside of the range of research misconduct as described in University's research integrity framework, the matter will be dealt with in accordance with relevant University policies and procedures.

Suspension or Discontinuation of Research

(47) Any breaches or allegations of misconduct relating to the conduct of research, including but not limited to ethical violations, non-compliance with research protocols and improper handling of research materials or data, will be managed in accordance with the Macquarie University Code for the Responsible Conduct of Research.

(48) If dealings with GMOs or work with High Risk Microorganisms without prior Committee approval or outside the conditions of approval are suspected or reported, the Committee or the authorised officer/agent will investigate. The Committee will instruct the chief investigator as to what work can be undertaken while the investigation is underway. The Director, Research Ethics and Integrity will be advised of the matter.

(49) Following investigation, if it is determined that dealings with GMOs and work High Risk Microorganisms has occurred without prior assessment and approval by the Committee, or outside the conditions of approval, a formal report will be prepared by the Committee and submitted to the Director, Research Ethics and Integrity and the Deputy Vice-Chancellor (Research).

(50) The Committee secretary, Chair and the Director, Research Ethics and Integrity will take remedial steps to ensure that the situation is managed. Remedial steps may include education, auditing, inspection, and containment.

(51) A risk assessment will be undertaken by the Biosafety and Biosecurity Officer to ensure that any risks imposed by the GMOs or High Risk Microorganisms are contained.

(52) At the discretion of the Deputy Vice-Chancellor (Research), a report of the matter will be submitted to the Office of the Gene Technology Regulator (OGTR) or the relevant statutory body.

(53) If an individual breaches a licence that has been issued by the OGTR or DAFF directly, (e.g., a Dealing with No Intent to Release or Dealing with Intent to Release or import permit), the issue will be reported to the OGTR or DAFF (as appropriate) immediately.

(54) If the Committee suspects or is notified that work with Risk Group 2 or above microorganisms is being carried out in contravention of AS/NZS 2243.3:2022, the Committee or its delegate may report the matter to the relevant Head of Department and laboratory/facility manager. The Committee may also notify the Executive Dean of Faculty and the

Director, Risk and Assurance if deemed appropriate.

Section 4 - Variations

(55) Variations to this Terms of Reference must be approved by the Deputy Vice-Chancellor (Research).

Status and Details

Status	Current
Effective Date	16th October 2024
Review Date	16th October 2027
Approval Authority	Deputy Vice-Chancellor (Research)
Approval Date	14th October 2024
Expiry Date	Not Applicable
Responsible Executive	Sakkie Pretorius Deputy Vice-Chancellor (Research) +61 2 9850 8645
Responsible Officer	Robert Willows Chair, Institutional Biosafety Committee
Enquiries Contact	Michelle Keeling Animal Ethics and Biosafety Manager