

UNIVERSITY OF NEWCASTLE

Institutional Biosafety Committee (IBC)

Terms of reference

1.0	Introduction.....	1
2.0	Terms of reference	1
3.0	Membership.....	2
4.0	Rights of Attendance	4
5.0	Terms of Office	5
6.0	Training	5
7.0	Reporting.....	6
8.0	Administrative Arrangements.....	6
9.0	Servicing of Committee.....	7
10.0	Review of the Committee and Terms of Reference.....	7
11.0	Essential Supporting Documents	7

1.0 Introduction

- 1.1 The Institutional Biosafety Committee (IBC) was established to assist the University to manage the safety and regulatory aspects of research and teaching activities involving biological material (AS/NZ 2243.3) and gene technology (Gene Technology Act 2000) and as such is directly responsible to the Vice-Chancellor. The committee also assists the University to meet its obligations relating to the *Work Health and Safety Act 2011* and associated regulations. The committee provides the University with a forum for the consultation of WHS matters involving biological material that may impact on the operations of the University and its community.
- 1.2 The Deputy Vice-Chancellor (Research and Innovation) is the officer of the University accountable for ensuring compliance of The University of Newcastle with the Gene Technology Act and Regulations, and as such oversees the activities of the IBC and reports to the Vice-Chancellor regarding these responsibilities.
- 1.3 It should be noted that IBCs are not intended to be responsible for the conduct of the organisations that they assist. Ultimately, in regard to gene technology the Regulator encourages organisations to make representations to the Regulator on their own behalf. IBCs are intended to provide relevant experience and a useful check and balance in the performance of dealings with genetically modified organisms (GMOs) without attracting liability for damages, in the course of providing that assistance.

2.0 Terms of reference

- 2.1 The IBC will discuss and make recommendations to promote work health and safety best practice at University work sites in relation to the use of biologicals and Gene Technology utilised within research or teaching activities at the University.
- 2.2 The IBC will assist the University to meet its obligations under the Work Health and Safety Act 2011, and Gene Technology Act 2000 and their associated Regulations and Codes of Practice, with respect to the use of GMOs, pathogenic microorganisms, and other biological hazards, utilised within Research or Teaching and Learning activities at the University; The IBC will:
 - 2.2.1 Provide advice and assistance to applicants for approvals. Review all proposed

Institutional Biosafety Technical Committee (IBC)

Terms of reference

research and teaching activities that involve high risk biological materials and gene technology as described in legislation and University Policies and procedure documents in a timely and facilitatory manner..

- 2.2.2 Inform the Deputy Vice-Chancellor (Research and Innovation) and the Health and Safety Team immediately of any unsafe working practice or deficiency in equipment or apparatus brought to its notice that affects safety from hazardous biological material and recommend immediate remedial action.
- 2.2.3 Review all investigations of incidents and accidents that involve research or teaching and learning activities or other events where biological materials or genetically modified organisms are involved.
- 2.2.4 Assess the classification of GM dealings
- 2.2.5 Monitor the acquisition, transport, production, handling, storage, containment and disposal of biologically hazardous materials, including GMOs;
- 2.2.6 Review and comment on University plans and policies that may affect biological safety;
- 2.2.7 Conduct Annual Inspections of all certified containment facilities
- 2.2.8 Participate in the planning, design and installation stages of proposed biological containment facilities
- 2.2.9 Record:
 - all notifiable low risk and licensed dealings conducted by the organisation/s;
 - minutes of meetings of the IBC
 - inspections of certified facilities.
- 2.3.9 Perform all other duties required by the Legislation.

3.0 Membership

- 3.1 The IBC shall comprise members with the collective technical scientific expertise to review and assess all the matters which are referred to it for consideration, assessment, and advice by the organisations for whom it acts. In regard to Gene Technology, the IBC will possess the collective technical and scientific expertise to assess and advise on the identification and management of risks associated with GMO dealings for which the IBC is requested or required to provide assessment and advice. Note: The IBC will be compliant with this condition if it is necessary for it to rely on the advice of an expert (i.e. not a member of the IBC) to address specific, short-term skills deficits in the IBC.
- 3.2 When deemed appropriate a particular role on the committee may be shared by two persons to ensure minimum attendance requirements can be met.
- 3.3 The Chair, appointed by the Deputy Vice-Chancellor (Research and Innovation) on the nomination of the committee, should be a person holding a senior position in the University, and should possess the following attributes:

Institutional Biosafety Technical Committee (IBC)

Terms of reference

- an ability to bring impartiality to the task
 - the skills to manage the business of the IBC
 - an ability to communicate, negotiate and to resolve issues; and
 - an understanding of biological safety, gene technology and the WHS legislation
- 3.3.1 The Chair of the IBC will be selected on the basis of an election by all IBC members following a nomination process.
- 3.3.2 In the event that no nomination is forthcoming the DVC(R&I) will appoint a suitable staff member to the role.
- 3.3.3 When elections are due, nominations for Chair are requested by return email to the Committee Secretary from sitting committee members and PVC's of the Faculties the IBC services. All nominees for Chair require endorsement from the DVC (R&I) prior to being included on the ballot form
- 3.3.4 A confidential committee ballot is conducted for the role of Chair by return email to the Committee Secretary with the result conveyed to the DVC (R&I) for endorsement prior to confirmation of the new Chair at the next IBC meeting
- 3.3.5 Where the Chair is unable to be present at a meeting, the Deputy Chair will preside.
- 3.3.6 Where both the Chair and Deputy Chair are unavailable to be present at a meeting the Chair will nominate a committee member to chair the meeting in their absence.
- 3.3.7 The Chairperson is also the IBC representative on the University OH&S Committee and the Research Integrity Accountability and Compliance Committee (RIACC) - although delegation of this responsibility may be appropriate under certain conditions.
- 3.4 When election for Deputy Chair is due, nominations from sitting committee members from the current membership are requested by return email to the Committee Secretary and a confidential committee ballot is conducted by return email to the Committee Secretary with the result announced at the next IBC meeting
- 3.5 The committee membership is expected to hold the collective expertise to cover the following:
- 3.5.1 Experience in gene technology techniques;
 - 3.5.2 Experience in the classification of genetically modified organisms;
 - 3.5.3 Experience in veterinary practices and zoonoses;
 - 3.5.4 Experience in Molecular Plant Biology;
 - 3.5.5 Experience in biological safety;
 - 3.5.6 Experience in microbiology (bacteriology, virology, and mycology)
 - 3.5.7 Knowledge of legislation and standards pertaining to biological safety;
 - 3.5.8 Knowledge of Security Sensitive Biological Agents

Institutional Biosafety Technical Committee (IBC)

Terms of reference

- 3.6 The IBC may include such additional members, as it deems necessary to ensure its adequate functioning and representation of the nature of dealings with animals, microorganisms and/or GMOs undertaken by the organisations for which it acts.
- 3.7 Before appointment, all members of the IBC shall acknowledge in writing their acceptance of the Terms of Reference of the IBC and the requirements for confidentiality imposed by the University.
- 3.8 The membership of the IBC should, if practicable, include at least one employee representative from each of the organisational units within the University using biologicals or gene technology:
- 3.8.1 Research and Innovation Division
 - 3.8.2 School of Biomedical Sciences and Pharmacy
 - 3.8.3 School of Health Sciences;
 - 3.8.4 School of Medicine and Public Health;
 - 3.8.5 School of Environmental and Life Sciences
 - 3.8.6 School of Psychology
- 3.9 The membership of the IBC should include at least one employee from each of the campuses where biological and genetically modified organisms are handled (an employee listed under 3.8 may also perform this as a dual function):
- 3.9.1 Callaghan Campus
 - 3.9.2 Central Coast Campus
 - 3.9.3 Hunter Medical Institute of Research Building
- 3.10 The membership will also comprise:
- 3.10.1 The Senior Health and Safety Advisor (Laboratory/Research)
 - 3.10.2 A Student Representative
 - 3.10.3 Nominee from Facilities Management who has experience in, or responsibility for, the testing and maintenance of biological containment for facilities
 - 3.10.4 An independent (lay) person who should have no affiliation with the organisation/s the IBC acts for.
- Note: The intention in requiring an independent member is to include someone who can exercise unfettered and independent judgement in relation to their participation in the IBC. The lay person will have no ongoing, substantive association (including personal, pecuniary or research interests) with matters likely to be considered by the IBC. While it is not a requirement, the Regulator encourages members who satisfy the independence criterion to be free of any business or other relationship with the organisation that could materially interfere with the exercise of unfettered and independent judgement in contributing to decisions made by the IBC, including a relationship of employment.

4.0 Rights of Attendance

- 4.1 The Committee may invite any person to inform its deliberations, subject to the agreement of the Chair.
- 4.2 The Associate Director, Health and Safety may attend meetings of the IBC and shall have rights of audience and debate.

Institutional Biosafety Technical Committee (IBC)

Terms of reference

4.3 The DVC (R&I) may attend meetings of the IBC and shall have rights of audience and debate

5.0 Terms of Office

5.1 Committee membership tenure shall be two years or less in the following circumstances

- The committee member leaves the University; or
- Is no longer a member of the organisational unit being represented; or
- Withdraws from their position; or
- Does not meet membership requirements such as minimum attendance

5.2 The Chair and Deputy Chair are elected for a term of 24 months. The persons elected to these positions are eligible for re-election.

5.3 All members may be re-appointed to serve for consecutive terms. In general, members would not be expected to serve more than six years continuously, but it is recognised that in some circumstances, the availability of suitably qualified potential members will require some members to serve for longer periods.

5.4 A member's term of office may be extended in order to avoid more than 50% of the membership from being turned over.

5.5 The members of the IBC are appropriately indemnified. The University (or other organisation using the UoN IBC as its IBC) shall indemnify individual members who serve on the IBC for any costs arising as the result of legal action against individual members, as a result of work that they undertake as a committee member.

5.6 Before appointment all committee members shall acknowledge in writing their acceptance of the terms of reference and the University's requirements for confidentiality.

5.7 Details of committee membership shall be recorded and posted online.

Non-Attendance

5.8 All committee members must attend 70% of scheduled meetings on an annual basis, subject to extraneous circumstances. Where committee members cannot attend meetings apologies must be given to the Secretary.

5.9 Committee members whom have continued absences from scheduled meetings will be approached by the Chairperson or their delegate with a view to discussing continued membership. If the committee member opts to remain on the committee but continues to be absent from meetings they will be asked to end their term on the committee.

6.0 Training

6.1 The University will ensure that each member of the IBC undertakes accredited Health and Safety or technical training where identified as appropriate following their appointment or election to the Committee.

6.2 In accordance with WHS regulations, the University will maintain any records of training of committee members.

Institutional Biosafety Technical Committee (IBC)

Terms of reference

7.0 Reporting

- 7.1 The IBC shall provide minutes of meetings to the DVC (R&I) for information and monitoring. The DVC (R&I) may require the Chair of the IBC to report to them on a periodical basis.
- 7.2 The IBC chair or their delegate will attend the University Health and Safety committee meetings as a nominated representative of the DVC (R&I) and will table IBC reports as required.
- 7.3 The IBC chair or their delegate will attend the Research Integrity Accountability and Compliance Committee (RIACC) as a representative of the IBC and will table IBC reports as required.
- 7.4 The Accredited organization (University of Newcastle) shall submit an annual report to the OGTR in accordance with the regulator's requirements. The annual report shall include a record of all IBC approved notifiable low risk dealings for the previous 12 months.

8.0 Administrative Arrangements

- 8.1 The IBC will meet every five weeks or more frequently as necessary.
- 8.2 Arrangements should be made for persons to deputise for the Secretary if they are unable to attend a meeting.
- 8.3 The quorum for meetings of the IBC shall be the nearest whole number above one half of the membership at that time, including the Chairperson (or deputy).
- 8.4 Conduct of an inquorate meeting will be in accordance with the University's Meeting Protocols - Policy 000229 <http://www.newcastle.edu.au/policylibrary/000229.html>.
- 8.5 An IBC member who has a conflict of interest must declare the conflict of interest prior to the commencement of any meeting to consider that matter. If the IBC member does not have notice of the matter prior to the meeting, the member must declare the conflict of interest immediately upon becoming aware of it. The minutes of IBC meetings will contain records of all declared conflicts of interest and of measures taken to address the conflict of interest.
- 8.6 The IBC may, with the approval of the DVC (R&I), establish sub committees and /or working parties in respect of specific issues to assist it to meet its obligations.
 - 8.6.1 The IBC must establish clear purpose and guidelines for any other sub-committees or working groups as required to facilitate the work of the IBC ensuring that the Terms of Reference are consistent with applicable University policies.
 - 8.6.2 Any such sub-committees or working parties will report to the IBC. The report will provide advice, make recommendations, and notify the IBC of any action required.
- 8.7 A copy of the minutes of the IBC meetings will be issued to all members of the IBC to ratify prior to the next meeting commencing. The DVC (R&I) will receive a copy of all ratified minutes. The Agenda, associated documentation (including safety review applications) and Minutes of the meetings are to be treated as confidential documents as per the confidentiality agreement.
- 8.8 All decisions shall be made by a majority vote of attending committee members (the conditions for a quorum must be met). Each committee members vote counts for one.

Institutional Biosafety Technical Committee (IBC)

Terms of reference

- 8.9 The secretary will prepare the minutes of the previous meeting and the agenda and distribute them within 5 working days of a meeting to all committee members. Minutes will be approved by the Chairperson and relevant others prior to distribution and accepted at the next committee meeting.
- 8.10 The Chair may call an extraordinary meeting to consider an urgent item of business.
- 8.11 A scheduled meeting may be postponed at the discretion of the Chairperson if matters on the agenda cannot be addressed due to unforeseen circumstances. The meeting must be re-scheduled within ten working days of the original meeting date.
- 8.12 Records of meetings of the IBC must be kept for a minimum of 3 years from the date of each meeting.
- 8.13 Records of IBC facility inspections must be kept for a minimum of 3 years from the date of each inspection.
- 8.14 Records of assessment of notifiable low risk dealings must be kept for a minimum of 8 years after the date of assessment by the IBC.
- 8.15 Records must be made available for inspection by the Regulator upon request.
- 8.16 The University of Newcastle being an accredited organisation must provide a notice to the Regulator within 30 days, if the accredited organisation
- wishes to access or establish an IBC other than the UON IBC
 - disbands or ceases to use an IBC
 - changes its IBC contact, CEO or IBC Chair, or their contact details change

9.0 Servicing of Committee

- 9.1 The Health and Safety Team will appoint a Secretary to support the operations of the IBC and ensure its effective and efficient functioning.

10.0 Review of the Committee and Terms of Reference

- 10.1 These Terms of Reference will be reviewed at least every 2 years.

11.0 Essential Supporting Documents

- 11.1 [*The Gene Technology Act 2000*](#) and [*The Gene Technology Regulations 2001*](#)
- 11.2 Work Health and Safety Act 2011 <http://www.comlaw.gov.au/Details/C2011A00137> and Regulations 2011 <http://www.comlaw.gov.au/Details/F2011L02664>
- 11.3 OGTR Guidelines for Accreditation of Organisations
<http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accredguideV2-2Aug12-htm>
- 11.4 [*The National Security Act 2007*](#) and [*The National Security Regulations 2008*](#)
- 11.5 AS/NZS 2243.3 Safety in Laboratories Part 3 – Microbiological Aspects and Containment Facilities

Institutional Biosafety Technical Committee (IBC)

Terms of reference

12.0 Related Documents

- 12.1 Conflict of Interest Policy 000934
- 12.2 Responsible Conduct of Research Policy 000873
- 12.3 Health and Safety Procedure HSP 8.2
- 12.4 The Laboratory Animal Allergy (LAA) information sheet
- 12.5 UON Animal Hazard Procedure 001035
- 12.6 KRA 1.2 Genetically Modified Organisms
- 12.7 KRA 1.8 Biological Hazards and Infection Control

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