

Institutional Biosafety Committee (IBC)

TERMS OF REFERENCE

BACKGROUND

Organisations that deal with Genetically Modified Organisms (GMO) and other non-GMO biological hazards are bound by the Gene Technology Act 2000, Gene Technology Amended Regulations 2019 and Australia New Zealand Standards Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities (AS/NZS 2243.3).

The Austin Health Institutional Biosafety Committee (IBC) will assist by advising Accredited organisations who have agreed to utilise the services provided by the Austin Health IBC , namely Austin Health, The University of Melbourne, the Olivia Newton John Cancer Research Institute, and any third party in meeting legislated requirements for dealing with GMOs including the provision of information to the regulator. Ultimate responsibility for ensuring that the organisation has quality assurance systems in place to enable them to comply with the legislation rests with the Individual Accredited Organisations. The IBC's role is one of assistance and facilitation and as such bears no responsibility under the legislation for ensuring that conditions of accreditation are met. The Regulator will continue to be the ultimate decision maker.

Prior to undertaking work with a GMO an accredited organisation must examine the legislation to determine the type of approval that is required. The particular application must be submitted to the organisation's IBC. Dealings NOT involving an Intentional Release (DNIR) or dealings involving an Intentional Release (DIR) of GMOs into the Australian environment must be licensed by the Gene Technology Regulator (the Regulator). The IBC must forward supporting information including their assessment of the application to the organisation, for submission to the Regulator. The Regulator will undertake an independent risk assessment of the proposal to determine risks to health and safety of people, environment. The dealings with the GMO may only proceed if the Regulator grants the applicant a licence. The activities must then be undertaken in accordance with any conditions that the Regulator considers necessary based on a case by case basis.

1. ROLE

The Austin Health IBC will provide advice and assistance to proponents in relation to dealings with GMOS for the accredited organisations that have agreed to utilise the Austin Health IBC and have agreed to be bound by the terms and conditions as detailed in the agreement and the Gene Technology Amended Regulations 2011. The IBC will provide advice on the transport, storage and Disposal of GMOs in accordance to the OGTR's "Guidelines for the Transport, Storage and Disposal of GMOs".

2. REPORTING and RECORD KEEPING REQUIREMENT

The Austin Health (IBC) Institutional Biosafety Committee reports to the Director of the Office for Research at Austin Health:

After the end of each financial year and before the following 30th September, Austin Health IBC must complete and submit an annual report to the Regulator in the required format.

The Regulator's guidelines for accreditation of organisations require that the accredited organisation maintain accurate records including:

- Record of IBC meetings of three years from the date of each meeting
- Records of conflict of interest declared to the IBC
- Record of certified facility inspection should be retained for at least 3 years from the date of each inspection.
- Records of assessment of NLRDs to be kept for a minimum of 8 years after the date of assessment by the IBC.

3. IBC WORKING PROCEDURES

- 3.1 The IBC shall make all decisions by consensus. If a satisfactory agreement cannot be reached, the IBC Chair should discuss the remaining issues with the applicants so that a consensus may be achieved. If a consensus is still not achieved conditions applied to the proposal should be explored so that an agreement can be reached.
- 3.2 If consensus is still not achieved, the IBC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.
- 3.3 In relation to **Exempt dealings** with GMO's: The IBC shall:
- Assist individuals within organisations to correctly identify the proposed dealing with the GMO as an exempt dealing in accordance with the GT regulations.
- 3.4 In relation to **Notifiable Low risk dealings (NLRDs)** with GMOs the IBC shall:
- Assist the applicant to correctly identify the dealing as a NLRD.
 - Assist the applicant to understand the conditions applying to NLRDs.
 - Consider proposals prepared by applicants in accordance with the legislation [Regulation 13].
 - Make a NLRD record of assessment (RoA) and provide a copy to the person or accredited organisation that submitted the proposal.
- 3.5 In relation to dealings with **GMOs requiring licensing** by the Regulator the IBC shall:
- Assist applicants to prepare applications for licence in accordance with the Regulator's application requirements
 - Consider proposals in accordance with the Legislation
 - Provide advice to the Regulator on applications for licence.
 - The IBC will not send the information directly to the Regulator once they have completed their evaluation. Instead the IBC should return the application to the applicant. It will be the applicant organisation's responsibility to send the information to the Regulator including the IBCs supporting information.
 - Once a licence and associated conditions have been issued by the Regulator, it is expected that the IBC will provide some assistance and advice to the organisation but the ultimate responsibility for ensuring compliance with the Regulator's requirements will rest with the organisation of the applicant.
- 3.4 In relation to **Inspection of facilities**, the IBC shall:
- Inspect all of the organisation's containment facilities, against the Regulator's requirements for containment, at least once per year.
 - Inspect new PC2 facilities for which certification from the Regulator are sought. Provide a copy of the IBC members' report to the Regulator.

- In relation to existing facilities, provide a copy of the IBC members' report to the Regulator regarding compliance with the Regulator's conditions as part of the Organisation's Annual Report to the Regulator.
- 3.5 In relation to **Annual Reporting to the Regulator** the IBC shall assist in the preparation of the Annual Report.
- 3.6 In relation to internal training, the IBC will review internal training procedures.
- 3.6 In relation to **hazardous chemicals, biohazard material and Security Sensitive Biological Agents**, the IBC shall provide advice if requested to do so. The hospital safety person should be involved if required.
- 3.6 In the event that non-compliance is identified the IBC has authority to request corrective action or to suspend a project. The IBC may suspend approval of a project at their discretion. Investigators will be advised of this suspension in writing within 7 days of such a decision. The principal investigator will be advised of the reasons as to why the suspension has occurred and will be provided with steps to reinstate compliance and study approval.

4. MEMBERSHIP

- 4.1 The IBC shall include people with skills and experience in at least the following fields and relevant to the type of research, training and teaching activities that they may review:
- Animal Facility management and expertise in physical containment of organisms.
 - Biological safety
 - Microbiology and
 - Molecular biology or genetics.
- 4.2 The IBC shall include at least one independent member. The IBC shall comprise members with expertise relevant to work undertaken within the organisation. If the Accredited Organisation is undertaking work involving intentional release of a GMO into the environment then the IBC shall include a person with experience in an area or areas relevant to the intentional release of the GMO into the environment.
- 4.3 A quorum for the IBC shall comprise a minimum of 4: the Chair, the Secretary and an independent member and an internal member.
- 4.4 A member of the IBC must be appointed as chair of the IBC.
- 4.5 The IBC will notify to the Regulator any changes to its membership at least once per year. Appointment of a new Chair or primary contact must be reported to the Regulator, within 30 days of the appointment.
- 4.6 It is expected that if an IBC does not have appropriate expertise to deal with a particular application, the IBC will invite an expert (including a Biological Safety Officer as required) to assist with the assessment.
- 4.7 All members are appropriately indemnified by Austin Health.

5. CONFIDENTIALITY

- 5.1 Members and attendees of the IBC must comply with any confidentiality policies of Austin Health.
- 5.2 When documents are circulated electronically they are kept confidential.
- 5.3

6. CONFLICT OF INTEREST PROCESS

- 6.1 It is recognised that there may be occasion where an application comes before an IBC and one of the members of the IBC is either putting forward the application or has been closely involved in the development of the project.
- 6.2 Conflicts of Interest will be declared at the start of the meeting or at the time of conflict and recorded.
- 6.3 The affected member will not be party to the discussion whilst the application is assessed but will be called upon for clarification as required.

7. MEETING FREQUENCY

- 7.1. The Austin Health IBC shall meet on a yearly basis if possible and general business is conducted out of session.
- 7.2. Provisional approval/advice (Quorum of 2 including the IBC Chair and an external IBC member) may be sought in instances of urgency or absences of IBC members. This will be ratified at the next meeting

8. GRIEVANCE PROCESS

If a member of the IBC or a researcher has any grievance about the operation of the IBC, they should discuss this, in confidence, with the IBC Chairperson. If the grievance cannot be resolved they should then take their concerns to the Director of Research at Austin Health.

9. RELATED DOCUMENTS

- 9.1. Gene Technology Act 2000
- 9.2. Gene Technology Amended Regulations 2019
- 9.3. Australia New Zealand Standards Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities (AS/NZS 2243.3).
- 9.4. Guidelines for the Transport, Storage and Disposal of GMOs
- 9.5. Guidelines for Accreditation of Organisations
- 9.6. Explanatory Information on the Guidelines for Accreditation of Organisations 18 April 2013

Revision date

The Terms of Reference shall be reviewed every three years.