Flinders University
Institutional Biosafety Committee

Terms of Reference

Approved 13th January 2020

The Terms of Reference and the operations of the Flinders University Institutional Biosafety Committee (IBC) must comply with the terms of the national regulatory scheme for genetically modified organisms (GMOs), including the *Gene Technology Act 2000* (the Act), the *Gene Technology Regulations 2001* (the Regulations), associated guidelines and standards and corresponding state law. Flinders University has been accredited by the Office of the Gene Technology Regulator (OGTR) to undertake certain dealings with gene technology and GMOs. The role of the IBC is to assess these dealings and to oversee compliance with the Act and Regulations.

In addition to gene technology dealings, the IBC oversees research and teaching activities involving microbiological organisms that are risk group 2 or higher, consistent with definitions and guidelines outlined in *Australian Standard 2243.3 'Safety in Laboratories – Microbiological Safety and Containment'*.

The IBC oversees gene technology dealings, and research and teaching activities involving risk group 2 or higher microorganisms, for staff and students of Flinders University and the Southern Adelaide Local Health Network (SALHN), and for external bodies conducting work within physical containment facilities located on Flinders University premises or in the Flinders Medical Centre (FMC).

Establishment and Reporting

The IBC is established in accordance with the *Gene Technology Act,* and reports to the Deputy Vice-Chancellor (Research) (as the Vice-Chancellor's delegate), who is responsible for overseeing compliance with the Act and Regulations.

Membership and Appointments

Recruitment and appointment of the Chairperson is undertaken by the Deputy Vice-Chancellor (Research).

Other Committee members are appointed by the Deputy Vice-Chancellor (Research) on the recommendation of the Chair. Membership must have the collective technical and scientific expertise to review, assess and oversee all matters likely to be put before the Committee. The IBC may use a non-member expert to address specific, short-term skills deficits.

The IBC shall include the following membership:

- Chairperson;
- Deputy Chairperson (elected by and from the Committee membership);
- At least one person who is independent from the University and SALHN, who need not have a technical background;
- At least two molecular biologists with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of gene technology and GMOs, including, but not limited to, genetically modified plants and genetically modified animals;
- At least one virologist with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of genetically modified and non-genetically modified viruses;

- At least one microbiologist with the requisite knowledge and expertise to assess, evaluate and oversee work involving the use of genetically modified and non-genetically modified microorganisms;
- The Deputy Vice-Chancellor (Research) or nominee;
- The CEO, SALHN or nominee;
- The Manager, College of Medicine and Public Health Animal Facility;
- A member of the University Work Health and Safety Unit (nominated by the Head, Work Health and Safety Unit, Flinders University);
- A member of the SALHN Work Health and Safety Services (nominated by the Head, Work Health and Safety Services, SALHN);
- A person with the requisite knowledge and expertise in testing biological safety facilities and equipment (nominated by the Director, Biomedical Engineering, FMC);
- Executive Officer; and
- Any other person or persons that the Committee sees fit to appoint to assist in its function.

The term of office for members shall be 2 years, commencing on the first day of January, with eligibility for further terms. With the exception of the Executive Officer, all members shall have voting rights. All members of the IBC are indemnified by the University.

Responsibilities of Members

Each member is required to comply with any procedures established by the University for the effective functioning of the IBC, as well as any other internal policies or procedures pertaining to participation in University Committees.

Conflicts of Interest

An IBC member who has a conflict of interest must declare that conflict at the commencement of any meeting at which the matter is considered. If the IBC does not have notice of the conflict prior to discussion of the matter, the member must declare the conflict of interest immediately upon becoming aware of it. All declared conflicts of interest, and any measures taken to address these conflicts, shall be minuted.

Confidentiality

All members are required to respect the confidentiality of documents circulated and business discussed at meetings, and to sign a confidentiality agreement to this effect. Any visitors, guests, or observers present at IBC meetings, must also sign confidentiality agreements.

Information may be sought by IBC members from contacts outside of the IBC with regard to specific issues, but all reasonable care should be taken so that applicants are not identified, with minimal information divulged that could identify projects or applicants, or that could be regarded as scientifically, commercially or socially sensitive. Members may seek advice from the Chair if they are unsure how to balance their responsibilities with regard to confidentiality.

Functions and Responsibilities of the IBC

The IBC will:

1. Receive and review, and approve, approve with conditions, or reject, applications relating to the following:
    - any research or teaching activity constituting a dealing involving gene technology and/or GMOs;
    - any research or teaching activity involving work with microbiological organisms that are risk group 2 or higher, including handling samples known to contain these microorganisms, or the isolation or culture of unknown microorganisms from samples

that are likely to contain risk group 2 or higher microorganisms, but excluding clinical or diagnostic activities such as specimens collected from patients and specimen testing;
- any clinical or diagnostic activity constituting a dealing defined in Schedule 3, Part 2 of the Regulations; and
- any use of an agent defined under the national Security Sensitive Biological Agents Regulatory Scheme;

2. Ensure that information supplied to the OGTR is complete, for licenced dealings defined under Schedule 3, Part 3 of the Regulations,

3. Ensure that laboratory activities are planned and executed in such a way that every reasonable precaution is taken with regards to biosafety hazards, to protect the health and safety of each employee, the public, students, and environment, and to prevent damage to property;

4. Make recommendations relating to the granting of approvals to conduct, or participate in, activities defined under Item 1 to members of academic staff, research students and other persons who wish to use University or FMC facilities for the purpose of such work;

5. Make recommendations to the Deputy Vice-Chancellor (Research) in relation to the terms upon which such approvals shall be held, provided that the Deputy Vice-Chancellor (Research) shall be free to terminate any such approval at any time. Any applications considered to involve high potential for reputational risk to the University, as determined by the IBC, shall receive final approval from the Deputy Vice-Chancellor (Research) at the IBC's recommendation;

6. Make recommendations to the Deputy Vice-Chancellor (Research) and/or the CEO SALHN relating to safety precautions, either generally or for particular projects, which must be observed by those involved in relevant activities as defined under Item 1;

7. Cooperate closely, for the purpose of evolving effective safety standards, with Australian Government, Australian Academy of Science, Australian Standards, and South Australian State Government committees invested with the responsibility to monitor the activities defined under Item 1, with a view to making fully effective, improving and applying to local circumstances, the guidelines laid down from time to time by the above committees;

8. Establish appropriate auditing systems to monitor compliance with obligations under the Act and Regulations and to ensure that biosafety guidelines laid down for approved projects are adhered to;

9. Establish a register of approved projects relating to activities defined under Item 1 and ensure that this register is kept up-to-date;

10. Refer to the Chair any requests to participate in public discussions about the biosafety of research or teaching conducted within the Flinders University and SALHN;

11. Refer to the Deputy Vice-Chancellor (Research) and/or the CEO SALHN any biosafety-related media enquiries received in relation to research or teaching activities conducted within the Flinders University and SALHN;

12. Ensure that processes are in place for dealing with biosafety accidents, incidents, unintentional releases of GMOs or parts thereof, or non-compliances with the Act, Regulations, or relevant guidelines or standards;

13. Ensure that processes are in place for avoiding potential breaches of biosafety procedures;

14. Oversee the certification of physical containment facilities located on University or FMC premises, including applications for certification, variations to, suspensions of, and terminations of facility certification, routine facility inspections and facility compliance matters;

15. Support and promote the education and training of staff and students in the use of gene technology and/or microorganisms of risk group 2 or higher for scientific purposes;

16. Submit annual reports to the University and the OGTR; and

17. Perform all other duties required by the OGTR.

The IBC may:

1. Where appropriate, examine and comment on Flinders University plans and policies that may affect physical containment facilities, compliance with the Act and Regulations, or the safety of gene technology or microbiological research or teaching activities;

2. Appoint, from its membership, subcommittees or working parties to assist in its function. Membership of subcommittees may include persons from outside the membership as agreed by the Committee; and

3. Assess applications from external bodies, subject to reviewer expertise, workloads and discussion with the Deputy Vice-Chancellor (Research).

The IBC does not oversee activities involving:

- Radiation;
- Hazardous chemicals;
- Purified toxins (excluding those defined under the national Security Sensitive Biological Agents Regulatory Scheme);
- Techniques that are not gene technology, as defined under Schedule 1A of the Regulations *2001*;
- Work involving microorganisms of risk group 2 or higher if performed exclusively for clinical or diagnostic purposes; and
- Exempt dealings (as defined under Schedule 2 of the Regulations) if performed exclusively for clinical or diagnostic purposes.

Terms of Reference Review

It is recommended that the IBC Terms of Reference be reviewed every three years, or as required.