

Terms of Reference

Overview

The Institutional Biosafety Committee (IBC) is a vital component of the overall monitoring and surveillance of genetic manipulation work. The IBC will assist the University to meet the requirements of the Gene Technology legislation.

The Gene Technology Act was introduced by the Federal Government in December 2000. This Act (and two others) forms part of the new national scheme for regulation of GMO's. In 2001 the Gene Technology Regulations were then introduced to form the second component of the scheme. The Regulations determine the way the legislation will operate on a day-to-day basis.

Accreditation

The Regulations require that UNE is an Accredited Organisation. This accreditation is provided by the Office of the Gene Technology Regulator (OGTR, the Regulator) and is necessary before UNE applies for a licence to deal with GMO's or undertake any other dealings with a GMO.

This accreditation means that the Regulator is satisfied that UNE has a properly constituted IBC. It also shows that the IBC is ready to assist UNE in meeting the legislated requirements for dealings with GMO's, including the need to provide information back to the Regulator.

Accreditation also shows the Regulator that UNE has the necessary quality assurance systems in place.

The IBC can only assist UNE with compliance. The ultimate responsibility for ensuring compliance with the legislation rests with the University.

Name of the Group:

4.19.1 Institutional Biosafety Committee

Composition of the Group

4.19.2 Membership of the IBC will comply with Part G, Chapter 5 of Appendix 2 of the *Handbook on the Regulation of Gene Technology in Australia*, as set out in the points below:

- the University Health & Safety Consultant;
- the University Engineer;
- the Biosafety Officer;
- persons with skills in microbiology;
- persons with skills in molecular biology or genetics;

- persons with skills appropriate to the types of dealings with GMO's which are carried out by the organisation;
- at least one layperson;
- the IBC will comprise a minimum of 6 people;
- the IBC may co-opt suitable persons with appropriate skills for the evaluation of proposals in particular areas;
- the IBC may co-opt suitable persons to serve on the committee when conflicts of interest arise;
- membership of the committee will be subject to renewal every two years. However, due to the limited availability of persons with expertise in designated areas, members may serve on the committee for an indefinite period.

4.19.3 Roles and responsibilities may be combined in the same person where appropriate.

The Biological Safety Officer

4.19.4 UNE will have a designated Biological Safety Officer.

4.19.5 The Biological Safety Officer will normally be a member of academic staff with a background in microbiology, or a related discipline.

4.19.6 The Biological Safety Officer will provide advice on any matters relating to biosafety, including the handling of infectious agents which may present a risk to people, animals or the environment.

4.19.7 The Biological Safety Officer will report to the Pro Vice-Chancellor, Research and International.

4.19.8 The Biological Safety Officer shall act as adviser to the University in all matters relating to containment, biological hazards, and the safety of staff. Regular safety audits and the supervision of a regular testing program for appropriate pieces of equipment shall be undertaken by the Biological Safety Officer in conjunction with the IBC.

4.19.9 The Biological Safety Officer will liaise with the OHS Officer, the Quarantine Officer, the IBC and persons with appropriate expertise, either from within the University or external to the University.

Conflicts of Interest

4.19.10 Where possible, members should not assess their own proposals. It is recommended that the IBC have sufficient scientific members so that it is not dependent on the advice of the person submitting

the proposal. However, to ensure that no conflicts of interest arise, it is recommended that proposals be assessed in the absence of the originator.

- 4.19.11** Where investigators have, in addition to their usual responsibilities, other commercial affiliations or interests, it is recommended that, in such cases, members should declare their interests and leave the meeting when a related item of the agenda is being considered.

Monitoring of Work

- 4.19.12** The IBC shall ensure that GMAC's and its own advice on specific proposals is conveyed to the principal investigator(s) and, where necessary, is acted upon. The IBC shall visit laboratories and facilities from time to time to monitor safety aspects of ongoing projects.

- 4.19.13** The IBC may draft whatever rules it considers appropriate to supplement the Guidelines provided by the Regulator or to give effect to their intent. It shall have appropriate powers to ensure that any Guidelines and rules are observed. These rules may relate to laboratory practice, or to handling, transport and storage of genetically manipulated organisms.

Role of the Committee

- 4.19.14** The main functions of the IBC are to:
- oversee compliance of the University of New England with the requirements of the *Gene Technology Act 2000* and related legislation;
 - assess proposals for work with genetically-modified organisms (GMOs), and take the appropriate steps as outlined in the *Handbook on the Regulation of Gene Technology in Australia*;
 - oversee the certification of facilities for dealings with GMOs;
 - carry out an annual inspection of all certified facilities;
 - maintain a register of all dealings with GMOs, including exempt dealings;
 - have appropriate procedures for dealing with accidents and incidents;
 - maintain a list of staff authorised to work in the organisation's certified facilities;
 - oversee the preparation of the *Accredited Organisation Annual Report to the Gene Technology Regulator*;

- have appropriate procedures in place to address potential conflicts of interest;
- keep a record of all meetings;
- report to the Pro Vice-Chancellor, Research and International;
- in addition to overseeing compliance with the requirements of the OGTR, the IBC will provide advice on other matters relating to biosafety, as required

Training of Members

4.19.15 The University will provide the necessary training for members of the IBC, as appropriate to carrying out their duties.

Reporting Requirements

4.19.16 At the time of establishment, the IBC shall provide GMAC with a completed 'Institutional Biosafety Committee Information' form (This form is available from the GMAC Secretariat).

4.19.17 Once a year, the University will report to Regulator details of the following:

- membership of the Committee (including members qualifications and positions in the organisation);
- current exempt , NLRD and licensed dealings being conducted;
- certified PC2 laboratories, plant houses, animal houses, bird houses, insectaries and aquaria;
- any contraventions of the legislation;
- any other matter which the University deems necessary to report to the Regulator.

4.19.18 As a condition of all licences, once a year, each licence holder will report to the Regulator details of the following:

- additional information that the licence holder may become aware of as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence;
- if the licence holder becomes aware of any contraventions of the licence by a person covered by the licence;
- if the licence holder becomes aware of any unintended effects of the dealings authorised by the licence.

Accidents and Incidents

- 4.19.19** The IBC will record accidents and the action taken in dealing with accidents. If the IBC Chair is satisfied that an accident or incident occurred which was directly attributable to work with genetic manipulation, and was of sufficient significance, he/she shall make a report to the Regulator and the Deputy Vic-Chancellor Research.

References

'Handbook on the Regulation of Gene Technology in Australia – a user's guide to the Gene Technology Act 2000 and related legislation'

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