

THE NEW WAY TO DO UNI

VICTORIA UNIVERISTY INSTITUTIONAL BIOSAFETY COMMITTEE

TERMS OF REFERENCE

July 2021 Version 4.0

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1 INTRODUCTION

The objective of the Institutional Biosafety Committee (IBC) at Victoria University is to protect the health and safety of members of the Australian community and the Australian environment by identifying risks posed by, or as a result of, work within the University with agents or materials that are potential biosafety and biosecurity hazards, and to manage those risks by regulating "dealings" with such materials.

2 FUNCTION OF THE COMMITTEE

- 2.1.1 Recommend to the University the measures needed to ensure compliance with biosafety and biosecurity legislation, regulations and standards including "dealings" involving:
 - o Genetically Modified Organisms
 - Biological Risk Group Agents
 - o Biosecurity Sensitive and Dual Use Biological Agents
 - \circ $\;$ Any other matters involving Biosafety and Biosecurity that the University requests the IBC to consider
- 2.1.2 Assess, review and approve "dealings" at the University in light of the intrinsic nature of the materials and the experiments, the competence of the personnel and the security of the facilities.
- 2.1.3 Prescribe conditions under which a "dealing" may proceed, or to forbid it altogether unless (or until) the IBC is satisfied that the work should begin.
- 2.1.4 Monitor and audit existing projects and review Annual and Final Reports.
- 2.1.5 Provide consultation on novel biological technologies, and where appropriate, assess and/or review and/or approve new and novel research activities that utilise such technologies.
- 2.1.6 Approve the process required to ensure persons dealing with agents of biosafety and biosecurity concern are adequately trained and that a record of trained personnel is maintained by the University.
- 2.1.7 Deal with alleged non-compliance and grievances via Committee decisions, including referral to the University and the associated external regulatory agencies, as required.
- 2.1.8 Review policy related procedures pertaining to biosafety and biosecurity. Minor procedure changes will be reviewed via an Executive Committee and tabled at the following meeting for noting. Major procedure changes or new procedures will be reviewed and ratified by the whole Committee, either within scheduled meetings or out-of-session.
- 2.1.9 Examine reports and information relating to biosafety and biosecurity ramifications including risk analyses and environment and safety audits.
- 2.1.10 Review incidents and recommend control measures to substantially reduce the number and severity of these incidents. All decisions will be based on current Government regulations provided by the Office of the Gene Technology Regulator (OGTR) and Work Health and Safety Regulations, as well as applicable Australian Standards, including AS/NZS 2343.3.
- 2.1.11 Assist in evaluating proposed changes in the work environment or in work practices, which may have implications on biosafety and biosecurity.
- 2.1.12 Approve the process of internal certification and inspection of areas where biological agents are used, handled or stored including research facilities, teaching laboratories, quarantine facilities, animal facilities, and clinical laboratories.
- 2.1.13 Approve the process of certification and inspection of containment facilities at the University certified by external agencies.
- 2.1.14 Report annually to the University using the Internal Annual Audit Form.
- 2.1.15 Provide advice on any relevant biosafety matters referred by the University.
- 2.1.16 Have a responsibility to report annually to external agencies, specifically the OGTR.

3 MEMBERSHIP OF THE COMMITTEE

3.1 VOTING MEMBERS

- 3.1.1 **Category A, External Member:** external members must not be employed by the University and must be assessed to be independent of the University.
- 3.1.2 **Category B, Biosafety Expert**: is a biosafety or occupational health and safety professional who is an expert in biosafety practices and legislative and regulatory compliance.
- 3.1.3 **Category C, Biocontainment Facilities Expert:** is an engineer (or equivalent) with expertise in testing biological safety facilities and equipment.
- 3.1.4 **Category D, Scientific Expert**: A Gene Technologist, Microbiologist, Virologist, and/or Animal Researcher with technical and scientific expertise who can assess the risks and hazards associated with "dealings".

3.2 NON-VOTING MEMBERS

- 3.2.1 **Category E, Non-voting Member**: The IBC may also consist of non-voting members whose skills are considered to enhance the capacity of the IBC to undertake its work.
- 3.2.2 From time to time it is necessary for the IBC to rely on the advice of an expert (i.e. not a voting member of the IBC) to address specific, short-term skills deficit in the IBC.
- 3.2.3 The committee may require representatives of stakeholders to participate in meetings.
- 3.2.4 These non-voting members are co-opted at the discretion of the Committee.

3.3 CHAIR & DEPUTY CHAIR

- 3.3.1 The chair and deputy chair must be; a voting member, appointed by the Deputy Vice Chancellor, Research (DVC-R), employed by the University, and a staff member within the organisation who possesses the skills to manage the business of the Committee, including the ability to resolve conflicts.
- 3.3.2 The deputy chair shall be appointed by the DVC-R to receive delegation of all chair duties in the absence of the chair.

3.4 QUORUM FOR MEETINGS

- 3.4.1 The Committee must have a quorum in attendance to conduct meetings.
- 3.4.2 Unless a quorum is in attendance the Committee may discuss proposals, but must not approve or reject proposals.
- 3.4.3 For a meeting to be quorum, it must contain at least one representative from Category A, B or C, and two Category D members.
- 3.4.4 If the quorum does not contain the collective technical and scientific expertise to assess the projects, the Committee may invite additional non-voting experts to report to the Committee.
- 3.4.5 Attendance of quorate meetings may be facilitated by video-linking, teleconferencing or other remote linking technology of some members in circumstances where face-to-face attendance is not possible. Such remote members may authorise the Chair to record their support of any proposals or other decision outcomes.
- 3.4.6 Any duly convened meeting at which a quorum is in attendance shall be competent to consider and resolve any business of the Committee and shall have and may exercise all the functions of the Committee.
- 3.4.7 Meeting by circulation may be conducted if deemed necessary and appropriate by the Chair.

3.5 EXECUTIVE COMMITTEE

- 3.5.1 The Committee may establish an Executive Committee at any time from the available members which must include the Chair and at least one other voting member.
- 3.5.2 The Executive Committee may consider 'out of session' business as detailed in 5.2.

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3.6 MEMBERSHIP REQUIRED FOR CERTIFICATION & INSPECTION OF FACILITIES

- 3.6.1 Certification of facilities must be approved by the Committee.
- 3.6.2 Inspections must be approved and ratified by the Committee and signed off by two voting members.
- 3.6.3 The Committee may delegate the authority to inspect labs on behalf of the IBC, to individuals with the appropriate expertise.

3.7 VARYING AND REPLACING MEMBERS

- 3.7.1 The Committee may recommend to the University that membership be amended.
- 3.7.2 In the event of a member being obliged or electing to retire or resign during the term of the Committee, the University will seek nominations for a replacement member.
- 3.7.3 Details of the eligibility of the nominated member should be determined by the University, such as the DVC-R.

3.8 TERM OF OFFICE FOR MEMBERS

- 3.8.1 All appointments to the Committee shall be for a period of three years. There is no restriction on the number of three year terms a member can be appointed.
- 3.8.2 Members will be advised in writing of their appointment to the Committee and its conditions.
- 3.8.3 The University will extend to external members of the Committee the provision of an honorarium to be set and managed through the VU Research Services office.
- 3.8.4 Any individual's membership of the Committee may be withdrawn by the University at any time during the proposed period of appointment. Such a decision will be advised in writing by the DVC-R. Membership may also be withdrawn in the instances where members are unable to attend two consecutive meetings and do not provide justification to the Committee for their non-attendance.
- 3.8.5 Not less than three months prior to the expiry of the term of appointment of the Committee, and subject to the continuance of the Committee, the Committee shall call for nominations for the next term of appointment. With the objective of continuance of effective committee functioning, a staggered re-appointment of the Committee members will be attempted.

4 APPOINTMENT OF THE COMMITTEE

4.1 APPOINTMENT OF MEMBERS

- 4.1.1 The University shall call for volunteers.
- 4.1.2 Endorsement will be obtained by the relevant College Dean, Director of Research and DVC-R.
- 4.1.3 Appointment will be made by the DVC-R in writing.

4.2 APPOINTMENT OF THE CHAIRPERSON

- 4.2.1 The DVC-R will appoint a Chair:
 - who possesses the relevant attributes to bring impartiality to the matters submitted to the Committee for consideration;
 - with skills to manage the business of an IBC including communicating, negotiating and resolving conflicts; and
 - with an understanding of the relevant biosafety, biosecurity, ethical and animal welfare issues.

4.3 APPOINTMENT OF EXECUTIVE OFFICER / SECRETARY

4.3.1 Research Services shall provide an Executive Officer/Secretary to provide support services to the Committee. The Executive Officer will be the first point of contact for investigators wishing to make contact with the Committee.

5 MEETINGS

5.1 CONDUCT OF MEETINGS

- 5.1.1 Meetings shall be conducted in accordance with the operating procedures established by Research Services. Proposals must be assessed in accordance with the guidelines published by the relevant regulators.
- 5.1.2 General meetings: Meetings will be held at dates and times to be determined by the Committee with the aim to meet at least four times per year to facilitate regular consideration of Committee matters. The submission dates for items that need to be reviewed by the committee will be set at regular intervals at the end of each calendar year for the ensuing 12 months.
- 5.1.3 Special Meetings: If circumstances or the nature of business is urgent or extraordinary, the Chair may call additional meetings provided that at least 14 days' notice is given to Committee members.
- 5.1.4 Agenda items must be notified to the Secretary at least four weeks before the agenda close date.

5.2 OUT OF SESSION APPROVALS BY THE EXECUTIVE COMMITTEE

- 5.2.1 The Executive Committee may only:
 - approve amendments to projects which have been granted conditional approval by the Committee;
 - approve activities that have been deemed by the Committee to be Minor Amendments/Low Risk and can be ratified by the Executive Committee;
 - initiate urgent action required in response to reports of incidents, adverse events or emergencies; and,
 - approve minor amendments to Biosafety Procedures.

6 REVISION OF TERMS OF REFERENCE

6.1 REVIEW

6.1.1 The Terms of Reference will be reviewed every three years or as necessary in response to changes in legislation, University policy or concerns expressed by members of the Committee.

6.2 CHANGES AND AMENDMENTS

6.2.1 Changes and amendments to the Terms of Reference will require the endorsement of the IBC and approval of the University.

Document Hie	erarchy link	Biosafety Manager, IBC, Research Services, DVC-			
	-	Research, Research & Research Training Committee,			
		Vice Chancellor			
Responsible	Officer	Director of Research	Director of Research		
Contact Offic	cer	Biosafety Manager	Biosafety Manager		
Administrativ	ve Officer	IBC Executive Officer	IBC Executive Officer		
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