



**ST VINCENT'S  
HOSPITAL**  
MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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**St Vincent's Hospital (Melbourne)  
Institutional Biosafety Committee (IBC)**

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**TERMS OF REFERENCE**

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**Introduction**

The Institutional Biosafety Committee (IBC) is a committee of St Vincent's Hospital (Melbourne). The Committee is constituted in line with the requirements of the Gene Technology Act 2000, the Gene Technology Regulations 2001 and Australia New Zealand Standards Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, AS/NZS 2243.3.

The IBC is responsible for the review, approval and ongoing monitoring of all research involving Genetically Modified Organisms (GMOs) at St Vincent's Hospital, which is an organisation accredited by the Office of the Gene Technology Regulator (OGTR), and at other OGTR-accredited organisations on the St Vincent's campus which use the St Vincent's Hospital IBC. These organisations include St Vincent's Institute, Bionics Institute, Centre for Eye Research Australia, The University of Melbourne at St Vincent's Hospital, and any other institutions as required.

**Purpose**

The IBC is responsible for ensuring that the use of GMOs and other non-GMO biological hazards is conducted in compliance with the standards outlined by the *Gene Technology Act 2000*, the *Gene Technology Regulations 2001*, and the *Australia New Zealand Standards Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, AS/NZS 2243.3*

**Function**

The IBC is constituted to ensure compliance with the Gene Technology Act 2000, the Gene Technology Regulations 2001, and the Australia New Zealand Standards Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, AS/NZS 2243.3, by:

- Reviewing all dealings involving the use of GMOs, as outlined in the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001* and any other related legislation or regulations. This review must include a consideration of the actual and potential risks involved in the dealing/s, the qualifications and training of research personnel, and the security/compliance of the facilities in which the work will be undertaken.
- Reviewing all dealings involving the use of agents classified as Risk Group 2 and above (as defined in the *Australia New Zealand Standards Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities, AS/NZS 2243.3*), regardless of GMO status.

- Reviewing all applications involving the use of other non-GMO agents which may present potential biological risk, with the exception of radioactive substances. For radioactive substances refer to Department of Medical Engineering & Physics 'Radiation Safety & Management Manual' 7th Edition 2015.
- Making recommendations to the applicable Accredited Organisations for the final approval of projects reviewed by the IBC.
- Monitoring compliance with the *Gene Technology Act 2000* and *Gene Technology Regulations 2001* by requesting submission of annual progress reports for approved dealings, during periodic IBC protocol audits.
- Reviewing the certification of all facilities which require physical containment status and ensuring OGTR approval is obtained and maintained.
- Ensuring adequate training specific to the *Gene Technology Act 2000* and *Gene Technology Regulations 2001* is provided to all persons undertaking work in a certified facility.
- Ensuring each certified facility is inspected at least annually to ensure compliance with statutory requirements. Inspections of certified facilities shall be undertaken in accordance with *The OGTR Guidelines for the Certification of Facilities/ Physical Containment Requirements*.
- Maintaining a register of all certified facilities, and all dealings involving GMOs and other agents classified as Risk Group 2 and above.
- Ensuring that all researchers maintain adequate records involving GMOs and agents classified as Risk Group 2 and above.

### **Membership**

IBC members must be formally appointed by the Chief Executive Officer, and informed of their appointment in writing. Members are appointed for a period of three years, with the opportunity to extend appointment for subsequent terms as applicable. The IBC may co-opt persons who are not members of the IBC in the event additional expertise is required.

In accordance with the OGTR conditions of accreditation, the IBC must maintain a minimum membership of at least four persons, with at least one member in each of the following categories:

Independent Member: At least one person who does not have any business or other relationship with St Vincent's Hospital (Melbourne) and is not an employee or associate.

Scientific/Technical Expertise: At least two members with appropriate scientific and/or technical expertise to ensure a rigorous review of all applications. This may include those with experience in biological safety, microbiology, molecular biology and/or genetics.

Chair: A person who holds a senior position and possesses the skills to manage the business of the IBC including the ability to resolve conflict. A Deputy Chair may also be appointed from the existing membership. The Deputy Chair shall receive a formal delegation of authority to assume duties of the Chair in their absence, as required.

The IBC membership may also include non-voting members whose skills enhance the capacity of the IBC to undertake its work, such as an expert in Occupational Health and Safety.

#### **Meetings**

The frequency of meetings should be sufficient to allow for effective functioning of the IBC. The St Vincent's Hospital (Melbourne) IBC shall meet at least once per calendar year with meetings scheduled on a quarterly basis.

The IBC may also meet (in person or via electronic means) on an ad hoc basis to consider applications as required, but must ensure the minimum membership is present. In accordance with the OGTR conditions of accreditation, the IBC must ensure membership includes at least four persons, including a Chair, two people with scientific/technical expertise and at least one independent member.

All IBC members must declare all potential, perceived and /or an actual conflict of interest. Members with a declared conflict may answer questions relating to the research project but must leave the room during the decision process.

The IBC must complete a formal record of assessment for all applications, of which a copy must be provided to the applicant and retained on file.

#### **Reporting**

IBC activities must be reported to the OGTR on an annual basis.

#### **Indemnification**

Members of the IBC are indemnified by the Professional Indemnity Insurance Policies held by St Vincent's Hospital (Melbourne), in respect of liabilities that may arise in the course of the conduct of IBC member's duties.

#### **Administrative Management**

The Research Governance Unit will be responsible for the administrative management of the IBC, including the collation and distribution of applications to Committee members, taking the minutes of all IBC meetings, writing correspondence on behalf of the IBC, managing ongoing documentation and records, and develop and maintain administrative Standard Operating Procedures, Institutional Policies and Procedures, and any other administrative function required by the IBC and/or Institution.

Approved by:



Dr Megan Robertson  
Director of Research  
St Vincent's Hospital (Melbourne)