University Biosafety Committee Constitution

Committee established by Research Committee: Meeting SEP 2012 (Minutes 05/2012)

Previous version of constitution approved by Research Committee: Meeting 05/2022 (7 June 2022) (2022/0000504)

Current version of constitution approved by Research Committee: Meeting 06/2024 (8 October 2024) (2024/0001133)

1. Introduction

1.1. **Research Committee** has established the University Biosafety Committee (**Committee**) to provide Griffith University advice on policies, procedures and compliance related to Genetically Modified Organisms (GMOs), Security Sensitive Biological Agents (SSBAs), materials regulated by biosecurity legislation (approved arrangements, biosecurity material), and other high risk biological materials (Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the Schedule of High Risk Biological Materials Monitored by the University Biosafety Committee).

The Committee performs the functions of an Institutional Biosafety Committee (IBC) as outlined in the Office of the Gene Technology Regulator's (OGTR) Guidelines for Accreditation of Organisations (August 2012), and in accordance with the Gene Technology Act 2000 (Cth), Gene Technology Regulations 2001 (Cth), Gene Technology Act 2016 (QLD), and performs, if required, the functions of a Management Committee as outlined in the Security Sensitive Biological Agent (SSBA) Standards (March 2013), and in accordance with the Biosecurity Act 2015 (Cth), National Health Security Act 2007 (Cth), National Health Security Regulations 2018 (Cth), and the SSBA Guidelines (August 2014). The Committee also assists and advises individuals within Griffith University regarding compliance with the Queensland Biotechnology Code of Ethics, the Australian Code for the Responsible Conduct of Research (2018), and the Griffith University Responsible Conduct of Research Policy as they relate to research with such biological materials.

According to the legislative requirements mentioned above, the Committee oversees the certified facilities at Griffith University through the Biosafety/Biosecurity specialists. These specialists act on behalf of the Committee to plan and conduct annual inspections for all facilities regulated under the *Gene Technology Act 2000* (Cth) and the *Biosecurity Act 2015* (Cth). During each committee meeting, the outcomes of annual inspections of certified (e.g. OGTR and Approved Arrangement Biosecurity) and non-certified physical containment facilities are reviewed.

2. Interpretation

2.1. In this constitution, references to academic elements and academic management positions shall be as defined in the *Griffith University Governance Framework*.

2.2. Any reference to "the Committee" means the University Biosafety Committee.

2.3. Any reference to "the Regulator" means the Gene Technology Regulator (OGTR).

2.4. Any reference to "The Department" means the Department of Agriculture, Fisheries and Forestry (DAFF).

2.5. Any reference to "the SSBA Regulator" means the Department of Health and Aged Care.

2.6. Any reference to "the Schedule" means the Schedule of High Risk Biological Materials Monitored by the University Biosafety Committee.

2.7. The terms “Risk Group 3” and “Risk Group 4” microorganisms are as defined in the Australian/New Zealand Standard 2243.3:2022 Safety in laboratories - Microbiological safety and containment.

2.8. The terms “Tier 1” and “Tier 2” agents are as defined by the List of Security Sensitive Biological Agents, published on the Department of Health website.

2.9. The term “GMO” is as defined by the Regulator.

3. Mandate

3.1. The Committee is a standing committee established by Research Committee and reports directly to and is accountable to Research Committee.

3.2. Committee contributes to risk and governance oversight and supports the Academic Committee and University in meeting the requirements of the following Domains and Standards within the *Higher Education Standards Framework (Threshold Standards) 2021* (HESF 2021):

(a) Domain 4: Research and Research Training

- Standard 4.1 – Research
- Standard 4.2 – Research Training

(b) Domain 5: Institutional Quality Assurance

- Standard 5.1 – Course Approval and Accreditation
- Standard 5.2 – Academic and Research Integrity
- Standard 5.3 – Monitoring, Review and Improvement
- Standard 5.4 – Delivery with Other Parties

(c) Domain 6: Governance and Accountability

- Standard 6.3 – Academic Governance

4. Functions

4.1. The Committee will:

(i) contribute to the development of Griffith University policies and procedures related to GMOs, SSBAs, materials regulated by biosecurity legislation, and other biological materials by;

(a) performing the functions of an Institutional Biosafety Committee (IBC) as outlined in the Office of the Gene Technology Regulator’s *Guidelines for Accreditation of Organisations (2012)*, and in accordance with the *Gene Technology Act 2000* (Cth), *Gene Technology Regulations 2001* (Cth), *Gene Technology Act 2016 (QLD)*, including: assisting Griffith University staff and students to correctly identify dealings with a GMO, and conditions applicable to those dealings;

(b) considering proposals prepared by Griffith University staff and students for exempt dealings with GMOs, notifiable low risk dealings (NLRDs) and dealings with GMOs requiring licences, in accordance with the legislation (proposals relating to NLRDs and exempt dealings will normally be assessed between meetings by a technical review panel composed of a sub-set of the UBC membership with the necessary collective scientific and technical expertise to appropriately assess the dealing – recommendations will be considered for approval at the next meeting of the Committee);

(c) providing advice to the Regulator on Griffith University applications for licences;

(d) providing advice to Griffith University with regards to compliance for NLRDs and with licence conditions, training requirements, and reportable events;

(e) inspecting Griffith University’s containment facilities, against the Regulator’s requirements

for containment, at least once per year;

(f) inspecting new Griffith University physical containment facilities for which certification from the Regulator is sought;

(g) maintaining records and providing an annual report on dealings with GMOs, including the Committee's assessment of NLRD proposals, and facility inspections, in accordance with the legislation, to Research Committee via the Deputy Vice Chancellor (Research); and

(h) performing the functions of an IBC (as outlined in the Office of the Gene Technology Regulator's *Guidelines for Accreditation of Organisations (August 2012)*, and in accordance with the *Gene Technology Act 2000* (Cth), *Gene Technology Regulations 2001* (Cth), *Gene Technology Act 2016 (QLD)* for other institutions on a commercial basis from time to time, if appropriate (and subject to compliance with the *Consultancy and Commercial Research Policy*);

(ii) perform, if required, the functions of a Management Committee as outlined in the *Security Sensitive Biological Agent (SSBA) Standards (March 2013)*, and in accordance with the *National Health Security Act 2007* (Cth), *National Health Security Regulations 2018* (Cth), and the *SSBA Guidelines (August 2014)*, including:

(a) reviewing and approving, where appropriate, protocols and risk assessments for work involving SSBAs;

(b) reviewing information relating to significant incidents, non-compliance, data trends, associated local/entity actions and associated communication needs;

(c) ensuring biosecurity issues are formally recorded; actions allocated, tracked and closed out effectively; and internal inspection reports are reviewed;

(d) advising Griffith University staff and students on reportable events under the *National Health Security Act 2007* (Cth) and *National Health Security Regulations 2018* (Cth);

(e) reviewing, at least annually for Tier 2 agents and at least six-monthly for Tier 1 agents, all SSBA-related activities, in accordance with *SSBA Guidelines*; and

(f) advising Griffith University on the authorisation of persons to handle SSBAs, access the facilities where SSBAs are handled, or access sensitive information related to SSBAs unescorted or unsupervised; and on the approval of persons who need to handle SSBAs, access the facilities where SSBAs are handled, and/or access sensitive information related to SSBAs either under escort or under supervision;

(iii) monitor and advise Griffith University on matters regulated by biosecurity legislation, including:

(a) reviewing applications for import permits including but not limited to related to Approved Arrangements and applications for facility certifications (applications will normally be assessed between meetings by a technical review panel composed of a sub-set of the UBC membership – recommendations will be ratified by the Chair of the UBC as required, and noted at the next meeting of the Committee);

(b) advising on compliance with regulatory requirements;

(c) undertaking internal audits of regulated practices, as appropriate;

(d) monitoring the outcomes of external audits; and

(e) maintaining records related to compliance requirements;

(iv) monitor and advise Griffith University on activities using biological materials (such as Risk Group 3 and Risk Group 4 microorganisms, as defined in the *Australian/New Zealand Standard 2243.3:2022 Safety in laboratories, Part 3:- Microbiological safety and containment,* prions, and any additional biological materials listed in the *Schedule of High Risk Biological Materials Monitored by the University Biosafety Committee*), including:

(a) reviewing and approving, where appropriate, internal project applications for activities using Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the *Schedule*;

(b) advising on compliance with the requirements set out for physical containment facilities used for activities involving Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the *Schedule*;

(c) undertaking audits of physical containment facilities used for activities involving Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the *Schedule*, as appropriate;

(d) reviewing information relating to significant incidents resulting from activities using high risk biological materials (Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the *Schedule);*

(e)

(v) maintain a record of proposals and projects considered by the Committee;

(vi) advise Griffith University on reported potential breaches in compliance with legislation and regulations related to GMOs, SSBAs, materials regulated by biosecurity legislation, and other biological materials (such as Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the *Schedule*), and, if appropriate, order a temporary cessation of related activities while investigating the potential breach;

(vii) monitor and advise Griffith University on any commercialisation agreements related to GMOs in collaboration with the Griffith University Office for Research, SSBAs, materials regulated by biosecurity legislation, and other biological materials (such as Risk Group 3 and Risk Group 4 microorganisms, prions, and any additional biological materials listed in the *Schedule*); and

(viii) assist in the preparation of compliance and other reports to external agencies.

5. Authority

5.1. As provided for in the Academic Committee Constitution, the Council has delegated certain of its powers to the Committee in accordance with section 11(1)(b) of the *Griffith University Act 1988* (Qld).

5.2. The Committee may exercise such powers as the Council may delegate to the Committee from time to time, as set out in the University's register of delegations.

5.3. The Council authorises the Committee to perform its role as established within the scope of this constitution. In discharging its responsibilities, the Committee shall:

(a) review and approve Exempt Dealing (ED) Applications;

(b) review and approve Notifiable Low Risk Dealings (NLRDs);

(c) review and approve Dealings Not involving Intentional Release (DNIRs) submissions to the regulator, and review approvals of DNIR applications by the regulator;

(d) approve facility management processes through OGTR mechanisms;

(e) provide advice to the University for Biosafety matters and Biosecurity.

6. Committee Composition

6.1. The Committee is composed of 13 categories of members:

i. The Deputy Vice Chancellor (Research) or nominee as Chair, *ex officio*;

ii. Three academic representatives from the Griffith Sciences Academic Group with appropriate expertise, nominated by the Griffith Sciences Group PVC and approved by the Deputy Vice Chancellor (Research);

iii. One representative from Griffith Sciences – Technical Services, nominated by the Griffith Sciences Group PVC and approved by the Deputy Vice Chancellor (Research);

iv. Three academic representatives from the Health Academic Group with appropriate expertise, nominated by the Health Group PVC and approved by the Deputy Vice Chancellor (Research);

v. One representative from Griffith Health – Technical Services, nominated by the Health Group PVC and approved by the Deputy Vice Chancellor (Research);

vi. One representative from the IBG GC or IBG NA, nominated by the Director and approved by the 'Deputy Vice Chancellor (Research)' (DVCR);

vii. The Biosafety Resources Facility Manager, *ex officio;*

viii. The High Containment Facility Manager, *ex officio;*

ix. The Associate Director, Health and Safety Standards and Assurance, *ex officio;*

x. The Safety Specialist (Biosafety/Biosecurity), *ex officio;*

xi. One representative from Campus Life who has appropriate engineering expertise, nominated by the Director, Campus Life and approved by the Deputy Vice Chancellor (Research);

xii. At least one, but preferably two or three, external independent persons with appropriate expertise, specifically for IBC-related functions, as outlined in the legislation. External members will be appointed by Research Committee but can be nominated by any interested persons;

xiii. Griffith University's Responsible Officer and Deputy Responsible Officer for each facility registered with the Commonwealth Department of Health, in accordance with the SSBA Regulatory Scheme.

6.2. The Committee shall appoint one or more Deputy Chair(s) at the first meeting of each year.

6.3. The Committee chairperson is appointed by DVCR.

6.4. The quorum of the Committee shall be the whole number next above one-half of those persons who are Committee members.

6.5. When the Committee is undertaking the functions of the IBC, in accordance with the *Gene Technology Act 2000* (Cth), *Gene Technology Regulations 2001* (Cth), *Gene Technology Act 2016 (QLD)*, and the Office of the Gene Technology Regulator's *Guidelines for Accreditation of Organisations (2012),* an external member must be present and the members present must collectively possess the scientific and technical expertise required to assess and advise on the dealings being considered.

6.6. When the Committee is undertaking the functions of the Management Committee, in accordance with the *Security Sensitive Biological Agent (SSBA) Standards (March 2013)*, the *National Health Security Act 2007* (Cth), *National Health Security Regulations 2018* (Cth), and the *SSBA Guidelines (August 2014),* the relevant Responsible Officer or Deputy Responsible Officer must be present.

6.7. Members are required to identify any conflict of interest, including family or other personal relationship/s as outlined in the University policies on Conflict of Interest and Personal Relationships in the Workplace, which may exist in respect of any of the items on the agenda. When an interest has been declared, the Chair may resolve that the member:

i. Leaves the meeting while the item of business is discussed; or

ii. Participates in the discussion but withdraw from the meeting before the vote and/or decision; or

iii. stays but does not participate in either the debate or vote/decision; or

iv. stays with full debating and voting/decision rights.

6.8. All declarations of interest will be recorded in the minutes, together with any ensuing action.

7. Term of Appointment

7.1 The term of office of members is for a period of two years up to 31 December of the relevant anniversary year. To ensure continuity of the membership, and where practicable, the terms of the office of members shall be set to stagger the expiry of terms at any one time.

7.2 Additionally, The Committee may invite the attendance and participation at its meetings of such persons who, by reason of their special expertise or experience, can assist the Committee's deliberations on any particular matter or matters. However, before inviting such persons, the Committee will balance the need for expertise versus the need to keep the details of SSBA information restricted to those who have a need to know, as outlined in the *Security Sensitive Biological Agent (SSBA) Standards*.

8. Rights of Audience and Debate

8.1 The following persons shall have rights of audience and debate:

(a) Deputy Director, Research Strategy, Systems Policy, Office for Research or nominee;

(b) Director, Griffith Enterprise or nominee

(c) Secretary to the Committee

9. Operating Principles and Procedures

9.1 The Committee will operate and meetings will be conducted in accordance with the Council Committees Procedure (*Standing Orders*) except where the constitution states otherwise.

10. Obtaining Advice

10.1 The Committee will have the power to seek advice from any member of the University community or external expert where particular expertise or insights are required and to direct enquiries to any element of the University.

11. Secretariat Services

11.1 The Director, Office for Research is responsible for appointing the Secretary to the Committee, who has rights of audience.

12. Meetings

12.1 The Committee will meet as required and normally four times per year- in February, May, August, and November.

13. Reporting

13.1 The Committee will report its activities to the Research Committee after each meeting of the Committee. This report may be oral or in writing.

13.2 The Committee will provide an annual report to the Research Committee.

14. Sub-Committees

14.1 There are no sub-committees currently reporting to the Committee.

15. Evaluation of Performance

15.1 The Committee will evaluate its own performance annually under the coordination of the Chair, University Biosafety Committee. Training needs will be monitored by the Chair.

16. Review of Constitution

16.1 The Committee will review this constitution annually. Any proposed changes to the constitution will be recommended by the Committee to the Research Committee for approval.