McMaster University

Risk Management Manual Program

Complete Program Title: **Presidential Biosafety Advisory Committee Terms of Reference**	Risk Management Manual (RMM) Number: **106**
Approved by: **Vice-President, Research and International Affairs** **President and Vice-Chancellor**	Date of Most Recent Approval: **March 2014**
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1 PURPOSE

1.1 The Presidential Biosafety Advisory Committee (hereafter referred to as the Committee) is a *University review board and subject matter expert committee*. It is constituted by the President and is responsible to the President with a support, reporting and oversight structure through the Office of the Vice President, Research and International Affairs. The President has delegated responsibilities to the Committee for matters relating to the use of infectious materials, organisms, and toxins affecting humans, terrestrial animals, aquatic animals, and plants which may be used in work, research, and teaching by University stakeholders.

1.2 The purpose of the Committee is to provide biosafety and biosecurity advice to the President based on a group review of matters pertaining to the controlled activities with respect to infectious materials, organisms, and toxins. By doing so, the Committee serves both the University and its stakeholders by providing advice on how to best meet all legal, moral, and ethical responsibilities with respect to the use of infectious materials, organisms, and toxins.

2 SCOPE

2.1 The Committee reviews and provides advice to the President on all matters pertaining to biosafety and biosecurity associated with the University.

3 Related Documents

3.1 Human Pathogens and Toxins Act (S.C. 2009, c. 24). (2009)

3.2 Human Pathogen Importation Regulations (SOR/94-558). (1994)

3.3 Canadian Biosafety Standards and Guidelines, 1st Edition (2013)

3.4 Health of Animals Act (S.C. 1990, c. 21). (2007)

3.5 Health of Animals Regulations (C.R.C., c. 296). (2011)

3.6 Reportable Diseases Regulations (SOR/91-2) (1990)

3.7 Plant Protection Act. (1990)

3.8 Containment Standards for Facilities Handling Aquatic Animal Pathogens (2010)

3.9 Containment Standard for Facilities Handling Plant Pests (2007)

3.10 Agreement on the Administration of Agency Grant and Awards by Research Institutions

3.11 McMaster University Research Integrity Policy

3.12 McMaster University RMM #600 – Biosafety Program

3.13 McMaster University RMM #600, Appendix C – Use of BSL 3 Biocontainment Facility

3.14 McMaster University RMM #601 – Hepatitis B Policy

3.15 McMaster University RMM #602 – Rabies Policy

3.16 McMaster University RMM #603 – Medical Monitoring of Personnel Working with Biological Agents

3.17 McMaster University RMM #604 – Adenovirus Biocontainment Downgrade Criteria Policy

4 DEFINITIONS

4.1 **controlled activities** – possessing, handling or using; producing; storing; permitting any person access to; transferring; importing or exporting; releasing or otherwise abandoning; disposing

4.2 **non-compliance** – where any requirement derived from legislation, external policy or institutional policy is not met

4.3 **President** – President and Vice Chancellor

4.4 **quorum** – the minimum number of voting members who must be present at a meeting in order to conduct business in the name of the Committee

4.5 **reporting channel** – the route whereby the Committee Chair reports to the Associate Vice President, Research who then reports through the Vice President, Research and International Affairs to the President.

4.6 **stakeholders** – McMaster University faculty, employees and students

4.7 **the University** – the legal entity represented by the President; the employer

4.8 **toxins** – poisonous substances that are produced or derived from a microorganism and can lead to adverse health effects in humans, animals or plants

4.9 **Acronyms:**

AREB – Animal Research Ethics Board

CJHSC – Central Joint Health and Safety Committee

EOHSS – Environmental & Occupational Health Support Services

FHS – Faculty of Health Science

HIREB – Hamilton Integrated Research Ethics Board

HR – Human Resources

PBAC – Presidential Biosafety Advisory Committee

RMM – Risk Management Manual

5 RESPONSIBILITIES

5.1 Office of the President

The President shall:

- Monitor the effectiveness of the Committee in executing its delegated authority and responsibilities.
- Appoint members to the Committee.

5.2 Office of the Vice President, Research & International Affairs

The Vice President, Research & International Affairs shall:

- Provide the direction and resources necessary to support the activities of the Committee.
- Shall appoint an Associate Vice President, Research to liaise with the Committee.

5.3 Office of the Associate Deans (Research)

The Associate Deans of Research shall:

- Support the dissemination of biosafety and biosecurity information on a Faculty-wide scale to ensure all stakeholders in their area have access to education and resources appropriate for working safely and in compliance.
- Select candidates for the voting membership from the stakeholder group in their Faculty for appointment by the President.

5.4 The Committee

The Committee shall:

- Support a culture of biosafety and biosecurity awareness and a level of compliance that meets or exceeds all relevant standards without bringing undue pressure to bear on researchers.
- Discuss and formally recommend to the President through the reporting channel, creation of new policies or changes in existing policies which support the responsible management of biosafety and biosecurity.
- Support the dissemination of biosafety and biosecurity information on a University-wide scale to ensure all stakeholders have access to education and resources appropriate for working safely and in compliance.
- Review audit reports as provided by the Biosafety Auditor for the purposes of measuring compliance of stakeholders with respect to levels of containment and established biosafety and biosecurity policies and procedures.
- Facilitate compliance of stakeholders where warranted as a result of audit deficiencies.
- Review incident/injury reports which involve infectious materials, organisms and toxins in order to evaluate the quality, completeness and relevancy of the report, the follow-up and the proposed corrective measures, respectively. As per RMM#1000, upon review, to recommend corrective measures to management and/or to accept the supervisor's corrective measures.
- Review new and existing academic research, clinical research, commercially funded research and teaching projects which describe controlled activities involving infectious materials, organisms and toxins for the purpose of prescribing an appropriate containment level and associated training based on a local risk assessment. Such review shall be in the context of those documents listed in Section 3 and any other relevant Canadian legislation or standard or institutional policy. Such research and projects are deemed to be "approved" when all requirements derived from legislation; external policy and institutional policy have been met for working at the prescribed containment level.
- Through the reporting channel and the Committee Chair, suspend any controlled activities being carried out by any stakeholder, based on evidence of a situation

or action which may put any person immediately at risk of exposure or other harm to their person or wellbeing.

- Withdraw of approval based on 90 days of continual, documented non-compliance per section 8.1 - “Monitoring Non-Compliance” and report such withdrawal through the reporting channel.
- Cooperate with other University administrative committees and offices (including but not limited to AREB, HIREB and funding offices) as required while maintaining the purpose of the Committee.
- Through the Committee Chair, notify the President immediately of any serious or potentially serious issues of biosafety or biosecurity.
- Review, discuss, provide feedback and where warranted to recommend corrective measures as per RMM#606 – Use of Level 3 Containment Zones.
- Participate in risk assessments.
- Adjust committee membership to reflect change of use or nature of infectious materials, organisms and toxins.
- Maintain transparency in policy, procedure and in process to ensure complete, fair and accurate application.
- Through the Committee Chair, seek consultation with listed External Advisors or other appropriate authorities on subject matters which fall outside the expertise of the Committee, the scope of biosafety-relevant legislation or approved policies.
- Make the following decisions or perform the following functions:
    - Deem whether a project proposal matches the requested containment level based on a local risk assessment or prescribe a containment level if the project proposal does not match the requested containment level based on a local risk assessment.
    - Create relevant and reasonable local operational procedures or engineering controls based on a local risk assessment if legislated containment levels do not mitigate the risk or risks associated with the project proposal.
    - Deem whether a local risk assessment is reasonable and perform that local risk assessment. “Reasonable” in the respect that if a local risk assessment was not done, it is likely that the Committee, and by extension the University, could be considered negligent.
    - Deem whether a local audit is reasonable and perform that local audit. “Reasonable” in the respect that if a local audit was not done, it is likely that the Committee, and by extension the University, could be considered negligent.

- Deem whether an action or situation is in non-compliance with the assigned or prescribed containment level.

- Provide a transparent appeals process which provides arm's length recourse on behalf of the appellant. See section 8.2 – "Appeals Process".
- Review RMM #106 – Presidential Biosafety Advisory Committee Terms of Reference on a regular basis.

5.5 **Role of Central Joint Health and Safety Committee:**

The CJHSC shall:

- Receive minutes of meetings held by the Committee for informational purposes.

5.6 **Role of Environmental and Occupational Health Support Services and Faculty of Health Sciences Safety Office:**

EOHSS/FHS Safety Office shall:

- Provide the Committee with incident reports which involve infectious materials, organisms or toxins.

5.7 **Role of McMaster Biosafety Office:**

The Biosafety Office shall:

- Provide the administrative resources which support organization and documentation of Committee meetings.
- Facilitate processing of biohazard project applications through the Committee review process and assist stakeholders at all stages.
- Provide and present regular reports to the Board of Governors through the Vice President, Research and International Affairs on Committee activities and the Biosafety Programme.

6 ORGANIZATION

6.1 Chair

- Presides at all meetings and forward recommendations to the President through the reporting channel.
- Chair and set the agenda for Committee meetings.
- Cooperate with stakeholders on behalf the Committee where warranted.
- Cooperate with administrative offices on behalf of the Committee where warranted.
- Cooperate with the President or designate on behalf of the Committee where warranted.
- Disseminate biosafety and biosecurity-relevant information to the Committee.

6.2 Secretary

- Prepares notice of meetings and agenda and maintain minutes of all meetings.
- Prepares minutes following The Canadian Style as described by Public Works and Government Services Canada – Translation Bureau.
- Forwards copies of minutes to the Committee.

6.3 Term of Office

- 3 year appointment that has a renewable term.

6.4 Confidentiality

- All members of the Committee and guests in attendance will be asked to review and sign a confidentiality agreement.

6.5 Quorum

- A quorum shall be 50% + 1 of the voting membership.
- The Committee will endeavor to reach consensus on all topics. Formal votes will only be taken after motions are made.

6.6 Number of Meetings

- 10 meetings per year on the last Monday of the month.

6.7 Notice of Meeting and Agenda

- A notice of meeting and agenda shall be distributed at least seven (7) days in advance.
- Biohazard Utilization Protocols and any supporting or discussion documents shall be distributed at least (7) days in advance.

6.8 Membership

- Voting members
    - Expertise from the membership described below should include:
        - *an environmental expert/engineer*
        - *a cell culture expert*
        - *a virologist*
        - *a microbiologist*
        - *a biochemist*
        - *an undergraduate teaching representative*
    - Committee Chair
    - One Central Animal Facility representative
    - One faculty representative from the BSL3 facility
    - One worker representative from the BSL3 facility
    - One manager or coordinator representative from a Central Facility
    - Candidate voting-members who hold Faculty positions shall be chosen by the Associate Deans of Research for all faculties employing Faculty undertaking work, teaching or research involving infectious materials, organisms or toxins. Appointments will be made by the President.
- Non-voting members
    - Biosafety Manager
    - Biosafety Auditor
- External Advisors
    - Infectious Diseases Physician
    - University Veterinarian
    - Associate Director, Health, Safety and Risk Management, Human Resource Services
    - Health and Safety Specialist, Environmental & Occupational Health Support Services

7 RECORDS

7.1 Minutes

- Minutes of the meetings shall be maintained by the Biosafety Office as permanent records.
- Copies of minutes of meetings shall be distributed as follows:
    - Members of the Committee

- Associate Vice President, Research
- Associate Dean, Research, Faculty of Health Sciences
- Associate Dean, Research and External Affairs, Faculty of Science
- Associate Dean, Research and External Affairs, Faculty of Engineering

8 NON-COMPLIANCE AND APPEALS

8.1 Monitoring Non-Compliance

- All notifications shall be documented and retained by the Biosafety Office.
- Notification of non-compliance as a result of an audit or annual review of the stakeholder's Biohazard Utilization Protocol shall be forwarded to the stakeholder by the Biosafety Auditor, copied to the Biosafety Manager.
- At 30 days, if all issues of non-compliance are not resolved, a second notice shall be sent to the stakeholder by the Biosafety Manager, copied to the Committee Chair.
- At 60 days, if all issues of non-compliance are not resolved, a third notice shall be sent to the stakeholder by the Committee Chair, copied to the Departmental Chair and Associate Dean, Research.
- At 90 days, if all issues of non-compliance are not resolved, approval will be automatically withdrawn and such withdrawal shall be reported through the reporting channel to the President.
- At any point during this process, the stakeholder may solicit assistance from the Biosafety Office or the Committee or initiate the appeals process.

8.2 Appeals Process

- Any stakeholder may initiate the appeals process if they wish to appeal any Committee decision or action. This process includes the following steps:
- Contact the Biosafety Office to initiate the process. The Biosafety Office shall support administration and documentation of the process.
- The stakeholder is invited to the following Committee meeting to clarify any information or supply any information relevant to the decision. The decision will be re-reviewed and re-issued to the stakeholder.
- If objection to the revised decision is based on an institutional requirement, the process shall be forwarded to the Associate Vice President, Research and Associate Dean, Research to determine if such objection has merit.
    - If the objection is deemed to have merit, then Associate Vice President, Research and Associate Dean, Research shall determine the outcome and facilitate the revision of the institutional requirement.

- If the objection to the revised decision is based on a legislated requirement, the relevant government body shall be consulted by the Associate Vice President, Research and Associate Dean, Research to determine if such objection has merit.
    - If the objection has merit, then the governing body shall determine the outcome or give guidance to Associate Vice President, Research and Associate Dean, Research to determine the outcome. The interpretation of the legislated requirement shall be forwarded to the Committee by Associate Vice President, Research.
- If the stakeholder feels that resolution has not taken place with the Associate Vice President, Research and the Associate Dean, Research, the stakeholder and the Associate Dean, Research shall consult the Vice President, Research and International Affairs directly for resolution.