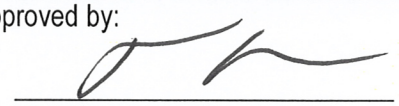
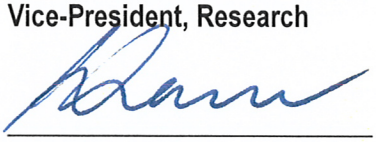
McMaster University

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**  **President and Vice-Chancellor**	Date of Most Recent Approval: **February 2017**
Date of Original Approval: **December 2008**	Supersedes/Amends Program dated: **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. 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, through the reporting channel, provides advice to the President on all matters pertaining to biosafety and biosecurity associated with the University.

2.2 The Committee has the authority to operate within the boundaries of this Terms of Reference.

2.3 The Committee has the authority to create procedures to support the legal requirements related to documents listed in section 3 without contravention to any other Canadian legal requirement or institutional policy.

2.4 The scope of Committee obligation or responsibility does not extend beyond legal requirements related to biosafety and biosecurity or reporting lines documented on the McMaster Organizational Chart.

3 RELATED DOCUMENTS

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

3.2 Human Pathogens and Toxins Regulations (2015)

3.3 Canadian Biosafety Standard, 2nd Edition (2015)

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. (S.C. 1990, c. 22). (1990)

3.8 Canadian Environmental Protection Act (S.C. 1999, c. 33). (1999)

3.9 New Substances Notification Regulations (Organisms) (SOR/2005-248). (2005)

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

3.11 Containment Standard for Facilities Handling Plant Pests (2007)

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

3.13 McMaster Organizational Chart (http://www.mcmaster.ca/vpadmin/OrgChart-Main.htm)

3.14 McMaster University Research Integrity Policy

3.15 McMaster University RMM #600 – Biosafety Program

3.16 McMaster University RMM #601 – Hepatitis B Policy

3.17 McMaster University RMM #602 – Rabies Policy

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

4 DEFINITIONS

4.1 **Biosafety Office** – the Biosafety Manager, the Research Compliance Auditor, the responsible person declared on the HPTA license and any other person declared on the HPTA license.

4.2 **compliance** - achievement of all requirements derived from any legislation, external policy or institutional policy or directive which is relevant to undertaking work, teaching and research involving infectious materials, organisms and toxins.

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

4.4 **external advisor** - any non-member deemed by the committee to be a subject matter expert with reference to the issue requiring consultation

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

4.6 **President** – President and Vice Chancellor

4.7 **project** - any endeavor on behalf of the University which includes but is not limited to: academic research, clinical research, commercially funded research, unfunded research and teaching activities

4.8 **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

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

4.10 **stakeholders** – McMaster University Faculty, employees, students, visitors and volunteers or any on-site contractors or consultants with interest towards any stakeholder or containment zone.

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

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

4.13 **Acronyms:**

CJHSC – Central Joint Health and Safety Committee

EOHSS – Environmental & Occupational Health Support Services

FHS – Faculty of Health Sciences

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

The Vice President, Research shall:

- Provide the direction and resources necessary to support the activities of the Committee and Biosafety Office.
- Shall appoint an Associate Vice President, Research to regularly liaise with and act on behalf of the Committee and Biosafety Office, where necessary and serve as the “License Holder” on the Human Pathogens and Toxins Act license.
- On reports received for documented non-compliance spanning 90 or more days, implement sanctions deemed appropriate, which may include suspension of access to research funding and/or access to laboratory facilities.
- On reports received for positive identification of dual use potential, provide support to ensure that recommendations are implemented.
- Ensure that informational reports received from the Biosafety Manager are submitted to the Board of Governors, via the Audit Committee, on a regular basis.

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.
- Identify within their Faculty, any unmet biosafety or biosecurity needs and communicate such needs to the Committee Chair or the Biosafety Manager.
- In consultation with departmental Chairs and supervisors of employees, select candidates for the voting membership from the stakeholder group in their Faculty for appointment by the President.
- Facilitate compliance on behalf of stakeholders upon notification of non-compliance as per section 8.1.

- Facilitate resolution on behalf of stakeholders within the appeals process as described in section 8.3.

5.4 Departmental Chairs

Departmental Chairs shall:

- Support the dissemination of biosafety and biosecurity information on a Departmental-wide scale to ensure all stakeholders in their area have access to education and resources appropriate for working safely and in compliance.
- Identify within their department, any unmet biosafety or biosecurity needs and communicate such needs to the Committee Chair or the Biosafety Manager.
- Facilitate compliance on behalf of stakeholder upon notification of non-compliance as per section 8.1.

5.5 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 stakeholders.
- 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 while at the same time, strive to keep such policies appropriate and reasonable.
- Support the dissemination of biosafety and biosecurity information on a University-wide scale to ensure all stakeholders have access to education and other informational resources appropriate for working safely and in compliance.
- Review audit reports as provided by the Research Compliance Auditor for the purposes of identifying areas of risk and for 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.
- In a consultative capacity, review processed incident/injury reports to determine if there are any outstanding biosafety and biosecurity issues with respect to investigation, follow up and prescribed corrective measures. Results of such review shall be communicated to EOHSS or FHS Safety Office as applicable.
- Review incident trend reports and recommend program improvements such as safety training or equipment, where required.

- Support the Joint Health and Safety Committees in the execution of their responsibilities by providing necessary information and expertise.
- Review monthly, new and changes to existing projects which describe controlled *in vitro* and *in vivo* 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 relevant to biosafety and biosecurity have been met for working at the prescribed containment level.
- Review monthly amendments to BUPs based on provided risk assessment information.
- Where possible, recommend reduction of higher risks to biosafety if a lower risk organism is available or a non-biohazardous method can substitute.
- Where possible, recommend reduction of higher risks to biosecurity (door signage and locks) if a lower risk location (key-carded entry and/or security patrolled) is available.
- 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 departments and committees, which have processes that depend upon the Biosafety Program, 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 activities identified by the Biosafety Office for possible dual-use potential. Such identification is found in the Biosecurity section of the BUP. Should any activity be deemed positive for dual use potential, recommendations for management and control are to be forwarded to the supervisor. Such recommendations can include elements of physical security, changes to experimental plans, information security or redacted publication. Positive identification of dual use research and recommendations for management and control are also to be forwarded to the Associate Dean, Research and Associate Vice President, Research.

- Review, discuss, provide feedback and where warranted to recommend corrective measures with respect to the use of level 3 containment zones.
- Participate in risk assessments related to biosafety and biosecurity, where necessary.
- 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 External Advisors or other appropriate authorities on subject matters which fall outside the expertise of the Committee, the scope of biosafety- and biosecurity-relevant legislation or approved policies.
- Forward approved minutes to the Central Joint Health and Safety Committee
- 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 appropriate and reasonable local operational procedures or engineering controls based on a local risk assessment if legislated containment levels do not mitigate the biosafety and biosecurity risk or risks associated with the project proposal.
    - For issues that arise, 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 with respect to biosafety and biosecurity.
    - For issues that arise, 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 with respect to biosafety and biosecurity.
    - Deem whether an action or situation is in non-compliance with the assigned or prescribed containment level based on all relevant standards and guidelines.
- Provide a transparent appeals process which provides arm’s length recourse on behalf of the appellant. See section 8.2 – “Appeals Process”.
- Provide information to the Associate Vice-President, Research as requested.

- Direct issues or concerns to the Associate Vice-President, Research when such issues or concerns fall outside the scope of the Committee Terms of Reference for forwarding to the appropriate Vice President or other such body for resolution.
- Review RMM #106 – Presidential Biosafety Advisory Committee Terms of Reference on a regular basis.

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

The CJHSC shall:

- Consult with Committee on areas in which their expertise may be required
- Receive a copy of the Committee minutes.

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

EOHSS/FHS Safety Office shall:

- Provide the Committee with injury/incident reports which involve infectious materials, organisms or toxins for a consultative review.

5.8 **Role of McMaster Biosafety Office:**

The Biosafety Office shall:

- Provide the administrative resources which support organization and documentation of Committee meetings.
- Facilitate processing of all biosafety- and biosecurity-related documentation requiring review by the Committee and assist stakeholders at all stages.
- Provide information for review by the committee in order to fulfill their responsibilities as described in section 5.5.
- Provide and present regular reports to the Board of Governors through the Vice President, Research on Committee activities and the Biosafety Program.

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 the option of renewals.

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
    - Membership should include expertise which reflects the activities being undertaken by the stakeholder group.
    - 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
  - Research Compliance Auditor

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:
  1. Members of the Committee
  2. Associate Vice President, Research
  3. Associate Dean, Research, Faculty of Health Sciences
  4. Associate Dean, Research and External Affairs, Faculty of Science
  5. Associate Dean, Research and External Affairs, Faculty of Engineering
  6. Central Joint Health and Safety Committee

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 review of the stakeholder's Biohazard Utilization Protocol or any Biohazard Approval shall be forwarded to the stakeholder by the Research Compliance Auditor or Administrative Assistant, 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 and Departmental 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 and to the related offices of research administration.
- 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 Non-Compliance with Federal and Provincial Importation Regulations

- All communications will be through the Chair of the Committee.
- Each instance of non-compliance with importation regulations will be communicated to the Departmental Chair, the Associate Dean of Research and the Associate Vice President of Research without delay.
- Each instance of non-compliance with importation regulations will be investigated by the Biosafety Office to determine root causes. Documentation of such investigations and any subsequent corrective actions and follow-up will be reviewed by the Committee and retained by the Biosafety Office.
- On a first offence, notification as described above will follow.
- On a second offence, notification, withdrawal of BUP approval, and a recommendation from the Committee to the Associate Vice President, Research to initiate a case of research misconduct.
- On a third offence, notification, BUP approval withdrawal and initiation of a case of research misconduct by the Committee without delay.

8.3 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:
    1. Contact the Biosafety Office to initiate the process. The Biosafety Office shall support administration and documentation of the process.
    2. 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.
    3. 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 the objection has merit.
        a) 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.
    4. If the objection to the revised decision is based on a legislated requirement (municipal, provincial or federal), the relevant government body shall be

consulted by the Associate Vice President, Research and Associate Dean, Research to determine if the objection has merit.

a) 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.

5. 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 directly for resolution.

9 REVIEW

9.1 This RMM shall be reviewed by the Committee in consultation with the Associate Deans of Research on an annual basis.