McGill University Biosecurity Plan

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I. SCOPE

Provide a template for the management of biosecurity risks identified in the Biosecurity risk assessment.

II. PURPOSE

The purpose of this Biosecurity plan is to define the measures taken to address the Biosecurity risks in the diverse laboratory environment at McGill University in compliance with the Human Pathogens and Toxins Act (HPTA). The most recent version of the Canadian Biosafety Standard (CBS) defines biosecurity as:

> *"Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g., personnel, equipment, non-infectious material, and animals)."*

We discuss the risk mitigation strategies for biological agents up to risk group 2, toxins and select risk group 3 Pathogens that can be used in a containment level 2 setting with additional precautions. In addition to the security measures identified in this document the CL3 Facility Manual describes the specific biosecurity requirements for entry into the CL3 Facility and is available to authorized personnel.

III. RESPONSIBILITIES

Environmental Health and Safety (EHS)

- EHS owns and maintains the Biosecurity Plan.
- EHS oversees laboratory compliance with the Biosecurity Plan.
- EHS provides biosecurity awareness training for all users of biological materials.
- EHS supports the Principal Investigator (PI) in developing mitigation strategies for managing biosecurity threats, where necessary.

McGill Research Security & Compliance

- Supports PI in implementing best practices in safeguarding research and navigating federal government policies and guidelines.

Principal Investigator

- Ensures compliance with the Biosecurity Plan at all times.

The PI is responsible for ensuring biological materials are secured during all operational procedures in the laboratory.

- Identifies any local biosecurity threats and develops mitigation strategies with the assistance of EHS where necessary.

McGill Campus Public Safety

- Security Services maintains the General Access Protocol.
- Security Services monitors alarm devices and responds to emergency situations.
- Emergency Management and Preparedness maintains the University Emergency Response Plan (UERP).

McGill IT

- Maintains the McGill Policy on the Responsible Use of McGill Information Technology Resources.

- Identifies and notifies McGill personnel of potential cyber threats.

Human resources
- Provides support to the PI in hiring new personnel.
- Provides support services to McGill personnel.

Student Services
- Provides support services to McGill students working with hazardous materials.

IV. PROCEDURE

All work with biological agents will be captured using the "Application to use Biohazardous Materials" (https://www.mcgill.ca/ehs/laboratory/biosafety/biosafety-application) that must be completed before starting any work with these agents. The Application includes a section to assess biosecurity risks and dual-use potential of the materials being handled and the experimental procedures being performed. The Export Controls and Security Officer in the McGill Research Security and Compliance team will be notified and Biosafety threats and/or Dual-Use potential identified. PIs are responsible for ensuring that all measures identified in this plan are implemented in the laboratory and the appropriate mitigation strategies are developed and implemented for any additional biosecurity risks identified. The Application is reviewed and documented by a Biosafety Officer. The information provided on the application should be reviewed on an annual basis and any updates provided to EHS. If the risk assessment determines that a Security Sensitive Biological agent (SSBA), as defined in the Human Pathogens and Toxins Act (HPTA), is present, security clearances will be required for personnel intending to handle the SSBA. At this time, the McGill PHAC Pathogens and Toxins License does not cover work with SSBAs. Before work with SSBAs is approved, EHS will ensure that all security measures are in place and the PHAC Pathogens and Toxins License will be amended. All applications will be reviewed to ensure all the following elements of the Biosecurity Plan have been met.

1. Assets and Activities with Dual-Use Potential

The Canadian Biosafety Standards defines Dual-Use Potential as the:

"Qualities of a pathogen or toxin, scientific method, intellectual property, or other related asset that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused to cause harm or disease. Examples of assets with dual-use potential include pathogens or toxins that could be used as a biological weapon (i.e., for bioterrorism), a method that facilitates propagation of such pathogens in a non-traditional laboratory setting, or the discovery that a certain mutation results in resistance to all available treatments."
Use and handling of SSBA as identified by the HPTA will be limited to CL3 Facilities with an appropriate PHAC Risk Group 3 Pathogen and Toxin License. Specific controls for these facilities will be described within the dedicated Facility Safety Manual.

The McGill Research Security & Compliance team (https://www.mcgill.ca/research/about/research-security-compliance) supports Researchers in implementing best practices in safeguarding research and navigating federal government policies and guidelines. In addition to pathogens identified as SSBAs the Export Controls & Security Officer, a member of the Research Security & Compliance team oversees the export controls for materials and technologies on the Export Control List (ECL), https://www.international.gc.ca/trade-commerce/controls-controles/ecl-lec/export_control_list-guide-liste_exportation_controlee_2023-2.aspx?lang=eng#dual-use-biological) under the authority of the Export and Import Permits Act (EIPA). Biological agents included on the export controls list are identified through the myLab system as "Select Agents". The Export Controls and Security Officer is notified of any transfer of materials included on the ECL and will co-ordinate any export permit requirements for the materials on the ECL.

McGill University does not currently possess any risk group 2 SSBA toxins above or below the threshold limits. EHS is informed of any purchase or production an SSBA toxin and will document use, authorize quantities allowed and track quantities across the University to ensure quantities are below the threshold quantities, or use of an SSBA is added as an authorized activity to McGill's risk group 2 Pathogens and Toxins License and the Biosafety Program documentation is updated to reflect the updated program intent. PIs are responsible for obtaining EHS authorization for the use of SSBA toxins, respecting quantity limits imposed by EHS and ensuring that inventories and usage records are kept up to date and provided to EHS upon request.

Research conducted at McGill with regulated pathogens having a dual-use potential could lead to the tangible transfer of said pathogen, or to an intangible transfer of technology or information related to said pathogen. Such transfers are also regulated and may require obtaining a license under the *Export and Import Permits Act* (EIPA). Activities with regulated pathogens at McGill are assessed for the potential for dual-use following the PHAC decision tree (Appendix I). If it is assessed that the risks identified are not adequately mitigated by the biosecurity elements built into McGill's Biosafety Program, EHS and the PI will identify the additional mitigation measures required and they will be documented in laboratory specific Standard Operating Procedures available to authorized personnel. When a license is required under EIPA, the PI will work in collaboration with McGill's Research Security office (Export Control Officer) to obtain such license before any transfer, tangible or intangible, is completed.

2. Physical security

Access to the laboratories and biological materials storage areas is restricted to authorized personnel only. All McGill staff and students are issued ID cards and must carry this on their person at all times when working in the laboratory for easy identification. Guidelines for access control are maintained by McGill Campus Public Safety, details are available online (https://www.mcgill.ca/campussafety/security-services/access-control).

Laboratories and biological materials storage areas are kept locked when left unattended.

Freezers, refrigerators and other storage devices located outside the laboratory are identified and kept locked.

Campus Public Safety must be notified when suspicious behaviour is observed.

3. Personnel suitability and reliability

The PI with the assistance of McGill Human Resources ensures that the laboratory personnel have the appropriate credentials, skills, and personal traits to undertake the work, and are the best fit for the position.

Personnel who handle or have access to infectious materials or toxins are to be trained by the PI or a competent delegate and training records are documented and kept in the laboratory files.

A record of all visitors who enter the laboratory must be maintained, this includes maintenance staff, suppliers and visiting students. When SSBAs are present, all visitors must be issued a visitors' badge and accompanied by a staff or student with a valid security clearance at all times.

All McGill employees have access to counselling services through the McGill Emergency and Family Assistance Program (https://www.mcgill.ca/hr/benefits/eap). Assistance is confidential and available for broad range of personal and work-related stresses such as, personal stress, parenting issues and financial or legal problems.

McGill Student Services offers various counselling and mental health services to all McGill students (https://www.mcgill.ca/studentservices/health-wellness).

4. Accountability of infectious material and toxins

An inventory of stock biological materials will be kept by the PI or designate.

Using the inventory, the PI or designate will track storage location, transfer and disposal of stock biological materials. EHS will be notified when any materials are transferred.

Students and lab personnel must record usage of stock biological materials.

5. Incident and emergency response

Incidents, such as missing infectious materials or toxins or unauthorized entry must be reported to the PI or designate and to Environmental Health and Safety. EHS will report the incident to the Public Health Agency of Canada.
The PI or designate will investigate the discrepancies and with the assistance of Environmental Health and Safety.

If necessary, Environmental Health and Safety will request the assistance of the Campus Public Safety. In the event of an external emergency (ie. power failure, flood, fire etc.) emergency procedures are described in the McGill University Emergency Response Plan. In the event of an emergency involving a building that houses biological materials, the EHS Biosafety Officer will be notified. Campus Public Safety will dispatch personnel to maintain access control at the site of the emergency.

Following an investigation, recommendations and corrective actions will be implemented by the PI in collaboration with all responsible parties.

For any incidents or accidents, an "Accident & Incident Reporting Form" must be submitted to EHS. The form can be found on the following link: https://mcgill.ca/ehs/forms/forms/accident-and-incident-report.

Emergency contact information:

- Downtown campus: 514 398-3000
- Macdonald Campus: 514 398-7777
- Montreal Neurological Institute: 514 398-5555

6. Information management

Sensitive information such as access codes, passwords, infectious material and toxin inventories, and storage locations is protected from unauthorized access and the appropriate level of confidentiality is ensured as laid out in the Policy on the Responsible Use of McGill Information Technology Resources (https://www.mcgill.ca/it/information-security). McGill IT Services provides guidelines for safely managing cyber-security, including:

- Privacy protection
- Data protection
- Cybercrime protection
- Training and resources

Use of IT Services supported services for data storage (network and cloud-based) and email services is recommended to ensure cyber-safety.

7. *Biosecurity Training and Awareness*

Biosecurity training is provided in McGill's Introduction to Biosafety. This training covers the following information on McGill's Biosecurity practices

- How to perform a biosecurity risk assessment
- Defines Security Sensitive Biological Agents
- Describes how to identify activities and assets with dual-use potential
- Identifies key biosecurity practices that are required for activities with biological materials including:
    - Access control
    - Signage
    - Inventory controls

Training is required for all personnel handling biological materials and must be refreshed every 3 years.

V. DOCUMENTATION

Accident & Incident Reporting Form: https://mcgill.ca/ehs/forms/forms/accident-and-incident-report

Application to use Biohazardous Materials: https://www.mcgill.ca/ehs/laboratory/biosafety/biosafety- application

VI. REFERENCES

Human Pathogens and Toxins Act, 2009 (https://lois-laws.justice.gc.ca/eng/acts/h-5.67/fulltext.html)

Human Pathogens and Toxins Regulations, 2015 (https://laws.justice.gc.ca/eng/regulations/SOR-2015-44/index.html)

Canadian Biosafety Standards (CBS), 3rd edition. Public Health Agency of Canada, Ottawa, Canada, 2022 (https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/third-edition.html).

Canadian Biosafety Handbook (CBH), 2nd edition. Public Health Agency of Canada, Ottawa, Canada, 2016.(https://www.canada.ca/en/public-health/services/canadian-biosafety-standards- guidelines/handbook-second-edition.html).

A Guide to Canada's Export Control List (https://www.international.gc.ca/trade-commerce/controls-controles/ecl-lec/export_control_list-guide-liste_exportation_controlee_2023-2.aspx?lang=eng#dual-use-biological).

VII. REVISION HISTORY

Revision #	Date	Initiated by	Description of Change/Amendment
1.0	1Nov2014	BSO	Initial release
1.1	11Nov2020	BSO	Introduce document control, update links, update regulatory references & define roles and responsibilities of different areas of McGill Research and Administration
1.2		BSO	• Update reference to the Canadian Biosafety Standard, 3rd 3dition • Review and update links • Add sections on Dual-Use and Biosecurity training and awareness • Add role and responsibilities of Research Security & Compliance • Add biological agents on the Export Controls list