



Biosafety Permit Application Process	Biosafety Permit Application Process		
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Applicable Sites:	☐ Unity Health ☐ Providence ☐ St. Joseph's ☐ St. Michael's		
Keyword(s):	Biosafety, permit, research		

1.0 PURPOSE

For all research work involving the handling, use or manipulation of biohazardous or potentially biohazardous material within St. Michael's Hospital, a group must hold a valid biosafety permit. Biohazardous materials include viruses, bacteria, fungi, parasites, prions and other micro-organisms / genetic systems, and human and animal tissues, cells, blood and body fluids.

2.0 PROCEDURE

- All principal investigators conducting wet-bench research must possess a valid biosafety permit.
 Research groups self-declare any potential hazards, specify storage locations, and outline risk mitigation measures.
- Permit applications are available through the Research Biosafety Officer who will also provide guidance and assistance in completing the form.
- The designated individual filling in the form is expected to detail all biohazardous or potentially biohazardous material that the group currently holds, their location within the lab and what mechanisms are in place to safety handle, manipulate or use the material described.
- The BSO conducts a thorough assessment that extends beyond the scope governed solely by the Public Health Agency of Canada (PHAC). This assessment encompasses radiological and chemical hazards and involves collaboration with research specialists, radiation safety officers, occupational hygienists, and subject matter experts, as required. This expanded assessment is designed to address the unique aspects of biological research work, distinct from clinical settings, and ensures that those performing assessments possess a hands-on understanding of associated risks.

- Biosecurity risks are identified by the BSO based on the levels and types of biohazards detailed on the biosafety permits held by each research group
- Following a review by the BSO in communication with the Director of Research Facilities, any
 comments or concerns expressed will be transmitted to the PI. If answered to the satisfaction, the
 biosafety permit application is approved and a letter of approval is issued.

Validation Period

All approved permits are valid for a 1 year period, although permits may be reviewed before this
time should the need arise.

Amendments

- The biosafety permit is an evolving document, the addition of new personnel, agents or any other
 change to the permit should be communicated to the BSO, who will provide guidance on whether
 the changes require a full review. Changes should only be made to the current version of the
 permit and submitted to the BSO. Types of amendments-
 - Location changes
 - New personnel
 - New biological agents
 - New Chemical agents
 - New animal protocols that require biosafety approval
 - Changes and/or additions to experimental procedures

Version	Approval/Sub-approval body	Approval date
01	Research Biosafety Committee	January 01, 2015
02	Director Research Facilities	February 01, 2021
03	Director Research Facilities	December 7, 2023
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