



Biosecurity Plan for Western University

Reviewed and Approved by: Biohazards Subcommittee, April 7, 2017

1. Introduction:

In addition to the Biosafety Manual, the University Biosecurity Plan provides guidance to ensure all research using biological agents at Western is conducted in compliance with all rules and regulations that govern the use of biological agents and toxins.

The Canadian Biosafety Standard for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins, 3rd edition, 2022 (CBS) requires Western University to have a biosecurity plan in place. The University must assess the risk of certain biological agents and determine the physical, personnel and pathogen controls required. The University must have a plan to address biosecurity incidents and emergency response.

Research groups must have a lawful purpose to possess, use and transport biological agents; they must also have procedures to identify and characterize the agents stored or used within their laboratory or research facility.

2. Scope

The University Biosecurity Plan specifies security requirements for Western University laboratories where biological agents of concern are used. The University Biosafety Committee requires all researchers who use biological agents follow the requirements outlined in the Biosafety Manual and this Biosecurity Plan.

Containment Levels will be established in accordance with the relevant Biosafety standards, including the Canadian Biosafety Standard for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins (CBS) and the Human Pathogens and Toxins Act (HPTA) and the Human Pathogens and Toxins Regulations (HPTR).

3. Definitions

Biosafety deals with all aspects of containment to prevent any exposure and accidental release of pathogens.

Biosecurity measures may be implemented to prevent the theft, misuse or intentional release of pathogens.

Biosecurity agents of concern are biological agents that, if misused, may constitute a risk to the Western University faculty, staff, students and/or the community as determined by the Biohazards Subcommittee.

Security Sensitive Biological Agents (SSBA) The subset of human pathogens and toxins that have been determined by the Public Health Agency of Canada (PHAC) to pose an increased biosecurity risk due to their potential for use as biological weapons. SSBA are identified as prescribed human pathogens and toxins by section 10 of the Human Pathogens and Toxins Regulations.

Toxins of biosecurity concern are agents that originate from biological systems and are able to induce harm.

4. Roles and Responsibilities

Principal Investigators (PIs) and departmental technicians are responsible for complying with all the requirements set out by the PHAC and all policies and procedures pertaining to Biosafety at Western University.

4.1 PIs are specifically responsible for the following:

- 4.1.1 Prior to beginning any work with Biological Agents and toxins, ensure the completion of a Western University Biological Agents Permit Application (BAPA) outlining the type of Biological agents and toxins to be used in research, and the names of all technicians, students and graduate students who will work on the research project. Please click on the following link under “Forms” to view the BAPA application form: <http://uwo.ca/hr/safety/topics/biosafety/index.html>
- 4.1.2 BAPA must contain all proposed work using biological agents or toxins and must be approved by the Institutional Review Committee, the Biohazards Subcommittee, before work can be conducted.
- 4.1.3 Adhering to all University policies and procedures relating to work with biological agents as listed the Biological Safety Manual: http://uwo.ca/hr/form_doc/health_safety/doc/manuals/biosafety_manual.pdf
- 4.1.3 If work is to be performed on any Risk Group 3 (RG3) agents or higher, or on any viruses, bacteria, toxins, or fungi listed as Security Sensitive Biological Agents (SSBA), contact the Biological Safety Officer (BSO) who will initiate the process of applying for governmental security clearances where applicable. Click on the

following link to view the SSBA list:

<http://www.phac-aspc.gc.ca/lab-bio/regul/ssba-abcse-eng.php>

- 4.1.4 Submit the BAPA to the BSO who will distribute it to the Biohazards Subcommittee members for review at the next Biohazards Subcommittee meeting.
 - 4.1.5 Maintain an up to date inventory of Risk Group 2 (RG2), RG3, and any toxins in the laboratory. Send a copy of the inventory every time it is updated and at least annually to the BSO. RG2 inventory requires a list of RG2 agents used, and RG3 inventory requires a more detailed description of all containers content, location of storage in lab, freezers, fridges, etc. Sample inventory form is available through the BSO, extension 88730, email: [c Cross2@uwo.ca](mailto:cross2@uwo.ca)
 - 4.1.6 **Immediately report to the BSO any occurrences involving unauthorized access to areas containing RG 3 agents and/or SSBA, theft, and theft of research information, misuse, loss of containment, exposure to a person, illegal use of personal devices, intrusion, etc.**
- 4.2 The Biological Safety Officer is responsible for the following:
- 4.2.1 Review all BAPAs for completeness and distribute for review by the Biohazards Subcommittee.
 - 4.2.2 Inspect all biological laboratories and promote compliance with the Public Health Agency of Canada requirements as stated in the Canadian Biosafety Standard, 3rd edition (CBS).
 - 4.2.3 Prepare an inventory database to indicate the laboratories working with RG2, RG3 and SSBA pathogens and toxins.
 - 4.2.4 Prepare governmental Security Clearance applications (on behalf of the License Holder) for all individuals working with Security Sensitive Biological Agents (SSBA).
 - 4.2.5 Report to PHAC all incidents of exposure to SSBA with 15 days of occurrence, and within 30 days all incidents of exposure to non-SSBA.

5.0 Identification of Biosecurity agents and toxins

All researchers must complete a Biological Agents Permit Application (BAPA). This form may be found at: <http://uwo.ca/hr/safety/topics/biosafety/index.html>. This is the mechanism by which all protocols are reviewed for biosafety and biosecurity purposes by the Biohazards Subcommittee.

When deemed a possible biosecurity risk, protocols are sent to the Biosafety Committee or the Biohazards Subcommittee for review. Because of the nature of biosecurity, each situation will be dealt with on a case by case basis. The Biosafety Committee and its Subcommittee have the expertise to conduct a risk assessment for each BAPA for the purposes of Biosafety and Biosecurity. It is the mandate of those committees to regulate, restrict or prohibit the use and storage of biological agents at Western University.

- 5.1 Where agents with biosecurity risk are handled or stored, Supervisors will be required to meet all of the conditions outlined by the Biohazards Subcommittee, which may include:

- 5.1.1 Implementing a safety, security and emergency response plan (see Section 9).
- 5.1.2 Restriction or additional security approval of all individuals that have access to biosecurity agents of concern (see Section 7).
- 5.1.3 A process to immediately report any theft, loss or release of biosecurity agent of concern (see Section 9).
- 5.1.4 Detailed records of information necessary to give a complete accounting of all activities related to biosecurity agents of concern (see Section 7).
- 5.1.5 Medical surveillance for all workers, as identified through the completion of the Hazard Communication Form from Workplace Health at Western.
- 5.1.6 Training including the safe storage, transport and use of the biological agent.
- 5.1.7 Physical security measures such as locked laboratories, research facilities, fridges and/or freezers.

6.0 Designation of a Responsible Officer

The Biosafety Officer is the Responsible Official (RO). The RO, Western Special Constable Service (WSCS) and the HAZMAT Team are accountable for the development, training and implementation of biosecurity and emergency response plans. As such, the RO is contacted as soon as possible in the event of any theft, loss or release of biosecurity agents of concern. The RO is also the person who is involved in the risk assessment process and the biosecurity measures taken such as inventory control, background checks, exposures, spill response, incidents of uncontrolled releases or transfers of biological agents.

7.0 Assessment of Biosecurity Risk

When performing a risk assessment to identify potential Biosecurity risk, the Biosafety Committee or the Biohazards Subcommittee will use the method set out by the Public Health Agency of Canada's Office of Laboratory Security (please see Figure 1 Assess Risk of Threat Scenarios) page 5, and implement a graded implementation approach to level of risk and necessary measures.

7.1 Asset Identification

- 7.1.1 Infectious disease risk
- 7.1.2 Weaponization risk

7.2 Evaluation of consequence or loss

- 7.2.1 High: Loss could result in a security event nationally or internationally resulting in a high number of casualties and/or economic damage
- 7.2.2 Moderate: Loss could result in an event of somewhat lesser magnitude

7.2.3 Low: Loss of asset could affect the local operations of an individual facility

7.3 Threat Identification

7.3.1 Establishment of threat scenarios

7.3.2 Definition of characteristics, motivations and capabilities of adversaries

7.3.3 Evaluate the probability and consequences of scenarios

7.4 Examples of Threats to Biosecurity:

7.4.1 Access by unauthorized personnel

7.4.2 Theft, loss, misuse of agents

7.4.3 Intrusion, forced entry, compromised security detection system, compromised access code

7.4.4 Inventory not maintained

7.4.5 Transportation between buildings, facilities or institutions

7.4.6 Illegal use of personal devices

7.4.7 Knowledge of the agent / toxin

7.4.8 Loss of containment

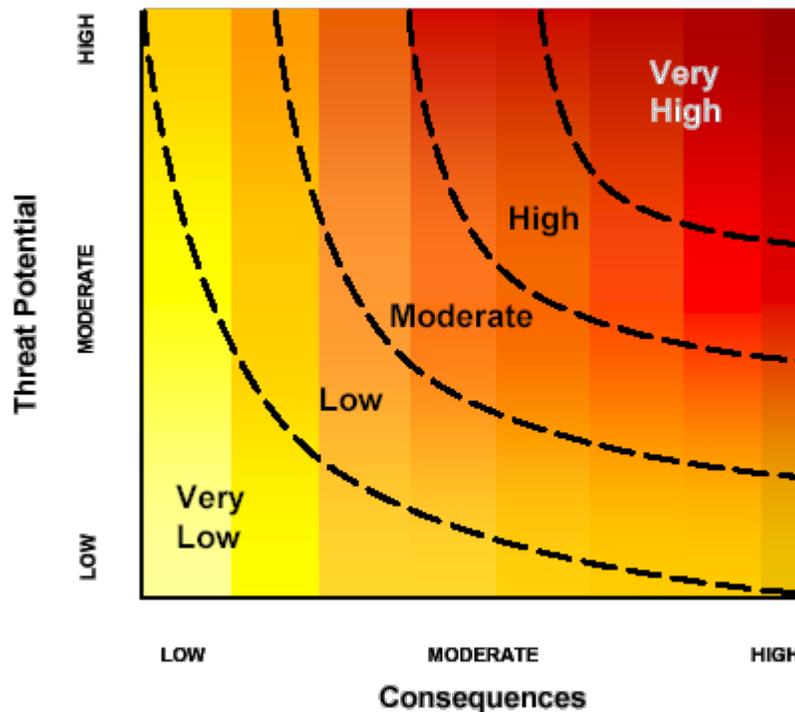


Figure 1. Assess Risk of Threat Scenarios.

Western University's Biosecurity Plan applies all levels of risk including; very low, low, moderate or high risk agents of concern through this biosecurity risk assessment process.

The BSO notifies the Biohazards Subcommittee when a Principal Investigator (PI) or other biological agents users intend to obtain unusual biological agents or toxins. The Subcommittee examines the proposed research project and evaluates it based on the risk of threat. Moderate and high threat scenarios would be further examined with the Western Special Constable Service (WSCS) "Crime Prevention through Environmental Design" (CPTED) coordinator. An in depth examination of the facility's security features as well as personnel suitability would be performed by the CPTED Coordinator who would prepare a report to be presented to the Biohazards Subcommittee. Based on the recommendations and findings in the report, the Biohazards Subcommittee would advise on additional measures to ensure the safe handling of the biological agents.

As a part of the biological program at Western, the risk assessment process (BAPA) includes the requirement for all researchers to complete a section specifically assessing the potential for Dual-Use including PHAC's "Decision Tree for the Identification of Dual-Use Potential in Life Sciences Research (Figure 2). If the potential for Dual-Use has been confirmed, an additional risk assessment is performed to assess the ways in which pathogens, knowledge, technology or products (e.g., toxin) could be misused, the ease with which they may be misused, and the scope and magnitude of the potential consequences of misuse.

7.5 Considerations of the following questions can help when performing the risk assessment:

- 7.5.1 What types of pathogens, knowledge, technology, or products are anticipated to be generated through the research?
- 7.5.2 How could pathogens, knowledge, technology, or products resulting from the research be misused to pose harm to public health and safety or national security?
- 7.5.3 What type of technical skills will be required to repeat the experiment?
- 7.5.4 Are the materials, tools and equipment expensive or difficult to acquire?
- 7.5.5 If released outside the laboratory, will the pathogen affect humans and/or animals?
- 7.5.6 What is the likelihood that the knowledge, information, technology, or products from the research will be used to harm public health and safety, the environment (including animals) or national security?
- 7.5.7 What is the scope and magnitude of the potential risk(s) identified?

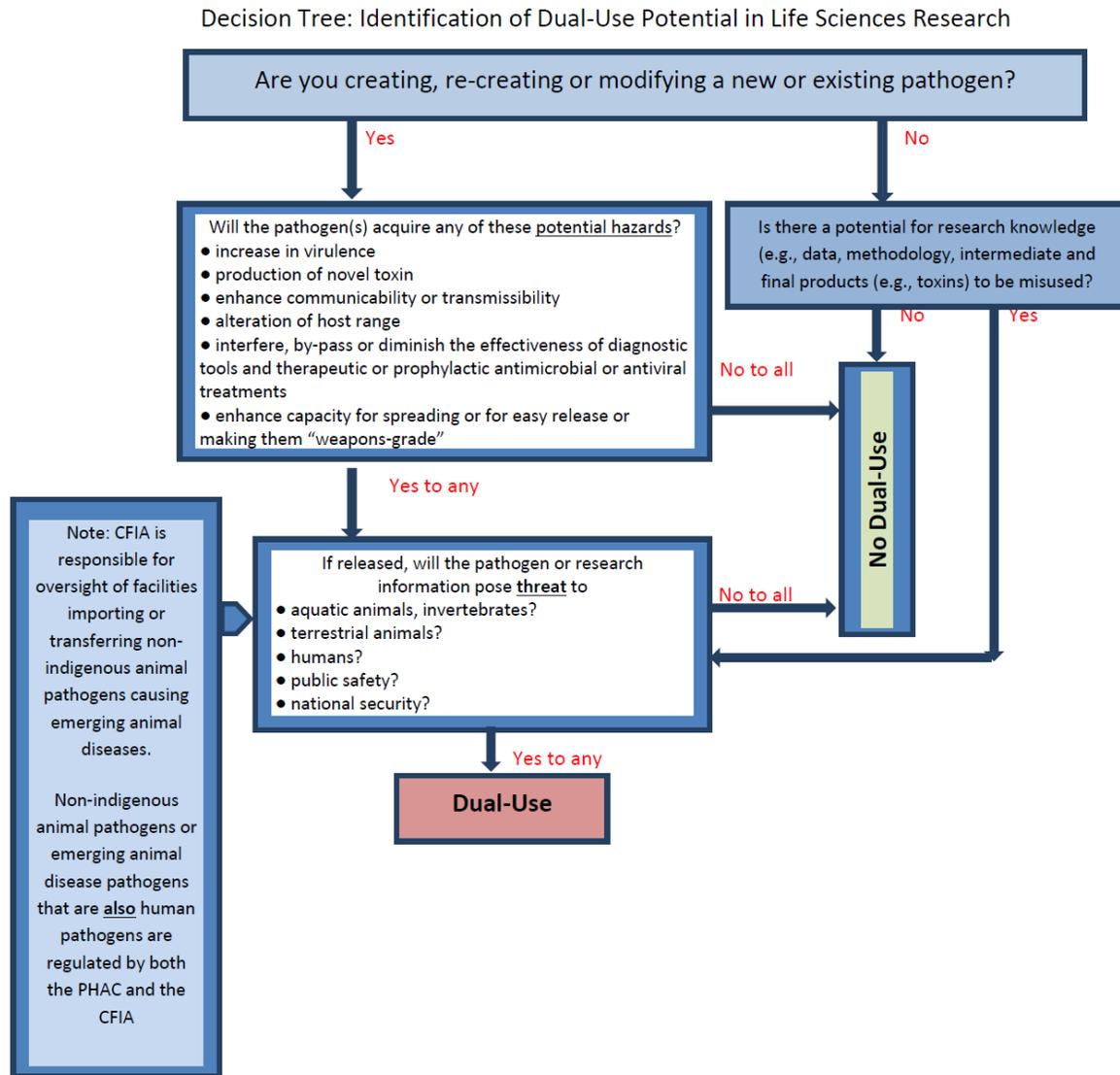


Figure 2. Decision Tree for the Identification of Dual-Use Potential in Life Sciences Research

An effective oversight system is based on identifying and managing the risks associated with the potential of misuse or misapplication of organisms, knowledge, technology, and products of research resulting in the harm to the public health and safety, animals, or national security. Therefore, risk mitigation plans should be created and measures implemented to address the identified risks. This will be done through the CPTED review.

7.6 Considerations of the following questions can help in creating an effective risk mitigation plan:

- 7.6.1 What is the strategy or strategies being implemented by the institution/organization to address the risks (e.g., applying specific biosafety and biosecurity measures or modifying experimental design or methodology such that an attenuated strain is used or strain's ability to proliferate outside of the lab or within different hosts is limited by using a different technique)?
- 7.6.2 Are there currently any countermeasures (e.g., treatments) to help mitigate the potential consequences? Are they readily available?
- 7.6.3 How will the results or products of the research be shared or distributed (i.e., will the results or products be shared openly or remain within the laboratory or institutions)?
- 7.6.4 How readily available are these results?
- 7.6.5 Who will have access to the knowledge, information, technology, or final products?

8.0 Physical Protection

Western University implements graded increased levels of protection based on the biosecurity risk of materials.

8.1 Methods may include:

- 8.1.1 Perimeter security such as fencing, gating or security personnel.
- 8.1.2 Facility security such as measures implemented by Western Special Constable Service (WSCS).
- 8.1.3 Laboratory security including facility or laboratory key/card access and secondary locking of fridges and freezers.
- 8.1.4 Agent specific security including limiting personnel with access to and locking of storage areas and freezers with sensitive agents.

9.0 Personnel Accountability in the Facility

Personnel access is restricted to areas where biosecurity agents of concern are used, stored or otherwise present. Approval may be required to have access to the area of agent of concern

(Security Clearance Forms are provided by PHAC for individuals who intend to work with SSBA).

Approval may include:

- 9.1 Personnel qualifications and training
- 9.2 Background checks and/or security clearances for personnel intending to work with or access Risk Group 3 Agents or Security Sensitive Biological Agents (SSBA)
- 9.3 Periodic / random inspections
- 9.4 Escorts for non-approved personnel
- 9.5 Identification such as University badges

10.0 Pathogen Accountability

Cradle to grave record keeping is required for pathogens with a biosecurity risk.

These records include:

- 10.1 Detailed inventory including location, agent, sample type and quantity
- 10.2 Record of transfers within and outside Western University
- 10.3 Record of personnel access
- 10.4 Disposal records including date and decontamination method
- 10.5 Labelling of samples
- 10.6 Notification of RO if there is a loss, theft, misuse of a pathogen with a biosecurity risk
- 10.7 Notification of RO if there is any exposure, spill or any unintentional release.

11.0 Incident and Emergency Response

Each area with biosecurity agents of concern must have a plan to report and investigate security incidents. This plan is developed by consulting with the Biosafety Committee or the Biohazards Subcommittee.

Examples of possible incidents include:

- 11.1 Unauthorized personnel in restricted areas
- 11.2 Unauthorized removal of pathogens
- 11.3 Breach of containment
- 11.4 Theft or loss
- 11.5 Exposure of an individual
- 11.6 Breach in containment
- 11.7 Failure of ventilation system / electrical

12.0 Biological Agents deemed Biosecurity Agents of Concern

- 12.1 Biological agents that are biosecurity agents of LOWEST RISK include:
 - 12.1.1 cell lines from plant, animal or human origins

- 12.1.2 biological agents that must be ingested to cause pathogenicity or other harm
 - 12.1.3 rodents or other animals not known to be infectious
 - 12.1.4 level 1 microorganisms
 - 12.1.5 other level 1 biological agents
 - 12.1.6 other biological agents to be identified as lowest biosecurity risk
 - 12.1.7 human and animal source materials such as tissues and blood
- 12.2 Biological agents of concern deemed to be possible Biosecurity threats (High Risk):
- 12.2.1 toxins of biological origin
 - 12.2.2 animals which may be infectious, including non-human primates
 - 12.2.3 other Level 2 or higher organisms or biological agents
 - 12.2.4 Security Sensitive Biological Agents (SSBAs)
 - 12.2.5 other biological agents to be identified as low, medium or high biosecurity risk

13.0 References

Public Health Agency of Canada. *Canadian Biosafety Standard for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins; third edition.*

<https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/third-edition.html>

Biosafety Guidelines and Procedures Manual for Containment Level 1 & 2 Laboratories

http://uwo.ca/hr/form_doc/health_safety/doc/manuals/biosafety_manual.pdf