

## Assessment on the Potential for Dual-Use Subform - Biosafety Permit Application (Level 1 and 2)

The Public Health Agency of Canada (PHAC) defines **dual-use potential in life science** as the qualities of a **pathogen** or **toxin** that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause harm (e.g., bioterrorism). The definition of dual-use potential also encompasses any asset related to a biological agent that could be used for nefarious purposes, including knowledge, technologies, or products that contribute to the weaponization of a pathogen or toxin. The questions in this section are based on [the life science dual-use decision tree from PHAC](#).

This questionnaire is designed to gather information for an assessment of the potential dual-use implications of the research described in this permit, including any resulting knowledge or technologies. The purpose of this assessment is not to restrict the research, but rather to ensure that appropriate safeguards are identified to provide support for the responsible continuation of the research.

Where potential dual-use concerns are identified based on responses to this questionnaire, an in-depth assessment will be conducted by an ad hoc committee established by the Associate Vice President, Research Oversight and Compliance Office. This committee will include academic experts as well as biosafety and biosecurity specialists from U of T. The committee will collaborate with the Principal Investigator throughout the assessment process. Based on their findings, the committee will provide a set of safeguards that must be followed.

### Examples of dual-use in life science:

- The creation of a high-risk pathogen or toxin.
- Modification of an existing pathogen or toxin resulting in increased risk of harm.
- Modifying a pathogen with a goal of increasing its ability to cause disease. For example, increasing the virulence of the H5N1 avian influenza virus to make it more transmissible among mammals.
- The development of a dispersal method.
- Engineering bacteria to be resistant to multiple antibiotics.
- Knowledge gained through research on drug resistant microorganisms. While a better understanding of the resistance mechanisms could lead to improved treatment, the same information could also be used to develop organisms capable of evading drugs.
- Increasing the potency of a toxin, such as botulinum toxin, to study its effects or develop countermeasures.
- Using synthetic biology to create novel pathogens or modify existing ones. This includes creating synthetic versions of viruses like smallpox, which could be used for vaccine development but also poses significant biosecurity risks.

**Instructions for completing this form:**

Review the questions below and fill out a form for each pathogen or toxin where potential for dual-use is applicable or identified.

**Check if Applicable:**

I have reviewed the questions below and I attest that they are not applicable to any of the research activities described in my biosafety permit application.

**Part A – Alteration of a Pathogen or Toxin**

**Pathogen and/or toxin:** \_\_\_\_\_

**1. Research Activities**

**Select all that apply:**

- Creating a new pathogen or toxin
- Re-creating a previously existing pathogen or toxin (i.e. an extinct pathogen or toxin)
- Modifying an existing pathogen or toxin
- None of the above

If creating, re-creating or modifying selected, briefly describe the objective of the research project(s).

**2. Potential Hazards**

**a. To the best of your knowledge, are the intermediate products or final products, likely to acquire any of these potential characteristics?**

**Select all that apply:**

- Virulence or increase in virulence
- Increase in activity of a toxin (e.g. toxicity)
- Enhanced communicability or transmissibility

- Alteration of the host range or tropism
- Enhance the susceptibility of a host population
- Disruption of immunity or the effectiveness of an immunization
- Interfere, by-pass or diminish the effectiveness of diagnostic tools
- Interfere, by-pass or diminish the effectiveness of therapeutic or prophylactic antimicrobial (including antiviral) treatments
- Enhanced capacity for spreading or for easy release or being made “weapons-grade” (includes enhanced stability)
- Other (describe below)

Please explain how the parental pathogen or toxin will be modified to achieve the characteristics selected in question 2a.

**b. Is there a potential for the intermediate or final products to be misused?**

**Yes**

**No**

If you answered YES to 2b, please comment on the likelihood of the products being misused. Consider matters such as the ease of acquiring resources or technical skills required. Describe the potential consequence of misuse.

### 3. Potential Threats

Will the altered pathogen or toxin, pose a threat to any of the following?

Select all that apply:

- Humans (research setting)
- Terrestrial animals, invertebrates, plants, or other eukaryotes
- Aquatic animals, invertebrates, plants, or other eukaryotes
- Agricultural sector
- Fisheries sector
- Forestry sector
- Public safety
- National security

## Part B – Research Knowledge

The potential for misuse of research knowledge should be considered, even in the absence of creating a new pathogen or modifying an existing pathogen. Examples of research knowledge include data, methodology, results and technology.

### 4. Potential for Misuse of Research Knowledge

Is there a potential for research knowledge (e.g., data, methodology, results), or technologies you are developing or creating to be misused?

Examples:

- Data, methods, results or technologies that could be used to generate a novel biological agent or to enhance the virulence of a biological agent.
- Data, methods, results or technologies that could be used to disperse or deliver a pathogen or toxin.
- Identification of a novel virulence gene in a pathogen.

**Yes**

**No**

If YES, please describe the knowledge or technology.

## 5. Potential Threats

Will the research knowledge being referred to in Question 4 pose a threat to any of the following?

Select all that apply:

Agricultural sector

Fisheries sector

Forestry sector

Public safety

National security

For each applicable project, please comment on the likelihood of research knowledge or technology being misused. Consider matters such as the ease of acquiring resources or technical skills required. Describe the potential consequence, if misused.