



# Official documents

## Procedure for the Certification of Research Projects Involving Biohazards

Version française

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### 0 Identification ▲

**Title:** Procedure for the Certification of Research Projects Involving Biohazards

**This document is intended for:** The entire Polytechnique community

**Person in charge:** Director of the BRCDT

**Approval:**

- Adopted by the Assemblée de direction on December 20, 2005 (ADD-446-227)
- Amended by the Assemblée de direction on September 30, 2008 (ADD-488-315)

### A Preamble ▲

This Procedure follows the [Politique sur l'administration des fonds de recherche](#) (policy regarding the administration of research funding) and is a detailed description of the principles and practices for research involving biohazards.

The Procedure was adopted following Polytechnique Montréal's adherence to the *Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards*, written by the three federal research councils (NSERC, SSHRC and CIHR), and signed by Polytechnique on June 20, 2002, and again on April 14, 2008.

### 1 Background ▲

The three federal research councils (NSERC, SSHRC and CIHR) require that all research activities involving the use of biohazards be approved by the Institutional Biosafety Officer (BSO) before funding is released and before the work begins. Polytechnique is subject to relevant federal and provincial guidelines, laws and regulations, including but not limited to the *Canadian Environmental Protection Act* (CEPA), the *Transportation of Dangerous Goods Act*, the *Health of Animals Act*, the *New*

*Substances Notification Regulations* (NSNR), and the guidelines of the Canadian Council on Animal Care (CCAC).

Technical guidance for working with biohazardous materials in laboratories is provided by the *Laboratory Biosafety Guidelines*<sup>1</sup> (Public Health Agency of Canada) and *Containment Standards for Veterinary Facilities* (Canadian Food Inspection Agency).

For ALL research activities involving the use of biohazardous materials, researchers must obtain a compliance certificate from Polytechnique confirming that containment measures meet the necessary safety standards for their research project or program.

## 2 Definitions ▲

**Researcher:** Anyone who carries out research activities

**Agencies:** All organizations that directly or indirectly fund research activities (through a grant, contract or other type of funding), i.e., federal and provincial granting agencies, private companies, industrial partners, foundations, government departments, universities, or any other individual or institution

**Institutional Biosafety Officer (BSO):** The person in charge of ensuring that research activities follow the safety procedures set out in the *Laboratory Biosafety Guidelines* published by the Public Health Agency of Canada. At Polytechnique, the BSO is the senior health and safety advisor. For projects conducted in the J.-Armand-Bombardier and André-Aisenstadt buildings, the person in charge is the Université de Montréal's biosafety specialist.

## 3 Targeted activities and materials ▲

This Procedure applies to all research projects that involve the use of biohazardous materials requiring containment:

- handling of human tissue<sup>2</sup> or animal tissue, including organic liquids, cells and cell cultures;
- the manipulation of DNA molecules produced by recombination;
- the importation and handling of organisms (bacteria, fungi, viruses, parasites, etc.), of their toxins, or of any material containing these organisms (e.g., cell cultures, tissues, diagnostic specimens);
- the manipulation of prions;
- the importation, manufacture and manipulation of new substances<sup>3</sup> (animate products of biotechnology);
- the handling of any other material that has been proven or can reasonably be expected to cause disease in humans or animals, or be harmful to the environment.

**Note:** We do not publish a risk group list of human pathogens. This list is available at the Public Health Agency of Canada's Pathogen Regulation Directorate and may be consulted on the Directorate website<sup>4</sup>. Publishing a static list in hard copy does not allow for a dynamic and ongoing assessment of risk or for the timely addition of new and emerging pathogens. As new risk factors are first identified and explored and more information becomes available, the selection of appropriate containment levels for work with potentially infectious materials is subject to change.

## 4 Biosafety compliance of research projects ▲

Polytechnique has put in place procedures to oversee research requiring the use of biohazardous materials. Polytechnique is committed to:

- a. adhering to the current edition of the *Laboratory Biosafety Guidelines*, published by the Public Health Agency of Canada;
- b. complying with all other relevant federal and provincial laws and regulations;
- c. releasing funds to researchers only after the BSO has approved the project procedures in accordance with the PHAC's *Laboratory Biosafety Guidelines* and other relevant federal and provincial laws and regulations, and after Polytechnique has issued a compliance certificate for the project and the laboratory or facility where the project will be carried out;
- d. immediately suspending access to funds granted by an agency if the institution finds out that an ongoing research project:

- i) contravenes the PHAC's *Laboratory Biosafety Guidelines*;
- ii) violates an applicable federal or provincial law;
- iii) fails to respect the conditions of approval imposed by the BSO;

- e. rescinding the suspension described in point d) above, once the contravention is rectified to the satisfaction of the BSO;
- f. advising the agencies in writing of any situation that results in a suspension of funds to a research project.

## 5 Internal project approval procedure ▲

1. Biosafety certificate application: The researcher must submit to the Dean of Research and Innovation an application for a biosafety compliance certificate, including the following information:

i) A free-form document indicating:

- a. the project title;
- b. the project objectives;
- c. the nature of the organic products to be imported, manufactured or used;
- d. the quantity of organic products to be imported, manufactured or used;
- e. the individuals who will be participating in the project;
- f. planned manipulations and experiments;
- g. the facilities or laboratories to be used and their OHS officers;
- h. planned containment measures, if required;
- i. measures to eliminate waste and effluent, if applicable;
- j. the project funding sources;
- k. any other information relevant to the project.

ii) Depending on the case, a copy of the project grant application or research contract and the reference number for the award or contract.

2. Processing of the application: Once he or she has received the application for a biosafety compliance certificate, the Dean of Research and Innovation issues an acknowledgment of receipt to the researcher and forwards the application to the BSO.

The BSO reviews the project and ensures it adheres to the Public Health Agency of Canada's *Laboratory Biosafety Guidelines*, in accordance with the *New Substances Notification Regulations* [NSNR (Organisms)]. Generally, the BSO calls a meeting with the lead investigator and, before the work begins, provides appropriate training to all individuals whose research activities involve biohazards, in accordance with the established rules.

When the BSO is satisfied that the project can be carried out in complete safety, he or she issues a biohazard containment certificate to the researcher and advises the Dean of Research and Innovation, who then issues a compliance certificate for the research project involving biohazards. The compliance certificate is sent to the researcher and a copy to the Office of Research / Centre for Technological Development (BRCDT).

If a project involving the use of biohazardous materials is to be carried out over several years or in several stages, and the work involving biohazards is not to be undertaken immediately, there can be a two-stage approval process. In this case, part of the funds may be released on a pro-rated basis, following an "in principle" approval of the research protocol (through a letter of agreement), up to the projected date of the work involving biohazards. In all cases, a compliance certificate must be obtained by the researcher for any research project involving biohazards before the research begins.

3. Compliance monitoring: For the duration of the project, the researcher must promptly notify the BSO of any changes in the research project involving the use of biohazardous materials, a different level of risk, or the importation, manufacture or use of a new substance as defined by the NSNR (Organisms), thereby requiring new or updated certification. The researcher is also required to send to the Dean of Research and Innovation a brief annual report indicating the progress of the project and any difficulties or delays, including any changes to the original project.
4. End of project: The researcher must notify the Dean of Research and Innovation at the termination of the research project.

## 6 Sanctions in case of non-compliance ▲

In cases of non-compliance with this Procedure, or any law, regulation, standard, policy or guideline applicable to research involving biohazards, including the *Transportation of Dangerous Goods Act* and the *Laboratory Biosafety Guidelines*, Polytechnique can impose whatever sanctions are deemed necessary.

Polytechnique can immediately suspend payments of research funds associated with the project or can take any other required measure, depending on the seriousness of the breach. If the project is funded by a granting agency, the latter will be informed without delay.

## 7 Effective date ▲

This Procedure is effective from the time it is approved by the appropriate bodies.

## 8 Responsibilities ▲

The Dean of Research and Innovation is responsible for amending this Procedure.

The Director of the BRCDT is in charge of applying this Procedure. The BRCDT, in close collaboration with the BSO, disseminates up-to-date information to Polytechnique professors and students, explaining the issues and responsibilities associated with conducting research involving biohazards.

## 9 Endnotes ▲

1 For more information, visit the Public Health Agency of Canada website (<http://www.phac-aspc.gc.ca/publicat/lbg-lmbl-04/index-eng.php>).

2 The Policy on the Ethical Conduct of Research Involving Human Subjects could apply.

3 A substance is considered new if it is listed on Environment Canada's Domestic Substances List(DSL). To determine whether a substance is new according to the *Canadian Environmental Protection Act* (CEPA), the researcher may refer to the following website:  
<http://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=47F768FE-1>

The list of organizations and micro-organizations included on the DSL is available at:  
<http://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=C4E09AE7-1>

4 <http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>