

## **Guidelines to the Biosafety Certificate (Research) Application**

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### ***Who needs to complete this certificate application?***

York University Biosafety Certificates are required for any Principal Investigator (PI) whose research laboratory activities involve any of the following:

- Parasites, fungi, bacteria, viruses, DNA and/or RNA (natural or recombinant), toxins produced by, or derived from a microorganism, plant or animal, and any synthetic form of a pathogen or biological toxin.
- Materials that can harbor pathogens of plants, humans or animals (vertebrates and invertebrates), including organs, tissues, tissue cultures, blood or other body fluids.

In these guidelines, this is collectively referred to as “biological materials”.

### ***Why do I need to complete this certificate application?***

It is a mandatory requirement for the University to have a certification process in place to regulate the use of biohazardous materials. This is further described in the Tri-Council Memorandum of Understanding Schedule 13: Research Involving Biohazards:

[www.nserc-crsng.gc.ca/NSERC-CRSNG/Politiques-Politiques/MOURoles-ProtocolRoles/13-Biohazards-RisquesBiologique\\_eng.asp](http://www.nserc-crsng.gc.ca/NSERC-CRSNG/Politiques-Politiques/MOURoles-ProtocolRoles/13-Biohazards-RisquesBiologique_eng.asp)

The certification process also helps the University and its employees to comply with biosafety-related legislation in occupational health and safety, human, plant, and animal pathogen control, and waste control.

### ***What are risk groups?***

By completing the application, you are conducting a risk assessment of the biological materials used in your lab. Your risk assessment is then reviewed (or reassessed) by members of the Advisory Committee on Biological Safety (ACoBS). Four risk group categories are used:

- Risk Group 1 (RG-1) low individual and community risk  
Any biological agent that is unlikely to cause disease in healthy workers or animals.
- Risk Group 2 (RG-2) moderate individual risk, limited community risk  
Any pathogen that can cause human or animal disease but, under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock or the environment. Laboratory exposures rarely cause infection leading to serious disease. Effective treatment and preventive measures are available and the risk of spread is limited.
- Risk Group 3 (RG-3) high individual risk, low community risk  
Any pathogen that usually causes serious human or animal disease, or which can result in serious economic consequences but does not ordinarily spread by casual contact, from one individual to another, or that can be treated by antimicrobial or antiparasitic agents.
- Risk Group 4 (RG-4) high individual risk, high community risk  
A pathogen that usually produces very serious human or animal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.

Risk groups are somewhat straightforward when assessing microorganisms, but may not be immediately obvious when dealing with other biological materials (e.g. blood, tissues, cell lines). To assign an appropriate risk group, one must consider the most dangerous pathogens/agents

that could potentially be harbored in the biological material being assessed. Even materials coming from apparently healthy donors must be considered in the same manner.

A list of some microorganisms and toxins classified into risk groups can be found in the Human Pathogens and Toxins Act (HPTA), Schedules 1-4:

<http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=4015133&file=4>

(Note: Scroll down to the bottom of the Act)

### **What are Containment Levels?**

Once the biological materials have been identified, one must determine the appropriate measures that should be in place to keep it “contained”. These are classified into containment levels one to four, and address the engineering, operational, technical, and physical requirements for manipulating the biological material. York University does not have the appropriate facilities for containment level three or four labs.

- Containment Level One (CL-1)  
Requires no special design features beyond those suitable for a well-designed and functional laboratory. Biological safety cabinets (BSCs) are not required. Work may be done on an open bench top, and containment is achieved through the use of practices normally employed in a basic microbiology laboratory.
- Containment Level Two (CL-2)  
The primary exposure hazards are through ingestion, inoculation, and mucous membrane route. Agents requiring CL-2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of aerosols or splashes. Primary containment devices such as BSCs and centrifuges with sealed rotors and safety cups are to be used as well as appropriate personal protective equipment. As well, environmental contamination must be minimized by the use of handwashing sinks and decontamination facilities (autoclaves).

When determining a containment level for each biological material, consider the assigned risk group and how it will be manipulated in the lab. Consider all steps in a procedure where exposure is most likely (e.g. where aerosols are generated, or if the quantity or concentrations of materials is high), and mitigate the risk accordingly (e.g. working in a biological safety cabinet). The highest containment level required for the materials assessed will be declared on the certificate.

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### **Additional Explanatory Notes**

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Section A. Only one Principal Investigator can be named on the certificate. An emergency number is requested and may be used by the biosafety officer, if an emergency occurs (including evenings and weekends) and no one from the lab can be reached using the other numbers provided.

Section B. A Principal Lab Contact has some responsibility in the daily lab activities. This person may be contacted by the Biosafety Officer if the PI cannot be reached during a certificate application review, or to make arrangements for a laboratory inspection.

Section G. If tissues in the lab are obtained from research animals whose use requires approval from the York University Animal Care Committee (YUACC), this must be indicated. This is also true for animals that are used in conjunction with biological materials. A copy of the YUACC approval letter and completion of Appendix I is required. If animal tissues are used that do not require approval through the YUACC (e.g. insects), this must also be indicated and Appendix II must be completed. Radioisotopes and any other form of radiation used in conjunction with the biological materials in the certificate also require an attached copy of approval documentation.

## References

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Public Health Agency of Canada (PHAC) Laboratory Biosafety Guidelines (LBG):

[www.phac-aspc.gc.ca/publicat/lbg-lmbl-04/index-eng.php](http://www.phac-aspc.gc.ca/publicat/lbg-lmbl-04/index-eng.php)

Canadian Food Inspection Agency (CFIA) Containment Standards for Veterinary Facilities:  
(Animal pathogen (AP) containment levels and requirements for working with animal pathogens)

[www.inspection.gc.ca/english/sci/lab/convet/convete.shtml](http://www.inspection.gc.ca/english/sci/lab/convet/convete.shtml)

CFIA, Containment standards for facilities handling plant pests:

[www.inspection.gc.ca/english/sci/bio/plaveg/placone.shtml](http://www.inspection.gc.ca/english/sci/bio/plaveg/placone.shtml)