HUMAN PATHOGEN AND TOXIN ACT LICENCE

The Public Health Agency of Canada regulates biological material and toxin outlined in the Human Pathogen and Toxin Act (HPTA), and are listed as a Risk Group 2, 3 or 4 or above Trigger quantities of a toxin.

The UNIVERSITY OF OTTAWA POSSESSES BOTH A RG 2 LICENCE AND A RG3 LICENCE (HIV ONLY). Which regulates it acquisition, use, transfer, disposal. With the biosafety officer approving all acquisition and transfer of material.

PHAC defines a pathogen is a **microorganism**, nucleic acid, or protein capable of causing **disease** in humans or terrestrial animals. This can include bacteria, viruses, fungi, parasites, **prions**, recombinant DNA, genetically modified microorganisms, viral vectors, and synthetic biology products. Human pathogens are capable of causing disease in humans; **animal pathogens** cause disease in animals. For the purposes of the CBS, the term "animal pathogens" from this point forward refers only to pathogens that cause disease in terrestrial animals, including avian and amphibian animals. **Zoonotic pathogens** are pathogens that cause diseases in humans and terrestrial animals and that can be transmitted from animals to humans or vice versa (i.e., **zoonoses**), and are, therefore, considered as both human and animal pathogens. In the context of the CBS, any isolate of a pathogen or any **biological material** that contains human or animal pathogens is referred to as "infectious material".


- Risk Group 1 (RG1; low individual and community risk)
- Risk Group 2 (RG2; moderate individual risk, low community risk)
- Risk Group 3 (RG3; high individual risk, low community risk)
- Risk Group 4 (RG4; high individual risk, high community risk)

A list of regulated material is found as:

- Risk Group 4 (not authorized) listed in HPTA Schedule 4
To ensure compliance the Biosafety Program requires all research to involved using these agents to seek institutional approval and to obtain a Biohazardous Material Use Certificate. Risk Group 1 use is also regulated internally but to a significant lesser degree; with the focus to ensure that RG2 agents are not used inadvertently (E-coli strains can be RG1 or 2) or work does not result in a higher risk group.

In addition the PHAC has issues from to time Directives, Notices and Advisories which are designed to clarify issues and are available at: [https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/biosafety-directives-advisories-notifications.html](https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/biosafety-directives-advisories-notifications.html)

The following specifically address issues of concern at the University:
