Office of the Chief Risk Officer
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BIOSAFETY AND BIOSECURITY GOVERNANCE FRAMEWORK OVERVIEW

Objective is to achieve:

BIOSAFETY
Containment principles, technologies, and practices implemented to prevent unintentional exposure to infectious material and toxins, or their accidental release.

BIOSECURITY
Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets.

BIOSURETY
The combination of security, biosafety, agent accountability, and personnel reliability needed to prevent unauthorized access to select agents of bioterrorism.

Through the use of:

Oversight & Accountability	Corporate Policy and Directives	Biorisk Program
☐ Roles and Responibilites	☐ Biosafety and Biosecurity Policy	☐ Risk Identification, Assessment and Control
☐ Institutional Oversight and Program Managment	☐ Institutional Biosafety Approval	☐ Implementation and Operational Procedures
☐ Academic and Research Activities and Facility Infrastructure	☐ Institutional Biosafety Directives	☐ Compliance Monitoring and Reporting

Biological Material:

As per the Canadian Biosafety Standard, Biological material refers to pathogenic and non-pathogenic microorganisms, proteins and nucleic acids as well as any biological matter that may contain microorganisms, proteins, nucleic acids, other infectious agents or parts thereof. Examples include bacteria, viruses, fungi, prions, toxins, genetically modified organisms, nucleic acids, tissue samples, diagnostic specimens, environmental samples, live vaccines and isolates of a pathogen or toxin (e.g., pure culture, suspension and purified spores).

REGULATORY OVERSIGHT

While numerous regulators are involved in managing biological materials in Canada, the lead agencies are the Public Health Agency of Canada and the Canadian Food Inspections agency.

Human Pathogen And Toxin Licences (including terestrial organisms)

The University operates under the authority of two Human Pathogen and Toxin Licences (RG2 including prions and,RG 3-HIV, HTLV) issued under the Human Pathoghen and Toxin Act and Regulations. These licences enforce compliance to the Canadian Biosafety Standards.The University Biosafey Program has been designed to address both PHAC and CFIA requirement, amoung other legislative obligations.

Biosafety and Biosecurity Governance Framework (PHAC- Plan of Adminsitrative Oversight)

A formal framework has been developed which outlines the roles, responsibilities and governance framework (policies, directives …) under which the Biosafety Program operates; including institutional

approvals granted to research and academic acitivities. This is provided to the Permit Holder at the time the Biological Material Use Certificates (BMUC) are issued.

Biorisk Assessment & Dual Use Research of Concern (PHAC Requirement)

To mitigate the risk of exposure or release, it is necessary to undertake a risk assessment. This process will also identify the potential for Dual Use Research of Concern (DURC). A more indepth assessment is required for potential DURC research. A variety of documents are available which outline this process.

Material Acquisition/Transfers (including importation and exportation)

Inventory records of all materials acquired need to be kept, regardless of the method (purchase, transfers among colleagues and importation/exportation). Each transfer requires the BSO approval.

Facility Design (Containment)

Depending upon the risk group being used, specific containment requirements are legislated so it is important to continually review laboratories to ensure that aging infrastructure is repaired, and new or renovated labs meet current standards.

BIORISK MANAGEMENT PROGRAM: (managed by the Office of Risk Management)

Compliance as well as safety, are the primary goal. To assist in comunicating the standards various tools are used;

- ✓ Getting Started on the Right Foot – A Biosafety Compliance Guide
- ✓ Performance Risk and Compliance Grade Matrix

The Program supports this by embedding into its design the **founding principles** of: Accountability/Responsibility, Communication/Education, Compliance and Monitoring Activities, Documentation and Data Management, and Security. These principles are then translated into thirteen **operational program elements** which have various tool designed to support the University Community:

1. Institutional Biosafety Approval
2. Training /Education
3. Compliance Verification
4. Inventory Control (acquisition & transfers)
5. Risk Assessment & Security
6. Transportation
7. Monitoring (medical, performance)
8. Waste Management
9. Public Awareness/Signage
10. Decommission
11. Inspections / Investigations /Audits
12. Reporting (internal/external)
13. Program Review