Human Resources, Health, Safety and Employee Well-Being

BIOSAFETY program

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PRIOR TO COMMENCING WORK IN A LABORATORY AT YORK UNIVERSITY THAT HANDLES BIOLOGICAL MATERIAL, ALL PERSONNEL MUST RECEIVE APPROPRIATE TRAINING AND INFORMATION REGARDING ALL HAZARDS THEY WOULD WORK WITH, AS WELL AS TRAINING ON APPLICABLE SAFE WORK PRACTICES. FOR FURTHER DETAILS, LAB PERSONNEL SHOULD CONTACT THEIR SUPERVISORS OR PRINCIPAL INVESTIGATORS.

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# Introduction and Objectives

York’s Healthy Workplace Policy outlines the University’s commitment to provide a hazard-free environment and minimize risks by adherence to all relevant legislation. Compliance to related legislation is achieved by developing, implementing, and following internal standards, programs, and procedures.

The Biosafety Program supports the University’s Healthy Workplace Policy through a system that aims to mitigate the risks of work involving biological materials, to protect lab personnel and the public from potential exposure to biological materials used within the University, and to prevent unintentional release into the environment.

The main objectives of York University’s Biosafety Program are to:

1. Provide a formal risk assessment process to identify the level of risk associated for each biological material used;
2. Advise on the mitigation of identified risks by assigning an appropriate level of containment with relevant hazard control measures; and
3. Ensure compliance with all Biosafety-related legislation and guidelines, and funding agency requirements.

This Program is not intended to extinguish rights, remedies and responsibilities under a collective agreement.

# Scope

The Biosafety Program monitors the use of the following biological materials (primarily for research purposes):

* Bacteria, fungi, protozoa, parasites, viruses (including viral vectors), prions, biologically derived allergens/toxins, genetically engineered protein or DNA products, with a real or potential ability to cause harm to humans, plants, animals or the environment;
* Any material with the potential to harbour a biological material (e.g. human or animal blood/blood fractions, tissues, body fluids, and cell cultures); and
* Any plant or animal manipulated in the lab with the potential to harbour a biological material.

Where ethics approval is required when working with animals or human participants, additional approval mechanisms will be required in conjunction with the York University Animal Care Committee (YUACC) or the Human Participants Review Committee (HPRC).

The Biosafety Program does not include potential exposure to human bodily fluids and other potentially biohazardous materials that are not the result of research or teaching activities (e.g. health services, administering first aid). These incidences would be covered under the York University Incident Investigation Program.

# Definitions/Abbreviations

**Accident:** An unplanned event that results in injury, harm, or damage.

**AHSO:** Area Health and Safety Officer

**Authorized personnel:** Individuals who have been granted unsupervised access to the containment zone by an internal authority (e.g., department, Principal Investigator, BSO). Access is dependent on personnel completing training requirements and demonstrating proficiency in the SOPs, as determined to be necessary by the facility.

**Biological material:** 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, but are not limited to, bacteria, viruses, fungi, prions, toxins, animals, 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, purified spores).

**BSO (Biological Safety Officer or Biosafety Officer):** An individual designated for overseeing the facility's Biosafety and biosecurity practices.

**Biosafety:** Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to regulated materials, and their accidental release.

**Biosafety Permit Holder/Laboratory Supervisor/Principal Investigator (PI):** Any individual who has charge of a laboratory, laboratory personnel or visitor; also known as the Biosafety Permit Holder. This includes principal investigators, faculty members, professors, or anyone with authority over the activities in the lab. See Supervisor definition below.

**Biosecurity:** Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of regulated materials, and other related assets (e.g., personnel, equipment, non-infectious material, animals, sensitive information).

**CBH:** Canadian Biosafety Handbook

**CBS:** Canadian Biosafety Standards

**CFIA:** Canadian Food Inspection Agency

**Decontamination:** The process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions; this may be accomplished through disinfection, inactivation, or sterilization.

**Dual Use:** Qualities of a pathogen or toxin, scientific method, intellectual property, or other related asset that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused to cause harm or disease. Examples of assets with dual-use potential include pathogens or toxins that could be used as a biological weapon (i.e., for bioterrorism), a method that facilitates propagation of such pathogens in a non-traditional laboratory setting, or the discovery that a certain mutation results in resistance to all available treatments.

**Exposure:** Contact with, or close proximity to, pathogens or toxins that may result in infection or intoxication, respectively. Routes of exposure include inhalation, ingestion, inoculation, and absorption.

**Facility:** Structures or buildings, or defined areas within structures or buildings, where regulated materials are handled or stored. This could include individual research laboratories, production areas, or animal housing zones. A facility could also be a suite or building containing more than one of these areas.

**HAA**: *Health of Animals Act*

**HAR**: *Health of Animals Regulations*

**Hazard:** A source of potential damage, harm, or adverse effects. In the context of Biosafety, examples include objects (e.g., sharps, needles), materials (e.g., pathogens, toxins), animals (e.g., bites, scratches), and situations (e.g., containment system failure).

**Healthy workplace:** Is one that actively works to: (1) prevent harm to an employee’s physical and psychological health and safety and (2) promote physical and psychological well-being.

**HPTA**: *Human Pathogen and Toxins Act*

**HPTR**: *Human Pathogen and Toxins Regulations*

**HSEWB:** Health, Safety & Employee Well-Being unit

**Incident:** An event or occurrence that has the potential of causing injury, harm, infection, intoxication, illness, disease, or damage. Incidents include accidents and near misses.

**Laboratory**: An area within a facility or the facility itself where biological material is handled.

**Laboratory work area**: An area inside a containment zone designed and equipped for in vitro activities (e.g., for research, diagnostics, and teaching purposes).

**Laboratory personnel:** All persons working in labs at York University including faculty, staff, technicians, students, visiting scientists, post-doctoral fellows and volunteers (all workers as defined under the *Occupational Health and Safety Act*) who conduct activities with biological material in a laboratory or who work sufficiently close to activities conducted with biological material inside a laboratory.

**License or Pathogen and Toxin Licence:**

An authorization issued by the PHAC:

a) under section 18 of the HPTA to conduct one or more controlled activities with human pathogens or toxins; and/or

b) under paragraph 51(a) of the HAR for the importation into Canada of terrestrial animal pathogens (except for EAD pathogens and non-indigenous terrestrial animal pathogens).

**Non-compliance:** A state of non-conformity with legislative and/or Biosafety Program requirements.

**PHAC:** Public Health Agency of Canada

**Regulated Material:** In addition to legislated regulated materials under the HPTA, HPTR and HAA, this also includes any biological material that the University’s Biosafety Committee deems that can pose an occupational risk to animals, plants, humans or the environment.

**Risk:** The probability of an undesirable event (e.g., accident, incident, breach of containment) occurring and the consequences of that event.

**SSBA:** Security Sensitive Biological Agents

**Supervisor:** In all cases, the person to whom an employee/lab personnel reports to; a person with charge of a workplace or authority over workers as defined in the *Occupational Health and Safety Act*. This includes faculty members, principal investigators, if they have teaching, graduate or research assistants reporting to them. In the case of academic employees, it is normally understood as follows:

* For full-time faculty – the Dean.
* For teaching assistants, contract faculty and graduate assistants – the Associate Dean.
* For laboratory personnel – this includes the Laboratory Supervisor/ Principal Investigator (as defined above).

**WIR:** Workplace Incident Report

**Workplace:** Where employees are assigned to or approved to perform work or such other university sanctioned activities. This includes the designated area where a worker performs work remotely.

# Roles and Responsibilities

## Vice President Research and Innovation

* Act as the License Holder of the HPTA License issued by PHAC;
* Designate appropriate and qualified individuals that possess the qualifications to oversee Biosafety and biosecurity practices;
* Support and collaborate with the BSO to ensure ongoing compliance with the HPTA, HPTR, licence conditions, and the HAA and HAR when applicable; and
* Meet required responsibilities for License Holder listed on PHAC’s Biosafety and Biosecurity website.

## York University Biosafety Committee (YUBC)

* Act in an advisory capacity to the Academic Policy Planning Research Committee on policy relating to research involving biological agents/materials at York University;
* Vet all applications for Biosafety approval that includes use of biological agents/materials on York University premises;
* Review risk assessments and determine the level of containment required; and
* Ensure that approval/Permit is granted prior to the commencement of any research activities.
* For detailed information, refer to the Biosafety Committee Terms of Reference.

## Office of Research Ethics

* Assist academics seeking to undertake research that involves human, animals or biological agents;
* Provide the research community at York University with support, guidance and oversight throughout the research process;
* Review and approve relevant guidelines, policies, and regulations through the ethics committee and/or its delegate; and
* Provide the resources and expertise necessary for faculty to complete the appropriate ethics review process in an efficient and timely manner.

## Principal Investigator/ Biosafety Permit Holder

* Complete the York Biosafety Permit Application along with relevant appendices and submit to the YUBC for review;
* Complete a Project Specific Biosafety Risk Assessment for any research project/grant that involves work with Biological Material to release funding;
* Obtain approval from the YUBC prior to initiating research;
* Maintain an up-to-date Biosafety Permit;
* Inform the BSO of any changes or amendments to the Biosafety Permit;
* Comply with and enforce standards set by regulatory and granting agencies, University policies, codes, terms and conditions of Permits;
* Provide competent supervision and site-specific training for all authorized workers (employees and students) and volunteers;
* Ensure that all visitors are supervised;
* Report immediately to the BSO all significant violations of the policies and procedures and all significant research-related incidents (spills, needle-sticks, exposures, injuries, etc.), which result in overt or potential exposure to infectious materials;
* Report immediately all confirmed or suspected illnesses, resulting from exposures to hazardous materials, to the BSO;
* Develop and implement methods for responding to accidental spills and personnel contamination of biohazardous agents;
* Follow appropriate importation, exportation and transportation/handling requirements as required by regulatory agencies and/or other organizations/institutions;
* Take appropriate and timely action to rectify areas of non-compliance or any unsafe acts or conditions to ensure the safety of any authorized worker(s), authorized service personnel, contractors, or visitors;
* Participate in incident investigations related to lab safety and Biosafety;
* Continually review and monitor work procedures and substitute less hazardous agents or procedures wherever possible to minimize risks and exposures;
* Ensure that any viable biohazardous agents/materials or waste is appropriately inactivated prior to its release into the environment unless otherwise specified and approved within the terms and conditions of the Biosafety Permit; and
* Report to the BSO when work activities are terminated and ensure the work areas are decommissioned appropriately.

## Biosafety Officer

* Carry out the functions set out for the Biosafety Officer in regulations under the Human Pathogens and Toxins Act;
* Manage the day-to-day operations of the Biosafety Program and related Biosafety matters;
* Develop procedures, guidelines, and reports pertaining to Biosafety matters;
* Implement directives/recommendations as applicable to the Biosafety Program;
* Perform initial review and approval of Biosafety Permit applications and risk assessments and coordinate review and approval with the YUBC Chair and PI;
* Review and sign (at their discretion) government checklists with PIs, as part of the mandatory import Permit process;
* Provide general Biosafety training to employees and students working with biological materials/agents in the lab;
* Provide general awareness training to York staff (e.g. Custodial staff, Dons/Porters) and researchers that may come in contact with biological materials/agents in the course of their job activities;
* Serve on the Animal Care Committee;
* Conduct regular laboratory inspections;
* Investigate all reported incidents involving biological agents/materials, including exposures, laboratory-acquired infections, spills, theft, or accidental release;
* Represent York Biosafety externally, and day-to-day, as required;
* Seek external advice and additional expertise as needed to fulfill needs that arise pertaining to Biosafety matters;
* Liaise with external regulatory bodies and other organizations, as required; and
* Provide advice and support, as requested, for all Biosafety-related matters across campus (e.g. research involving clinical activities, animal safety).

## Laboratory personnel

Personnel who work with, have access to, or may be exposed to, biological materials are responsible for:

* Participating in all applicable training, as required;
* Following all legislative requirements and contractual agreements as applicable in addition to procedures and requirements in this Program;
* Following all requirements from the Agreement on Biosafety for Lab Personnel.
* Reporting to the lab supervisor any workplace hazard;
* Reporting immediately to the Principal Investigator:
  + Any reason to believe that a biological material (e.g. toxins, genetically modified organism or microorganism) has been released inadvertently from the facility;
  + Any inadvertent production of that human, animal, or plant pathogen or toxin in the course of an activity;
  + Any reason to believe that an incident involving a human pathogen or toxin that is in their possession has, or may have, caused an exposure to an individual;
  + Any reason to believe that an incident involving a human pathogen or toxin that is in their possession has, or may have, caused disease in an individual;
  + Any reason to believe that a human, animal, or plant pathogen or toxin that was in their possession has been stolen or is otherwise missing;
* Following instructions, safety procedures, and best Biosafety practices;
* Using a Biosafety cabinet when required and as applicable;
* Wearing personal protective equipment (PPE) including lab coat, gloves, and safety glasses as applicable and as required;
* Refraining from operating equipment or working in a way that may pose a risk to the health and safety of any person; and
* Participating in the University’s medical surveillance programs when appropriate.

## Health, Safety and Employee Well-Being

* Lead the development and assist with implementation including ongoing management/coordination of this program;
* Liaise with relevant external governmental agencies (e.g., Ontario Ministry of Labour, Immigration, Training, Skills and Development (MLITSD), Public Health Agency of Canada (PHAC), Canadian Food Inspection Agency (CFIA) where required;
* Provide technical advice, support, education, consultation, and recommendations to applicable University parties (including, but not limited to department heads, supervisors, principal investigators, employees, unions, Joint Health and Safety Committees and the general University community) on matters related to Biosafety;
* Develop and coordinate applicable Health and Safety training for Lab Personnel;
* Assist and respond to emergency situations involving biohazardous materials;
* Review all Workplace Incident Reports (WIR), including all first aid incidents;
* Facilitate in the employee’s early and safe return to work; and
* Coordinate a review every three years of the Biosafety Program and make applicable revisions where needed.

The Director of Health, Safety, and Well-Being shall:

* Appoint a competent Biosafety Officer to implement the Biosafety Program; and
* Ensure adequate coverage when the Biosafety Officer is unavailable.

## Union(s) / Joint Health and Safety Committees

* Provide representation to employees in accordance with the applicable collective agreement and legislative requirements;
* Participate in the program review process through the Joint Health and Safety Committees; and
* Report any hazards identified during workplace inspections to the appropriate area manager/supervisor.

# Overview of Biosafety at York

The sections below outline various elements within York’s Biosafety Program, and the relevant procedures and processes to ensure Biosafety compliance.

## Legislative Requirements

As of February 2016, York University has been issued two licenses (RG2 and RG3) under the Human Pathogens and Toxins Act. The license Holder is the Vice President of Research and Innovation.

The safe handling, use, storage and disposal of biohazardous materials/agents is governed by several Acts, Regulations and bylaws. See Table 1 below for more information.

Table 1: Applicable Legislative Requirements

|  |  |  |
| --- | --- | --- |
| ***Act/Regulatory Agency*** | ***Regulation/Guidelines/Standards/Lists/ Bylaw*** | ***Enforcement Agency*** |
| Occupational Health and Safety Act | -O.Reg.833: Control of Exposure to Biological and Chemical Agents  -O.Reg.860: Workplace Hazardous Materials Information System | Ministry of Labour, Immigration, Training and Skills Development, Government of Ontario |
| **Pathogen Control: Human** | | |
| Human Pathogens and Toxins Act | - Canadian Biosafety Standards, 3rd edition  - Canadian Biosafety Handbook, 2nd edition | Public Health Agency of Canada, Government of Canada |
| Health Protection and Promotion Act | O. Reg 559/91 Specification of Reportable Diseases | Ontario Ministry of Health and Long-Term Care, Government of Ontario |
| **Pathogen Control: Plant/Animal** | | |
| Health of Animals Act | - Canadian Biosafety Standards, 3rd edition  - Containment Standards for Facilities Handling Aquatic Animal Pathogens  - Health of Animals Regulations  - Reportable Diseases Regulations | Canadian Food Inspection Agency, Government of Canada |
| Plant Protection Act | - Plant Protection Regulations  - Containment Standards for Facilities Handling Plant Pests |
| Animals for Research Act | - O. Reg. 22 General  - O. Reg. 24 Research Facilities and Supply Facilities | Ontario Ministry of Agriculture, Food, and Rural Affairs, Government of Ontario |
| **Environmental Protection & Waste Control** | | |
| Canadian Environmental Protection Act | - Domestic Substance List (DSL)  - New Substances Notification Regulations | Environment and Climate Change Canada, Government of Canada |
| Environmental Protection Act | - O.Reg.347: Waste Management  - Guideline C-4: Biomedical Waste Management  - Guideline C-17: Non-Incineration Technologies | Ministry of the Environment, Conservation and Parks, Government of Ontario |
| Sewers By-law | - Littering and Dumping of Refuse | City of Toronto |
| **Transportation of Biohazardous materials** | | |
| Transportation of Dangerous Goods Act | Transportation of Dangerous Goods Regulations | Transport Canada |
| **External Funding** | | |
| Funding Agency Requirements | Tri-Council’s Agreement on the Administration of Agency Grants and Awards by Research Institutions | Tri-Council, NSERC, CIHR, and others |

## Biosafety and Biosecurity

To support *HPTA* licensing and the Biosafety Program, York has additional mechanisms in place, which have been prepared by the BSO and are reviewed by the Biosafety Committee and submitted to PHAC:

* **Administrative Oversight Plan**

To facilitate the development of internal accountability structures or support accountability structures that currently exist by bridging gaps in the oversight of pathogens at an institutional level. This document is at a high level and provides an overview of the mechanisms that are in place at York to administratively manage and control Biosafety and biosecurity risks.

* **Biosecurity Plan**

The biosecurity plan details the mitigation strategies for identified biosecurity risks associated with biological assets. The biosecurity plan describes both the physical and operational controls implemented to prevent unauthorized access to assets, as well as to detect and respond to incidents where unauthorized access was attempted.

* **Overarching Risk Assessment**

The overarching risk assessment is a systematic review of the type of biological material that is or will be handled and stored, the locations and facilities where it will be handled and stored, the personnel handling the material, the type of work planned, and the various equipment and procedures that will be used.

## Administration and reporting

The Biosafety Program is managed and maintained by the Biosafety Officer, within York’s Health, Safety and Employee Well-Being (HSEWB) unit. The BSO directly reports to the Director of HSEWB. Biosafety falls under the scope of two divisions at York. As the VPRI is the License Holder, the BSO indirectly reports to the Biosafety committee and theDirector, Office of Research Ethics within the VPRIfor matters related to research compliance and Biosafety (see Figure 1 below).

Figure 1: Biosafety Reporting Structure

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Description automatically generated with medium confidence

# York University Biosafety Committee

The York University Biosafety Committee (YUBC) is responsible for setting and enforcing appropriate safety standards for work with biological materials within University workplaces. It reports to the Academic Policy and Planning Research Committee (APPRC) and provides oversight to the Biosafety Program.

The Committee has formally approved the contents of this Program and enforces the standards through the approval of Biosafety Permits for all work with biological materials.

The YUBC membership includes academic (voting) members representing the faculties of Science, Health and Engineering and ex-officio members (non-voting). The Biosafety Committee’s membership and Terms of Reference can be found in Appendix A.

# Permits, Projects and Enforcement

## Biosafety Permit application

Any researcher working with biological material on York University premises is required to hold a valid Biosafety Permit. The Permit Application Form and its pertaining appendices can be obtained from the BSO (see Appendix B). A completed Biosafety Permit Application Form should be returned to the BSO for review.

Biosafety Permits are valid for three years. Permit Holders may be granted an extension for a maximum of six months. Renewals of Permits and expired Permits require a full Biosafety Permit application.

No operation involving any biological agent shall be performed at York, nor shall any biological agent be obtained by any person in the employ of York or its grant or permit Holders without the prior possession of a valid Biosafety Permit. External contractors to York working on campus also come under the scope of these regulations with respect to handling and manipulating biological agents at York. External contractors are required to provide a copy of their HPTA license and valid Biosafety Permit to York’s BSO prior to bringing any materials onto York’s property.

## Biosafety Permit Holder Requirements

Biosafety Permit Holders shall be York University faculty members. They must have assigned and dedicated research space by their faculty (Chair or Dean) to conduct research according to the biological material used.

PIs are required to hold a valid Biosafety Permit in good standing for the timely release of funding and/or creation of cost centres for research that involves the use of biological materials.

Where research spaces are shared between more than one PI, all researchers are required to have valid Biosafety Permits, and will be held accountable for proper maintenance of the assigned space(s) in accordance with the Canadian Biosafety Standards.

Non-compliances in shared spaces will be documented in the inspection reports for all shared PIs and addressing the non-compliances are the responsibility of all the researchers using that space.

## Permit Amendments

To ensure adherence to the Tri-Council Agreement on grant awards and *the Human Pathogens and Toxins Act*, Biosafety Permits have to be kept updated throughout the validity of the Permit. Amendments to Biosafety Permits can be made by contacting the BSO. This includes addition or removal of lab personnel, projects/grants, research spaces and/or biological material.

Addition of projects/grants to an existing Biosafety Permit will require a complete Project Specific Biosafety Risk Assessment Form (see Appendix C).

## Dual Use Potential

When research with dual-use potential is identified, it is necessary to assess the risk associated with the research. The determination of risk takes into consideration the hazards identified, the likelihood of an event, and the consequences should an event occur. Refer to Appendix D for identifying research which has dual-use potential.

## Biological Materials Inventory

An updated biological material inventory must be maintained by the laboratory and be provided to the BSO annually. Records of inventory should include:

* Type of biological material (cells, tissues, viruses, etc.);
* Locations of manipulations, handling and storing of biological material;
* Source of biological material; and
* Any additional information, as applicable.

Receipt and shipping of biological material to/from Canadian institutions would require completion of the Biohazard Material Transfer Notification (See Appendix E).

## Non-Compliance and escalation of violations

Lack of follow up, continuing research with expired Biosafety Permits, deficiencies and/or other issues of non-compliance resulting from lab inspections will be documented. The BSO will notify the PI in writing on items that need to be addressed. The PI must address the follow-up actions and inform the BSO within a mutually agreed time frame.

If the PI does not address the infraction(s) then the issue(s) will be escalated as follows:

1. BSO will inform the Biosafety Committee Chair and Director of Office of Research Ethics regarding the infraction(s).
2. The Chair of the Biosafety Committee will provide a written notice to the PI to address the concerns within 21 days.
3. If there is no resolution, then the concern will be brought forward to the Associate Dean of Research (copying the Dean’s office) for appropriate action which may include revoking of Biosafety Permit, suspension of access to research funding and/or suspension of access to research facilities.
4. The Associate Vice President of Research and VPRI office will also be notified.

## Revoking and Reinstatement of Permits

The BSO or any member of the Biosafety Committee has the authority to initiate the procedure for revoking a Permit when there is an actual or perceived threat to health, safety or security involving biological materials.

Escalation Procedures:

1. On the occurrence which may include minor infractions which have been noted numerous times in regular inspections, the Permit Holder will be notified in writing (e.g. memo or as part of an inspection report) by the BSO or the Chair of the Biosafety Committee of the infractions or violations that were noted. The Permit Holder will be informed that a follow-up visit will be conducted by the BSO to review compliance and the consequence should a re-occurrence happen within six months.
2. On the second occurrence (within one year), the BSO or the Chair of the Biosafety Committee will send a letter to the Permit Holder, with a copy to the Department Chair and the Associate Dean of Research, outlining the infractions, the responsibilities of the Permit Holder in that respect and the consequences of further infractions. The Permit Holder will be informed that a follow-up visit will be conducted by the BSO and a member of the Biosafety Committee to review compliance.
3. On the third occurrence (within one year), the Permit will be revoked. Access to all biological material will be revoked from the lab personnel.

At least two voting members of the Biosafety Committee shall approve the action.

The BSO or a voting member of the Biosafety Committee reserves the right to bypass any one or more of the above noted steps if a serious, immediate risk to health, safety or security violation occurs.

For a revoked Biosafety Permit to be reinstated, the Permit Holder must prove to the BSO and at least two members of the Biosafety Committee (including the Chair) that all required remedial actions have been taken. As License Holder, the VPRI office will be kept informed.

## Teaching Laboratories using Biological Material

For laboratories that are using biological material for teaching purposes, the Course Director shall complete a Biosafety Permit Application prior to teaching. It is recommended that teaching labs use Risk Group 1 agents, with applicable safety practices in place. Use of Risk Group 2 agents for teaching labs will only be authorized upon approval of Biosafety Committee. All teaching spaces will be inspected according to Biosafety Standards as per inspection procedures.

# Laboratory Commissioning/Decommissioning

## Commissioning

If a biological material is required for use in a laboratory, which has not previously been designated as a Biosafety laboratory, the BSO shall commission the lab space in accordance with the Canadian Biosafety Standard before the laboratory can be considered for work with biological materials. The BSO will then designate the laboratory as a Containment Level 1 or 2 laboratory in accordance with the type of biological agents and the activities conducted in the laboratory.

The following should be posted when a lab is commissioned:

* Applicable Biosafety Signage (CL1 or CL2) (Appendix F)
* York University WHMIS Lab Door Poster (Appendix G)
* 24-hour emergency contact name and number.

## Decommissioning

Where biological material is no longer required to be used or stored in a laboratory, the Permit Holder shall notify the BSO and the lab will be decommissioned. Once decommissioned, Permit Holders will be asked to remove or deface all Biosafety signs.

## Renovations

Biosafety Standards apply to any new construction or major renovations. Older facilities will be assessed in accordance with the activities conducted in the laboratory.

# Biosafety Training

All personnel working with biological material must be trained prior to handling them. The BSO provides a full Biosafety Training session at the beginning of every semester. This consists of theories and practices in Biosafety, hands-on training on use of autoclaves, as well as an online test. Successful candidates will be provided with a proof of completion. After this course has been successfully completed, the person is allowed to work with biological materials.

All persons who do not work with biological materials, but who may regularly be in close proximity to them, shall complete Biosafety Awareness training from HSEWB. Refresher training for both the full Biosafety training (including hands-on use of autoclaves) and Biosafety Awareness shall be taken once every 3 years. Information on the next available course may be obtained by contacting the BSO.

All users who have completed training will also complete an Agreement on Biosafety for Lab Personnel form (see Appendix H). This form will be signed by the PI and the user and should be filed in the lab safety binder. It will be requested upon an inspection of the lab.

PIs / Permit Holders are responsible for ensuring that each person under their direction is trained, understands the specific hazards associated with their work, know how to protect themselves from such hazards, and know the proper policies and procedures for the use of biological materials at York before beginning work in CL1 or CL2 laboratories. Lab specific training must be provided by the PI or a lab manager in accordance with the biological hazards and equipment used in the lab. This training must be documented and include information on the safe use, handling, storage and disposal of biological agents as well as an explanation of the risks associated with their exposure.

Any users working under the Permit Holder who do not have valid, up to date training will affect the Permit Holder’s standing and will be documented as part of an inspection.

# Biosafety Inspections

The BSO will conduct annual inspections of CL2 labs for all listed research spaces to ensure adherence to the Biosafety program and Canadian Biosafety Standards. CL2 inspection checklists are available in Appendix I.

For CL1 Permits, self-inspections will be conducted once in a three-year period. For renewals of existing CL1 Permits, the BSO will conduct an inspection once every 3 years.

PI should address deficiencies in a timely manner. Items that are infrastructure-related would need to be addressed via the Facility Manager of the area. Deficiencies that are not addressed or those leading to non-compliance will be brought forward to the Biosafety Committee for escalation.

# Medical Surveillance

Medical surveillance is a tool used to identify diseases and/or injuries associated with occupational hazards. Medical surveillance involves the evaluation and support of an individual’s health status as it relates to potentially significant occupational exposures to specific hazardous agents, such as animal allergens or biohazards. Specific safety-sensitive work tasks might also require a certain degree of good health and fitness to ensure the health and safety of the employee and/or of the greater community. Pre-exposure intervention can be critical, and therefore medical surveillance requirements must be met before work begins, or as soon as possible after an exposure event occurs.

York’s Medical Surveillance Program establishes formal standards and procedures to assist York University employees and students conducting research, by providing occupational health and medical surveillance for the prevention and control of exposure to biological agents and/or to experimental animals. The program was developed to follow best practices and contribute to a healthy and safe work environment. This program also ensures compliance with related legislation and guidelines.

The Medical Surveillance Protocol for Experimental Animals and Biohazards is administered by the BSO (as part of the University’s HSEWB unit) in consultation with an occupational health physician with expertise in occupational health and medical surveillance.

## Special Precautions – Pregnancy

Ideally, workplace procedures should be set up with the assumption that any female lab personnel could be pregnant at any time. However, in some cases when laboratory personnel become pregnant, it may be preferable to change procedures and restrict certain activities (e.g., use of certain chemicals, biological agents, and radioisotopes).

Lab personnel who are pregnant may wish to self-disclose to their supervisors and/or HSEWB at the earliest opportunity so they can minimize potential exposures from laboratory hazards as early as possible. Should personnel be removed from certain activities, they may be accommodated, wherever possible, for the duration of their pregnancy.

# Personal Protective Equipment

Personal Protective Equipment (PPE) is equipment and/or clothing worn by personnel to provide a barrier against regulated materials, thereby minimizing the risk of exposure. PPE may include, but is not limited to, lab coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks, and respirators.

The matrix below outlines minimum PPE required for conducting work and handling biological materials inside CL1 and CL2 labs at York University. These are general guidelines. Specific requirements will vary according to biological agents handled, lab experimental procedures and primary containment devices used.

Table 2: Required PPE for CL1 and CL2 Labs

|  |  |  |
| --- | --- | --- |
| Biosafety Lab 🡪 | Containment Level 1 | Containment Level 2 |
| **Face** | Protective eyewear and appropriate face protection (face shields, masks) should be worn for procedures in which there is potential for splashes of microorganisms or other hazardous materials. | Manipulations should be carried out inside a certified Biosafety Cabinet, wherever applicable. Appropriate face protection (goggles, mask, face shield or other, as appropriate) should be used for anticipated splashes or sprays of infectious or other hazardous materials to the face (as determined by risk assessment) when the microorganisms are manipulated outside the BSC. |
| **Hair** | All hair must be restrained or covered when handling microorganisms or other hazardous materials. This also applies to facial hair. | All hair must be restrained or covered when handling microorganisms, infectious biological agents or other hazardous materials. This also applies to facial hair. |
| **Hands** | Gloves should be worn when working with risk group 1 materials.  Gloves are to be disposed in designated biological waste containers when work with biological materials is completed, or when the integrity of the glove is compromised. Disposable gloves are not to be washed, reused, stored for future use, or be used for touching "clean" surfaces (keyboards, telephones, etc.).  Gloves should not be worn outside the lab.  One hand glove policy applies to lab personnel exiting and entering a lab within a containment zone.  Hands are washed immediately following removal of gloves. | Gloves must be worn when working with risk group 2 materials or when coming into contact with potentially contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate for certain tasks.  Gloves are to be disposed in designated biological waste containers when work with infectious materials is completed, or when the integrity of the glove is compromised. Disposable gloves are not to be washed, reused, stored for future use, or be used for touching "clean" surfaces (keyboards, telephones, etc.). Gloves should not be worn outside the lab. One hand glove policy applies to lab personnel exiting and entering a lab within a containment zone.  Hands are washed immediately following removal of gloves. |
| **Clothes** | It is recommended that lab coats, gowns, be worn according to activity, to prevent contamination or soiling of personal clothing. | Protective laboratory coats and/or gowns, designated for lab use must be worn within the lab when working with risk group 2 materials.  All protective clothing is either stored or disposed of in the laboratory; lab personnel should never take PPE home. |
| **Feet** | Non-absorbent, closed-toed shoes with closed heels are required | Non-absorbent, closed-toed shoes with closed heels are required |

# Lab Equipment

As appropriate, containment level laboratories must be equipped with, or have ready access to, safety equipment that may include fume hoods, Biosafety cabinets, laminar flow hoods, eyewash units, deluge showers, flammable storage cabinets and fire extinguishers. Details of various equipment can be found in the Laboratory Safety Program.

## Biosafety Cabinets

Biosafety Cabinets (BSCs) are used to protect users from exposures to airborne biological agents. The system relies on air flow, and so all precautions must be taken to ensure that the protective air curtain is not breached. This includes not walking behind a Biosafety cabinet when it is in use. These units should not be used with hazardous chemicals. Biosafety cabinets should be certified annually in accordance with NSF-49 Standards, by a licensed technician.

Extensive descriptions of BSCs are available in Chapter 11 of the Canadian Biosafety Handbook, including characteristics of all class types, installation specifications, testing, certification, and proper use of a BSC. Note that hard-ducted Type B Biosafety cabinets require that the BSC to be connected to the exhaust system where the air is discharged directly to the outside atmosphere. You must consult with the Facility Manager or building engineer in advance in order to ensure that the ventilation system is appropriate for this type of BSC.

## Laminar Flow Hoods

Laminar flow hoods are used as clean bench spaces and are designed to protect the product within the work area from airborne particulates in the ambient air. Personnel and the environment are not protected from materials located in the laminar flow hood. These units should not be used to handle biohazardous materials, toxins, carcinogenic agents, radionuclides, or hazardous chemicals. Laminar flow hoods should be certified at least once every two years, using NSF-49 Standards, by a licensed technician. For more information, contact the BSO.

### Testing Services

Correct operation of BSCs and Laminar Flow Hoods must be verified before they are used and then annually, and following any repairs or relocation, in accordance with the field tests outlined in the most recent version NSF/ANSI 49: Biosafety Cabinetry Certification.

The testing of biological safety cabinets and laminar flow hoods at York is conducted by an external contractor. Fees for this service are charged to the Principal Investigator / researcher or, in the case of teaching, to the instructor’s department. For more information, contact the BSO and/or make arrangements for testing, servicing or repair of a biological safety cabinet directly with the service provider.

## Fume Hoods

The fume hood is the primary control device in most laboratories for protecting employees and students from exposure to hazardous chemicals. It is also an integral part of the building air handling system. The efficiency of operation is essential in maintaining good air quality in laboratories. It is therefore imperative that it function properly and that it be designed appropriately. This standard was developed in accordance with the Canadian Standards Association (CSA) Standard Z316.5-15 Fume Hoods and Associated Exhaust Systems.

Fume hoods should be tested by qualified personnel in accordance with the CSA Standard or equivalent. To report fume hood malfunctions, contact the Facilities Services as well as the department Facility Manager

Additional information on fume hood installation and associated standards for the University is available in the Laboratory Safety Program.

## Autoclaves / Steam sterilizers

Autoclaves can be used for both the disinfection of contaminated materials or for the sterilization of reagents and labware used in laboratory procedures. The use of autoclaves/steam sterilizers for decontamination poses additional hazards from those encountered in sterilization of reagents.

Efficacy monitoring of autoclaves used for decontamination of laboratory waste with chemical integrators must be done regularly, and the records of these results and cycle logs (i.e., time, temperature and pressure) must also be kept on file.

Chapter 15 of the Canadian Biosafety Handbook has more details on the principles of sterilization, disinfection, decontamination procedures, and validation.

For additional information, contact the BSO.

# Use of Animals for Research

All research involving animals is governed by provincial legislation (*Animals for Research Act* and national guidelines (Canadian Council on Animal Care (CCAC)).

The Animal Care Committee (ACC) at York University has oversight over all research involving animals conducted (on and off campus) by York University faculty, staff and/or students. It is the ACC's mandate to ensure that all research involving animals is conducted in a manner consistent with the guidelines of the CCAC and relevant regulations/legislation. It is the policy of the University that researchers intending to conduct research involving animals and/or use animals for teaching purposes must submit the appropriate protocol and obtain approval of said protocol by the ACC before animals can be ordered or a grant application endorsed by the University. Appropriate training and education are required by all researchers (student, faculty, and staff) in order to conduct research involving animals.

The University's animal care practices are monitored on an institutional level by both the relevant provincial Ministry and the CCAC. A consulting veterinarian conducts regular visits of the animal care facilities to inspect conditions and provide necessary care.

All aspects of the proposed use of animals in research and the operational procedures for the care and maintenance of animals must satisfy the Standards and Guidelines of the Canadian Council on Animal Care (CCAC), the Canadian Biosafety Standard, Containment Standards for Facilities Handling Aquatic Animal Pathogens and require approval from the Animal Care Committee, if the animals are exposed to or infected with biological materials. This should be done to ensure protection for laboratory personnel, the environment, and to ensure that every care is taken to avoid causing the animals unnecessary pain or suffering and to provide the animals with the highest quality of care.

# Shipping/Receiving Biological Material (HUman, Animal or Plant material)

Due to the complexity of the various regulations for importing or exporting human, animal and plant pathogens, consult the BSO before any importation or exportation. The BSO will guide you through the process of Public Health Agency of Canada, Canadian Food Inspection Agency, and Environment and Climate Change Canada requirements and will ensure you have all the required Permits and documents to comply with these regulations.

Note that the application for a Permit to import biological materials into Canada or to transfer biological materials within Canada MUST be reviewed and approved by the BSO.

Ensure the appropriate Material Transfer Agreement (MTA), which is a contract between the provider of material and the recipient is filled out. This grants the recipient a license to use the proprietary material and ensures that both parties understand how the materials can be used. MTAs govern issues such as ownership of derivatives and modifications of the materials, the transfer of risk, limits on use, confidentiality of information in relation to the materials and rights to inventions, and research results arising out of use of the materials. Just as research sponsorship agreements and confidentiality agreements can affect the ownership and dissemination of research results, so too can MTAs.

Transfer of biological materials within Canadian Institutions must require the completion of a Biohazard Material Transfer Notification (see Appendix E) prior to transfer. Transportation of Dangerous Goods Training must be valid for individuals shipping and/or receiving biohazards shipments.

# Biological Waste Management

It is a basic Biosafety principle and a critical component of containment that all contaminated material (lab supplies, equipment) is decontaminated prior to disposal. The principles of sterilization, disinfection, and decontamination are critical for reducing the risk of pathogen release within containment zones, to the environment, and within the community.

Decontamination is the process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions. The primary objective of decontamination is to protect containment zone personnel and the community from exposure to viable pathogens and toxins that may cause disease.

Decontamination can be achieved through disinfection or sterilization. Disinfection is a process that eliminates most forms of living microorganisms but is less lethal than sterilization. Typically, prepared solutions of 10% sodium hypochlorite (bleach) or 70% ethanol can be used as disinfectants in the lab. Labs may also use approved commercial products for disinfection.

Sterilization is a process that completely eliminates all living microorganisms, including bacterial spores. York University has autoclaves in Farquharson, Lumbers, Life Sciences Building and Bergeron Building. Sterilization is achieved by pre-programmed cycles in the autoclaves. The effectiveness of the sterilization process is affected by a number of factors, including the nature and quantity of microorganisms, the amount of organic matter present, the type and state of items being sterilized, and the temperature.

Prior to treatment, biological waste is considered untreated (and therefore potentially infectious) and must be stored safely in access-controlled areas (labs, waste storage rooms). Accumulation of untreated waste may result in non-compliance.

York University has procedures in place to ensure that lab waste is treated appropriately. All biological waste containers must display the biohazard symbol with the word “Biohazard” in a colour contrasting the container. Custodial staff will not pick up biological waste. It is the responsibility of lab personnel to decontaminate and dispose lab waste appropriately. All lab personnel therefore should be trained in the use of autoclaves and sterilization procedures prior to working in labs.

Below are some general guidelines on decontamination of lab generated biological waste, as per procedures established at York. Specific requirements may vary according to biological material and experimental procedures.

Table 3: Decontamination Guidelines

|  |  |  |
| --- | --- | --- |
| Type of Biological Material | Suggested Decontamination procedure | Suggested Disposal Procedure |
| **Contaminated solid biological waste (tips, tubes, gloves, etc.)** | * 70% ethanol * Autoclave * As per risk assessment | Designated non-hazardous waste bins outside the autoclave room |
| **Infectious material, cell culture** | * 70% ethanol * Autoclave * As per risk assessment | As per risk assessment |
| **Cell culture media** | 10% final concentration sodium hypochlorite (bleach) | In compliance with sewer by-laws |
| **Blood and other bodily fluids (human or animal)** | 10% final concentration sodium hypochlorite (bleach) | In compliance with sewer by-laws |
| **Contaminated sharps or glassware** | As per risk assessment | External biological waste contractor |
| **Anatomical tissues (human or animal)** | As per Vivarium training | External biological waste contractor |
| **Contaminate lab equipment, instruments** | As per risk assessment | As per risk assessment |

For queries related to biological waste or clarification of waste treatment procedures, contact the BSO.

# Emergency Response and Processes

At York University, ALL incidents involving biological materials (including incidents involving regulated materials, animals, failure of containment systems or control systems, missing pathogens, unauthorized access to sensitive information, spills, exposure incidents or loss or theft of biological material) must be reported to the BSO. During off hours, labs are advised to contact Security Services who will contact the BSO.

Immediate reporting allows for procedures to be promptly initiated to contain any release of regulated materials, repair or perform corrective actions to containment systems, secure assets with dual-use potential, and when applicable, notify the appropriate regulatory agencies.

## Biological Spills

Emergency response plans are required for Biosafety laboratories and must include procedures for dealing with spills and other laboratory incidents that can result in the release of biological materials or to an exposure, as per the risk assessment. Since the capacity of most commonly used laboratory containers is usually a small volume, it is anticipated that most spills within the laboratory will be limited and therefore of a minor nature. Although the specific response will depend on the nature of the biological material and the volume spilled, decontamination and clean-up procedures should follow common practices in Biosafety laboratories (see Chapter 17.3 of CBH). Effective disinfectants must be available in the laboratory at all times and for immediate use.

All laboratories handling biological material must post copies of the flow chart on Emergency Response to Occurrences involving Biological Materials (see Appendix J).

If there is potential for a large spill (>10L), specific procedures must be developed and approved by the BSO and Biosafety Committee. Contact the BSO for risk assessment and advice.

Each laboratory must have their own emergency plan according to the risk level associated with their specific biological material, location, concentrations and volumes. The laboratory specific emergency response plan must be available to all users at all times. Users must be instructed and trained in advance of an emergency in order to ensure an efficient and adequate response.

Chapter 17 of the Canadian Biosafety Handbook provides additional and general information on how to write your emergency response plan.

It is the responsibility of the PI to ensure that a well-thought-out spill kit is readily available and maintained for spills involving biological materials. Below is a suggested starting point for a basic kit; labs may need to customize this depending on the materials and type biological agents present:

* Paper towels or other absorbent material
* Appropriate disinfectant solution
* Gloves and any other applicable PPE
* Tongs, scoop, dustpan (for picking up broken glass, etc.)
* Container to dispose spill clean up items
* Biohazard waste bags

If bleach is used to clean up your spill, prepare a fresh dilution of 10% NaOCl (bleach). Keep a container in the spill kit for preparing the working dilution. Do not keep actual disinfectant in the spill kit as they have an expiry date.

CL2 labs will need biohazard bags or buckets for disposal of biohazardous waste. If putting any spill remains in biohazard containers, mark container “Spill Cleanup” and indicate what disinfectant it contains.

Instructions for cleaning up a spill involving biological agents should be posted near the spill kit and be clearly visible.

All major biological spills will be investigated and a debrief meeting will be held with the involved parties to discuss the incident and prevent future such incidents by implementing mitigation measures.

Where non-indigenous terrestrial animal pathogens are handled or stored, or in accordance with conditions of the terrestrial animal pathogen import Permit, the CFIA must be informed without delay of incidents involving:

1. regulated materials or regulated animals, including a possible release or animal escape; and
2. failure of containment systems or control systems.

## Exposures

Incidents that result in exposures or potential exposures to known pathogens must be reported to the BSO immediately. An internal investigation will be conducted and documented to determine root causes and recommended measures will be reported to mitigate future risks.

The PHAC may have to be informed without delay via the submission of a notification report following:

1. an exposure to a human pathogen or toxin;
2. recognition of a disease that has or may have been caused by an exposure to a human pathogen or toxin; or
3. non-exposure Biosafety and Biosecurity incidents.

An exposure follow-up report documenting the completed investigation to be submitted to the PHAC within

1. 15 days of the submission of an exposure notification report involving an SSBA; or
2. 30 days of the submission of an exposure notification report involving a human pathogen or toxin other than an SSBA.

## Accidental Release, Loss, theft of Biological Materials

Where regulated biological materials or data are accidentally released, possessed, missing or stolen, it is the responsibility of the PI to inform the BSO, who shall report to PHAC in accordance with the *Human Pathogens and Toxins Act* and applicable regulations. Table 4 below summarizes the incidents that require notification to PHAC without delay.

Table 4: Incidents Requiring PHAC Notification

|  |  |
| --- | --- |
| Incident | Reference |
| Inadvertent release of a human pathogen or toxin. | HPTA 12(1) |
| Inadvertent possession and inadvertent production of a human pathogen or toxin. | HPTA 12(2)  HPTR 9(1)(c)(ii) |
| Exposure to a human pathogen or toxin that has, or may have, caused disease. | HPTA 13 |
| Missing or stolen human pathogen or toxin. | HPTA 14 |

## Internal Reporting and Notifications

As per York’s Lab Safety and Incident Investigation Program, the following table will be followed for notifications of incidents involving biological materials.  
  
Table 5: Emergency Contact Information

|  |  |  |
| --- | --- | --- |
| Type of Emergency | Who to call | Phone number |
| Life-threatening or  Medical Emergencies | 911 **and**  Campus Security | 911  416-736-5333 or Ext. 33333 |
| Exposure / Spill Response  During business hours Weekdays (8:30am - 4:30pm) | 1. Your supervisor |  |
| 1. Area Health and Safety Officer | Faculty of Science:  Brad Sheeller (647-999-9806)  Faculty of Health:  Raj Ram (416-712-2769)  Faculty of Engineering:  Kitty Ki (437-929-2074) |
| 1. Biosafety Officer | Jay Majithia  Ext. 55491 orExt. 44745 |
| Exposure/Spills Response  Weekends and after hours | Campus Security | 416-736-5333 or Ext. 33333 |

# No-Reprisal

This program prohibits reprisals against lab personnel who exercise their rights or bring forward concerns pertaining to their health and safety. Employees/faculty who engage in reprisals or threats of reprisals may be disciplined up to and including termination from employment.

Reprisal includes:

* Any act of retaliation that occurs because a lab personnel has complained or provided information about an incident or concern;
* Intentionally pressuring a person to ignore or not report an incident or concern; and/or
* Intentionally pressuring a person to lie or provide less than full cooperation with an investigation.

# Non-Compliance

Any person who violates this program, and/or supervisor who fails to take action when advised of a violation, will be subject to appropriate disciplinary action, up to and including termination of employment.

Disciplinary action will also be taken if a complaint is found to have been made fraudulently and with malicious intent.

# Record Keeping

All labs should keep and maintain updated records on all their processes, procedures specific to the lab/lab-related activities, inventory (Pathogen Safety Data Sheets, supplier information sheets and other hazardous materials used) and personnel. In addition, labs should also keep training records of applicable hazards for all authorised personnel.

Records can be kept electronically or physically within the lab. They should be made available upon request for inspection/verification by Federal and/or Provincial authorities, management, BSO, or the Biosafety Committee. Examples include maintaining employee training records or any other health and safety courses that are not offered or provided by HSEWB.

# Related Policies / Programs / Procedures

* [Laboratory Safety Program](https://yulink-new.yorku.ca/documents/20182/29507656/Laboratory+Safety+Program/388ec4d8-728d-4f64-ae87-e96d6ceaac14)
* [Medical Surveillance Program](https://yulink-new.yorku.ca/documents/872311/5878071/Medical+Surveillance+Program.pdf/4ae7b2a0-e0a4-47ba-be1c-e1da162405c2)
* [First Aid Program](https://yulink-new.yorku.ca/documents/20182/1360664/First+Aid+Program/b1ac5adb-1d09-4985-bb0b-ec0155717dde)
* [Incident Investigation Program](https://yulink-new.yorku.ca/documents/20182/92034/Accident+Investigation/6b6a91fa-0445-49a6-9592-d189ad4282c6)
* [Risk Management Services Injury Reporting Procedure](https://www.yorku.ca/riskmanagement/incident-reporting/)
* [Transportation of Dangerous Goods Program](https://yulink-new.yorku.ca/documents/20182/92034/Transportation+of+Dangerous+Goods/0aa4d23c-d436-4685-8e7d-f1703795119f)
* [WHMIS Program](https://yulink-new.yorku.ca/group/yulink/whmis)
* [Work Alone Program](https://yulink-new.yorku.ca/documents/20182/1360664/Working_Alone_Program_2018.pdf/274810f9-3f9b-4259-9197-a84167ff2179)
* [York’s Fume Hood Standard](https://yulink-new.yorku.ca/documents/20182/29507656/YU+Fume+Hood+Standard.pdf/54668d25-3768-431c-b450-3a7fc814ff0c)
* [York University Guidelines on Eyewash and Emergency Showers](https://yulink-new.yorku.ca/documents/20182/92034/Eyewash+and+Emergency+Shower+Guideline/97ee377e-71ad-4a1b-8e0a-533579080049)
* [York University’s Laboratory Design Guidelines](https://yulink-new.yorku.ca/documents/20182/29507656/YU+LABORATORY+DESIGN+GUIDELINES.pdf/f9b817e7-5a17-4566-bd58-f493da05c2d0)
* [Service Animals in Laboratories SOP](https://yulink-new.yorku.ca/documents/20182/1414175/SOP+-+Service+Animals+in+Laboratories/8bacac40-8579-44b5-921e-064f49b745e3)
* Medical Surveillance Protocol for Experimental Animals and Biohazards
* [Biosafety Committee Terms of Reference](https://yulink-new.yorku.ca/documents/20182/1413550/York+U+Biosafety+Committee+-+Terms+of+Reference+2024.pdf/9d6f1a73-3fb0-4954-922b-8722710750ff)

Additional resources can be found in the Appendices section of this Program.

# Reviewed By

The Biosafety Program shall be reviewed once every three years in consultation with applicable Joint Health and Safety Committees, Area Health and Safety Officers and HSEWB.

This program was also reviewed by the following parties/areas:

* Biosafety Committee
* Office of Research Ethics
* Animal Care Committee

# References

* [Public Health Agency of Canada (PHAC) Biosafety and Biosecurity](https://www.canada.ca/en/services/health/biosafety-biosecurity.html)
  + [Human Pathogens and Toxins Act](http://laws-lois.justice.gc.ca/eng/acts/H-5.67/)
  + [Human Pathogens and Toxins Regulations](http://laws-lois.justice.gc.ca/eng/regulations/SOR-2015-44/index.html)
* [Canadian Food Inspection Agency](https://www.canada.ca/en/food-inspection-agency.html)
  + [Health of Animals Act](http://laws.justice.gc.ca/eng/acts/H-3.3/page-2.html)
  + [Health of Animals Regulations](http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._296/)
* [Canadian Biosafety Standards, Third Edition](https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/third-edition.html)
* [Canadian Biosafety Handbook, Second Edition](https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html)

# Appendices

Appendices and additional resources can be found on [York University’s Biosafety Program page](https://yulink-new.yorku.ca/group/yulink/biosafety) on YU-Link (note: Passport York credentials will be required for access).

Appendix A: [Biosafety Committee Terms of Reference](https://yulink-new.yorku.ca/documents/20182/1413550/York+U+Biosafety+Committee+-+Terms+of+Reference+2024.pdf/9d6f1a73-3fb0-4954-922b-8722710750ff)

Appendix B: [Biosafety Permit application](https://yulink-new.yorku.ca/documents/20182/1414216/Biosafety+Permit+Application.doc/18aab5a8-84d8-46ce-918d-db8c5c925c3a)

Permit application Appendices:

1. [Animals (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+I+Animals.doc/84d0a87d-8f94-47cd-b86b-e2d3ad9df74d)
2. [Bacteria, Fungi, Parasites, Microbial Toxins (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+II+Bacteria%2C+Fungi%2C+Parasites%2C+Microbial+Toxins.doc/2d10f5a7-d19d-405e-8b8c-314bbf8f2536)
3. [Viruses, Viral Vectors, Recombinant DNA, RNA (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+III+Viruses%2C+Viral+Vectors%2C+Recombinant+DNA%2CRNA.doc/37b685c8-dbeb-4031-8c80-d287428b6ccb)
4. [Tissue Samples (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+IV+Tissue+Samples.doc/2a78a2dc-744f-4c58-b34d-5cd075664e7c)
5. [Cell Lines (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+V+Cell+Lines.doc/3dc4365e-7071-48c3-9eb6-e982646f15bb)
6. [Blood, Blood Fractions & Body Fluids (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+VI+Blood%2C+Blood+Fractions+%26+Body+Fluids.doc/a7a2ac30-044e-48cc-829c-edb6ccaa9bb1)
7. [Plants (DOC)](https://yulink-new.yorku.ca/documents/20182/1414216/YU-Biosafety-Appendices-2015+-+VII+Plants.doc/f6941eff-be2c-42dd-b4ab-33e6b93f9842)

Appendix C: [Project Specific Biosafety Risk Assessment Form](https://yulink-new.yorku.ca/documents/872311/5878071/Project+Specific+Risk+Assessment+-+Final.pdf/ba09d6db-38e1-4818-aebb-6927e69f3551)

Appendix D: [Dual Use Potential Flow Chart](https://yulink-new.yorku.ca/documents/20182/1413550/Dual+Use+Identification.pdf/a5906589-161b-4f92-9ecd-bda120855eba)

Appendix E: [Biohazard Material Transfer Notification](https://yulink-new.yorku.ca/documents/20182/1413550/York+U+-+BSO+Human+Pathogen+and+Toxin+Transfer+Notification.pdf/e2260c4c-ff05-4e52-8039-2f444cd5984d)

Appendix F: Biosafety Signage: [CL1](https://yulink-new.yorku.ca/documents/20182/1413550/CL-1+lab+sign.pdf/6e3c172d-c4db-4774-859f-6687cfda5f06) | [CL2](https://yulink-new.yorku.ca/documents/20182/1413550/CL-2+lab+sign.pdf/532aab1c-4211-4d1f-9485-2b7810259afe)

Appendix G: [York University WHMIS Lab Door Poster](https://yulink-new.yorku.ca/documents/20182/1413550/New+WHMIS+Poster.pdf/66f530fd-0a7a-40a7-9c86-d9a0a76542cf)

Appendix H: [Agreement on Biosafety for Lab Personnel](https://yulink-new.yorku.ca/documents/872311/5878071/Agreement+on+Biosafety+for+Lab+Personnel.pdf/8fa0ec5d-742d-46b8-a411-a75eece89a0f)

Appendix I: [CL1 inspection checklist](https://yulink-new.yorku.ca/documents/872311/5878071/CL1+Inspection+Checklist+-+2018.pdf/d3c76336-ed37-4536-a611-57558355f410) / [CL2 Inspection checklist](https://yulink-new.yorku.ca/documents/872311/5878071/2017+Inspection+Checklist.pdf/41eb186f-80b2-4683-84d1-6b8da88764f1)

Appendix J: [Emergency Response to Occurrences involving Biological Materials](https://yulink-new.yorku.ca/documents/20182/1413550/Biological+Materials+Exposure+and+Spills+Response.pdf/5bbe12ea-d7bc-4cfb-a0d6-10e13fc03ca4)