Biosafety Protocol

St. Francis Xavier University
April 2017

Biosafety is a program of administrative controls and containment strategies to reduce or eliminate exposure of laboratory workers, other persons, animals, plants and the outside environment to biohazardous materials. This Biosafety protocol focuses on regulatory compliance issues involving the receipt, use, storage, shipment and disposal of biohazardous materials at St. Francis Xavier University. Biohazardous materials include infectious agents (i.e., bacteria, virus, fungi, protozoa) or materials produced by living organisms (i.e., microbiological toxins) that may cause disease in humans, plants or animals. Biohazard can also extend to cell cultures, isolates, diagnostic specimens or biological products. Recombinant DNA is also encompassed by this protocol. Biohazardous materials are classified as a Health Hazard (category 1) under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) which replaces the Workplace Hazardous Materials Information System (WHMIS) classification (biohazardous materials, Class D, Division 3).

The StFX Biosafety Committee is responsible to the office of the Academic Vice-President and Provost for ensuring all research and teaching projects involving the use of biohazardous materials are conducted safely and in compliance with established biosafety guidelines.

This Biosafety protocol applies to:

1. pathogenic organisms and parasites infectious to humans, animals or plants;
2. human and non-human primate cell cultures, tissues and body fluids (e.g., blood, urine);
3. potentially infectious cell cultures, tissues and body fluids (e.g., sheep amniotic fluids);
4. genetically-modified micro-organisms which may be hazardous to humans, animals or plants;
5. plasmids, phage or other vectors which may be hazardous to humans, animals, or plants;
6. recombinant DNA which may be hazardous to humans, animals or plants;
7. biological toxins and venoms.

This Biosafety protocol does not apply to:

1. transgenic organisms which are not micro-organisms, i.e., plants, animals;
2. human bodily fluids and other potentially infectious materials as might be encountered in normal clinical practice in Student Health Services, Occupational Health Services and the rendering of first aid;
3. consumer products for testing which have been obtained from retail outlets;
4. procedures associated with the control of zoonotic infections;
5. activities associated with licensed abattoirs;
6. activities associated with human anatomy laboratories.

Projects proposing the use of biohazardous materials must meet the Protocol for safe use, physical containment and personnel training in accordance with the appropriate Biohazard Risk Group as defined by the Government of Canada's *Canadian Biosafety Standard*, 2nd edition, 2015 [https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/second-edition.html], *Canadian Biosafety Handbook*, 2nd edition, 2016 [https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html] and the NIH

Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2016, [http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines]. The CBS Guidelines are the national standard for the handling and storing of human and terrestrial animal pathogens (including avian and amphibian animals but excluding aquatic animals and invertebrates) and toxins in Canada. Facilities handling or storing aquatic animal pathogens must comply with the Canadian Food Inspection Agency's (CFIA) *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, 1st edition, 2010 [http://www.inspection.gc.ca/animals/aquatic-animals/imports/pathogens/eng/1312436244596/1322885037191].

Pathogenic organisms are divided into four risk groups based upon virulence, transmissibility, and availability of treatment or prevention of disease and are described in the *Canadian Biosafety Standard*. Containment classification is based on the level of risk or hazard to be encountered while handling biohazardous materials. Containment involves the use of physical facilities, equipment and good microbiological technique to protect personnel, and reduce the probability of the release of biohazardous materials into the immediate work environment and the outside environment.

StFX facilities at present are designed to accommodate research or teaching projects requiring containment Levels 1 and 2 (Risk Groups 1 and 2) only. Approval to conduct research involving containment Level 3 will require additional funding for provision of the appropriate containment. StFX is not equipped for projects requiring containment Level 4. StFX is only licensed for Containment Levels 1 and 2.

Although classification of pathogens into risk groups is based upon virulence, transmissibility, and availability of treatment or prevention of disease, the risk group may be subsequently modified following:

- work that involves mutation or frequent subculturing of a pathogen which may affect the microorganism's virulence, transmissibility or pathogenicity;
- generation of a bacterial strain which becomes resistant to a wide range of antibiotics such that the disease it causes becomes difficult to treat; a researcher may consider classifying such a strain in a higher risk group.

Risk Group 1 (low individual and community risk)

A microorganisms that is unlikely to cause disease in healthy persons or animals.

Containment Level 1

This level applies to the basic laboratory for the handling of Risk Group 1 agents. Level 1 requires no special design features beyond those suitable for a well designed and functional laboratory. Containment cabinets are not required. Work may be performed on an open bench top. Containment is achieved through the use of good microbiological laboratory practices.

Risk Group 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 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.

When operating in a laboratory which uses Risk Group 2 organisms, it is the individuals responsibility to be aware of the particular organisms involved and the particular risks they present.

Primary exposure routes for RG2 include ingestion, inoculation and mucous membrane. These organisms are generally not transmitted by an airborne route, however care must be taken to prevent the generation of aerosols (aerosols can settle on bench tops and be transmitted via contact) and splashes.

Containment Level 2

In addition to the requirements of containment Level 1, the following are required:

- laboratory should be located away from public areas and general offices;
- biohazard signage with appropriate risk level must be posted on the entrance to the laboratory;
- laboratory furnishings should be constructed with impervious and readily cleanable work surfaces;
- coat hooks must be provide for laboratory coats near the exit;
- hand washing facilities must be located near the exit;
- autoclave must be available in or near the laboratory;
- class I or II biological safety cabinets are required for all manipulations involving the agent which may create an aerosol. The biological safety cabinet must have been tested and certified within the previous 2 years according to accepted standards.
- Centrifuges require sealed rotors, or safety cups and should be equipped with HEPA filters

Prior to commencing projects or courses involving biohazards, certification and approval must be received from the StFX Biosafety Safety Committee. Principal Investigators shall obtain a certificate for activities involving the use and storage of biohazardous materials. Certificates are obtained by submission of a Biosafety Certificate Application. The certificates are valid for two years. Modifications to approved protocols, including changes in personnel, microorganisms used, or location of handling or storage of microorganisms, must be approved by the Biosafety Committee prior to such changes being made. Applications for changes should be made by submitting a revised application and explanatory letter.

Funding for projects involving the use of biohazardous materials will not be released by the University to the Principal Investigator until the necessary biosafety certificate has been approved by the Biosafety Committee and Biosafety Officer. The University reserves the right to suspend access to funds for projects which are not in compliance with the certificate, this protocol, the *Canadian Biosafety Standard*, or other relevant policies and guidelines. As required by the Memorandum of Understanding between the University and the Federal Granting Agencies (NSERC, SSHRC and CIHR), the University will advise the relevant granting Agency of any changes in eligible status of Grant Holders and Award Holders and/or of serious problems in the use of research funds. The Biosafety Officer shall also be advised of such changes of status.

Laboratories handling and storing biohazardous materials in addition to establishing a biosafety protocol, must also have a biosecurity plan. **Biosafety** deals with all aspects of containment to prevent exposure to or accidental release of biohazards whereas **biosecurity** is implemented to prevent the theft, misuse or intentional release of biohazards. All laboratories should adopt biosecurity practices which minimize opportunities for unauthorized entry into work or storage areas, as well as the unauthorized removal of infectious materials. This is most easily accomplished by keeping the laboratory doors locked at all times. During normal working hours authorized personnel only are permitted in the laboratory.

Biosafety Committee Terms of Reference.

The Biosafety Committee reports to the Academic Vice-President and Provost. The committee is mandated to:

1. offer advice on the safe use of biohazardous materials;

2. ensure adherence to the Government of Canada's *Canadian Biosafety Standard*, *Canadian Biosafety Handbook* and to the National Institutes of Health *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

The Biosafety Committee members are appointed by the Academic Vice-President and Provost in consultation with the appropriate Dean(s) of Faculty. The Committee membership shall be appointed as follows:

1. one Faculty member from each building in which biohazardous materials are used;
2. one Science Faculty member who is a non-user and who Chairs the Committee;
3. The University Biosafety Officer;
4. The University Health and Safety Officer.

Members shall be appointed such that the committee has expertise in biohazardous materials, techniques and procedures utilizing these materials and infection control.

The term of office for all members shall be three years with the exception of the Biosafety Officer and the Health and Safety Officer who shall be permanent ex-officio members of the Committee. The University Biosafety Officer may not serve as Chair.

The Committee shall meet at least twice per year or more frequently as required to fulfill the responsibilities of the Committee. Minutes shall be recorded and distributed to members, the Academic Vice-President, the Associate Vice-President Research and Graduate Studies (AV-PRGS) and the appropriate Dean(s) of Faculty.

Where a member has an actual, potential or perceived conflict of interest regarding the approval of a project, the member shall not be present during the discussion and decision.

Responsibilities of the Biosafety Committee are to:

1. establish and from time to time review the University Biosafety Program governing activities involving the use of biohazardous materials;
2. review and approve all activities involving the use of biohazardous materials, determine the level of containment required and assess the biosecurity measures before the initiation of the activity;
3. assess the Principal Investigators qualifications, training, and experience in relation to the biohazardous materials to be used;
4. ensure that facilities in which biohazardous materials are used are inspected to ensure satisfactory containment measures are available and in use;
5. ensure that there are procedures for the acquisition, secure storage, transport, handling, and disposal of biohazardous materials;
6. ensure that there are methods of record keeping and biohazard inventory in place;
7. ensure that emergency response plans for biohazardous material incidents have been established;
8. interpret policies, standards, and guidelines where necessary and provide information to Principal Investigators as appropriate;

9. in cases of non-compliance with this protocol or any federal, provincial or municipal legislation,
    (i) inform the Principal Investigator, Department Chair, Associate Vice-President Research and Graduate Studies and appropriate Dean of the non-compliance, and in consultation with the Biosafety Officer specify actions to be taken to deal with the non-compliance and set deadlines for such actions.
    (ii) refer continuing issues of non-compliance to the Academic Vice-President.

The Chair of the Biosafety Committee shall:

1. submit an annual report on biosafety activities to the Associate Vice-President Research and Graduate Studies. A copy to be retained by the Biosafety Officer. Where the Chair of the Committee provides the Academic Vice-President with written recommendations on behalf of the Committee, the Academic Vice-President shall provide a written response to the Committee
2. sign approved biosafety certificates.

The University Biosafety Officer shall:

1. assist Principal Investigators to assess facilities and assist in the preparation of the biosafety certificate application;
2. co-sign approved biosafety certificates;
3. provide advice on biohazardous materials and work procedures;
4. provide general biosafety training;
5. perform inspections and sign documentation for import permit applications;
6. ensure that steam sterilization cycles are verified using biological indicators on a regular basis and that records of users and cycles are maintained;
7. investigate all incidents relating to biosafety;
8. in cases of non-compliance with this protocol or any federal, provincial or municipal legislation,
    (i) inform the Principal Investigator and Chair of the Biosafety Committee of the non-compliance, specify actions to be taken to deal with the non-compliance and set deadlines for such actions;
    (ii) refer continuing issues of non-compliance to the Academic Vice-President.

It is understood that the responsibilities of the Principal Investigator of any project involving biohazardous material include:

1. applying to and receiving approval from the Biosafety Committee **before** obtaining and/or commencing work with biohazardous material;
2. complying with and enforcing the guidelines and standards set by regulatory and granting agencies, University policies and all certificate and permit terms and conditions;
3. ensuring that amendments to the certificate including addition of new personnel, changes in organism or termination of projects are submitted in a timely manner;
4. maintaining a current inventory of biohazardous materials including the source;
5. providing competent supervision and ensuring that all persons working under his/her control have received appropriate training in working with biohazardous materials;
6. inspecting the work area routinely;
7. taking appropriate action to remedy unsafe acts and conditions;
8. ensuring the safety of any service personnel (e.g., Facilities Management), contractors or visitors and advise them of any potential hazards in the work area;
9. ensuring all visitors are supervised;
10. ensuring that all containment facilities are functioning and personal protective equipment is available;

11. developing and continually reviewing site-specific emergency response plans for the work areas and ensuring that appropriate spill response supplies are available;
12. ensuring that the work area is secured against unauthorized access at all times and that all biosecurity measures are followed.

All laboratory personnel involved with handling biohazardous materials are to:

1. follow the policies and safe work practices outlined in the StFX Biosafety Manual and by their supervisor;
2. participate in all training courses as directed by their supervisor;
3. use the appropriate personal protective equipment when working with biohazardous material;
4. ensure full understanding of the risks associated with the biohazards used in the laboratory and seek information when unsure about any potential biohazard;
5. report all incidents, laboratory acquired infections, and unsafe conditions to the Principal Investigator immediately.

Dr. K. Wamsley
Academic Vice-President and Provost

Dr. R. Isnor
Associate Vice-President Research and Graduate Studies