St. Francis Xavier University

Biohazard Certificate BIOSAFETY COMMITTEE

INSTRUCTIONS FOR:

(1) BIOHAZARD CERTIFICATE APPLICATION FORM - RESEARCH

General Instructions

Biohazard certificates are issued to Principal Investigators and give authorization to conduct *research projects* utilizing biohazardous materials. Certificates are issued by individual *research project*, not by micro-organism, laboratory room, or granting agency. Work on a project may not commence until approval has been granted by the StFX Biosafety Committee.

Laboratories are inspected to fulfil the requirements of obtaining import permits; facility inspections **do not** constitute permission to use biohazardous materials.

Principal Investigators who wish to ***store*** biohazardous materials for future use require a current Biohazard Certificate.

Forms must be completed in full and submitted to the Biosafety Officer* (L. Graham). *Incomplete forms will impede the review process and delay issuance of the permit.

Please note that boxes on forms will expand to accept text, but additional information may be appended on separate pages. Numbers below refer to numbered items on the Biohazard Certificate Application form.

1. **PROJECT NUMBER.** **Please leave blank.** Project numbers shall be assigned by the StFX Biosafety Committee.

2. **STARTING AND COMPLETION DATES.** Indicate the estimated dates of starting and completion. On-going projects may indicate a period not to exceed five years.

3. **PRINCIPAL INVESTIGATOR**

The **Principal Investigator** must be a member of faculty or professional staff. Only one person can serve as Principal Investigator. Co-investigators are named under P**ersonnel Associated with this Project** as **Associates**.

4. **RESEARCH PROJECT**

Title. Indicate the title of the research project and state funding source(s). More than one title may be listed if there is more than one source of funding. For granting agency audit purposes, please use exact titles as issued by the agency.

5. **FUNDING SOURCES.** List all sources of funding for the project including the title of each grant. More than one granting agency may be listed as long as the work, locations, and personnel are the same. For each funding source listed include the award number. (Note that the award number is not the StFX account number. Each grant awarded is assigned a grant award number, i.e., StFX UCR 1532.)

Use of animals, radioisotopes, and/or human subjects. Indicate the relevant certificate/permit numbers and in cases where use of human subjects is involved, attach Research Ethics Board (StFX and/other)

permission statements.

6. PROJECT SUMMARY

Describe the project such that persons who are not expert in the field can evaluate the project.

7. PERSONNEL ASSOCIATED WITH THIS PROJECT.

Associates are faculty members or colleagues at other institutions or corporations who are responsible for aspects of the project or are co-investigators named on the project.

Designates must be a member of faculty or professional staff who is knowledgeable of working with the biohazardous materials. Students, post-doctoral fellows, and unpaid persons, e.g., visiting faculty, may not be named as designates.

Emergency contact(s) must be available to attend to after-hours problems. There must be an adequate number of contacts to cover for vacation, illnesses, and other absences. Emergency contacts will be registered with Campus Community Police who are the first responders to campus incidents. All contact numbers will be kept confidential.

Investigative Staff. List all persons who will be working with the biohazardous materials. Complete and append the StFX Biosafety Training form (BSF-1). For Principal Investigators, submit biosafety qualifications and experience and/or resume. To add additional investigative staff to an ongoing project, complete Appendix A, and StFX Biosafety Training form (BSF-1). **Note**: BSF-1 must be completed and submitted to the StFX Biosafety Officer for all individuals working with biohazardous materials.

8. BIOHAZARDOUS AGENTS OR MATERIALS SUMMARY.

Risk Groups and Containment Levels. Information pertaining to risk groups and containment levels may be obtained from the StFX Biosafety Manual, the Public Health Agency of Canada 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 >, the Canadian Food Inspection Agency (aquatic animal pathogens, non-indigenous and emerging animal disease pathogens) < http://www.inspection.gc.ca/animals/biohazard-containment-and-safety/eng/1300121579431/1315776600051 >, pathogen safety data sheets < https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html >, and suppliers such as American Type Culture Collection < www.ATCC.org >.

Microorganisms. *Microorganisms:* specify genus and species; *Type*: specify bacteria, virus, etc.; *Pathogenic to:* specify all that apply - human, animal (indicate type), and/or plant (indicate type); *Risk Group:* specify the risk group as determined by the Public Health Agency of Canada Guidelines or Canadian Food Inspection Agency Containment Standards; *Proposed Containment Level:* indicate the proposed containment level at which the work will be conducted. *Source:* indicate origin/source of micro-organism.

Cell Cultures. *Cell type:* indicate name and species; *Primary or Established:* indicate whether it is a new cell line or an established one; *Known Pathogens:* if the cell line is known to be infected with pathogens, indicate which pathogens; *Risk Group:* specify the risk group; *Proposed Containment Level:* indicate containment level. Note that all human cell lines are considered to be a minimum of Risk Group 2 in Canada. *Source:* indicate origin/source of cell line.

Biological Toxins. *Toxin:* specify the name of the toxin; *Source:* indicate from where the material was obtained, organism and commercial source; *Risk Group:* specify the risk group; *Proposed Containment Level:* indicate containment level.

Human Source Material. *Substance:* indicate the type of material (organ, blood, bone, etc); *Source:* indicate from where the material was obtained; *Risk Group:* specify the risk group; *Proposed Containment Level:* indicate containment level.

Recombinant DNA. *Host organism:* specify the name of the host; *Vector:* indicate the corresponding vector; *Gene(s):* indicate the source of the genes to be cloned or expressed; *Risk Group:* specify the risk group following cloning/expression; *Proposed Containment Level:* indicate containment level to be used. Refer to NIH Guidelines <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.

9. LOCATION OF PROJECT.

9.1 Campus sites.

Building. Indicate building address and name. **Room Number.** Indicate each room in which the biohazardous material is used or stored. Use a separate line for each room number.

Description of Use. Indicate whether it is a laboratory, biological material freezer storage area, growth room, greenhouse, animal facility, etc.

Shared space. Indicate if the areas where biohazardous materials are used and/or stored are shared with other University personnel. If the area is under the control of another Principal Investigator (PI), then the PI's signature is required on the final page of Biohazard Certificate Application. If the area is a communal area such as an equipment room then the Departmental Chair's or Director's signature is required.

9.2 Storage Locations

Indicate the building name and room. Indicate the location and nature of the storage (-80C freezer; liquid nitrogen dewar, refrigerator, etc). Indicate if the storage location is shared (room and/or freezer) and the security measures in place to prevent unauthorized access, use or theft.

10. BIOCONTAINMENT CABINETS. Indicate location of the biocontainment cabinets by room, the model and serial number, date of last certification, and the responsible party.

Building. Indicate building name. **Room Number.** Indicate each room in which the biohazardous material is used or stored. Use a separate line for each room number.

Model and serial number. Indicate the model and serial number as shown on the manufacturer's name plate.

Date of last certification. Indicate the date of last certification as recorded on the certificate posted on the cabinet.

Person Responsible. Indicate the person responsible for maintenance and repair of the cabinet.

Phone Number. Indicate the extension / phone number at which the responsible person can be reached.

11. STEAM STERILIZERS (AUTOCLAVES). Indicate the location, last inspection date, responsible party, and biological indicator verification information.

Building. Indicate building name. **Room Number.** Indicate each room in which the biohazardous material is used or stored. Use a separate line for each room number.

Person Responsible. Indicate the person responsible for maintenance, repair, sterilization verification, and record keeping for the sterilizer.

Frequency of Biological Indicator Verification. Indicate how often the sterilizer is tested using spore

strips/vials.

Location of cycle and verification records. Indicate the building and room number where records are stored.

12. EXPERIMENTAL PROCEDURES AND LOCAL RISK ASSESSMENT. List all of the procedures in which biohazardous materials will be used, i.e., culture of microorganism; culture of animal cell line; infection assay (bacterial infection of animal cell culture). For each procedure listed, attach a step by step standard operating protocol. For each step indicate how the biohazard will be handled safely. Include quantities of biohazardous materials to be used. Include specific equipment, practices and personal protective equipment which will minimize risk of exposure or release of the biohazardous materials. Aerosols are of special concern; examples of procedures that produce aerosols include centrifugation, homogenization, sonication, grinding, blending, pipetting, intranasal inoculation, handling lyophilized material, spattering, transferring cultures etc. Indicate any use of sharps and how personnel shall be protected from sharps injuries.

13. PERSONAL PROTECTIVE EQUIPMENT. Specify any use of personal protective equipment, e.g., gloves, goggles, lab clothing, etc. and the method of decontamination.

14. EMERGENCY RESPONSE PLANS. Describe strategies to be implemented in the event of a spill, fire, medical emergency, loss of power, natural disaster (e.g. earthquake) or occurrence which threatens safety and health and requires immediate action. Users may refer to information provided in the StFX Biosafety Manual and alter so that it conforms to individual research space and protocols.

15. DECONTAMINATION AND WASTE MANAGEMENT PROTOCOLS. Describe protocols for each specific type of contaminated material including disposable contaminated materials, reusable contaminated material, and waste materials. Reusable materials include, but are not limited to, lab coats and glassware. Waste materials include, but are not limited to, cultures (liquid, solid), disposable equipment (pipet tips) and contaminated debris. If using steam sterilization, indicate time and temperature cycles. If using disinfectant, indicate the name of the disinfectant and kill times.

If the project generates mixed waste, ie., biohazardous material mixed with radioisotopes or hazardous materials, indicate how this waste will be handled.

16. TRANSPORTATION OFF SITE. Persons transporting infectious or toxic materials (dangerous goods) require a Transportation of Dangerous Goods training certificate. Training can be arranged through the StFX Occupational Health and Safety Officer. Dangerous Goods must be transported by common carrier or in University-owned or University-leased vehicles.

TRANSPORTATION ON SITE. Describe how the material will be transported between room and/or buildings through public spaces. Include means of packaging, e.g, sealed plastic containers and means of transport, e.g., walking, using a cart, using a university vehicle.

17. IMPORT/EXPORT. Indicate if you intend to import or export biohazardous materials per the requirements of the Public Health Agency of Canada and/or the Canadian Food Inspection Agency. Note that for many biohazardous materials, a permit is required from both agencies. Certain substances, primarily but not exclusively RG 3 and RG 4 materials, require an export permit. Export controls are under the jurisdiction of International Trade Canada as per the Chemical and Biological Weapons Non-Proliferation List.

TRANSFER. Principal Investigators may be asked for culture strains by colleagues at the University or at other facilities. All transfers of biohazardous materials must be approved by the Biosafety Committee. Material Transfer Agreements are required for all transfers of biohazardous materials whether to a University colleague or to an external agency. Material Transfer Agreements are generated by the Office of Research and may require permits from the Public Health Agency of Canada and/or the Canadian Food Inspection Agency.

18. SECURITY. Describe how the biohazardous materials will be secured from unauthorized use and theft.

Describe how the work areas will be secured from unauthorized access.

INVENTORY RECORDKEEPING AND CONTROL. An inventory of all infectious material and toxins that are handled and stored both within and outside the containment zones must be present. The inventory should include a description of the material (e.g., genus, species, strain) including risk group; quantity and form (e.g., lyophilized); location (e.g., cryotank, freezer, box/holder numbers); date of receipt or generation; associated documentation (e.g., ATCC information sheet; CFIA/PHAC import permit). Describe the method of recordkeeping, e.g., computer database, card file, etc. and where it is located. Describe how inventory is controlled, e.g., authorized persons only inputting data, password protection, etc.

19. IDENTIFICATION OF DUAL-USE POTENTIAL RESEARCH. This section is required to satisfy Element 4 of the Public Health Agency of Canada's Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting – Required Elements and Guidance (2015) and is designed to identify dual-use research.

20. PRINCIPAL INVESTIGATOR'S CERTIFICATION. Applications must be signed by all parties.

Modified April 2020