

**PLEASE DELETE THE INSTRUCTION BEFORE SUBMIT THIS FORM**

**Section I. Administrative Information**

Principal Investigator:

Address: Phone Fax:

Lab Room (s) number

Faculty/Institute/Center

E-mail Address:

Lab/Research Personnel Involved in this research:

Project Duration:…………………….….… Start Date:…………..….……..…… End Date:……………..…………

**Section II Required Research Review and Training**

**1. Does your research involve human blood, body fluids, tissues or organs?**

 🗆 Yes 🗆 No

**Instruction:** Please select Yes when your research project uses any of materials or fluids from the human being such as blood, body fluids, tissues or organs, no matter what sources of these are, included from anyone with intentionally provide or by any donation system. This is a qualitative subject, even use these materials in microliter could be account into Yes. Select No when your research project do not use these materials.

If yes,

 a) Has the project been reviewed and approved by the Human Research Committee (WU-EC)? 🗆 Yes (Approval No…….………, date……………..….) 🗆 No

**Instruction:** Please select Yes when your research project was approved by the Human Research Ethics Committee with an evidence/certificate for permission in the ethics issue. This must be the exactly same research project with the evidence of permission with the specify approval date. Select No when your research project was not approved or even in the process of submission or consideration.

 b) Specimens collected or manipulated/used in lab:

 🗆 Blood 🗆 Serum 🗆Feces 🗆 Urine 🗆 Semen

 🗆 Spinal fluid 🗆 Saliva 🗆 Tissues/Organs 🗆 Other………………………………………..

**Instruction:** Please select the materials used in your project, if not specify in any above categories please select other and specify your materials.

 c) Types of manipulation:

🗆 Centrifugation 🗆 Pipetting 🗆 Dissection 🗆 Blending/mixing

🗆 Sonication 🗆 Frozen Sections 🗆 Flow Cytometry

🗆 Fixed/preserved 🗆 Other…………………………………………………………………………………..……

**Instruction:** Please select the type/equipment of working for the selected materials used in your project, if not specify in any above categories please select other and specify your materials.

**2. Does your research involve human or other mammalian cell in culture?**

 🗆 Yes 🗆 No

 If yes,

 a) What cell lines do you use? Please indicate whether they are of human or animal origin, and whether they are primary, secondary or immortalized cultures

**Instruction:** Please also indicate the name of cell line, source or supplier (e.g., viral transformation from animal cells or ATCC). Briefly describe the method of viral transformation (if applicable).

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 b) Are you planning on immortalizing cell lines? 🗆 Yes 🗆 No

 c) Will you use viral transformation? 🗆 Yes 🗆 No

 If yes, specify …………………………………………………….………………..…………….……………………….

 d) Will you transform cell lines with oncogenes in culture? 🗆 Yes 🗆 No

 e) Will you use any of the following materials in cell culture?

🗆 Cytotoxic/chemotherapy agents Specify ……………………………...…………….……………

🗆 Toxins. Specify…………………………………………………...……….………..……………...……….……..

**3. Does your research involve infectious or potentially infectious to humans or animals and toxic biological agents?**

 (If no, mark 🗆 No and proceed to 4.)

 🗆 Yes 🗆 No

 If yes, please answer all of the following questions in a, b and c.

 a) Does your research involve the use of any of the following biological agents?

Bacteria 🗆 Yes 🗆 No Parasites 🗆 Yes 🗆 No

Fungi 🗆 Yes 🗆 No \*Viruses 🗆 Yes 🗆 No (\*excluding Phages)

 Rickettsia 🗆 Yes 🗆 No Prions 🗆 Yes 🗆 No

If yes, list each agent by species, strain/isolates, and risk group. (information on risk group classification of biological agents can be obtained at CDC

 https://www.cdc.gov/biosafety/publications/bmbl5/index.htm/ http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php)

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 b) Is this organism already available in your laboratory?

 🗆 Yes 🗆 No

 c) What is the largest volume of organisms used/produced /stored?

(liter or milliliter).….…...……………………………………………………………………………………………………….

**4. Will you conduct research involving selected toxins?**

 (If no, mark 🗆 No and proceed to 5.)

 🗆 Yes 🗆 No

 If yes, please answer all of the following questions in a and b.

 a) Is the toxin-producing organism inactivated prior to other lab manipulations?

 🗆 Yes 🗆 No

 b) Specify methods of inactivation:

 🗆 Heat 🗆 Chemical 🗆 Radiation 🗆 Other…....

If you concentrate the toxin-producing organism, specify methods of concentration: …………………………………………………………………………………………………………………………………………………..……..

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**5. Does your research involve the use of recombinant DNA?** **(This includes experiments involving transgenic rodents in which the animal’s genome has been altered by stable introduction of rDNA, or DNA derived there from, into the germ line (transgenic rodents).**

 If yes,

 a) Recombinant Insert (Transgene):

 1. Source(s) of DNA/RNA sequences (include species, gene name and abbreviation, ATCC No.) ..………………………………………………………………………………………

 ..………………………………………………………………………………………………………………………………

 2. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome? 🗆 Yes 🗆 No

 3. Will the biological activity of the gene product or sequence inserted pose a hazard to humans or animals? 🗆 Yes 🗆 No

 4. Will a deliberate attempt be made to obtain expression of *the foreign gene* encoded in the recombinant DNA? 🗆 Yes 🗆 No

 5. Will your research include the deliberate formation of recombinant DNA that contains genes for the biosynthesis of toxin molecules? 🗆 Yes 🗆 No

 6. Will you conduct experiments that will involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally? 🗆 Yes 🗆 No

 b) Vector

 1. Identify the host strain (include species and strain) used for propagation of the recombinant: …………………………………………….………………………………………………

 2. Is a vector (specific phage, plasmid or virus) required?

 🗆 Yes 🗆 No If yes, specify…………….……………………….….

 3. Is viral vector replication defective? 🗆 Yes 🗆 No

 4. Is a helper virus required? 🗆 Yes 🗆 No If yes, specify…………………………

 c) Others …………………………………………...…………………………………….………………………………………

 ……………………………………………………………………………………………………………………………..........

**Instruction:** If the recombinant insert or vector is used with animals or the animals have a recombinant insert in their genome, please clearly describe in this section. Clearly describe the transgenic animal strains or recombinant materials used with animals.

**6. Will animals be used with any biological agents listed in this application?**

 🗆 Yes 🗆 No

 If yes,

 a) Are the animals transgenic? 🗆 Yes 🗆 No

 b) Will you ship or receive any animal materials, blood, body fluids, tissues, or

 organs? 🗆 Yes 🗆 No

 c) Has this research been approved by the Institutional Animal Care & Use Committee?

 🗆 Yes (Protocol No. & Approval Date………………) 🗆 No

Animal Protocol Approval: …………………………………………………………….………….……………………………………………………………………………………………………………………………………….………….……………………………………………………………………………………

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**Instruction:** If animals are used in the present experiment, please clearly indicate animal protocol title, protocol number, name of principal investigator, date of approval, and expiry date in the Animal Protocol Approval section. Please also provide a copy of documentary proof of ethical clearance. If the animal proposal is under evaluation by animal ethic committee, please explain here.

**7. Will radioisotopes be used to label any biological agen****ts listed in this application?**

 🗆 Yes 🗆 No

8. Describe how each biological agent, cell line, tissue, etc. will be used. Provide sufficient detail so that the Institutional Biosafety Committee (WU-IBC ) can evaluate your activities.

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**Instruction:** Please provide a summary of your research plan – only parts that involve the biological agents; Key information you should include, as you deem relevant: forms of biological agents before and after the experiments (e.g. DNA into a host cell, live cells, DNA extract), conditions (including location of each experiment, if multiple labs/control equipments will be used) in which the experiments will be performed (e.g. closed tube, open bench, outdoor) lab, and scale of the experiments (e.g. volume of bacterial culture). You can add PSDS or link to SOPs page.

**9. If the organism is infectious, is there a vaccine available to research staff?**

 🗆 Yes 🗆 No

**Instruction:** List of vaccine-preventable diseases can be found at http://www.phac-aspc.gc.ca/im/vpd-mev/index-eng.php

**10. Have you and the personnel listed above received biological lab safety training?**

 🗆 Yes 🗆 No

 If yes, attach the training document.

**11. Do you have safety operation procedure (SOP)?**

 🗆 Yes 🗆 No

 If yes, attach the SOP

**12. Have you attached a Biohazard Control Plan?**

**Note:** For research that involves Risk Group 2 agents, the “Biohazard Control Plan” must be provided to assure adequate protection of employees, students, the community, and the environment.

 🗆 Yes 🗆 No

**Instruction:** If Yes, Please attached Biohazard Control Plan. If No, Please fill details in No. 14

**13. Exposure determination**

 1. List who will be working with biological agents, animals, or hazardous material (by name & job title). It is recommended that all lab personnel receive information about the risks associated with any research involving infectious agents. This is especially recommended for lab personnel who may be immune-compromised.

 2. Describe the general types of experimental procedures that will be performed (e.g. cell culture, protein purification, drawing blood, *etc*).

Name Job title Procedure

 *(Example: PhD student)* *(Example: Protein extraction)*

 *(Example: Housekeeper)* (*Example: Handling regulated waste)*

**14. Control methods:**

 1. Describe facility in which work is to be performed.

**Instruction:** List the equipments located in the room that will be used for biosafety purposes i.e. biosafety cabinet, hand washing station, eye washing station, cup-closed centrifuge, autoclave, biohazard waste bins. Do the equipments and the room have biohazard sign posted on them? Where will the work be performed inside the room?

 2. Describe who will have access to the facility and how access will be controlled?

**Instruction:** Who will have access to the room? Will the room be locked? How the room will be locked? Does the custodial have access to the room? If so, how does the custodial know which trash is biohazard (not to pick up) and which trash is not biohazard?

 3. How and when will facility be cleaned and decontaminated? Will Facilities Management custodial personnel have routine access, and if so, how will they be protected from hazardous materials?

**Instruction:** Give the name of the disinfectant that will be used to decontaminate the surface. How often the surface will be decontaminated? Does the custodial have access to the room? If so, how does the custodial know which trash is biohazard (not to pick up) and which trash is not biohazard? How will the biohazard waste be decontaminated? By whom? How? If the autoclave is not located within the room, describe how the waste will be transported to the autoclave?

 4. Describe safety devices that will be used. These may include some or all of the following: biosafety cabinets, hand washing facilities, mechanical pipetting devices, puncture resistant sharps containers, splash guards, self-sheathing needles.

**Instruction:** List the biosafety devices and equipments available in the lab.

 5. What types of personal protective equipment will be used (gloves, masks, lab coats, etc). How will the equipment be decontaminated, laundered, or disposed of?

**Instruction:** List personal protective equipment necessary for the protection of personnel from the biohazard agent used in the lab (need to do risk assessment and read the PSDS to decide which equipment will be suitable and necessary for the personnel to work safety with the type of bacteria, virus, parasite etc. used in the lab). How are these equipment decontaminated after use?

 6. Vaccination: Will it be necessary to vaccinate workers against infectious agents? If so, describe plans for vaccinations.

**Instruction:** Is there a vaccine available for protection against the infectious agent used in the lab? If so, describe how personnel will receive this vaccine?

 7. Accidents: What procedures will be followed in case of an accident?

**Instruction:** Describe procedures that will be used for each type of accident i.e. spill, needle stick accident, fire? Who do the personnels will report to? Where do the personnels will go to seek medical attention?

 8. Waste disposal: Describe provisions for disposal of hazardous materials. If all or part of hazardous material is to be decontaminated on site, specify procedures to be used.

**Instruction:** Describe in detail the procedures for packing, transporting, decontaminating the biohazard waste (separate for solid, liquid, and sharp waste). What will finally happen with the waste i.e. will the decontaminated/autoclaved waste be disposed of as regular waste? Where the autoclaved liquid waste go? What happen to the autoclaved sharp waste?

 9. Labeling: Describe tags, labels, or bags that will be used to identify hazardous materials. If hazardous material is to be decontaminated on site, specify how material will be labeled to indicate that it is no longer infectious.

**Instruction:** Describe where you will put the universal biohazard sign i.e. on room doors, bins, incubators, centrifuge, biosafety cabinet etc. What information will be included in the sign?

 10. Training: Describe how workers will be trained for biological lab safety and handle all hazardous materials (biological, chemical and radioactive).

**Instruction:** Describe the type of training the personnels have received. How the new personnel will be trained i.e. by whom? List trainings required by the new personnel to pass before allowed to be working with the agent.

**15. Others, if any** …………………………………………………………………………………..

 I acknowledge all requirements and restrictions of the most current TBC guidelines for the Biosafety Level authorized by the IBC. I accept responsibility for the safe conduct of the experiments conducted at this Biosafety Level. I understand that it is my responsibility to assure that all personnel working in my laboratory with any of these hazards are fully informed about their specific dangers, proper actions for safe use and steps to take in case of accidents, and are provided with all necessary safety equipment and instructions in its use. I will contact the WUIBC/Faculty IBC immediately following any adverse event that leads to an accidental exposure to any biological agents listed in this form that may be harmful to humans or animals.

 Date Signature of Principal Investigator

**PLEASE FILL OUT THE FORM BY ANSWERING ALL SECTIONS APPLICABLE TO THE PROJECT. Attach additional pages if necessary.**