Biosecurity Plan for Western University

Reviewed and Approved by: Biosafety Committee; March 22, 2016

1.0 Introduction:

There are a number of new rules and regulations that govern the use of certain biological agents and toxins.

*The Canadian Biosafety Standard for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins* requires Western University to have a biosecurity plan in place. The University must assess the risk of an agent and determine the physical, personnel and pathogen controls required. The University must have a plan to address a biosecurity incident and emergency response.

Research groups must have a lawful purpose to possess, use and transport the agents and procedures to identify and characterize the agents held at any University facility.

The University Biosecurity Plan specifies security requirements for Western University laboratories using biological agents. The University Biosafety Committee requires that all users of biological agents adopt the requirements outlined in this Biosecurity Plan.

2.0 Definitions

**Biosafety** deals with all aspects of containment to prevent any exposure and accidental release of pathogens.

**Biosecurity** measures are implemented to prevent the theft, misuse or intentional release of pathogens.

**Biosecurity agents of concern** are biological agents that, if misused, are a risk to the Western University faculty, staff, students and/or the community as determined by the Biohazards Subcommittee.

**Toxins of biosecurity concern** are agents that originate from biological systems that are able to induce harm.
3.0 Roles and Responsibilities

3.1 Principal Investigators (PIs) and departmental technicians are responsible for complying with all the requirements set out by the Public Health Agency of Canada and all policies and procedures pertaining to Biosafety at Western University. PIs are specifically responsible for the following:

a) Before the commencement of any work with Biological Agents and toxins, ensure the completion of a Western University Biological Agents Permit Application (BAPA) outlining the type of Biological agents and toxins, and the names of all students and graduate students who will work on the research project. (please see Appendix 1 to review the form)
b) If work is to be performed on any Risk Group 3 agents or higher, or on toxins listed in Appendix 2, contact the Biological Safety Officer (BSO) who will initiate the process of applying for governmental security clearances where applicable.
c) Submit the BAPA to the Biohazards Subcommittee
d) Maintain an up to date inventory of RG 2, RG3, and any toxins in their laboratory. Send a copy of the updated inventory every time it is updated. Risk Group 2 (RG2) inventory requires a list of RG2 agents used, and RG3 inventory requires a more detailed description of all containers, location of storage in lab, freezer, fridge, etc. Sample inventory form is available through the BSO, extension 88730, email: ahammoud@uwo.ca
e) Immediately report to the BSO any occurrences involving unauthorized access to areas containing RG 3 agents and/or toxins, theft, misuse, loss of containment, exposure to a person, illegal use of personal devices, intrusion, etc.

3.2 The Biological Safety Officer is responsible for the following:

a) Prepare all BAPAs for review by the Biohazards Subcommittee
b) Inspect all biological laboratories and promote compliance with the Public Health Agency of Canada requirements as stated in the Canadian Biosafety Standard, second edition
c) Prepare an inventory data base to indicate the laboratories working with RG2, RG3 and SSBA
d) Prepare governmental Security Clearance applications for all individuals working with RG 3 and Security Sensitive Biological Agents (SSBA); please see Appendix 2 for a list of prescribed list of SSBA.
e) Report to PHAC all incidents of exposure to SSBA with 15 days of occurrence, and within 30 days all incidents of exposure to non-SSBA

4.0 Identification of Biosecurity agents and toxins

All researchers must complete a Biological Agents Permit Application (BAPA). This form may be found at: http://uwo.ca/hr/safety/topics/biosafety/index.html. This is the mechanism by which all protocols are reviewed for biosafety purposes by the Biohazards Subcommittee.
When deemed a possible biosecurity risk, protocols are sent to the Biosafety Committee or the Biohazards Subcommittee for review. Because of the nature of biosecurity, each situation will be dealt with on a case by case basis. The Biosafety Committee and its Subcommittee have the right to restrict or prohibit the use and storage of agents at Western University.

Where agents with biosecurity risk are handled or stored, Supervisors may need to meet some or all of the following conditions:

1. A safety, security and emergency response plan implemented (see Section 9)
2. Restriction or approval of all individuals to have access to biosecurity agents of concern (see Section 7).
3. A process to immediately report any theft, loss or release of biosecurity agent of concern (see Section 9)
4. Detailed records of information necessary to give a complete accounting of all activities related to biosecurity agents of concern (see Section 7)
5. Medical surveillance for all workers, identified through the completion of the Hazard Communication Form from Workplace Health.
6. Training including the safe storage and use of the agent
7. Physical security measures such as locked facilities, fridges and/or freezers.

4.0 Designation of a Responsible Official

The Biosafety Officer is the Responsible Official (RO). The Responsible Official, Campus Community Police Services (CCPS) and the HAZMAT team are responsible for the development, training and implementation of biosecurity and emergency response plans. As such, the RO is contacted as soon as possible in the event of any theft, loss or release of biosecurity agents of concern. The RO is also the person who is involved in the risk assessment process and the biosecurity measures taken such as inventory control, background checks, exposures, incidents of uncontrolled releases and spills, and transfers of biological agents.
5.0 Assessment of Biosecurity Risk

When recognizing a possible biosecurity risk, the Biosafety Committee or the Biohazards Subcommittee will use the method set out by Public Health Agency of Canada’s Office of Laboratory Security (please see Figure 1 Assess Risk of Threat Scenarios) page 5, and implement a graded implementation approach to level of risk and necessary measures.

Asset Identification
- Infectious disease risk
- Weaponization risk

Evaluation of consequence or loss
- High: Loss could result in a security event nationally or internationally resulting in a high number of casualties and/or economic damage
- Moderate: Loss could result in an event of somewhat lesser magnitude
- Low: Loss of asset could affect the local operations of an individual facility

Threat Identification
- Establishment of threat scenarios
- Definition of characteristics, motivations and capabilities of adversaries
- Evaluate the probability and consequences of scenarios

Examples of threats:
- Access by unauthorized personnel
- Theft, loss, misuse
- Intrusion, forced entry, compromised security detection system, compromised access code
- Inventory not maintained
- Transportation between buildings
- Illegal use of personal devices
- Knowledge of the agent / toxin
- Loss of containment
Western University’s Biosecurity Plan applies to lowest, low, moderate or high risk agents of concern through this biosecurity risk assessment process.

The BSO alerts the Biohazards Subcommittee when a Principal Investigator (PI) or other biological agents users intend to obtain unusual biological agents or toxins. The Subcommittee examines the proposed research project and evaluates it based on the risk of threat. Moderate and high threat scenarios would be further examined with the Campus Community Police Services (CCPS) “Crime Prevention through Environmental Design” (CPTED) coordinator. An in depth examination of the facility’s security features as well as personnel suitability would be performed by the CPTED Coordinator who would prepare a report to be presented to the Biohazards Subcommittee. Based on the recommendations and findings in the report, the Biohazards Subcommittee would advise on additional measures to ensure the safe handling of the biological agents.

Where the Biohazards Subcommittee believes that a specific biological agent used in research could potentially be used for other unauthorized purposes, a risk assessment process is to be conducted as outlined below by PHAC’s “Decision Tree for the Identification of Dual-Use Potential in Life Sciences Research (Figure 2):
Figure 2: Decision Tree for the Identification of Dual-Use Potential in Life Sciences Research.

Once the dual-use potential has been confirmed, a risk assessment must be performed to assess the ways in which pathogens, knowledge, technology or products (e.g., toxin) could be misused, the ease with which they may be misused, and the scope and magnitude of the potential consequences of misuse.

The University’s BSO will consider the following questions in performing the risk assessment:
☐ What types of pathogens, knowledge, technology, or products are anticipated to be generated through the research?
☐ How could pathogens, knowledge, technology, or products resulting from the research be misused to pose harm to public health and safety or national security?

☐ What type of technical skills will be required to repeat the experiment?

☐ Are the materials, tools and equipment expensive or difficult to acquire?

☐ If released outside the laboratory, will the pathogen affect humans and/or animals?

☐ What is the likelihood that the knowledge, information, technology, or products from the research will be used to harm public health and safety, the environment (including animals) or national security?

☐ What is the scope and magnitude of the potential risk(s) identified?

An effective oversight system is based on identifying and managing the risks associated with the potential of misuse or misapplication of organisms, knowledge, technology, and products of research resulting in the harm to the public health and safety, animals, or national security. Therefore, risk mitigation plans should be created and measures implemented to address the identified risks.

The University’s BSO will consider following questions in performing the risk assessment:

☐ What is the strategy or strategies being implemented by the institution/organization to address the risks (e.g., applying specific biosafety and biosecurity measures or modifying experimental design or methodology such that an attenuated strain is used or strain’s ability to proliferate outside of the lab or within different hosts is limited by using a different technique)?

☐ Are there currently any counter measures (e.g., treatments) to help mitigate the potential consequences? Are they readily available?

☐ How will the results or products of the research be shared or distributed (i.e., will the results or products be shared openly or remain within the laboratory or institutions)?

☐ How readily available are these results?

☐ Who will have access to the knowledge, information, technology, or final products?
6.0 Physical Protection

Western University implements graded protection based on the biosecurity risk of materials. Methods may include:

- Perimeter security such as fencing and gating
- Facility security such as Campus Community Police Services (CCPS)
- Laboratory security such as card access and locking of laboratories, fridges and freezers
- Agent specific security including locking of storage areas and freezers

7.0 Personnel Accountability in the Facility

Personnel access is restricted to areas where biosecurity agents of concern are used, stored or otherwise present. Approval may be required to have access to the area of agent of concern (Security Clearance Forms are provided by PHAC). Approval may include:

- Personnel qualifications and training
- Background checks and security clearances for personnel intending to work with or access Risk Group 3 Agents or Security Sensitive Biological Agents (SSBA)
- Periodic / random inspections
- Escorts for non-approved personnel
- Identification such as badges

8.0 Pathogen Accountability

Cradle to grave record keeping is required for pathogens with a biosecurity risk. These records may include:

- Detailed inventory including location, agent, sample type and quantity
- Record of transfers within and outside Western University
- Record of personnel access
- Disposal records including date and decontamination method
- Labelling of samples
- Notification of RO if there is a loss, theft, misuse of a pathogen with a biosecurity risk
- Notification of RO if there is any exposure, spill or any unintentional release

9.0 Incident and Emergency Response

Research groups in possession of biosecurity agents of concern will be identified to CCPS where a “Crime Prevention Through Environmental Design” (CPTED) review will
be performed. Aspects of the review are discussed with the Principal Investigator (PI) with an emphasis on reporting security incidents to CCPS at 519-661-3300 and the BSO at 519-521-8444. Examples of possible and reportable incidents include:

- Unauthorized personnel in restricted areas
- Unauthorized removal of pathogens
- Breach of containment
- Theft or loss
- Exposure
- Breach in containment
- Failure of ventilation system / electrical

10.0 Biological Agents deemed Biosecurity Agents of Concern

Biological agents that are biosecurity agents of LOWEST RISK include:

- cell lines from plant, animal or human origins
- biological agents that must be ingested to cause pathogenicity or other harm
- rodents or other animals not known to be infectious
- level 1 microorganisms
- other level 1 biological agents
- other biological agents to be identified as lowest biosecurity risk
- human and animal source materials such as tissues and blood

Biological agents of concern deemed to be possible biosecurity threats:

- toxins of biological origin
- animals which may be infectious, including non-human primates
- other Level 2 or higher organisms or biological agents
- Security Sensitive Biological Agents (see Appendix 2)
- other biological agents to be identified as low, medium or high biosecurity risk

11.0 References

Appendix 1

BIOLOGICAL AGENTS PERMIT APPLICATION
Western University

Approved Biohazards Subcommittee: February 12, 2016
Biosafety Website: http://uwo.ca/hr/safety/topics/biosafety/index.html

This form must be completed when:
- A Principal Investigator holds a grant administered by the University and in charge of a University laboratory/facility where the use of Level 1, 2 or 3 biological agents is conducted in the laboratory.
- Any work proposed involves animals carrying zoonotic agents infectious to humans.
- Any work proposed involves plant pathogens, or fungi, that require Public Health Agency of Canada (PHAC) or Canadian Food Inspection Agency (CFIA) permits.
- Undergraduate courses that require the use of Risk Group1, Risk Group2, or Risk Group3 agents
- Any work proposed involves the manipulation of Human Source Materials

This form must be updated at least every 3 years or when there are changes to the biological agents being used.

Containment Levels will be established in accordance with the relevant biosafety standards, including the Canadian Biosafety Standard for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins (CBS) and the Human Pathogens and Toxins Act (HPTA) and the Human Pathogens and Toxins Regulations (HPTR).

Electronically completed forms are to be submitted to Occupational Health and Safety, (OHS), (Support Services Building, Room 4190 or to ahammoud@uwo.ca for distribution to the Biohazards Subcommittee. For questions regarding this form, please contact the Biosafety Officer at extension 88730 or biosafety@uwo.ca. If there are changes to the information on this form (excluding grant title and funding agencies), contact Occupational Health and Safety for a modification form. See website: http://www.uwo.ca/hr/safety/topics/biosafety/index.html.

Please ensure that all questions are fully and clearly answered. Failure to do so will lead to the form being returned, which will cause delays in your approval and frustration for you and your colleagues on the Committee.

If you are re-submitting this form as requested by the Biohazards Subcommittee, please make modifications to the form in capital letters. Please re-submit forms ONLY electronically.

<table>
<thead>
<tr>
<th>PRINCIPAL INVESTIGATOR:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DEPARTMENT:</td>
<td></td>
</tr>
<tr>
<td>ADDRESS:</td>
<td></td>
</tr>
<tr>
<td>PHONE NUMBER:</td>
<td></td>
</tr>
<tr>
<td>EMERGENCY PHONE NUMBER(S):</td>
<td></td>
</tr>
<tr>
<td>EMAIL:</td>
<td></td>
</tr>
</tbody>
</table>

Location of experimental work to be carried out:
For work being performed at Institutions affiliated with The Western University, separate permits are to be completed and reviewed by those institutions.

FUNDING AGENCY/AGENCIES: ____________________________________________

GRANT TITLE(S): ______________________________________________________

UNDERGRADUATE COURSE NUMBER AND NAME (IF APPLICABLE): ____________

List all personnel working under Principal Investigators supervision in this location:

Name ___________________________ Institutional E-mail Address ______ Date of Biosafety Training ______

Please provide a brief overview of the proposed research containing sufficient information to ensure adequate review of the protocol to determine compliance with Western University's Biosafety Program and provincial and federal regulations. DO NOT cut and past the specific aims section from a grant application.

a. Purpose of research (brief and in lay terms);

b. Assessment of risk to personnel working with the biological agent (what measures would you take in case of exposure/injury e.g. spill, splash or needlestick injury);

c. An outline of the procedures and techniques employed;

d. Description of the safe practices, equipment, PPE, and facilities used to protect personnel;

e. Describe any specific methods of inactivation or disposal of the biological agent(s).
All questions 1-15 MUST be answered by checking either YES or NO and complete appropriately

1.0 Microorganisms

1.1 Does your work involve the use of biological agents?  
☐ NO  ☐ YES  
Including but not limited to plant pathogens and animal microorganisms (eg. bacteria and fungi, viruses, prions, and parasites)  
(If no, please proceed to Section 2.0)

1.2 Please complete the table below:

<table>
<thead>
<tr>
<th>Full Scientific Name of Biological Agent(s)* (Be specific)</th>
<th>Is it known to be a human pathogen? YES/NO</th>
<th>Is it known to be an animal pathogen? YES/NO</th>
<th>Is it known to be a zoonotic agent? YES/NO</th>
<th>Maximum quantity to be cultured at one time? (in Litres)</th>
<th>Source/Supplier</th>
<th>PHAC or CFIA Containment Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: Human Adenovirus Type 5</td>
<td>☐ No</td>
<td>☑ Yes</td>
<td>☑ Yes</td>
<td>1mL</td>
<td>Vector BioLabs</td>
<td>☐ 1 ☑ 2 ☑ 2+ ☐ 3</td>
</tr>
<tr>
<td>Example: E. coli, DH5a</td>
<td>☑ Yes</td>
<td>☐ No</td>
<td>☐ No</td>
<td>500mL</td>
<td>Thermo Fisher</td>
<td>☐ 1 ☐ 2+ ☑ 3</td>
</tr>
<tr>
<td></td>
<td>☐ No</td>
<td>☑ Yes</td>
<td>☑ Yes</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>☐ No</td>
<td>☑ Yes</td>
<td>☑ Yes</td>
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<tr>
<td></td>
<td>☐ No</td>
<td>☑ Yes</td>
<td>☑ Yes</td>
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</tr>
<tr>
<td></td>
<td>☐ No</td>
<td>☑ Yes</td>
<td>☑ Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please attach a Safety Data Sheet or equivalent from the supplier if the agent used is not on this link:  
http://www.uwo.ca/hr/form_doc/health_safety/doc/procedures/cfia_ecoli_list.pdf

Additional Comments:  
______________________________________________________________________________________
2.0 Cell Culture

2.1 Does your work involve the use of cell cultures?  
☐ NO  ☐ YES  
*(If NO, please proceed to Section 3.0)*

2.2 Please indicate the type of primary cells (i.e. derived from fresh animal or plant tissue) that will be grown in culture:

<table>
<thead>
<tr>
<th>Cell Type</th>
<th>Is this cell type used in your work?</th>
<th>Source of Primary Cell Culture Tissue</th>
<th>AUS Protocol Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td>Rodent</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-human primate</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plant or insect</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.3 Please indicate the type of established cells that will be grown in culture in:

<table>
<thead>
<tr>
<th>Cell Type</th>
<th>Is this cell type used in your work?</th>
<th>Specific cell line(s)* [Containment Level(s)**]</th>
<th>Supplier / Source of cell line(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodent</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-human primate</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td>☐ No  ☐ Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please attach a Safety Data Sheet (SDS) or equivalent from the supplier. Product or technical data sheets from ATCC or equivalent are acceptable; generic SDS are not acceptable. (For more information, see www.atcc.org)

**Please include the Containment Level for EACH cell line

Additional Comments:

3.0 Use of Human Source Materials

3.1 Does your work involve the use of human source materials?  
☐ NO  ☐ YES  
*(If no, please proceed to Section 4.0)*

3.2 Indicate in the table below the Human Source Material to be used.

<table>
<thead>
<tr>
<th>Human Source Material</th>
<th>Source/Supplier /Company Name</th>
<th>Is Human Source Material Infected With An Infectious Agent? YES/UNKNOWN</th>
<th>Name of Infectious Agent (If applicable)</th>
<th>PHAC or CFIA Containment Level (Select one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Blood (whole) or other Body Fluid</td>
<td></td>
<td>☐ Yes  ☐ Unknown</td>
<td></td>
<td>☐ 1  ☐ 2  ☐ 2+  ☐ 3</td>
</tr>
<tr>
<td>Human Blood (fraction) or other Body Fluid</td>
<td>☐ Yes ☐ Unknown</td>
<td>☐ 1 ☐ 2 ☐ 2+ ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>----------------</td>
<td>-----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Organs or Tissues (unpreserved)</td>
<td>☐ Yes ☐ Unknown</td>
<td>☐ 1 ☐ 2 ☐ 2+ ☐ 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Organs or Tissues (preserved)</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 Do the personnel working with human source materials have up-to-date vaccinations against Hepatitis B?
☐ NO ☐ YES  If NO, please contact Workplace Health at 519-661-2111 ext. 85474

Additional Comments: __________________________________________________________

4.0 Genetically Modified Organisms and Cell lines

4.1 Will genetic modifications be made to the microorganisms, biological agents, or cells described in Sections 1.0 and 2.0?  ☐ NO ☐ YES  *(If NO, please proceed to Section 5.0)*

4.2 Will genetic modification(s) involving plasmids be done?  ☐ NO ☐ YES, complete table below

<table>
<thead>
<tr>
<th>Bacteria or yeast used for cloning *</th>
<th>Plasmid(s) **</th>
<th>Source of Plasmid</th>
<th>Gene Transformed or Transfected</th>
<th>Will there be a change due to transformation of the bacteria?</th>
<th>Will there be a change in the pathogenicity of the bacteria after the genetic modification?</th>
<th>What are the functional consequences due to the transformation of the organism?</th>
<th>If plasmids are being used to transfect cells what is the functional consequence the eukaryotic cells?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: E. coli DH5α</td>
<td>pcDNA-1</td>
<td>Clonetech</td>
<td>v-hRas oncogene</td>
<td>Bacteria will carry the plasmid</td>
<td>No</td>
<td>Bacteria will replicate the plasmid to levels suitable for purification</td>
<td>Depending on the cell type transfected, the cells expressing v-hRas will have increased proliferation and may become transformed.</td>
</tr>
</tbody>
</table>

* Please attach a Safety Data Sheet or equivalent if available.
** Please attach a plasmid map.
**No Safety Data Sheet is required for the following strains of E. coli:**

http://www.uwo.ca/hr/form_doc/health_safety/doc/procedures/cfia_ecoli_list.pdf

4.3 Will genetic modification(s) of bacteria and/or cells involving viral vectors be made?

<table>
<thead>
<tr>
<th>Virus/Plasmid Used for Vector Construction</th>
<th>Vector(s) *</th>
<th>Source of Vector/Plasmid</th>
<th>Gene(s) Transduced/Transfected</th>
<th>Describe the functional change that results from transduction/transfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: 3&lt;sup&gt;rd&lt;/sup&gt; generation Lentivirus (SIN) vector</td>
<td>Viropower vector</td>
<td>ThermoFisher</td>
<td>Luciferase</td>
<td>Cells transduced with this vector will express the reporter gene, luciferase</td>
</tr>
</tbody>
</table>

* Please attach a Safety Data Sheet or equivalent.

4.3.1 Will virus be replication defective? □ NO □ YES

4.3.2 Will virus be infectious to humans, animals, or plants? □ NO □ YES

4.3.3 Will this be expected to increase the containment level required? If yes, what containment level is now required? □ NO □ YES

5.0 Will genetic sequences from the following be involved? *(This section must be completed)*

- HIV □ NO □ YES, specify
- HTLV 1 or 2 or genes □ NO □ YES, specify
- T antigen oncogene □ NO □ YES
- E1A oncogene, eg. HEK 293 □ NO □ YES
- Known oncogenes □ NO □ YES, specify
- Other human, animal or microorganism pathogenic sequences and or their toxins □ NO □ YES, specify

5.1 Is any work being conducted with prions or prion sequences? □ NO □ YES

5.2 Will retroviral or lentiviral sequences be involved? □ NO □ YES

5.2.1 If YES, please describe:

5.3 Will any sequences, when introduced, enhance the pathogenicity of that pathogen? □ NO □ YES

5.3.1 If YES, please describe:

5.4. Are any of the sequences growth altering? □ NO □ YES □ UNKNOWN
5.4.1 If YES, please describe:

5.5 Will any sequences, when introduced to a cell and/or animal or plant, produce substances that are biological hazards to personnel handling those cells and/or animals or plants? □ NO □ YES

5.5.1 If YES or unknown, please describe:

Additional Comments: ____________________________________________________________

6.0 Human Gene Therapy Trials

6.1 Will human clinical trials be conducted involving a biological agent? □ NO □ YES

(including but not limited to microorganisms, viruses, prions, parasites or pathogens of plant or animal origin)

(If no, please proceed to Section 7.0)

6.2 If YES, please specify which biological agent will be used:
Please attach a full description of the biological agent.

6.3 Will the biological agent be able to replicate in the host? □ NO □ YES

6.4 How will the biological agent be administered?

6.5 Please give the Health Care Facility where the clinical trial will be conducted:

6.6 Has human ethics approval been obtained? □ NO □ YES, number: □

PENDING

7.0 Biological Toxins and Hormones

7.1 Will purified toxins or hormones of biological origin be used? □ NO □ YES

(If NO, please proceed to Section 8.0)

7.2 If YES, please name the toxin(s) or hormones(s)
Please attach information, such as a Material Safety Data Sheet, for the toxin(s) used.

7.3 What is the LD$_{50}$ (specify species) of the toxin or hormone

7.4 How much of the toxin or hormone is handled at one time*?

7.5 How much of the toxin or hormone is stored*?

7.6 Will any biological toxins or hormones be used in live animals or plants? □ NO □ YES

If YES, Please provide details:
*For information on biosecurity requirements, please see:  
http://www.uwo.ca/hr/form_doc/health_safety/doc/procedures/biosecurity_requirements.pdf

Additional Comments: ..........................................................................................................

**8.0 Animal Experiments**

8.1 Will live animals be used and/or will live animals be the source of cell, primary tissue, or body fluids?
☐ NO  **(If NO, please proceed to Section 9.0)**  ☐ YES

8.2 List the animal species to be used:

8.3 Identify any zoonotic agent(s) infectious to humans associated with the species of animal used:

8.4 Are the animals purpose bred or wild caught?  
Source:

8.5 Animal Use Protocol (AUP) number(s):

8.6 Will any of the agents listed in Sections 1-7 be used in live animals?
☐ NO  ☐ YES

8.7 Will the agent be shed by the animal:

☐ No, please justify  ☐ YES, indicate route(s) of shedding:

8.8 Indicate special precautions while handling animals and cage bedding:

8.9 Will bedding and animal remains required hazardous waste disposal:
☐ NO, please justify:
☐ YES

8.10 Indicate the PHAC or CFIA containment level required for research involving animals:

☐ 1  ☐ 2  ☐ 2+  ☐ 3

8.11 If work will be transitioning from one containment level to another, please explain:

**9.0 Insects**

Do you use insects that require a permit from the CFIA permit?  
☐ NO  ☐ YES

If YES, Please attach the CFIA permit & describe any CFIA permit conditions:
10.0 Plants

10.1 Do you use plant pathogens?  □ NO *(If NO, please proceed to Section 11.0)  □ YES

10.2 If YES, please give the name and description of the pathogen.

10.3 What is the name and origin of the plant?

10.4 What is the form of the plant (seed, seedling, plant, tree…)?

10.5 What is your intention?  □ Grow and maintain a crop  □ “One-time” use

10.6 Do you do any modifications to the plant?  □ NO  □ YES
If yes, please describe:

10.7 Please describe the risk (if any) of loss of the material from the lab and how this will be mitigated:

10.8 Is the CFIA permit attached?  □ NO  □ YES  □ PENDING
If YES, Please attach the CFIA permit & describe any CFIA permit conditions:

11.0 Training Requirements for Personnel Named on Form

All personnel named on the above form who will be using any of the above named agents are required to attend the following training courses given by OHS:
♦ Biosafety
♦ Laboratory and Environmental/Waste Management Safety
♦ WHMIS (Western or equivalent)
♦ Employee Health and Safety Orientation

As the Principal Investigator, I have ensured that all of the personnel named on the form who will be using any of the biological agents in Sections 1.0 to 9.0 have been trained.

*An X in the check box indicates you agree with the above statement...  □*
*Enter Your Name ______  Date: ______*

12.0 Containment Levels

12.1 For the work described in sections 1.0 to 9.0, please indicate the highest PHAC or CFIA Containment Level required.  □ 1  □ 2  □ 2+  □ 3

12.2 Has the facility been certified by OHS for this level of containment?
□ YES
□ NO, please certify
□ NOT REQUIRED for Level 1 containment
12.3 Please indicate permit number (not applicable for first time applicants):

13.0 Procedures to be Followed

13.1 As the Principal Investigator, it is your duty to annually conduct refresher training on emergency procedures and spill control measures. Please keep records of all training in a binder and available to show an inspector.

13.2 As the Principal Investigator, I will ensure that this project will follow the Western Biosafety Guidelines and Procedures Manual for Containment Level 1 & 2 Laboratories (and the Level 3 Facilities Manual for Level 3 projects). I will ensure that UWO faculty, staff and students working in my laboratory have an up-to-date Hazard Communication Form, found at https://webapps.uwo.ca/positionhazard/login?

Please print and sign this page and submit it. This signature page is needed for approval.

Researcher: SIGNATURE: _________________________
Date: ________________________________

Additional Comments: __________________________________________________________

14.0 Approvals

1) Safety Officer for the University of Western Ontario
SIGNATURE: _________________________
Date: ________________________________

2) UWO Biohazards Subcommittee: SIGNATURE: _________________________
Date: ________________________________

Approval Number: __________________

Expiry Date (3 years from Approval): __________________

Special Conditions of Approval:
Appendix 2
List of Security Sensitive Biological Agents

Security Sensitive Biological Agents List – Viruses

Andes virus
Chapare virus
Chikungunya virus
Choclo virus
Congo-Crimean haemorrhagic fever virus
Dobrava-Belgrade virus
Eastern equine encephalitis virus
Ebola virus
Guanarito virus
Hantaan virus
Hendra virus (Equine morbillivirus)
Highly pathogenic avian influenza virus
Japanese encephalitis virus
Junin virus
Kyasanur Forest virus
Laguna Negra virus
Lassa fever virus
Louping ill virus
Lujo virus
Machupo virus
Marburg virus
Monkey pox virus
Murray Valley encephalitis virus
Nipah virus
Omsk haemorrhagic fever virus
Oropouche virus
Powassan virus
Rift Valley fever virus
Rocio virus
Sabia virus
Seoul virus
Sin nombre virus
St Louis encephalitis virus
Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
Variola virus
Venezuelan equine encephalitis virus
Western equine encephalitis virus
Yellow fever virus

Security Sensitive Biological Agents List – Bacteria

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Chlamydophila psittaci (formerly known as Chlamydia psittaci)
Francisella tularensis
Burkholderia mallei (Pseudomonas mallei)
Burkholderia pseudomallei (Pseudomonas pseudomallei)
Yersinia pestis
Coxiella burnetii
Security Sensitive Biological Agents List – Toxins (and trigger quantity)

- Alpha toxin (5 mg)
- Botulinum neurotoxin (0.5 mg)
- Cholera toxin (20 mg)
- *Clostridium botulinum C2 and C3 toxins (5 mg)*
- *Clostridium perfringens Epsilon toxin (5 mg)*
- Hemolysin (10 mg)
- Shiga-like toxin (verotoxin) (1 mg)
- Shigatoxin (1 mg)
- Staphylococcus enterotoxins, Type B (1 mg)
- Staphylococcus enterotoxins, types other than Type B (10 mg)
- *Staphylococcus aureus Toxic shock syndrome toxin (5 mg)*

Security Sensitive Biological Agents List – Fungi

- *Coccidioides immitis*
- *Coccidioides posadasii*

Laboratories that work with strains of bacteria that produce SSBA toxins are not captured by the SSBA designation as long as the SSBA toxin is not produced to levels above the trigger quantity. If work with strains of bacteria that produce SSBA toxins results in the production of quantities of SSBA toxins that exceed the SSBA toxin trigger quantities, the work would be subject to the SSBA designation.

**Footnote i**

If you exceed the toxin trigger quantity, you will need a security clearance.