CERTIFICATION REVIEW PROCESS:

Authorization must be obtained from UOIT’s Biosafety Committee for all projects involving biohazardous substances, whether used onsite or offsite, prior to 1) purchasing or importing such agents, 2) commencing any research, or 3) commencing any teaching activities. Agents include all toxins, Risk Group 1 and Risk Group 2 animal and human pathogens. In addition, certificate holders will need to meet the requirements of the UOIT Biosafety Program and must adhere to the Policies and Procedures as outlined in UOIT’s [Biosafety Manual](#).

Please note that Risk Group 3 and 4 agents are not permitted for use at UOIT.

It is recommended that a Biosafety Certificate application be submitted as far in advance of the proposed use as possible to the Biosafety Committee through the Ethics and Compliance Officer (compliance@uoit.ca). Approval times may vary depending on the agent, the containment level and factors such as shared laboratories. Please contact the Biosafety Officer or the Ethics and Compliance Officer, Office of Research Services, if you have any questions regarding the proposed work.

### 1. APPLICANT HOLDER INFORMATION:

| Applicant’s Name: _______________________ | Title/Position: _______________________ |
| Faculty: _________________________ | Telephone Extension: __________________ |
| Email: _______________________________ | Lab Phone Extension: _______________ |
| Office Address: ______________________________________________________________ |
| Type of Permit: Onsite ☐ Offsite ☐ |
| Location(s) to be certified (onsite /offsite): ________________________________ |

*Note: Each location where biohazardous materials are to be handled, stored or transported must be certified for use by the Biosafety Committee. Prior to approval, the Biosafety Officer will inspect the proposed facilities to ensure that appropriate containment standards can be met.*
2. PERSONNEL WORKING ON PROJECT AND TRAINING

List the names of all individuals (including the applicant) who will be working with the agents identified on this application and state current training (WHMIS, Biosafety, and Radiation Safety).

<table>
<thead>
<tr>
<th>Names to be Added</th>
<th>Position/Role</th>
<th>WHMIS/GHS Training Passed</th>
<th>Biosafety Training Passed</th>
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3. PROJECT AND FUNDING INFORMATION

Project Title/Program:___________________________________________________________

*Please describe the proposed work in 250 words or less. Attach a copy of the procedures/protocols for the work including proposed incident reporting, medical surveillance procedures (if appropriate) and waste disposal methods.*

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

Description: ☐ Research ☐ Teaching

Is the research funded? ☐ YES ☐ NO

Funding Sources:

Program: _______________________ UOIT Fund/Organization: ____________

*Note: Pending research funds will not be released until a Biosafety Certificate is issued.*
4. PROPOSED LEVEL OF BIOLOGICAL CONTAINMENT AND AGENT USAGE

It is the responsibility of the researcher applying for the Biosafety Certificate to propose an appropriate level of containment and standard operating procedures for working with the particular agent including incident reporting and medical surveillance if applicable. The Biosafety Committee will review the application and make a final determination regarding the appropriate level of containment as per the Human Pathogens Toxins Act (HPTA) and Canadian Biosafety Standard, as well as any other necessary precautions.

Location usage and containment level (onsite/offsite):

<table>
<thead>
<tr>
<th>Building</th>
<th>Room No.</th>
<th>Room Use (e.g. storage, tissue culture)</th>
<th>Proposed Level of Containment (CL1/CL2)</th>
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For Level 2 Only: Attach a copy of reports on testing and certification of biological safety cabinets performed during the previous 12 months. Where work is to be done in Level 2 containment, proof must be submitted with the application that a biosafety cabinet is available in the lab and has been certified within the last 12 months.

5. BIOLOGICAL AGENTS USED

Biological Agents Used:

For human tissues, see Section 6.

- [ ] bacteria
- [ ] viruses
- [ ] fungi
- [ ] parasites
- [ ] microbial toxins
- [ ] recombinant DNA/RNA
- [ ] other (specify) ____________________________________________

Identify the biological agents used in the specified location(s):

<table>
<thead>
<tr>
<th>Common Name/Species</th>
<th>Risk Group</th>
<th>Location</th>
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To list additional agents, please append a listing of all agents in use or in storage to this application.

6. USE OF HUMAN TISSUES

According to Article 2.1 of the Tri-Council Policy Statement 2 (TCPS2), research involving human biological materials (from both living and deceased individuals), as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells is subject to Research Ethics Review, unless the samples collected are anonymous, as per Article 2.4 which states that REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. If you are uncertain if your work requires REB approval, please consult with the Ethics and Compliance Officer at compliance@uoit.ca.

Will human tissues, cultures or cell lines be used? □ Yes □ No

Please list all human tissues, cultures or cells to be used:

☐ human tissues/organs ☐ human blood/plasma/serum ☐ human DNA/RNA/ proteins

☐ human cells lines ☐ established human cell lines

☐ bodily fluids (urine, saliva and other body fluids)

☐ materials related to human production (embryos, fetuses, fetal tissues and human reproductive materials)

☐ other (skin, hair, nail clippings) list: ______________________________

If the collection and use of Human Tissues requires Research Ethics Board Approval, please provide the following:

☐ Research Ethics Board Approval (attach a copy)

☐ Research Ethics Board Approval pending (attach copy of Human Tissue Form)
7. USE OF ANIMAL TISSUES OR MATERIALS

If you plan to work with any animal material or live animals, a separate animal use protocol must be submitted to the Compliance Office if this material has been derived for the purposes of research. Please contact the Compliance Officer in advance of these activities and review the “Requirements for Working with Animals Guide” found under Research Services Policies and Procedures: [http://research.uoit.ca/faculty/policies-procedures-forms.php](http://research.uoit.ca/faculty/policies-procedures-forms.php).

Will animal tissues, cultures or fluids be used? □ Yes □ No

If Yes, please list if the following will be used:

- □ animal tissues and cells
- □ animal blood and blood fractions
- □ animal body fluids
- □ primary animal cell cultures
- □ established animal cell lines
- □ non-primate mammals
- □ non-human primates
- □ other animals (specify) _____________________________

Will animal tissues or materials be derived exclusively for research or teaching purposes
□ Yes □ No

If yes, please provide the following documentation:

- □ Approved Animal Use Protocol # (if applicable) __________________________
- □ Pedagogical Merit Review (Teaching Only)
- □ Pending Animal Use protocol (please append Animal Use Protocol)

8. RADIATION OR DESIGNATED SUBSTANCE USE

Will ionizing radiation be used in conjunction with biological agents? □ Yes □ No

If yes, provide Radioisotope Number: __________________________

List the isotopes to be used: _______________________________________________

Are any designated substances used? □ Yes □ No

If yes, please specify______________________________________________________
9. TERMS AND CONDITIONS OF BIOSAFETY PERMIT HOLDERS:

I. Acquisition or Purchasing of Biological Materials:

Any biohazardous materials listed on the approved Biosafety Certificate must be purchased or acquired via an “Authorization to Acquire Biohazardous Material” prior to procurement. In addition, a copy of the receiving documentation must be forwarded to the BSO upon receiving the material.

II. Amendments to Biosafety Certificate:

Biosafety Certificates are usually issued for a particular biohazardous agent in a specified location, using specified containment and procedures with specified personnel. Changes to any of these parameters, will require either an amendment to the certificate or the issuance of a new certificate via a “Request to Amend Biosafety Certificate Form”.

The Biosafety Officer must be notified immediately of any proposed changes to authorized permits, including: 1) change in location or addition of rooms; 2) addition of new agents (toxins, agents or pathogens); 3) changes in personnel, and/or 4) the cessation of work with these substances.

Biosafety Committee Oversight:

A revised permit signifying approval must be obtained from the Biosafety Officer before any new biohazardous substances including toxins may be acquired. Depending on the nature of the request, the approval process may require the full review and approval of the Biosafety Committee.

III. Termination of Permit:

The researcher must contact the Biosafety Officer upon termination of a permit and will be required to demonstrate that any remaining agents will be properly disposed of. Termination of a permit will normally require that any remaining agents be either destroyed or transferred to another Biosafety Permit holder.
IV. **Renewal Requirements:**

Please note that each Biosafety Certificate must be renewed annually prior to the anniversary date of the original approval. Renewals will be issued by the Biosafety Officer pending ongoing satisfactory inspection of the lab(s) as per the Biosafety laboratory requirements.

V. **Routine Inspection and Issues of Non-Compliance:**

The Biosafety Officer and Biosafety Committee members will be conducting routine spot inspections throughout the year to ensure that approved containment practices are being upheld.

Issues of non-compliance that arise will be documented within the Biosafety file and the researcher will be notified accordingly. Researchers will have up to one week to respond to any issues of non-compliance in writing to the Biosafety Officer.

Researchers who fail to correct issues of non-compliance will receive notification that their “use of biohazardous materials” has been suspended until rectified.

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10. **SIGNATURES**

By signing below, I agree to the above terms and conditions for Biosafety Permit Holders as outlined and will conduct my research/teaching in accordance with The University of Ontario’s Institute of Technology’s Biosafety Manual.

________________________________________

Applicant Name

________________________________________

Signature                        Date
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<th>Conditions</th>
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<th>Approvals</th>
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<tr>
<td>Biosafety Officer</td>
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<td>Chair or Designate, Biosafety Committee</td>
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