# LABORATORY BIORISK ASSESSMENT

*The outcome of the risk assessment is the development of mitigation strategies. These are stand alone and supporting documents that must be available to all users on a regular basis. Please custom this risk assessment template so it will be an overarching assessment, and the design also allows for an annual review. You can use this template as* ***a great tool for onboarding when new users com****e.*

*Use* ***A Reference Guide: the Multi-Facets of a Biorisk Assessment*** *to help you fill out this template. Meanwile, the uO Biosafety Program has many procedures that support research and thus does not require the PI to redevelop lab specific procedure. These are easily accessed on the Biosafety website.*

*Please send a copy to uOttawa biosafety team (bio.safety@uottawa.ca) for record retention. Please don't hesitate to contact us if you need clarification and assistance.*

## PART A CONTACT INFORMATION

| | | | |
|---|---|---|---|
| Principal Investigator | | Biohazardous Materials Use Certificate (BMUC) # | |
| Phone | | Lab (building/rms) covered by this assessment | |
| Email | | | |
| Office (building/rm) | | | |

## PART B RESEARCH PROJECTS COVERED BY THIS RISK ASSESSMENT

*NOTE: Any research being undertaken for which this risk assessment is not applicable, must have its own dedicated risk assessment.*

| RE/ Contract # | Grant /Contract Title and a short description of the work | Source Of Funding | Start Date | End Date | Renewal Date |
|---|---|---|---|---|---|
| | | | | | |
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## PART C PATHOGENIC AGENTS AND REGULATED TOXINS

### AGENT CHARACTERISTICS

Refer to the PSDS/MSDS for the bio agents listed on your inventory list and fill out the questions below:

1. What are the sources of your pathogenic agents:

   ☐ Commercial supplier; name of the suppliers:

   ☐ Colleagues at uOttawa; name of the PI(s):

   ☐ External collaborators ☐ within Canada ☐ outside of Canada.

   ☐ Clinic and diagnostic samples, from:

   ☐ Cultured/generated from lab

Note: any transfer of regulated biological material must be approved by the Biosafety Officer (BSO). A Biohazardous Material Transfer Notification (BMTN) form is required.

2. Your bio agents will be characterized in terms of potential risk through the following documentation

   ☐ Pathogen Safety Data Sheet (PSDS)

   ☐ Supplier data sheet of the agent(s)

   ☐ Relevant literature

   ☐ Others:

3. Identify host species and any vector considerations associated with the biological agents.

   ☐ Humans ☐ Animals ☐ Plants ☐ Aquatic species ☐ Avian

4. List the biological agent(s) that are non-indigenous to Canada (may cause diseases in humans, animals and plants that haven't been found in Canada):

5. Will you be working with samples that exceed the infectious dose of the agent?

   ☐ Yes ☐ No ☐ N/A ☐ Unknow

   If unknown, do you expect the infectious dose to be less or greater than the parental strains/types?

   ☐ Less ☐ Greater

6. Is any pathogen approved to be attenuated?

   ☐ Yes ☐ No ☐ N/A

   If yes, explain determination criteria:

7. Clinical or diagnostic samples are used?

   ☐ Yes ☐ No

If yes, describe the scope and results of the prescreening activity:

If no, use the Universal Precaution to reduce exposure risk.

8. If applicable, have you obtained the Human Ethics Approval for clinical samples?

   ☐ Yes ☐ No ☐ N/A

9. Will this project involve working with prions, toxins and security sensitive biological agents (SSBA)?

   ☐ Yes ☐ No

   If yes, what are they and quantities (for SSBA)?

10. If any of the agents being used present any specific health risks to the immunocompromised/vulnerable/pregnant/nursing individuals, the completion and submission of a Health Assessment form by any considered individuals to HR will allow a confidential discussion to occur.

After consideration of the **biological agent characteristics** (virulence, pathogenicity, mode of transmission, toxicity, medical surveillance), I have determined the risk to be (refer to the *A Reference Guide: the Multi-Facets of a Biorisk Assessment – Appendix B* to determine):

☐ Low ☐ Medium ☐ High

## PART D LOCAL RISK ASSESSMENT

### RESEARCH DESIGN

1. Does your research involve the generation of replicative competent biological agents?
   ☐ Yes ☐ No ☐ Unknown

   If yes, please describe the risk and any measures to reduce the risk:

2. Is there a possibility undergoing recombination/mutagenesis for the biological agent to potentially increase the pathogenicity?

   ☐ Yes ☐ No ☐ Unlikely ☐ Unknown

   If yes, please describe the risk and any measures to reduce the risk:

3. Will you be using recombinant DNA/cloning techniques in this project?
   ☐ Yes ☐ No

   If yes, (a) describe the source of DNA and the recipient organism (organism, species, strain):

4. Will there be a deliberate attempt to express the foreign gene?
   ☐ Yes ☐ No

   If yes, describe how the expression of the inserted gene will differ from the non-modified one:

5. Will this project involve the use of viral vectors (Lentiviral, Retroviral, Adenoviral, etc.)?
   ☐ Yes ☐ No

   If yes, please describe:

## ADDITIONAL INSTITUTIONAL APPROVAL REQUIRED

### Dual Use Research of Concern Approval

To comply with the PHAC requirements to assess dual use risk in terms of research activities the University has created two supporting documents to assist you in understanding their concerns and to provide you with guidance on how a risk assessment of this kind can be undertaken.

- Biosecurity and the Evolving Concerns Regarding Dual Use (BSDU), and
- Biosecurity and Dual Use Research of Concern - Identification, Evaluation and Mitigation Guide (BDURC).

The following questions must be considered and should any of your research be deemed as potentially DURC a more comprehensive risk assessment be undertaken as outlined in the BGURC.

| Dual Use Research Assessment Elements | Applies | Does not apply | Potentially applies |
|---|---|---|---|
| Demonstrates how to render a vaccine ineffective. | | | |
| Confers resistance to therapeutically useful antibiotics or antiviral agents. | | | |
| Enhances the virulence of a pathogen or rendering a non-pathogen virulent. | | | |
| Increases transmissibility of a pathogen. | | | |
| Alters the host range of a pathogen. | | | |
| Enables the evasion of diagnostic/detection modalities. | | | |
| Enables the weaponization of a biological agent or toxin. | | | |

If any [Applies] and [Potentially applies] check marked, explain the preventive measures for exposure and release:

Note: an additional duel-use capacity will be subsequented and a review will be conducted by the Biosafety Committee.

### Animal Care Committee Approval

Name all active PRG Protocols that will be impacted and the agents used in each protocols.

| PRG Protocol # | Agents Involved | Exposure Control Plan – For Animal Work filed with ACVS |
|---|---|---|
| | | |

| | | |
|---|---|---|
| | | |
| | | |

**Radiation Safety Committee Approval**

If work will involve radioactive material listed the Radioisotope Permit Number, radioisotope, and activity. Contact rad.safety@uottawa.ca to determine what management practices are required.

## PERSONNEL

Risk associated with personnel primarily pertain to knowledge, experience and competency. Only trained and experienced individuals should be delegated the task for training new users, and adequate supervision is required until competency is demonstrated.

| **Training** | |
|---|---|
| All mandatory training is received (such as Biosafety, Lab safety, WHMIS, etc.) | ☐ Yes ☐ No |
| Is training needs assessment undertaken?<br>If yes, the assessment it conducted by | ☐ Yes ☐ No |
| Is additional training received on new protocols and equipment's use?<br>If yes, the training is provided by ☐ PI ☐ lab manager/technician ☐ senior lab member ☐ other: | ☐ Yes ☐ No |
| Is additional or refresher training provided as determined by the review process?<br>If yes, the training is provided by | ☐ Yes ☐ No |
| Is emergency response training undertaken **annually** as required by PHAC?<br>If yes please indicate when and how | ☐ Yes ☐ No |
| Users must complete a Biohazardous Materials User Registration (BMUR) form **upon entry the lab** and when they **intend to work with new pathogens** | ☐ Yes ☐ No |
| Users' knowledge and experience are assessed with respect to the agents and procedures **upon entry the lab** and when they **intend to work with new pathogens** | ☐ Yes ☐ No |
| Trainees to be supervised by authorized personnel when engaging in activities with infectious material (as well as the equipment's use) until competency is demonstrated<br>If yes, supervision is provided by | ☐ Yes ☐ No |
| Are training records available to PHAC/CFIA during their site inspection? | ☐ Yes ☐ No |
| **Medical Surveillance (optional requirements)** | |
| Biosafety Health Assessment Survey completed and submitted to HR<br>(This is important to indicate if individual could be vulnerable to agents and if immunization or a more involved medical surveillance program is required) | ☐ Yes ☐ No<br>☐ N/A |
| Post-Exposure Prophylaxis protocol for Blood Borne Pathogens is provided | ☐ Yes ☐ No |

| | |
|---|---|
| | ☐ N/A |
| Allergies and vaccination considered | ☐ Yes ☐ No<br>☐ N/A |
| **Exposure Control** | |
| Requirement of wearing proper personal protective equipment (PPE) is standardized in your lab.<br>If no, explain why: | ☐ Yes ☐ No |
| Is there any exceptions that not wearing PPE is permitted.<br>If yes, please clarify: | ☐ Yes ☐ No |
| Lab coats are frequently washed or changed.<br>If yes, explain how:<br>If no, explain why: | ☐ Yes ☐ No |
| Lab coats are decontaminated before sending to be washed or disposal.<br>If yes, explain how:<br>If no, explain why: | ☐ Yes ☐ No |
| Exposure control plan is provided and discussed.<br>Refer to the ORM's Personnel Biological Agent Exposure Plan<br>If you have developed your own plan please list steps personnel will follow during exposure or attach your plan:<br>If no, please explain why: | ☐ Yes ☐ No |
| Emergency response plan for CL2 labs provided and discussed **annually** as required by PHAC.<br>Refer to the ORM's Emergency Response Plan (ERP) for CL2 Labs | ☐ Yes ☐ No |
| Personnel are aware that they have to report all incidents to the supervisor and the Biosafety Officer.<br>Refer to the uOttawa's Report Accident or Incident Online Form<br>How often is this discussed in the lab: | ☐ Yes ☐ No |

## EXPERIMENTAL FACTORS

1. Pathogenic samples:
    a. Do you screen your samples for any contamination or suspected contamination:

    ☐ Yes ☐ No

    If yes, describe:

    Note: lab personnel should be able to determine if an exposure lead to laboratory acquired infections (LAI). All exposures are required report to PHAC by the BSO.

b. Replication competency of the pathogen are ☐ low ☐ medium ☐ high

c. Is any pathogen experimentally modified? ☐ Yes ☐ No

If yes, what are the implication and result?

(Refer to *A Reference Guide: the Multi-Facets of a Biorisk Assessment*)

d. Cell line characteristics are

☐ established ☐ new ☐ attenuated ☐ non-replicating

Documented/determined by:

e. Is there a toxin production? ☐ Yes ☐ No

If yes, what is the amount and what is the LD50 (lethal dose that kills 50% of test samples):

f. List any experimental protocols (procedures) which may increase exposure or release:

g. Do you manipulate pathogen with volume larger than 10L scale (large scale)?

☐ Yes ☐ No

2. Aerosol generating/deposition potential:

Inhalation and contamination/absorption risk when aerosols settle: for example, centrifuging, vortexing, homogenizing and flaming loops.

Activities that pose potential risk of aerosol generation in your lab:

Prevention techniques (e.g. elimination, substitution, engineering control, good practices, etc. explain the details):

3. Self-inoculation risk potential

Absorption risk: for example, use of sharps (needle stick, lesion).

Activities that pose potential risk of self-inoculation in your lab:

Prevention techniques:

4. Potential viral shedding, bites and scratches

Absorption risk: when work with animals.

Prevention techniques (refer to SOPs from ACVS):

5. Recombinant DNA

   (Refer to *A Reference Guide: the Multi-Facets of a Biorisk Assessment*)

   a. If recombinants are used, is the inserted gene

      ☐ an oncogene ☐ alters cell cycle ☐ integrates with host DNA ☐ N/A

   b. Do any of these modify the risk associated with the pathogen

      ☐ Yes ☐ No ☐ Unlikely ☐ Unknown

   c. If vectors are used

      Describe the manipulation:

6. Inventory control

   Pathogen inventory records are kept at/in:

   The inventory is catalogued/searchable by ☐ agent, ☐ user, ☐ location, ☐ preparation date.

   Note: if the storage location/equipment is shared with other labs, samples **MUST** be labelled by PI's name.

7. Contingency Plans

   List the Contingency Plan in place (with respect to exposure, accidental release/spills)

8. Decontamination/disinfection (disinfectants used as directed)

   Chemical agent used:

   Concentration:

   Contact time:

   Shelf life:

## EQUIPMENT AND PPE FACTORS

1. Personal protective equipment (PPE) factors

   a. PPE required for entering the lab are:

   b. Indicate other specific PPE required for specific operation (face masks, heavy gloves, double gloves, etc.)

2. Equipment factors

   a. List any equipment pose any unique risks (such as aerosol production, cold injury, etc.):

b. Equipment (centrifuges, aspirators, etc.) are maintained _____ (frequency) by _____ (name/position of person)

c. Equipment are decontaminated _____ (frequency) by using _____ (name of disinfectant) by _____ (name/position of person)

Note: equipment maintenance record must be retained as required by PHAC; equipment must be decontaminated before repairing, relocation and disposal.

d. List all the alarmed equipment:

Note: emergency contact must be posted on/close to the alarmed equipment.

e. Storage equipment used are

☐ freezer ☐ fridge ☐ cold temperature environment (ETC) room ☐ liquid nitrogen vessel ☐ incubator ☐ other:

3. Biological safety cabinets (BSC)

a. Annual certificates and records are available at

b. Service contact can be found at/on

c. Equipment guideline or SOP is available at

Contact bio.safety@uottawa.ca for additional details about your BSCs (age, historical repair, relocation and replacement record, etc.).

4. Vacuum/aspiration system

a. Name of disinfectant used:

b. Disinfectant final concentration:

c. Disinfectant is prepared _____ (frequency).

Waste reservoirs (aspirators, flasks, etc.) are emptied/decontaminated _____ (frequency).

In-line HEPA filter is connected between _____ and _____; it is replaced _____ (frequency).

Refer to the Cheat Sheet Use of bleach as Disinfectant for how to install the liquid aspritaion system in an appropriate manner.

5. Autoclaves

Autoclaves used for waste decontamination are available: ☐ Yes ☐ No

a. If yes, the autoclaves are located at _____

Autoclave SOP is available in the lab: ☐ Yes ☐ No

Autoclaves used for waste decontamination must be validated by using biological indicators every six operating days. Validation SOP and records available at

_____

Waste transfer preparation:

☐ Put a completed "uOttawa Hazardous Waste" label on the bag

☐ Surface of the bag is decontaminated (spray with disinfectant or double bagged)

☐ Secondary/spill tray used

☐ Transfer cart is used

b. If no, describe the alternative waste decomtamination/disposal method:

6. List the names of equipment which have a standard operating procedure (SOP)/manual/guideline in the lab:

Note: all equipment must have a SOP in place as required by PHAC. Please refer to the uOttawa *Biosafety website* – *Operational Hub* for supporting guidelines and SOPs.

7. List any equipment located within the adjoining labs or core facilities

| Equipment | Location (and name) of the shared lab/core facility | SOP available (Y/N) | Use log available (Y/N) | Personnel provide training | Maintenance personnel and frequency | Disinfectant used and contact time |
|---|---|---|---|---|---|---|
| | | | | | | |
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## CONTAINMENT FACTORS

Level of containment that is required and available (as per Canadian Biosafety Standards v.2, status of facilities, i.e. not compromised due to age or use):

| Location (bldg. room#) | Room discerption (types of work/room function) | Access controlled (Y/N) | Status of room |
|---|---|---|---|
| | | | ☐ Good ☐ Needs minor repair ☐ Aging with moderate repair required |
| | | | ☐ Good ☐ Needs minor repair |

| | | | |
|---|---|---|---|
| | | | ☐ Aging with moderate repair required |
| | | | ☐ Good ☐ Needs minor repair<br>☐ Aging with moderate repair required |
| | | | ☐ Good ☐ Needs minor repair<br>☐ Aging with moderate repair required |

Schedule a site visit though bio.safety@uottawa.ca. Contact the Faculty Facility for corrective measures if [Needs minor repair] or [Aging with moderated repair required] is check marked; review and modify this section annually to make sure your lab status is [Good].

Based on the risk assessment process it has been determined that the:

Overall Risk Group for the material is: RG # _____

Control can be managed by using is: CL # _____ operational practices

Containment Level required is: CL # _____

**Declaration and Signature**

*(Please tick to ensure that these declarations have been read and understood)*

☐ I am aware of the inherent risks associated with this project and implemented the appropriate measures to eliminate or mitigate the risk. I certify that the information provided herein is complete and accurate and consistent with any proposal(s) submitted to external funding agencies. I agree to comply with all conditions which may be applied to the corresponding certificate and to undertake the authorized research in an ethical manner.

Complete / Update the footer as required.

_____ _____

Applicant's signature Date