



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 come.***

*Use **A Reference Guide: the Multi-Facets of a Biorisk Assessment** to help you fill out this template. Meanwhile, 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



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 dual-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.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is training needs assessment undertaken? If yes, the assessment it conducted by	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is additional training received on new protocols and equipment's use? If yes, the training is provided by <input type="checkbox"/> PI <input type="checkbox"/> lab manager/technician <input type="checkbox"/> senior lab member <input type="checkbox"/> other:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is additional or refresher training provided as determined by the review process? If yes, the training is provided by	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is emergency response training undertaken annually as required by PHAC? If yes please indicate when and how	<input type="checkbox"/> Yes <input type="checkbox"/> No
Users must complete a Biohazardous Materials User Registration (BMUR) form upon entry the lab and when they intend to work with new pathogens	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> 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 If yes, supervision is provided by	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are training records available to PHAC/CFIA during their site inspection?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Medical Surveillance (optional requirements)	
Biosafety Health Assessment Survey completed and submitted to HR (This is important to indicate if individual could be vulnerable to agents and if immunization or a more involved medical surveillance program is required)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Post-Exposure Prophylaxis protocol for Blood Borne Pathogens is provided	<input type="checkbox"/> Yes <input type="checkbox"/> No



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

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 discription (types of work/room function)	Access controlled (Y/N)	Status of room
			<input type="checkbox"/> Good <input type="checkbox"/> Needs minor repair <input type="checkbox"/> Aging with moderate repair required
			<input type="checkbox"/> Good <input type="checkbox"/> Needs minor repair



			<input type="checkbox"/> Aging with moderate repair required
			<input type="checkbox"/> Good <input type="checkbox"/> Needs minor repair <input type="checkbox"/> Aging with moderate repair required
			<input type="checkbox"/> Good <input type="checkbox"/> Needs minor repair <input type="checkbox"/> 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