Local Risk Assessment (LRA)

The outcome of a risk assessment is the development of mitigation strategies. Please tailor this risk assessment template to make it an overarching assessment whose design also allows for annual review. This template can also be **a great tool for onboarding new workers**.

Use **A Reference Guide: The Multi-Facets of a Biorisk Assessment** to help you fill out this template. Meanwhile, the uOttawa Biosafety Program has generated many procedures that support research and can be easily accessed on the Biosafety webpage. This means that the principal investigator should not need to redevelop lab-specific procedures.

Remember to send a copy of your LRA to the uOttawa Biosafety Office (bio.safety@uottawa.ca) for record retention purposes. Feel free to contact us if you need clarification or 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 to which this risk assessment does not apply 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 biological materials on your inventory list and answer 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. Which type of documentation will you use to characterize your biological material in terms of potential risk?

   ☐ Pathogen Safety Data Sheet (PSDS)

   ☐ Supplier data sheet of the agent(s)

   ☐ Relevant literature

   ☐ Other:

3. What host species and vector considerations are associated with the biological material?

   ☐ Humans ☐ Animals ☐ Plants ☐ Aquatic species ☐ Avian

4. What are the biological materials that are non-indigenous to Canada and may cause diseases in humans, animals and plants that have yet to be found in Canada:

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

   ☐ Yes ☐ No ☐ N/A ☐ Unknown

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

   ☐ Less ☐ Greater

6. Is any pathogen approved for attenuation?

   ☐ Yes ☐ No ☐ N/A

   If yes, explain the determination criteria:

7. Are clinical or diagnostic samples 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 Human Ethics Approval for clinical samples?

   ☐ Yes ☐ No ☐ N/A

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

   ☐ Yes ☐ No

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

10. If any of the materials being used present any specific health risks to 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 material's 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 materials?
   ☐ Yes ☐ No ☐ Unknown

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

2. Could the biological material undergo recombination/mutagenesis that would 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 (DURC) Approval

To comply with PHAC requirements to assess dual use risk during research activities, the University has created supporting documents to help you understand the risk and to provide guidance on how to conduct this kind of risk assessment.

- Biosecurity and Dual Use Research of Concern, BDURC (which contains guidance for identification, evaluation and mitigation).

The following questions must be considered. If any of your research is potentially DURC, you must undertake a more comprehensive risk assessment, as outlined in the BDURC.

Elements of a Dual Use Research Assessment	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 renders 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 you have checked any [Applies] or [Potentially applies], explain the measures to prevent exposure and release:

Note: You will be required to conduct a subsequent DURC risk assessment, which the Biosafety Committee will review.

Animal Care Committee Approval

Name all active Protocol Review Group (PRG) protocols that will be affected and the biological materials used in each protocol.

PRG Protocol #	Biological materials involved	Exposure control plan – for animal work filed with ACVS

Radiation Safety Committee Approval

If your work will involve radioactive material, list the Radioisotope Permit Number, radioisotope, and activity. Contact the uOttawa Radiation Safety Group to determine what radiation management practices are required.

Personnel

Personnel-related risks primarily involve knowledge, experience and competency. Only trained and experienced individuals should be assigned to train new users, and users must be properly supervised until they demonstrate competency.

Training	
Has the worker completed all mandatory training (such as Biosafety, Lab Safety, WHMIS, etc.)?	☐ Yes ☐ No
Has a training needs assessment been conducted? If yes, who conducted the assessment?	☐ Yes ☐ No
Has the worker completed additional training on new protocols and equipment? If yes, was the training provided by the ☐ PI ☐ lab manager/technician ☐ senior lab member ☐ other:	☐ Yes ☐ No
Does the review process indicate that additional or refresher training is required? If yes, who will provide this training:	☐ Yes ☐ No
Has the worker undertaken emergency response training **annually,** as required by PHAC? If yes, please indicate when and how:	☐ Yes ☐ No
Has the worker completed, as required, a Biohazardous Materials User Registration (BMUR) form **upon entry to the lab** and when they **intend to work with new pathogens?**	☐ Yes ☐ No
Has an assessment been conducted of the worker's knowledge and experience with respect to the agents and procedures **upon entry to the lab** and when they **intend to work with new pathogens?**	☐ Yes ☐ No
Are trainee workers supervised by authorized personnel when engaging in activities with infectious material and when operating equipment until competency is demonstrated? 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)	
If you have any questions or concerns related to medical surveillance or post	

exposure, please contact Health and Wellness Sector for a confidential discussion.	
Is a Post-Exposure Prophylaxis protocol for Blood Borne Pathogens available?	☐ Yes ☐ No ☐ N/A
Have the allergies and vaccination status of workers been considered?	☐ Yes ☐ No ☐ N/A
Exposure Control	
Have you standardized the requirement to wear proper personal protective equipment (PPE) in your lab? If no, explain why:	☐ Yes ☐ No
Are there any exceptions to the wearing of PPE? If yes, please clarify:	☐ Yes ☐ No
Are the lab coats frequently washed or changed? If yes, explain how: If no, explain why:	☐ Yes ☐ No
Are lab coats decontaminated before sending them to be washed or disposed of? If yes, explain how: If no, explain why:	☐ Yes ☐ No
Have you provided an exposure control plan and discussed it with all concerned? Refer to OCRO's Personnel Biological Agent Exposure Plan, on the Biosafety webpage. If you have developed your own plan, please list the steps workers will follow during exposure or attach your plan: If no, please explain why:	☐ Yes ☐ No
Have you implemented, reviewed and updated your emergency response plan for CL2 labs? Have you communicated it to the workers? Have you conducted yearly refresher training and documented such training? Refer to OCRO's Emergency Response Plan (ERP) for CL2 Labs on the Biosafety webpage.	☐ Yes ☐ No
Are all workers aware that they must report all incidents to the supervisor and the Biosafety Office? Refer to uOttawa's Report Accident or Incident Online Form 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 how:

Note: lab personnel should be able to determine if an exposure has led to laboratory acquired infections (LAI). The BSO must report all exposures to PHAC.

b. The replication competency of the pathogen is ☐ low ☐ medium ☐ high

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

If yes, what are the implications 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 toxin production? ☐ Yes ☐ No

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

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

g. Do you manipulate pathogens at volumes greater than 10L (large scale)?

☐ Yes ☐ No

2. Aerosol generation and deposition potential:

Inhalation and contamination/absorption risks occur when aerosols settle, for example when centrifuging, vortexing, homogenizing or using flaming loops.

What activities pose potential risks of aerosol generation in your lab?

What prevention techniques (e.g. elimination, substitution, engineering control, good practices, etc.) have you implemented? Explain the details:

3. Self-inoculation risk potential

Self-inoculation, such as when using sharps (needle sticks, lesion), presents an absorption risk:

What activities pose potential risks of self-inoculation in your lab?

What prevention techniques have you implemented?

4. Potential viral shedding, bites and scratches present an absorption risk when work with animals.

   What prevention techniques have you implemented? 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 ☐ cell cycle altering ☐ host DNA integrating ☐ N/A?

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

      ☐ Yes ☐ No ☐ Unlikely ☐ Unknown

   c. If vectors are used,

      Describe the manipulation:

6. Inventory control

   Where are pathogen inventory records kept:

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

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

7. Contingency plans

   List the contingency plan(s) 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. The PPE required to enter the lab is:

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

2. Equipment factors

a. List any equipment that poses any unique risk (such as aerosol production, cold injury, etc.):

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

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

Note: Equipment maintenance and repair records must be retained as required by PHAC; equipment must be decontaminated before it is repaired, relocated or disposed of.

For centrifuges: Regular maintenance and replacement of O-rings and other seals is essential. The risk of releasing pathogens can also be reduced by unloading sealed safety cups (or rotors) in a biological safety cabinet (BSC).

d. List all the alarmed equipment:

Note: emergency contacts must be posted on, or close to, the alarmed equipment.

e. The storage equipment being 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 the uOttawa Biosafety Office for additional details about your BSCs.

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 on how to use bleach as a disinfectant, posted on the Biosafety webpage, for how to correctly install the liquid aspiration system.

5. Autoclaves

   Are autoclaves available for waste decontamination? ☐ Yes ☐ No

   a. If yes, the autoclaves are located at _____

      Is the autoclave SOP available in the lab? ☐ Yes ☐ No

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

      _____

      Waste transfer preparation:

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

      ☐ Decontaminate the surface of the bag (sprayed with disinfectant or double bagged)

      ☐ Use a secondary container/spill tray

      ☐ Use a transfer cart

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

6. List any equipment that has a standard operating procedure (SOP)/manual/guide in the lab:

   Note: PHAC requires that all equipment have an SOP in place. Please refer to uOttawa Biosafety webpage – 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)	Usage log available (Y/N)	Personnel who 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.3, status of facilities, i.e. not compromised due to age or use):

Location	Room description (type of work/room	Is access controlled	Repair status of room

(bldg. room#)	function)	(Y/N)	
			☐ Good ☐ Needs minor repairs ☐ Aging with moderate repair required
			☐ Good ☐ Needs minor repairs ☐ Aging with moderate repair required
			☐ Good ☐ Needs minor repairs ☐ Aging with moderate repair required

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: CL # _____ operational practices

Containment Level required is: CL # _____

Schedule a site visit by contacting the Biosafety Office.
Contact the Facility representative for the faculty to implement corrective measures if [Needs minor repair] or [Aging with moderated repair required] is checked.
Review and modify this section annually to make sure the status of your lab is [Good].

Declaration and Signature

(Please tick to confirm that you have read and understood the declaration below)

☐ I am aware of the inherent risks associated with this project and I have implemented the appropriate measures to eliminate or mitigate these risks. 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 that may be applied to the corresponding certificate and I agree to undertake the authorized research in an ethical manner.

Complete or update the footer as required.

_____ _____

Applicant's signature Date