Biohazardous Material Management Procedure

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Office of the Chief Risk Officer

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Version Control Table

Version Number	Owner	Approver	Change Summary	Status
1	OCRO	OCRO	New	N/A

1. Document Background

Purpose and Scope of Document

The Biohazardous Material Management Procedure serves to outline the University of Ottawa (hereafter referred to as "uOttawa") procedure for working with biohazardous materials on uOttawa premises. This document is a part of the uOttawa Occupational Health and Safety (OHS) Management System and the Biosafety Program.

The procedure applies to uOttawa employees and also serves as a reference for other stakeholders at uOttawa.

Users of the procedure must also comply with the minimum requirements and procedures outlined in the General OHS Program Manual, Laboratory Safety Program Manual, and Biosafety Program Manual**. This procedure serves as a standard for biohazardous material safety-specific matters.**

Terms and Definitions

Refer to the OHS Glossary for the OHS terms and definitions that apply to the documents within the OHS Management System.

Responsibilities

Responsibilities for roles are detailed in Administrative Procedure 14-1 (Internal Responsibility Procedure for Health and Safety Issues) and the Biosafety Program Manual; please refer to the manuals in the box above and Procedure 14-1 for detailed responsibilities.

Reference Documents

- Biosafety Program Manual
- Hazard Identification and Risk Assessment (HIRA) Procedure
- Local Risk Assessment
- Incident Management Procedure

2. Procedure

Procedural Steps

The following procedural steps **must be followed** when planning for or performing work in which biohazardous materials are involved:

1. Conduct a hazard identification and risk assessment (HIRA) and complete necessary documentation. In addition, complete a Local Risk Assessment (LRA) specific to the agents used and the procedures performed
2. Identify and procure necessary biohazardous materials
3. Ship/receive biohazardous materials
4. Design and implement safe storage and usage practices
5. Monitor and manage biohazardous contamination
6. Dispose of biohazardous waste and decommission relevant equipment

Additional steps may be required based on the project or scope of work.

Details for each of the procedural steps are included below.

STEP 1 Hazard Identification and Risk Assessment (HIRA) and Additional Documentation, such as the Local Risk Assessment (LRA)

Main Activities

- Conduct a preliminary qualitative survey to identify the work hazards present, including a review of current hazard identification and risk assessments (HIRAs) and the standard procedures in place
- If the hazard(s) of the specific work have not been previously assessed by completing a HIRA or equipment/activity specific procedure (that includes the outcome of a HIRA), conduct a HIRA with reference to the Hazard Identification and Risk Assessment Procedure
- In addition, conduct a Local Risk Assessment that is specific to the biological agents in use and the procedures to be conducted. Send the completed and signed form to the Biosafety Specialist for record retention
- Complete the Biohazardous Materials Use Certificate (BMUC) Application Form(for new hires).
- Check that relevant stakeholders have completed the Biohazardous Materials User Registration (BMUR) Form and relevant biosafety training. Send the registration form and training certificates to the Biosafety Specialist

Contextual Details

Hazard Identification and Risk Assessment (HIRA)

Those who supervise projects and workspaces on uOttawa premises shall identify and evaluate current and potential biohazardous materials and associated hazards by conducting a preliminary

qualitative survey. They must also consult workers and relevant committee(s) to identify additional hazards that may be present.

Based on the findings of the preliminary hazard survey, the biohazards that have been identified shall be addressed by:

1. Identifying an existing assessment of the work hazard(s), reviewing the HIRA, conducting the Biorisk Assessment Process and the associated standard procedure to mitigate the hazard risks.
2. If an assessment or standard procedure do not already exist, the supervisor must conduct a HIRA as outlined in the Hazard Identification and Risk Assessment Procedure as well as the Biorisk Assessment Form work aid for additional biosafety context and considerations.

The supervisor must also conduct a local risk assessment and must complete the BMUC application form which must be provided to uOttawa for institutional approval prior to starting work.

The assessment shall incorporate an evaluation of biohazards that includes but is not limited to:

- Biohazardous agent characteristics, including pathogenicity/virulence, transmissibility, endemicity, recombinants, infectious dose, environmental stability, economic considerations
- Research design, including experimental protocols
- Lab operations, including procedures, equipment, material storage, and containment
- Any stakeholders
- Location associated with the work
- Security and emergency response, including biosecurity considerations*
- Relevant regulation and official control considerations

Potential biohazardous exposures, contamination, and leaks identified through the initial and ongoing assessments shall be prioritized and appropriately addressed. Ongoing assessments shall be conducted whenever the scope of work or physical workspace has changed significantly, or when there has been a biohazardous material-related incident or near miss, or legislative change or directive pertaining to biohazardous material.

Biohazardous material management requirements identified during the assessment shall be documented and communicated to the appropriate parties. Documentation shall meet the OHS document management and control requirements detailed in the General OHS Program Manual.

*NOTE: Biosecurity considerations and dual-use research of concern (DURC) classification must be reviewed in each LRA with reference to the Identification, Evaluation, and Mitigation Guide (if DURC is applicable). The relevant assessment outcome and the associated DURC criteria and implications must be detailed in the assessment documentation.

Additional Documentation

Upon approval, the principal investigator must verify that workplace personnel have submitted the Biohazardous Materials User Registration (BMUR) Form to the Biosafety Specialist along with the necessary biosafety-specific training. The Biosafety Program Checklist will support the completion of necessary documentation and tasks upon arrival. The Office of the Chief Risk Officer (OCRO) will facilitate an initial inspection to verify compliance and address questions prior to starting work.

STEP 2 Identify and Procure Necessary Biohazardous Materials

Main Activities

- Maintain records and documentation of Risk Group 1, 2, and 3 materials to demonstrate compliance and proper inventory control
- Reference the security sensitive biological agents (SSBA) list and any relevant regulation when procuring biohazardous material
- Complete the Biohazardous Material Transfer Notification (BMTN) form for transfer of biohazardous material

Contextual Details

Purchasing shall reference and follow the requirements and procedures defined by and managed through Procurement. This Biohazardous Material Management procedure outlines additional requirements relevant to the procurement of biohazardous materials.

Inventory Control

- **Risk Group 2 and 3 Materials**
    - The laboratory must also retain additional records of derived cell cultures or modified pathogens on site. Inventory records must be available for review by regulators during site visits or by the Biosafety Specialist during inspections
    - Storage locations must have written records indicating the contents of freezers, liquid nitrogen dewars, etc. and should be compiled by the PI/Supervisor. These records should be stored in an online database or a physical binder at the storage location. This is especially important in the case of equipment failure, where immediate intervention may be required, or key samples must be recovered
    - Due to the need to establish and maintain biosecurity, access to contents and full disclosure of such content should be restricted to authorized persons
- **Risk Group 1 or Diagnostic Samples**
    - While Risk Group 1 and diagnostic samples are not regulated by the Public Health Agency of Canada (PHAC), the Biosafety Program does manage this material to avoid misclassification and establish that the necessary information is readily available in an emergency.

Procurement

The *Human Pathogen and Toxin Act* licenses held by uOttawa for materials in Risk Group 2 and Risk Group 3 (HIV and HTLV only) regulate the import, export, acquisition, and transfer of these substances. Security Sensitive Biological Agents (SSBA) and Toxins are prohibited at uOttawa because the uOttawa license does not allow for possession of these substances, except for exempt quantities of specific toxins. To check which are allowed, refer to SSBA list.

Both the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) regulate substances and publish criteria that the University of Ottawa must meet. Other regulatory

bodies, such as Environment Canada and Climate Change, Fisheries and Ocean etc., may also publish requirements that must be met or reported on.

The Biohazardous Material Transfer Notification (BMTN) form for biohazardous material must document the University's approval and must specify the inventory authorized to be acquired. The BMTN must also be issued to the requesting principal investigator and must be established and available for reference before making arrangements to acquire material from colleagues or from medical institutions (in the case of human samples). Commercial suppliers must contact the Biosafety Specialist through procurement processes for approval before processing a purchase.

STEP 3 Ship and Receive Biohazardous Materials

Main Activities

- Complete the Biohazardous Material Transfer Notification Form for any transfer of biohazardous materials, with approval from Biosafety Specialist.
- Refer to the Shipping Infectious Substances and Transportation of Dangerous Goods guidance to verify proper shipment.

Contextual Details

Transferring Biohazardous Material

Use the Biohazardous Material Transfer Notification Form to engage both the Consignor and Consignee in the transfer of biohazardous materials. This form is specific to biohazardous materials: it documents relevant biohazardous concerns as well.

The form, once completed, must also be verified and approved by the Biosafety Specialist.

Shipping Biohazardous Material

Before shipping of any biohazardous material, refer to Shipping Infectious Substances bulletin issued by Transport Canada. Those who transport biohazardous material are required to have previously completed Transportation of Dangerous Goods training and must follow the guidelines contained in such training.

STEP 4 Designing and Implementing Safe Storage and Usage

Main Activities

- Identify the relevant work aids to use based on the scope of work with biohazardous materials
- Ensure that individuals working with biohazardous materials or related equipment receive the required biosafety-specific and lab-specific training

Contextual Details

Projects and workspaces that work with biohazardous materials must refer to the following table to identify the key resources to follow, based on the scope of work:

Table 1: Relevant work aids based on the scope of biohazardous material work.

Scope of Work	Work aid
All stages of work	Good Microbiological Practice and Containment
Containment	Containment Level 2 Checklist - Mandatory Requirements Containment Level 2 Checklist - Additional Requirements for Prions
Use of open flames in biohazardous safety cabinets	Use of Open Flames in Biological Safety Cabinets
Biological safety cabinets (BSC) and laminar fume hoods (LFH)	Difference between BSC and LFH Certification of BSCs and LFHs Installation of BSCs Working with BSC
Clinical and Diagnostic Samples	Blood Spill Procedures Measures to minimize exposure to bloodborne pathogens and post-exposure prophylaxis

Training Requirements

Individuals working with biohazardous materials or related equipment should receive training that aligns with the minimum training requirements and training courses outlined in the General OHS Program Manual, Laboratory Safety Program Manual, and Laboratory Safety Training Framework. Where a need for new training is identified for a particular subject matter or newly introduced process, the OCRO will update the framework accordingly.

Supervisors shall ensure that individuals are informed and educated on the appropriate safety procedures and relevant safety devices for the proposed laboratory work.

STEP 5 Monitoring and Managing Biohazardous Contamination

Main Activities

- Refer to the PPE requirements outlined in the General OHS Program Manual
- Risk assessment will determine the need for medical surveillance, which is coordinated through Health and Wellness
- Onboard and monitor individuals working with, and potentially exposed to, biohazardous agents
- Identify personnel who require additional consideration, such as pregnant laboratory workers
- Evaluate incidents for exposure; report the incident according to requirements outlined in the OHS Incident Management procedure and to regulatory agencies as necessary
- Refer to disinfectant and autoclave procedures to implement and enforce minimum decontamination requirements

Contextual Details

PPE

Individuals working on projects, or in workspaces, where biohazardous material are present must use appropriate PPE during work (as assessed and determined using the HIRA and Biorisk Assessment processes). Procurement, maintenance, and general PPE requirements are established in the General OHS Program Manual.

Medical Surveillance

When applying for BMUC and conducting a HIRA, the principal investigator must identify any potential biological risks and, where required, discuss medical surveillance considerations with Health and Wellness.

Individuals working with, or potentially exposed to, biohazardous agents are advised to maintain an up-to-date vaccination status for relevant disease pathogens. Individuals can discuss their health status with a health-care professional to determine if vaccinations are available and necessary.

For biohazardous materials and toxins in Risk Groups 2 or 3, the following requirements are mandatory:

- Containment zone personnel must immediately inform the appropriate internal personnel or authority of any:
    - Incident that may have resulted in an exposure of an individual to a human pathogen or toxin
    - Disease that has been, or may have been, caused by an exposure to a human pathogen or a toxin
    - Non-exposure biosafety and biosecurity incidents
- Emergency medical contact cards must be issued to containment zone personnel handling non-human primates or a pathogen identified by the risk assessment

Some pathogens pose special concern for expecting or lactating mothers. Such considerations are detailed in the Pregnant workers procedure.

The inventory of biohazardous agents must be documented and periodically reviewed. This includes communicating the results of such reviews to the appropriate medical professional. Such documents can include:

- A report sorted by inventory
- A report sorted by Principal Investigator (PI), Faculty, Department and their inventory

Incidents must be assessed to identify potential exposure and must be included in post-exposure medical surveillance. Health and Wellness will coordinate medical follow-up for an incident. To report and manage incidents, follow the OHS Incident Management procedure. The Biosafety Specialist shall lead and support an investigation of the incident and report the incident to the Public Health Agency of Canada, where required.

Decontamination

At a minimum, disinfection of biohazardous materials and associated equipment should involve autoclaving and disinfectants. Labs should implement procedures as necessary based on the principal investigator and lab owner. Minimum procedures include:

- Bleach as a Disinfectant
- Autoclave Procedures and Autoclave Guidelines

Refer to the table below: suitable items must be decontaminated by autoclaving.

Table 2: Items that can and cannot be autoclaved.

Can be autoclaved	Cannot be autoclaved
• Cultures and stocks • Culture dishes and related devices • Discarded live and attenuated vaccines • Contaminated solid items, including petri dishes, Eppendorf tips, pipettes, and gloves • Items for sterilization, including glassware, media, water, and equipment	• Materials containing solvents, or volatile or corrosive chemicals • Material contaminated with chemotherapeutic agents • Radioactive materials

Autoclaves must be used in accordance with the Autoclave Procedures and must take into consideration:

- PPE
- Transportation
- Autoclave cycles, loading, operation, and unloading
- Waste disposal
- Training requirements
- Recordkeeping
- Quality control and maintenance

STEP 6 Disposing of Biohazardous Waste and Decommissioning Relevant Equipment

Main Activities

- Follow the Hazardous Material and Waste Management Procedure, Laboratory Decommissioning Procedure and the Biomedical Waste Disposal Procedure
- Document, and maintain records of, biohazardous waste and forward such records to the OCRO
- Use the Decommissioning/Relocation of Biohazardous Materials Form to guide you in decommissioning biohazardous materials and related equipment or spaces

Contextual Details

Waste Management

Projects and workspaces involving biohazardous waste must comply with the Hazardous Material and Waste Management Procedure and additional biohazard related procedures as outlined below. Waste management can reference the Biomedical Waste Management SOP as a template.

Biohazardous waste can be classified as pathogenic and non-pathogenic and is further broken down into types including:

- Biohazardous material
- Laboratory associated waste, such as microbiology laboratory and biomedical sharps waste
- Anatomical waste, including human and animal anatomical waste
- Blood and bodily fluids waste, including animal and human blood and bodily fluids
- Other biohazardous waste

Biohazardous material must be properly segregated, contained, labeled, handled, transported, treated, and stored during disposal. Some waste requires additional procedural steps. This includes mixed waste, radioactive carcass waste, cytotoxic waste, and ethidium bromide. This is further detailed in procedural steps in the Biomedical Waste Disposal Procedure.

Biohazardous waste must be properly documented to outline the nature of the waste, including proper labelling and send copies of records to the OCRO. The OCRO maintains records of the type of waste, weight, and corresponding cost of disposal.

Decommissioning

Decommissioning can apply to a permit, a room, or a piece of equipment and is guided by Laboratory Decommissioning Procedure and the completion of the Decommissioning/Relocation of Biological Materials Form.

These procedures must be followed prior to sending any piece of equipment for repair or relocating it beyond the laboratory area.

The BMUC holder is responsible for completing the decommissioning form and submitting it to the Biosafety Specialist, who will check that the appropriate measures have been taken and approve the form. The OCRO retains all decommissioning forms for three years.

3. Emergency Procedures

Biohazardous Spill Response Plan

Each lab shall have and refer to a biological spill response plan to comply with both general requirements and lab-specific procedures. The spill plan will vary, depending on the biohazardous materials being used. Principal Investigators must complete this plan and communicate its details to stakeholders.

Biohazard Spills

1. Alert everyone on site and evacuate the room. Minimize the spread of the spill as much as possible. Do not remove contaminated material from the spill area. Close the door and post a warning sign that states your name, direct telephone number, date and time, and the following message "no entry - biohazardous material spill". Specify the hazardous agent. If aerosolization is a risk, remove contaminated clothing and leave the area for at least 30 minutes to allow aerosols to settle. Thoroughly wash exposed skin with soap and water
2. Restrict access to the area to only those cleaning the spill
3. Ensure that everyone cleaning up the spill wears appropriate personal protective equipment; such equipment could include respiratory protection, gloves, protective eyewear and clothing, etc.
4. Quickly block or contain the size and spread of a spill by using appropriate absorbent material available in the laboratory spill kit, or by using any of the following: paper towels, sand, vermiculite, inert absorbent, spill pillows, berms, etc.
5. Using an appropriate concentrated disinfectant, cover the spill area. Pour disinfectant from the exterior spill boundary toward the centre. For hazardous substances, allow the disinfectant to act for 20 minutes
6. Clean the spill from the outer perimeter inwards and address obstacles (such as broken glass, physical objects, etc.) as you clean toward the centre. Use forceps or tongs to handle broken materials
7. All contaminated materials and equipment shall be properly decontaminated or properly disposed of as hazardous waste. Equipment must be disinfected with a comparable disinfectant that is non-corrosive (rinse with water if necessary). Contaminated materials can be sent directly to be autoclaved
8. All adjacent areas should also be disinfected
9. Remove contaminated clothing by turning the exposed area inward and autoclaving the clothing
10. Wash all exposed skin with disinfectant soap, following standard washing practices
11. Inform the principal investigator responsible for the laboratory / research project
12. Complete an Accident, Incident, Occupational Illness or Near Miss form (refer to the Incident Management Procedure for details on reporting incidents) and a Hazardous Materials Technical Services Regular Collection Request
13. Remain in a safe location so that you can answer questions if further information is required

Emergency Response Plan for Containment Level 2 Laboratories

Principal Investigators in Containment Level 2 Laboratories shall annually review and inform other stakeholders of the emergency response plan. Keep records of the annual training provided.

Equipment Alarms

For each equipment, ensure that a Response Procedure to Equipment Alarm form is completed. This will identify the designated personnel to contact and any additional action that should be taken.

Post-Exposure Response Plan

Post-exposure response plans should outline the specific procedures to follow and actions to be taken in the event of a known, suspected, or potential exposure to a pathogen or toxin (e.g., reporting, medical testing and treatment). For containment zones where pathogens or toxins are handled or stored, a post-exposure response plan may be created in consultation with the occupational health care provider or practitioner, the institutional biosafety committee, the Biosafety Specialist and the occupational health and safety advisor. This plan must be communicated to individuals working in the containment zone.