University of Ottawa Biosafety Program
Getting Started on the Right Foot

Introduction:

Welcome to the University or to the Biosafety Program, which has been designed to assist in compliance to regulatory requirements, such as those issued by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA), among others.

As you may well be aware, the field of biosafety and biosecurity is evolving quickly and as a result, there is more demand being placed on the Principal Investigators (PI) in terms of:

- Undertaking a risk assessment,
- Inventory control and security, and
- Training and oversight.

Setting up your lab, and ensuring that lab meets the containment requirements (again as stipulated by the PHAC and the CFIA) and have appropriate procedures, the Office of Risk Management (ORM) has standardized certain activities to facilitate and support research.

To obtain the Human Pathogens and Toxins Act (HPTA) Licence from the PHAC, the University had to develop a Biosafety and Biosecurity Governance Framework; which outlines the program and the roles and responsibilities (including yours). It is mandatory to have a bio-risk assessment undertaken and it must be reviewed annually, and security measures appropriate to the risk is also a regulated requirement

Start Up Steps:

Step 1: Information Required Prior to Seeking Institutional Approval

- Important Dates: what date will you be arriving at the University, plan to transfer biological agents, and commence research activities.
- Institutional Approval is obtained by completing both the Biomaterial Use Certificate (BMUC) application. (If no material will be transfer this step can be completed upon arrival.)
- Biological Material Transfer: Risk Group 2 (RG2) material is regulated and requires by law the approval and sign off by the Biosafety Office of each institution. (This is also a requirement if material is being transferred between PI within the same institution.)
- Documented Risk Assessment: PHAC requires a documented risk assessment for research involving RG 2 and 3 materials, please forward your current risk assessment(s) if these are acceptable there will be no need to recreate a risk assessment.

Step 2: Upon Arrival

- Biohazardous Material Use Certificate (BMUC) Application Form completed and submitted, if not done earlier.
- User Registration Form for all users.
- Training requirements to be met.
- Facility Containment requirements will be verified.
- Biosafety Program Checklist is a tool to help ensure all requirements are met and all tools are available to you.

Step 3: Prior to Starting Research

- An inspection will be undertaken to assist you in meeting compliance, clarify any confusion and address any questions.
- Grading Matrix is provided to inform you on how risk is assessed and how compliance is graded. It is designed to address best practices and areas that require further support or diligence.

UO Biosafety Checklist:

To ensure you have all the biosafety information and resources available to you, this table will provided you with a list of useful information. Where possible we have standardized procedures or posters (some which you can fill in the missing information so that it is tailored to your facility). As our webpage is in the process of being redesigned, not all information is available yet, but we have attached the most commonly used documents; others are available upon request. In addition, we have noted below the date of the first start-up visit just to make any last minute recommendations. We are always available at bio.safety@uottawa.ca or ext. 3153.

RG 1 materials represent a less risk associated with exposure and release and thus are not required to comply with all RG2 and RG3 (HTLV and HIV) materials.

NOTE:

1. More information is on the Biosafety Web Page (please be patience, we are in the midst of a migration).
2. University is not licenced for any other RG3 agents other than those referenced, not for any Security Sensitive Biological Agents and Toxins.
3. Set-up Checklist outlines mandatory requirements (unless not applicable), in some cases, the requirements are recommended but not mandatory for RG1 materials: these will be noted where applicable by (RG1-R).
4. Biosafety Health Assessment Form is a confidential form sent directly to the HR – Health and Wellness medical professionals, and is used to identify anything in your past or current health status that may place the individual at greater risk. Completion and submission are recommended but not mandatory.

Biosafety Program Checklist

(a template developed on your behalf to facilitate your lab start-up)

Compliance Items	Comments	Available from
Institutional Biosafety Approval		
Biosafety Program Requirements	Review Biosafety Policy and Biosafety and Biosecurity Governance Framework (PHAC – Plan of Administrative Oversight) will be forwarded.	UO Biosafety webpage – Biosafety Program & Manual
Biohazardous Materials Use Certificate (BMUC) Application Form	To be submitted by **PI** to the Biosafety Compliance Specialist to obtain a BMUC.	UO Biosafety webpage – Operational Hub

Risk Assessment Document	To be submitted by **PI** to the Biosafety Compliance Specialist to obtain a BMUC.	UO Biosafety webpage – Biosafety Manual 4.3.1 and 4.3.2
Personnel		
Biohazardous Materials User Registration (BMUR) Form	To be submitted by all the users/new users to the Biosafety Compliance Specialist.	UO Biosafety webpage – Operational Hub
Biosafety Health Assessment Form	To be submitted to the Human Resource – Health, Wellness and Leave, recommended but not mandatory for any user.	UO Biosafety webpage – Operational Hub
Biosafety Training	Register for the next training session and attend the class. (https://web47.uottawa.ca/en/lrs/node/1400)	UO Biosafety webpage – Operational Hub
Interim Training Requirements	To be followed if the most recent ORM Biosafety Training was missed.	UO Biosafety webpage – Operational Hub
Practical Training	To be received in the lab from the PI or other senior users.	-
Experimental Requirements		
Risk Assessment and Pathogen Safety Data Sheets (PSDS)	Read the PSDS (http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php), or reference the supplier technical information. Prepare a binder for these documents and make sure it is available in the lab.	UO Biosafety webpage – Operational Hub
Biohazard Warning Signage	To be filled out and posted at the entry of the lab.	UO Biosafety webpage – Operational Hub
Biological Spill Response Plan	To be filled out and posted in the lab.	UO Biosafety webpage – Operational Hub
Facility Requirements		
Laboratory Design	To meet the Public Health Agency of Canada's (PHAC) Canadian Biosafety Standards (CBS).	UO Biosafety webpage – Biosafety Manual 4.7
Operational Requirements		
Standard Operating Procedures and Guidelines:		
Autoclave Procedures	To be effective, you must know the factors and communicate these to the operator.	UO Biosafety webpage – Operational Hub
Biomedical Waste Management Procedures	Ensure your waste is managed appropriately – basic knowledge is often not known.	UO Biosafety webpage – Operational Hub
Guideline: Use of UV Lamps in Biological Safety Cabinet	MOL has investigated exposures, be proactive and learn how to protect yourself.	UO Biosafety webpage – Operational Hub

Working with Biological Safety Cabinet	Avoid exposure, contamination and expense.	UO Biosafety webpage – Operational Hub
Cheat Sheets (Quick Reference Guides):		
Good Microbiological Practices (GMP)	Mitigates exposure and contamination.	UO Biosafety webpage – Operational Hub
Lab Coat Selection Guideline	Lab coats to be worn to protect you from your research and your research from you.	UO Biosafety webpage – Operational Hub
Use of Bleach as a Disinfectant	Bleach solutions are not effective if guideline not applied.	UO Biosafety webpage – Operational Hub
Use of Open Flame in BSC	The safe and alternative available.	UO Biosafety webpage – Operational Hub
HEPA Filter Certification	Overview of process.	UO Biosafety webpage – Operational Hub

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FOLLOW-UP INSPECTION

An inspection will occur to ensure you are compliant and have the appropriate procedures to ensure you start on the right foot. This will be scheduled 1 month after the BMUC has been issued. If you are not ready, it will be rescheduled to meet your expected start up.

Biosafety Grade Matrix is a tool we use to help identify both best practices and areas that require further support.

Principal Investigator		**Department/Faculty**	
Lab Delegate		**Laboratory Location**	
BMUC #		**Inspection Date**	