

Biosafety Administrative Oversight Plan

RATIONALE:

The University of Winnipeg is committed to providing a safe and healthy environment for students, faculty and staff. The University's Health and Safety policy, https://www.uwinnipeg.ca/institutional-analysis/docs/policies/health-and-safety-policy.pdf approved by the Board of Regents and the University Administration, describes the University's commitment to health and safety at all levels with responsibility outlined.

The Biosafety Administrative Oversight Plan for pathogens and toxins is required under section 3 of the Human Pathogens and Toxins Regulations, http://laws.justice.gc.ca/eng/regulations/SOR-2015-44/page-1.html.

The University of Winnipeg has developed a Biosafety Administrative Oversight Plan which has been approved by the University of Winnipeg Biosafety Committee. The Biosafety Administrative Oversight Plan outlines the University's Biosafety program.

BIOSAFETY ADMINISTRATIVE OVERSIGHT PLAN DESCRIPTION

The University of Winnipeg Biosafety Administrative Oversight Plan involves ten elements. This document describes how these elements are managed and represented at the University of Winnipeg.

Element 1 – Commitment from senior management to manage and control biosafety and biosecurity risks at the institution/organization.

The Biosafety Administrative Oversight Plan, approved and signed by the Associate Vice-President – Human Resources, demonstrates the commitment of the University's senior administration to manage the biosafety program at the University.

The Biosafety Program is managed and maintained by the Biological Safety Officer (BSO) and Biosafety Committee (BSC) members. The BSO works in conjunction with the Manager, Safety and Health of the University of Winnipeg on matters pertaining to biosafety.

The BSC is comprised of University of Winnipeg faculty members knowledgeable in the use of biohazardous materials and not actively involved in research involving human pathogens and toxins at the University of Winnipeg. Members of the BSC are appointed by the Dean of Science and the Vice-President – Research and Innovation, in consultation with the Chairs of the relevant departments. Non-academic members include the BSO and the Alternate Biosafety Contact.

The BSC will meet twice a year and as required to review risk assessments, permit applications and incident reports and to assist with the development of the Biosafety manual and the Biosafety training at the University of Winnipeg.

Element 2 - Delineation of the roles and responsibilities for committees, individuals, departments etc., which have a role in the control/management of biosafety and biosecurity risks.

Responsibilities:

Biosafety Committee (BSC):

The BSC is comprised of staff and faculty members knowledgeable in the use of biohazardous materials and not actively involved in research involving human pathogens and toxins at the University of Winnipeg. All business before the committee must be approved by consensus by a quorum of the committee (half of the committee members). If the committee must conduct business outside of bi-annual committee meetings, this may be conducted via email.

- Advises on the safe use of biological materials, agents and other sources of biological hazards, and prescribed equipment such as the Biological Safety Cabinet (BSC), autoclaves etc.
- Develops, reviews, updates, and maintains Biosafety policies, procedures, risk assessments and training applicable to the Biosafety of laboratory personnel and students
- Enforces Biosafety policies and procedures
- Performs internal inspections bi-annually to identify hazards and reviews findings of these inspections
- Reviews reports related to laboratory activities, incidents, and non-conformances in laboratory areas. Recommends corrective actions for non-conformances
- Issues Biosafety Permits to control the use of all biological materials and to manage the release of research funds in conjunction with the office of the Vice-President Research and Innovation
- Revokes the Biosafety Permit from individuals who contravene the University biosafety policy and procedures
- Reports its activities to the University Workplace Safety and Health Committee quarterly through the Manager, Safety and Health
- Reports as required to the Vice-President Research and Innovation, and the Dean of Science

The term of BSC members are three years renewable.

Biological Safety Officer (BSO):

The BSO acts as the liaison between the University of Winnipeg and the Public Health Agency of Canada on regulatory issues. The BSO is responsible for the day-to-day operations of the biosafety program, including but not limited to:

- Verifying the accuracy and completeness of licence applications;
- Communicating with the PHAC on behalf of the licence holder;
- Promoting and monitoring compliance, including but not limited to:
 - arranging for documentation and training related to biosecurity policies, standards, and practices;
 - submitting copies of biohazard permits to the Research Office to monitor the release of research funds
 - o notifying the PHAC of any inadvertent possession of human pathogens and toxins or of any Security Sensitive Biological Agents (SSBA) not received as expected;
 - conducting periodic internal inspections and biosafety audits and reporting findings to the licence holder;
 - o informing the licence holder of any non-compliance by a person conducting activities under the licence that is not resolved after that person has been made aware of it.
- Assisting in the development and maintenance of the Biosafety Manual and standard operating procedures (SOPs) related to biosafety and biosecurity, and assisting with internal investigations of incidents.

Alternate Biosafety Contact: to act as a Biological Safety Officer in the absence of the Biological Safety Officer.

Manager, Safety and Health: Supports and ensures the safety program is operationally efficient (reports to the Associate Vice-President – Human Resources).

Associate Vice-President – Human Resources: Supports the program by acting as license holder.

Department Chairs:

- Ensure that their staff and faculty are trained in Biosafety procedures.
- Ensure compliance with biosafety matters in their respective areas and reporting back to BSC.
- Ensure that any new activities in their departments are assessed for risk level and are presented to the BSC prior to commencement of activities.
- Provide the BSO and security services with a list of individuals who are allowed access to containment level 2 zones.

Principal Investigator (PI)/Faculty Members/Lab Technicians/ Lab Workers:

- Submit the general scope of work, an up-to-date inventory of biological material and a local risk assessment along with the permit application.
- Keep biological agents secure.
- Ensure that students are trained and supervised at all times.

Students:

- Follow biosafety procedures in which they have been trained.
- Report any incidents to their supervisor and report unauthorized personnel to security services.

Executive Director, Facilities (reports to the Vice-President – Finance and Administration):

• Maintaining control of access to Containment Level (CL) 2 laboratories by enabling/disabling electronic/physical access as required.

Manager, Safety and Health (reports to the Associate Vice-President – Human Resources):

Coordinate and execute the medical surveillance program;

Risk and Insurance Manager (reports to the Vice-President – Finance and Administration):

• Involved in risk assessment and management of the biosafety activities being carried out at the University. In case of a loss, misuse or theft of biological agents, the Risk and Insurance Manager would meet with the BSO and with a representative from the BSC.

Reporting Structure:

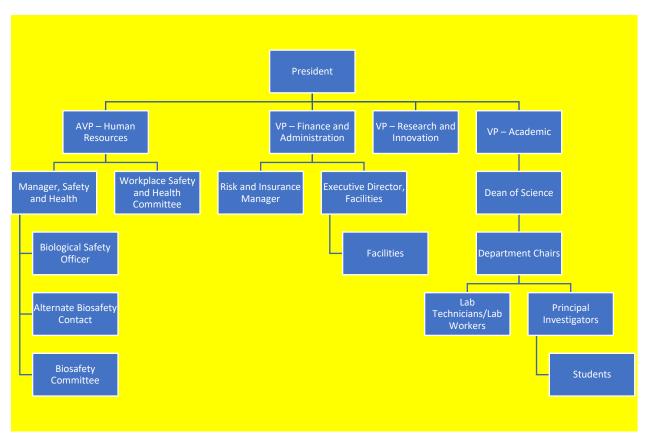
The appointed Biological Safety Officer is Alan McGreevy and Alternate Biosafety Contact is Kevin Smith. The Biological Safety Officer reports to the Manager, Safety and Health (Kevin Smith) for the matters pertaining to biosafety, who in turn reports to the Associate Vice-President – Human Resources (Marni Yasumatsu), who reports to the President of the University of Winnipeg (Todd Mondor). Alan McGreevy is not actively involved in research involving human pathogens and toxins at the University of Winnipeg, which avoids any perceived conflict of interest. Department Chairs report to the Dean of Science and all principal investigators/faculty members/lab technicians are affiliated with the research and academic Faculties.

The Biosafety Committee reports to the Workplace Safety and Health Committee through the Manager, Safety and Health. The BSO's role as a resource member to the BSC provides a link to

the Faculty of Science Office and that of the Vice-President – Research and Innovation for matters pertaining to biosafety program implementation and non-conformances.

The Manager, Safety and Health collaborates with the Risk and Insurance Manager, the Dean of Science, the Vice-President – Academic, and the Vice-President – Research and Innovation and allows them to make unbiased decisions related to all safety issues at the University of Winnipeg.

The Manager, Safety and Health also collaborates with the Executive Director, Facilities and facility users in order to ensure that any new buildings, laboratories and renovations include relevant information specifically related to the requirements of the various health and safety regulations and guidelines, as well as any that relate specifically to biosafety and biosecurity. The Manager, Safety and Health is also responsible for providing resources to the BSO for biosafety enhancement when required.



Element 3 - Establishment of a single point of contact to provide guidance on the plan and a senior level "Champion" who can represent biosafety issues at a senior level on their behalf

At the University of Winnipeg, the single point of contact for guidance on the Biosafety Administrative Oversight plan and biosecurity matters is the BSO. The senior level champion is Marni Yasumatsu (Phone Number: 204.789.1451, E-mail m.yasumatsu@uwinnipeg.ca),

Associate Vice-President – Human Resources who represents biosafety and biosecurity matters to senior management.

Element 4 - Overview of how biosafety and biosecurity risks, including those from research with dual-use potential, are identified at the institution/organization.

In order to use regulated biological agents and toxins at the University of Winnipeg, a principal investigator must complete the permit application form (includes Local Risk Assessment) and submit the form to the Biological Safety Officer along with an updated biological material inventory and biosecurity assessment, and all applicable site-specific SOPs. All applications and risk assessments will be reviewed and approved by the BSC and then the permit will be signed by the Chair of BSC. Copies of permits are retained by the BSO and are also sent to the Research Office. Permits are valid for three years and must be updated within 14 days when inventory, scope of work or personnel changes occurs.

Local risk assessments, identifying risks and the measures to be implemented to mitigate these risks, are completed for any procedures involving work with biohazards as a part of the permit application and review process.

Overarching risk assessment (identification of hazards, type of biological material present, locations where the material is handled and stored, and the activities being conducted) is in progress for existing biosafety locations. With assistance from the Principal Investigators, the BSO and BSC will determine the required biosafety program components and develop risk mitigation strategies which may include the use of engineering and administrative controls, practices, and procedures, and training.

The overarching risk assessment by the BSO and the BSC will be performed when any new biosafety location has been added. The biosecurity risk assessment will be performed by the Principal Investigators annually.

Research office fund release:

For work in locations controlled by the University an applicant must hold a valid Biosafety Permit and biological workers must be listed on the permit.

Funds will be released by the Research Office only after the BSO provides an approval certificate to the Research Office. In order to release the approval certificate the committee must be satisfied that the containment level and safety procedures identified are appropriate for the proposed work submitted with the permit application. The certificate is valid until the grant expires.

Element 5 – Overview of how biosafety and biosecurity risks, including those from research with dual-use potential, are assessed once they have been identified at an institutional/organizational level.

Using the PHAC "Decision Tree: Identification of Dual-Use Potential in Life Sciences Research", the University of Winnipeg does not conduct research with any agents which have dual-use potential.

The Biosafety Risk Assessment is also a part of the Overarching Risk Assessment which is in progress. Currently the biosafety risks at the University of Winnipeg have been classified as risk groups 1 and 2 only.

- Any work with Risk Group 2 pathogens will be performed only in the CL2 containment zones.
- Access to CL2 labs is controlled and maintained by Facilities.
- Cleaning staff are not allowed to enter CL2 zones.
- Facilities (maintenance staff) requires permission and must follow entry procedures either from BSO or the lab occupant to enter into the CL2 zones prior to commencing any work.
- PI's must perform a local risk assessment of their work and present their findings to the BSC.
- Pl's must submit their biological agents' inventory to the BSC on a yearly basis.
- Currently there are no Security Sensitive Biological Agents (SSBA) present at the University of Winnipeg.

Any new research project or laboratory sessions involving biohazards must undergo local risk assessment to ensure all hazards are identified and develop Standard Operating Procedures (SOPs) to mitigate these identified risks. These are included in the biohazard permit application process which is reviewed and assessed by the BSC.

Element 6 – Overview of how the biosafety and biosecurity risks, including those from research with dual-use potential, are managed and controlled at an institutional/organizational level.

As stated in element 5, the University of Winnipeg does not conduct research with anything that has a dual-use potential.

Biosafety and biosecurity risks are controlled by the Principal Investigators according to the recommendations made by the BSO and BSC during the permit application process, which includes the control mechanisms/hierarchy of controls (elimination, substitution, engineering controls, administrative controls and personal protective equipment).

All labs use RG1 organisms whenever possible however RG2 pathogens are used in teaching and research areas and are captured in University of Winnipeg control mechanisms.

The overarching control mechanism is the University of Winnipeg's Biosafety Program which includes many of the control mechanisms that are being used. These include:

Biosafety Manual:

The development of a Biosafety manual is in progress for individuals who handle or work in proximity to potentially infectious materials and toxins, and is based on an overarching risk assessment of the protocols in use at the University of Winnipeg.

Biohazard Permit System:

Local work regulated by the HPTA is controlled by a permit system. To apply for a permit a local risk assessment must be taken by the Principal Investigators. This process must be completed before beginning any activities with biological materials for teaching or research use, or if there are significant changes (i.e., new materials or procedures) or incidents of non-compliance found in an internal audit to a previously approved biohazard permit. Pls are required to annually submit an inventory of biological agents to the BSO.

Research Approval Certificate:

For funded projects, a Biosafety Permit is required before the Research Office will release research funds. The BSO is responsible for submitting a copy of the permit to the Research Office.

Biosafety Committee:

This committee meets at a minimum twice a year to review and approve biohazard permit applications to ensure appropriate containment levels have been assigned and that the biosafety practices are in place. If serious and imminent risks have been identified in an internal audit or reported, the BSC has authority to stop the work immediately/revoke the permit. The BSC will inform the Research Office so that research funding is frozen until the matter has been resolved.

Cross Committee Appointments:

The BSO and the Alternate Biosafety Contact are resources/appointed members to other committees (i.e., Science Laboratory Safety, Radiation Safety, Animal Ethics, and Workplace Safety and Health Committees). Any biosafety or biosecurity issues can be identified and rectified before potential unsafe work is initiated. This cross appointment has also built more awareness and collaboration across work units.

Internal Audit/Inspection Program:

Bi-annual inspection of CL2 containment zones are performed by the BSO and the BSC. The Alternate Biosafety Contact, along with safety committee members, conducts inspections on behalf of the University of Winnipeg on a quarterly basis to measure compliance with all federal, provincial, municipal and internal requirements and to continually improve the health and safety programs. The outcomes of the inspections/audits can impact the status of a biosafety permit. Principal Investigators who are found to be in non-compliance during inspections are notified by the BSO and an investigation will be carried out by the BSC. Research funding may be frozen according to the procedures outlined above.

Training Program:

Biosafety training is mandatory for all students, faculty, staff, volunteers and visitors working with biohazardous materials, as well as for anyone who oversees spaces where these materials are used or stored. Basic lab safety training and site-specific biosafety training is documented by each PI for each CL2 lab.

Accident/Incident Reporting:

This is a mechanism that facilitates reporting of all incidents at the University of Winnipeg. This process has been in existence for many years and is well established. All incidents are reported to the individual's supervisor and follow institutional reporting. If warranted, an investigation is initiated and consequent recommendations implemented. Any incident of exposure or accidental release of biological agents is to be reported to the BSO and in the absence of the BSO to the Manager, Safety and Health. The BSO will investigate in case of a theft, loss, misuse or accidental release of biological agents to assess risk to staff, students and surrounding community.

Element 7 – Description of all work areas covered by the plan (research areas, teaching, offsite, etc.)

The Biosafety Administrative Oversight Plan covers laboratories at the University where Risk Group 2 pathogens are used. Biosafety measures implemented under the Biosafety Administrative Oversight Plan apply to all laboratories that work with human and/or animal blood and body fluid.

Element 8 – Description of all individuals covered by the plan (researchers, faculty, students etc.)

Individuals at the University the Winnipeg who are covered by the Biosafety Administrative Oversight Plan are the individuals listed in the permits: Pls, lab staff, and students who work in

CL2 containment zones. Existing and new individuals will be made aware of the plan by their supervisors. Supervisors will be made aware of the plan by the Chair of the BSC.

Element 9 – summary of how the plan is communicated

The Biosafety Administrative Oversight Plan is reviewed and approved by the BSC members. The Biosafety Administrative Oversight Plan is available to the related stake holders through the University of Winnipeg Safety Office website.

Element 10 – Overview of the procedures to review and monitor the plan

- Annual inspection of CL2 labs by the BSC members once a year.
- Regular quarterly workplace inspections by WSHC and SLSSC members.
- Hazard occurrence and monitoring incidents analysis by the Manager, Safety and Health.
- Review of the biosafety program including the Biosafety Administrative Oversight Plan by the BSC every three years or as required (if new work areas are added, identified trends in non-conformances during audits by the BSC, and trends in incidents/accidents investigations).

University of Winnipeg Biosafety Administrative Oversight Plan, approved by the Biosafety Committee (Date: September 4, 2018, Amended: February 13, 2023)	
Tabitha Wood, Chair Biosafety Committee	
Signature:	Date:
Marni Yasumatsu, Associate Vice-President – Human Resources	
Signature:	Date: