



UNIVERSITY OF MANITOBA PROCEDURE

Procedure:	BIOSAFETY
Parent Policy:	Biosafety Policy
Effective Date:	May 16, 2011
Revised Date:	June 26, 2020
Review Date:	June 26, 2030
Approving Body:	Administration: President
Authority:	Biosafety Policy
Responsible Executive Officer:	Vice-President (Administration) and Vice-President (Research and International)
Delegate: (If applicable)	Chief Risk Officer and Associate Vice-President (Research)
Contact:	Biological Safety Officer
Application:	All Employees; All Students; External Parties (including All Contractors; Visitors)

Part I Reason for Procedure

- 1.1 To set out procedures and responsibilities in connection with the University of Manitoba Biosafety Policy.

Part II Procedural Content

Definitions

- 2.1 The following terms have the following defined meanings for the purpose of this Policy and Procedure:
- (a) **“Biological Agents”** shall refer to any live or unfixed risk group 1-4 agents which affect humans, animals, plants or insects and can include, viruses, bacteria, mycoplasmas, protozoa, helminths, prions, molds, fungi, biological toxins, allergens, algae, cells, human and animal tissues, human and

animal tissue cultures or any other biological material used or stored at the University of Manitoba.

- (b) “**Biological Safety Officer**” means a person appointed by EHS to fulfill the role and responsibilities of a Biological Safety Officer.
- (c) “**Biological Worker(s)**” refers to a person or persons working with or otherwise using Biological Agents under the supervision of a Program Permit Holder and who is/are listed on the supervisor’s Program Permit.
- (d) “**Biosafety**” shall refer to the safe use and storage of biological agents to prevent workers, students or other persons from exposure to Biological Agents.
- (e) “**Biosafety Manual**” means a document produced by the Biosafety Program which is intended to guide permitted users, Biological Workers and other affected members of the University Community in the safe and secure operation of permitted facilities according to the University of Manitoba Biosafety Policy and Procedure.
- (f) “**Biosafety Program**” refers to the administrative oversight program in place at the University of Manitoba to facilitate the safe and secure use of Biological Agents and technologies used to propagate Biological Agents by the University of Manitoba. It is documented in the University of Manitoba Biosafety Policy, Biosafety Procedure, Biosafety Manual and Human Pathogens and Toxins Act License.
- (g) “**Biosecurity**” shall refer to the measures taken to prevent the theft, loss and intentional misuse of biological agents and technologies used to produce and enhance the pathogenicity of biological agents.
- (h) “**Committee**” means the Biosafety Committee established and maintained by the University of Manitoba pursuant to the Biosafety Policy and Procedure. The Committee shall be comprised of members of the University community and stakeholders knowledgeable in the safe use of biological materials, agents and other sources of biological hazards. A representative number of Committee members shall also have a research background working with biological materials.
- (i) “**EHS**” means Environmental Health and Safety unit at the University of Manitoba.
- (j) “**Exposure**” shall refer to a workplace incident which results in direct contact with skin, mucosal membranes or by inhalation, ingestion or injection by a worker, student or other person with a biological agent.
- (k) “**Facility Certification**” means a Biosafety Facility Certification issued by the Biological Safety Officer or their designate and is intended to register

the Facility Certification Holder's handling, storage and waste disposal facilities, staff, biosafety equipment and to establish the appropriate containment level for those facilities.

- (l) **“Facility Certification Holder”** means a person who holds a Biosafety Facility Certification approved by the Biological Safety Officer or designate.
- (m) **“Generic Biosafety Training”** means safety training designed to teach Biological Workers the basic or core concepts and practices of biosafety.
- (n) **“Generic Biosafety Refresher Training”** means safety training designed to update Biological Workers on the basic or core concepts and practices of biosafety taught in outdated versions of Generic Biosafety Training.
- (o) **“Program Permit”** means a Biosafety Program Permit issued by the Chair of the Biosafety Committee and is intended to document the permit Holder's biosafety and biosecurity risk assessment for work in facilities owned or directly controlled by the University of Manitoba or in which there is a formal agreement in place where the University of Manitoba is specifically committed to provide Biosafety services.
- (p) **“Program Permit Holder”** means a person authorized by the University of Manitoba and named on a Program Permit as the responsible party.
- (q) **“Site Specific Biosafety Training”** means detailed training on the safe use of specific Biological Agents and procedures established and provided by the Program Permit Holder in a facility.

Commitments and Objectives of this Procedure

2.2 The University of Manitoba is committed to:

- (a) Complying with the *Human Pathogens and Toxins Act* SC 2009, c 24 and Regulation SOR/2015-44, Canadian Biosafety Standard 2nd edition 2015, *The Workplace Safety and Health Act* C.C.S.M. c. W210, and all other applicable federal, provincial and municipal legislation with respect to the procurement, use, storage, transfer and disposal of all Biological Agents;
- (b) Prevention of exposure to Biological Agents by all staff, students and members of the public from the use of Biological Agents is the primary concern; achieved by the control measures outlined in the University of Manitoba Policy and Procedures including training, risk assessment, controls, oversight and any other measures necessary and reasonably achievable;
- (c) Ensuring a high standard of biosafety and biosecurity is maintained at all times in the work and learning environment.

Scope

- 2.3 This Procedure applies to all employees, students at external parties who are or may be working with or otherwise using Biological Agents at the University of Manitoba, whether directly or incidentally through their work, research, or otherwise.

Roles and Responsibilities

- 2.4 Associate Vice-President (Research) is authorized to:

- (a) Apply for and hold the *Human Pathogens and Toxins Act* Licenses on behalf of the University of Manitoba; and
- (b) Act as the executive authority for Biosafety matters at the University of Manitoba.

- 2.5 Biosafety Committee

- (a) The Committee is authorized to oversee the use of Biological Agents at the University of Manitoba and ensuring compliance with institutional governing documents and other applicable federal, provincial and municipal regulatory documents.
- (b) The Biosafety Committee has authority to stop any and all work with Biological Agents deemed to be unreasonably hazardous or which contravenes any relevant act, regulation or University of Manitoba governing documents according to the enforcement section identified in the University of Manitoba Biosafety Procedure.
- (c) Committee Membership shall be composed of persons knowledgeable in the use of Biological Agents according to the Biosafety Committee Terms of Reference.
- (d) Chairperson of the Committee
 - (i) The Chair shall be appointed to the Committee by and report to the Associate Vice-President (Research).
 - (ii) The Chair is free to participate to an equal extent as any other member in the discussions and decisions of the meeting.
 - (iii) The Chair shall appoint one (1) member of the committee to act as Vice-Chair in the event of the Chair's absence.
- (e) The Institutional Biological Safety Officer(s) shall be appointed as ex officio member(s) of the Committee.

- (f) Meetings of the Committee shall be scheduled and conducted according to the Biosafety Committee Terms of Reference.
- (g) The Committee is authorized to:
 - (i) Review and approve (or deny) Program Permit applications;
 - (ii) Review and recommend a course of corrective action regarding Permit enforcement incidents in cooperation with the Biological Safety Officer;
 - (iii) Revoke Program Permits previously approved;
 - (iv) Make recommendations regarding governing documents related to Biosafety and Biosecurity at the University of Manitoba;
 - (v) Review, advise, amend and approve Biosafety Manual and program materials for use at the University of Manitoba; and
 - (vi) Investigate incidents which result or which may result in lab acquired infections at the University of Manitoba, biosecurity breaches, current or potential concerns pertinent to biosafety;
 - (vii) Recruit and recommend the appointment of new members to the Associate Vice President (Research);
 - (viii) Recommend the appointment of a Vice Chair to the Chair of the committee through a consensus process.

2.6 Environmental Health and Safety

- (a) EHS is responsible for appointing a Biological Safety Officer who possesses the qualifications and fulfills the duties and responsibilities prescribed in the Human Pathogens & Toxins Act and Regulation and the Canadian Biosafety Standard. The Biological Safety Officer and their designate(s) shall implement the Biosafety Program acting in consultation with the Committee and the Associate Vice-President (Research).
- (b) EHS will be responsible for recording minutes of meetings, for correspondence arising from meetings, and for issuing notices of meetings after consultation with the Chair.
- (c) EHS will be responsible for maintaining a file of minutes of Committee meetings.
- (d) EHS shall maintain a file of all correspondence to and from the Committee.

2.7 Program Permit Holder

The Program Permit Holder is responsible to:

- (a) Ensure compliance with the terms and conditions of their Facility Certification and Program Permit;
- (b) File an amendment to their Facility Certification and Program Permit that declares any changes to the information provided as part of their applications;
- (c) Ensure that all Biological Workers listed on their Facility Certification complete the current version of the University of Manitoba Generic Biosafety Training or Generic Biosafety Refresher training;
- (d) Ensure that all Biological Workers listed on their Facility Certification receive documented Site Specific Biosafety Training in which the competency of the trainee is validated and documented before working independently in the lab facility;
- (e) Inspect their facilities to ensure compliance with their Facility Certification conditions and to keep written records of those inspections;
- (f) Ensure that any incidents that occur in their area are promptly reported to EHS and investigated in accordance with University of Manitoba reporting requirements;
- (g) Ensure that any incidents involving Biological Agents that occur in an area not under the direct control of the Biological Worker's direct supervisor are reported to the facility director or equivalent for that facility;
- (h) Conduct accident/incident investigations in cooperation with the Biological Safety Officer for incidents involving Biological Agents;
- (i) Provide such documentation and/or reports as requested by the Biological Safety Officer or their designate(s);
- (j) Appoint another eligible alternate Program Permit Holder to oversee their lab operations if the Program Permit Holder expects to be away from their lab for any reason for a period of thirty consecutive days or more until they return to resume control of their lab. The appointment of an alternate Program Permit Holder must be documented by amending the Program Permit and Facility Certification; and
- (k) If an alternate Program Permit Holder is not appointed and in cases of emergency where the Program Permit Holder is not available, the Program Permit Holder's Department Head or Dean assumes responsibility for the Program Permit Holder in question.

2.8 Biological Worker

The Biological Worker is responsible to:

- (a) Comply with the University of Manitoba Biosafety Program;
- (b) Work according to the conditions stipulated on the Program Permit on which they are listed; and
- (c) Report all incidents to the Program Permit Holder.

2.9 Occupational Health Coordinator

The Occupational Health Coordinator is responsible to:

- (a) Receive Notice of Injury Reports from staff and students at the University of Manitoba; and
- (b) Forward all Notice of Injury Reports related to incidents involving Biological Agents to the Biological Safety Officer for review and follow up.

2.10 Office of Research Services

- (a) The Office of Research Services will release research funds for work with Biological Agents to University of Manitoba Program Permit Holders when the Biosafety Program provides proof of a the Program Permit Holder's approval from the Biosafety Committee Chair;
- (b) The Office of Research Services will release research funds for work with Biological Agents to University of Manitoba faculty members working in facilities not directly controlled by the University of Manitoba when the faculty member provides proof of an External Biosafety Permit (or equivalent) approved by the external facility's safety program.

Eligibility Requirements

2.11 External Agencies Operating Lab Facilities on University Property

- (a) If an agency external to the University of Manitoba intends to operate a laboratory facility working with Biological Agents they must be sponsored by a University of Manitoba Program Permit Holder. The Program Permit Holder will list the agency representatives on their Biosafety Facility Certification and act as the responsible individual for the activities and actions of the external agency including any incidence of non-compliance.
- (b) If an agency external to the University of Manitoba intends to operate a laboratory facility working with Biological Agents and is not sponsored by a University of Manitoba Program Permit Holder, they must:

- (i) Show proof of Human Pathogens and Toxins Act licensure (supply a copy of the license and all conditions and authorizations) prior to starting controlled activities;
- (ii) Designate a Biological Safety Officer who will communicate with the University of Manitoba Biological Safety Officer on behalf of the company license Holder;
- (iii) Provide a list of workers for the proposed space along with personnel suitability and reliability documentation required as per the Human Pathogens and Toxins Act licensure;
- (iv) Meet all University of Manitoba Biosafety Policy and Procedure requirements with the exception of holding a University of Manitoba Biosafety Program Permit;
- (v) Provide a comprehensive inventory of all Biological Agents proposed for use during the term of the lease and a list of all rooms the company will be authorized to access at the University of Manitoba;
- (vi) Adhere to all University of Manitoba lab waste handling procedures, lab hazard clearance and decommissioning procedures and all Standard Operating Procedures and safe work practice documents used by Physical Plant, Security Services and any other campus service provider;
- (vii) Submit to compliance inspections by the University of Manitoba Biological Safety Officer (or their designate); and,
- (viii) Supply any documentation to the University of Manitoba Biological Safety Officer required to demonstrate compliance with the policies or procedures listed above.

2.12 Facility Certification

- (a) In order to be eligible to hold a Facility Certification the applicant must be a faculty member with the rank of assistant professor or higher appointed to the University of Manitoba and is supervised by a Vice-President, Dean, Director, or Department Head.
- (b) The Facility Certification will specify:
 - (i) The name of the Facility Certification Holder;
 - (ii) The names of the Biological Workers;
 - (iii) The approved locations;

- (iv) The containment level of the lab facilities identified; and
- (v) The biosafety equipment.
- (c) The Biological Safety Officer or their designate shall issue a Facility Certification.

2.13 Program Permit

- (a) In order to be eligible to hold a Program Permit the applicant must be a faculty member with the rank of assistant professor or higher appointed to the University of Manitoba, is supervised by a Vice-President, Dean, Director, or Department Head and hold a valid Facility Certification.
- (b) The Program Permit will specify:
 - (i) The name of the Permit Holder;
 - (ii) The name of the grant recipient;
 - (iii) The University of Manitoba Project Number;
 - (iv) The name(s) of any University of Manitoba co-investigators or core facilities included in the proposed work;
 - (v) A detailed description of the proposed work, procedures and Biological Agents;
 - (vi) The Facility Certification;
 - (vii) Risk assessment;
 - (viii) Safe work procedures; and
 - (ix) Waste disposal procedures.
- (c) The Program Permit must be endorsed by the permit holder at the time of submission.
- (d) A Program Permit applicant must complete and submit their application to EHS. The Committee or designate(s) of the committee shall assess the application which is composed of a detailed description of the program's Biological Agents and procedures. Based on that information the committee will evaluate the risk and the program's safe work procedures. Once the Committee is satisfied, the Chair of the Committee shall approve and issue the Program Permit to the Program Permit applicant. The Program Permit documents their risk assessment for proposed work with Biological Agents.

- (e) A Program Permit Holder must file an amendment to their approved Program Permit:
 - (i) if the information included as part of their initial or subsequent application(s) is no longer current and correct;
 - (ii) to release research funds from the Office of Research Services for projects involving the use of biological agents.
- (f) The Program Permit Holder shall ensure that there is full compliance with all the conditions specified on the Program Permit and that Biological Workers are oriented and trained on the hazards of working with Biological Agents and safe work procedures.

Inspections, Audits and Reports

2.14 Inspections, Audits and Reports

- (a) EHS shall make periodic inspections of certified facilities and permitted activities. Inspections of facilities may be announced or unannounced.
- (b) EHS may require periodic written reports from the Program Permit Holder.
- (c) All Program Permit Holders and Biological Workers are required to cooperate with the Biological Safety Officer and their designate in the execution of audits or inspections.
- (d) The Biological Safety Officer, their designate, or Committee representative are authorized to enter, inspect and audit documents in non-certified facilities controlled by the University of Manitoba if there is reasonable evidence that indicates Biological Agent work is conducted in those facilities without an approved Biosafety Program Permit.

Offences

2.15 Offences

- (a) The following shall constitute an incident of non-compliance with the University of Manitoba Biosafety Procedure:
 - (i) Undertaking work with Biological Agents without being designated as an approved Program Permit Holder or Biological Worker;
 - (ii) Failure on the part of the Program Permit Holder or Biological Worker to adhere to all conditions and parameters listed on their approved Program Permit or Biosafety Facility Certification;

- (iii) Failure on the part of the Program Permit Holder or Biological Worker to adhere to all responsibilities listed in the University of Manitoba Biosafety Policy and Procedure;
 - (iv) Failure on the part of Program Permit Holders and Biological Workers to complete Generic Biosafety Training, Generic Biosafety Refresher Training and site specific training; and
 - (v) Interfering with the Committee, the Biological Safety Officer or their designate in the execution of their duties as established in the University of Manitoba Biosafety Policy and Procedure or as required by any relevant Federal, Provincial or Municipal Acts, Regulations or Bylaws.
- (b) Failure to comply with this Procedure may result in additional investigation and disciplinary action according to the Responsible Conduct of Research Investigation Procedure or other applicable University Policy and or Procedure.

Enforcement

2.16 Enforcement

- (a) On the first occurrence of non-compliance related to any terms and conditions of the Program Permit or Facility Certification:
- (i) The Biological Safety Officer or designate shall notify the Program Permit Holder of the first incident of non-compliance in writing with specific reference to circumstances that contravene the University of Manitoba Biosafety Policy and Procedure, the duties of the Program Permit Holder in that respect, and the consequences of further infractions;
 - (ii) The notification shall be copied to the Program Permit Holder's direct supervisor and the Dean of the appropriate Faculty;
 - (iii) The Program Permit Holder will be expected to come into compliance as directed by the Biological Safety Officer or designate; and
 - (iv) Failure to correct the occurrence of non-compliance within a reasonable period of time as specified by the Biological Safety Officer or designate will constitute a second offence.
- (b) On the second occurrence of non-compliance within a twelve (12) month period:
- (i) The Biological Safety Officer or designate shall notify the Program Permit Holder of the second incident of non-compliance in writing

with specific reference to circumstances that contravene the University of Manitoba Biosafety Policy and Procedure, the duties of the Program Permit Holder in that respect, and the consequences of further infractions;

- (ii) The Biological Safety Officer or designate shall forward a copy of the second written notice of non-compliance to the direct supervisor of the Program Permit Holder, the Dean of the appropriate Faculty, all members of the Committee and the Office of Research Services;
 - (iii) The Program Permit Holder will be expected to come into compliance as directed by the Biological Safety Officer or designate;
 - (iv) Failure to correct the occurrence of non-compliance within a reasonable period of time as specified by the Biological Safety Officer or designate will constitute a third offence.
- (c) On the third occurrence of non-compliance within a twelve (12) month period:
- (i) The Program Permit Holder's Biosafety Permit approval and Facility Certification will be suspended until full resolution of the circumstance(s) of non-compliance;
 - (ii) The Biological Safety Officer shall inform the Program Permit Holder, the Chair of the Committee, the Program Permit Holder's direct supervisor, the Dean of the appropriate Faculty, and the Office of Research Services of the suspension in writing;
 - (iii) The Chair of the Committee shall call an emergency *ad hoc* meeting of the Committee to be held within seven (7) days. The Chair will invite the Program Permit Holder, their direct supervisor and any other individual(s) deemed to be relevant or necessary for the effective resolution of the non-compliance issue. The Office of Research Services will also be advised of the meeting;
 - (iv) During the emergency meeting the Program Permit Holder and/or their direct supervisor will be required to demonstrate why the suspended Program Permit(s) and Facility Certification(s) should be reinstated;
 - (v) If a majority of the membership of the Committee members in attendance is not satisfied that the Program Permit Holder has provided justification for reinstating their Program Permit(s) and Facility Certification(s), they shall be revoked;
 - (vi) The Committee shall arrange for the transfer of all Biological Agents in the revoked Program Permit Holder's Biological Agent inventory

to another appropriate Program Permit Holder with a Facility Certification that meets the containment requirements;

- (vii) If transfer of the Biological Agent inventory is not possible the inventory items will be disposed by means which are deemed to be safe and appropriate; and
 - (viii) The Chair of the Committee will notify the Program Permit Holder, their direct supervisor, the Dean of the appropriate Faculty, the Associate Vice-President (Research), and the Office of Research Services of the Committee's decision in writing.
- (d) A revoked Program Permit Holder may appeal a decision to revoke their Program Permit(s) and Facility Certification(s). The appeal will be referred to the Vice-President (Research) and/or his/her designate who will investigate the matter and render a final and binding decision.
- (e) If any worker is found working with Biological Agents without a valid University of Manitoba Program Permit:
- (i) The worker's direct supervisor and the Dean of the appropriate Faculty will be notified by the Biological Safety Officer or designate in writing. This notification will identify the specific activity of concern, provide instructions on meeting compliance and a deadline for completion.
 - (ii) If the worker's supervisor fails to meet compliance by the identified deadline all work with Biological Agents must be halted immediately. The Biological Safety Officer or designate will notify the worker's supervisor, the Department Head for the area, the Dean of the appropriate Faculty, the Associate Vice-President (Research), and the Office of Research Services of the failure to meet compliance. This notification will identify the worker's supervisor, the activities of concern and a copy of the written notice provided to the lab supervisor by the Biological Safety Officer or designate.
- (f) Notwithstanding any of the above actions, if it is the opinion of the Biological Safety Officer or designate that a serious, immediate risk to health, safety, environment or security exists, the Biological Safety Officer or designate shall have the authority to immediately suspend operations and temporarily suspend a Program Permit. The Biological Safety Officer or designate shall immediately report on the situation and the steps taken to the Chair of the Biosafety Committee, the Dean of the appropriate Faculty, and the Associate Vice-President (Research) by the most expedient means possible. The incident will be administered according to the process identified for a third occurrence of non-compliance.

Part III Accountability

- 3.1 The Office of Legal Counsel is responsible for advising the Vice-President (Research and International) and the Vice-President (Administration) that a formal review of this Procedure is required.
- 3.2 The Chief Risk Officer and Associate Vice-President (Research) are responsible for the implementation, administration, interpretation and review of this Procedure.
- 3.3 All employees, students and external parties (adjunct and nil-salaried appointments) are accountable for complying with the applicable Federal, Provincial and University of Manitoba policies, procedures and guidelines.

Part IV Review

- 4.1 Governing Document reviews shall be conducted every ten (10) years. The next scheduled review date for this Procedure is June 26, 2030.
- 4.2 In the interim, this Procedure may be revised or repealed if:
 - (a) The Chief Risk Officer and Associate Vice-President (Research) for Approving Body deems it necessary or desirable to do so;
 - (b) The Procedure is no longer legislatively or statutorily compliant;
 - (c) The Procedure is now in conflict with another Governing Document; and/or
 - (d) The Parent Policy is revised or repealed.

Part V Effect on Previous Statements

- 5.1 This Procedure supersedes all of the following:
 - (a) Biological Safety Procedure (May 16, 2011);
 - (b) all previous Board of Governors/Senate Governing Documents on the subject matter contained herein; and
 - (c) all previous Administration Governing Documents on the subject matter contained herein.

Part VI

Cross References

- 6.1 This Procedure should be cross referenced to the following relevant Governing Documents, legislation and/or forms:
- (a) [Biosafety Policy](#)
 - (b) [Health and Safety Policy](#)
 - (c) [The Dangerous Goods Handling and Transportation Act \(Manitoba\)](#)
 - (d) [The Workplace Safety and Health Act \(Manitoba\)](#)
 - (e) [The Workplace Safety and Health Regulation \(Manitoba\)](#)
 - (f) [Canadian Biosafety Standard](#)
 - (g) [Human Pathogens and Toxins Act \(Canada\)](#)
 - (h) [Human Pathogens and Toxins Regulation \(Canada\)](#)
 - (i) [Health of Animals Act \(Canada\)](#)
 - (j) [Health of Animals Regulation \(Canada\)](#)
 - (k) [Federal transportation and importation legislation](#)
 - (l) [City of Winnipeg Waste By-Laws](#)
 - (m) [Transportation of Dangerous Goods Act, 1992 \(Canada\)](#)