HUMAN RESOURCES

ENVIRONMENTAL HEALTH AND SAFETY

BIOSAFETY PROGRAM

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REVISION HISTORY

Revision Number	Document Section	Details of Amendments	Date
0		Program	2007
1	All	Review & Update	February 2016
2	All	Review & Update	June 2018
3	All	Review & Update including formatting	January 2023

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1.0 PURPOSE AND SCOPE

The Biosafety Program focuses on regulatory and contractual compliance issues involving the receipt, use, storage, shipment, transfer, and disposal of biohazards at the University.

1.1 Application

This program applies to teaching programs, research projects, and diagnostic facilities at the University campuses, research stations, and field sites.

The Policy and Program shall also apply to:

(a) activities involving the use of University facilities conducted under Section 9 of the Collective Agreement between the University of Guelph and the University of Guelph Faculty Association; and

(b) activities conducted by other organizations involving the use of University operated facilities under a service agreement with the University.

1.2 Program Scope

The University holds the following approvals issued by the Public Health Agency of Canada (PHAC):

- Risk Group 2 Human Pathogen and Toxin Licence
- Risk Group 2 Terrestrial Animal Pathogen Permit

As such Risk Group 3 and 4 (RG3 and RG 4) biohazardous materials as well as other Security Sensitive Biological Agents above regulatory threshold values are prohibited for storage, use or handling in University facilities.

All activities must be in compliance with the University's Human Pathogen and Toxin license.

The Biosafety Program applies to direct handling, storing and/or processing of:

(a) **Risk Group 1 or 2 microorganisms** [includes bacteria, fungi, viruses, and parasites (protozoa and helminths only)] and/or its nucleic acids or its toxins and/or infectious proteins (e.g., prions) pathogenic or potentially pathogenic to humans, animals (terrestrial and aquatic) and/or plants

(b) **potentially infectious human tissues and/or body fluids**, (e.g., brain tissue, feces, lymphocytes, blood, muscle, adipose tissue, etc.)

(c) **human cell lines, animal cell lines with intact pathogen, other regulated imported animal cell lines** or other regulated infectious materials)

(d) potentially **oncogenic** biological materials

(e) **genetically-modified microorganisms** (a microorganism in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally)

(f) **viral vectors** (viruses used to deliver genetic material into cells)

(g) **recombinant nucleic acid** (constructed by joining nucleic acid molecules that can replicate in a living cell or can be transcribed or translated or integrate to form a pathogenic genome)

(h) **synthetic biological products**, e.g., nucleic acids or peptides (synthesized chemically but may be assembled into microbial genome, or redesigning of a microbial genome or bioengineered microorganisms)

(i) **microbial toxins** (poisonous substances produced or derived from certain microorganisms) excluding Security Sensitive Biological Agents (SSBA) above regulatory threshold values

(j) research animals and/or animal tissues experimentally **infected** with microorganisms or microbial genome

(k) **prions** (small proteinaceous infectious particle)

(l) research with **untreated sanitary sewage**

(m) **environmental samples** (including soil, plant, air, water or food) for microbiological analysis (i.e., isolate, culture, grow/enrich, produce microorganism or perform test to confirm its presence)

1.3 Exclusions

The program does not include:

(a) microorganisms in their **natural** environment that are not cultured, nor isolated nor produced, nor tested nor grown/enriched using media

(b) **transgenic organisms** that are not microorganisms, e.g., plants, mammals

(c) **live vaccines** approved for human or veterinary clinical use

(d) human bodily fluids and other potentially infectious materials as might be encountered in normal clinical practice in Student Health Services, Occupational Health and Wellness, and/or the rendering of first aid

(e) **approved commercial products**, food items or animal feeds **not otherwise inoculated** with experimental microorganisms or toxins

(f) animal tissues and bodily fluids and other potentially infectious materials, as might be encountered during **normal animal handling and veterinary clinical practices** in units such as OVC-Health Sciences Centre, Research Station operations and Central Animal facilities, etc.

(g) management of manure during normal animal husbandry practices; (Nutrient Management Act and Regulations)

(h) activities associated with licensed abattoirs; Consult the Meat Lab Coordinator, Department of Animal and Poultry Science. (Ontario Food Safety and Quality Act and Regulations)

(i) activities associated with the Human Anatomy teaching program through Human Health and Nutritional Sciences. (Ontario Anatomy Act and Regulations)

2.0 RELATED LEGISLATION AND GUIDELINES:

Human Pathogens and Toxins Act

Human Pathogens and Toxins Regulation

Health of Animals Act and Regulations

Plant Protection Act and Regulations (1990 / 95-212)

New Substance Notification Regulations (Organisms)

Canadian Biosafety Standards, 2nd Edition 2015. Public Health Agency of Canada

Containment Standards for Facilities Handling Aquatic Animal Pathogens, 1st Edition

Containment Standards for Facilities Handling Plant Pest – 1st Edition

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Agreement on the Administration of Agency Grants and Awards by Research Institutions

3.0 RELATED UNIVERSITY GUIDELINES AND PROCEDURES

Animal Care Policies and Procedures

Biosafety Program and Forms

Research Ethics/Protection of Human Participants.

Responsible Conduct of Research Policy and Procedures

Occupational Health Surveillance Programs

4.0 RESPONSIBILITIES:

4.1 Vice-President, Finance and Operations:

(a) appoint members of the Biosafety Committee; and

(b) receive and act upon recommendations of the Biosafety Committee and its Chair and provide a written response to the Committee in consultation with the Vice-President, Research as appropriate

4.2 Vice-President, Research:

(a) approve projects identified as having significant risk of dual use

(b) establish and administer the appeal procedure (see section 7.0)

(c) provide resources for the administration of Material Transfer Agreements involving biohazardous materials

4.3 Research Services Office:

(a) establish procedures to identify research utilizing biohazards requiring a biohazard permit and release research funds only when an approved biohazard project permit is in place as appropriate.

(b) approve terms and conditions for research involving biohazardous materials conducted by other organizations involving the use of University facilities under a service agreement with the University; such research shall also be approved by the Biosafety Committee

(c) investigate allegations of research misconduct related to the biosafety program and initiate actions including but not limited to suspension of funding and notification of research sponsors in accordance with the Responsible Conduct of Research Policy and Procedures

(d) prepare and submit New Substance Notifications as required by the *New Substances Notification Regulations* of the *Canadian Environmental Protection Act* with a copy to the University Biosafety Officer

4.4 Occupational Health and Wellness:

(a) offer advice regarding infection control, medical treatment, and prophylactic measures available regarding biohazardous materials

(b) provide medical surveillance programs for employees and students working with biohazardous materials

(c) report any cases of lab-acquired infections of which they become aware to the University Biosafety Officer

4.5 Student Health Services:

(a) report any cases of lab-acquired infections of which they become aware to the University Biosafety Officer and the Biosafety Committee

4.6 Biosafety Committee (IBC):

(a) establish in consultation with Environmental Health and Safety, the University Biosafety Program governing activities involving the use of biohazardous materials. The Committee shall review the program every 3 years or more often if required

(b) review and approve the Committee's Terms of Reference at least every 3 years or more often if required

(c) review and approve activities involving the use of biohazardous materials (RG2), confirm and/or determine the level of containment required, and assess the biosecurity measures before the initiation of the activity

(d) assess the Principal Investigator’s qualifications, training, and experience in relation to the biohazardous materials to be used

(e) review summaries of inspection results in which biohazardous materials are used to assess that containment measures are satisfactory, available and in use;

(f) review the adequacy of procedures to control the acquisition, secure storage, transport, handling, transfer, and disposal of biohazardous materials;

(g) establish minimum training requirements for persons who are potentially exposed to biohazardous materials

(h) review and assess the content and availability of a medical surveillance program in use for those who may be exposed to biohazardous materials

(i) review and assess the emergency response plans established for biohazardous material incidents

(j) review any incidents involving biohazardous materials including but not limited to, PHAC notifiable exposures, and lab-acquired infections

(k) report on biosafety activities to the Vice-President, Finance and Operations

(l) respond to concerns and complaints under this program and make recommendations to the Vice-President, Finance and Operations as appropriate

(m) recommend disciplinary action when a Principal Investigator is found to be in non-compliance with this program or any federal, provincial, or municipal legislation. Such actions may include but are not limited to the following:

i. informing the Principal Investigator and the Department Chair or Director of the non-compliance

ii. referring continuing issues of non-compliance to the Vice-President, Finance and Operations for further action

iii. recommending to the Vice-President, Finance and Operations, the immediate closure of facilities that are in serious non-compliance

4.7 Chair of the Biosafety Committee:

(a) provide leadership and advice to the University Community regarding biosafety issues

(b) liaise on behalf of the Committee with the Vice-President, Finance and Operations, the Vice-President, Research, the University Biosafety Officer, and representatives of regulatory agencies

(c) set the agenda in consultation with the members and chair meetings of the Biosafety Committee

(d) review compliance audits and incident investigations and report the findings to the Biosafety Committee, the Vice-President, Finance and Operations, and the Vice-President, Research as deemed necessary

(e) provide approval for biohazard permits on behalf of the committee.

4.8 Vice Chair of the Biosafety Committee:

(a) fulfil the duties of the Chair in the absence of the Chair

(b) provide approval for biohazard permits on behalf of the committee where there is an actual, potential, or perceived conflict of interest on the part of the Chair

4.9 University Biosafety Officer (BSO):

(a) Both the Senior Health and Safety Consultants (Biosafety) and (Research) will fulfil the responsibilities of the University Biosafety Officer, noting that the Senior Health and Safety Consultant (Biosafety) is the identified BSO for the University's Human Pathogens and Toxins license. serve as the audit and control manager for the Biosafety Committee

(b) interpret policies, standards and guidelines where necessary and provide information to the University community including but not limited to the Biosafety Committee and Principal Investigators as appropriate

(c) assist Principal Investigators to assess facilities and advise on the preparation of the biohazard permit application

(d) provide approval for biohazard permits in conjunction with the Chair or Vice-Chair of the Biosafety Committee ensuring compliance with the current license as applicable

(e) in consultation with the Chair of the Biosafety Committee, approve *Risk Group One Biohazard Permits,* and/or *Storage only* permits

(f) maintain and provide information on all elements of the biosafety program

(g) provide advice on biohazardous materials and work procedures

(h) provide general biosafety training

(i) liaise with units within and external to the University including but not limited to: PHAC, the Canadian Food Inspection Agency (CFIA), Animal Care Services, Research Ethics, Occupational Health and Wellness, Student Health Services, Campus Safety, and Physical Resources on biosafety and biosecurity issues

(j) inspect work areas for compliance with permit requirements, legislation, and standards and submit reports to the Principal Investigator

(k) perform compliance inspections and sign documentation for CFIA import permit applications

(l) approve movement requisitions (e.g. import, export, purchase, domestic transfer) for all biohazards and co-sign material transfer agreements for the acquisition and/or transfer of biohazardous materials

(m) investigate incidents involving biohazardous materials including exposures and lab-acquired infections and report the findings to the Chair and PHAC as required

(n) maintain project files including permits and associated documentation

(o) coordinate and maintain records of the annual certification of biological safety cabinets

(p) order, on advice of the Vice-President, Finance and Operations or the Vice-President, Research, the suspension of any activity involving biohazardous materials when there is reason to suspect that the health and safety of University personnel, the public, and/or the environment is at risk or that regulatory conditions of the project have been breached

(q) serve as a resource to the Animal Care Committee regarding biosafety issues

4.10 Department Chair/Director:

(a) require that any activities involving the use of biohazardous materials in his/her department receive approval prior to the acquisition of the biohazardous materials and the commencement of the activities

(b) confirm that Principal Investigators in his/her department are fully aware of the University policies and guidelines regarding biohazardous materials

(c) approve all permit application forms confirming the validity of the information

(d) confirm facilities used with biohazards are appropriately decommissioned upon the departure of a Principal Investigator from the University and inform/notify the University Biosafety Officer when a Principal Investigator is no longer employed by the University

(e) Post current inspection certificates for steam sterilizers in the department, confirm that sterilization cycles are verified using biological indicators on a regular basis, and that records of users, cycles, and verification are maintained

(f) affirm that activities involving biohazardous materials in the department are in compliance with the permits

(g) report issues regarding non-compliance to the Chair of the Biosafety Committee and the University Biosafety Officer

4.11 Principal Investigator:

(a) apply to and receive approval from the Biosafety Committee before obtaining and/or commencing work with biohazardous material

(b) obtain all University approvals related to the biohazard work as required

(c) obtain and submit all approvals to the Biosafety Committee if conducting work at an external facility which requires such approvals

(d) obtain approvals if working with biohazardous materials that require notification under the Canadian Environmental Protection Act, New Substances Notification Regulations

(e) comply with and enforce the legislation, guidelines, and standards set by regulatory and granting agencies, University policies, and permit terms and conditions

(f) co-operate with the Environmental Health and Safety Department, Office of Research, the Joint Health and Safety Committee, and any person including the University Biosafety Officer exercising duties as required by regulatory agencies and/or within University policies

(g) submit amendments to the permit, including termination of the project, in a timely manner

(h) when acquiring biohazardous materials, obtain documented approval from the University Biosafety Officer before the purchase of such materials. When acquiring such materials free of charge, obtain a Material Transfer Agreement through the Research Innovation Office

(i) maintain a current inventory of biohazardous materials including the source of the material, identity, location and risk group

(j) obtain written approval from the University Biosafety Officer before transferring biohazardous materials to another party

(k) provide competent supervision and ensure that all persons working under his/her control have received appropriate training in working with the biohazardous materials. Such training shall be documented.

(l) identify a competent designate to act in his/her absence

(m) inspect the work area routinely

(n) take appropriate action to remedy unsafe acts and conditions

(o) safeguard service personnel, contractors, or visitors and advise them of any potential hazards in the work area

(p) provide for supervision of all visitors

(q) consult with Occupational Health and Wellness regarding the components of the medical surveillance program as required

(r) require completion of Agreements on Biosafety by all persons working with the biohazardous materials and make them aware of the medical surveillance program

(s) confirm that appropriate engineering controls are functioning, and personal protective equipment is available and in good condition

(t) write and regularly review all Standard Operating Procedures/Lab Specific Biosafety Manualassociated with the permit

(u) develop and review at least annually site-specific emergency response plans for the work areas and confirm that appropriate spill response supplies are available

(v) post project documentation, equipment certificates, emergency response plans, biohazard permit and door signage

(w) secure work area against unauthorized access at all times, confirm that biosecurity measures are followed, and that any breaches of security are reported immediately to Campus Safety

(x) report all incidents involving biohazardous materials including all confirmed or suspected illnesses resulting from possible exposure to biohazardous materials using the University's incident reporting process, to the University Biosafety Officer in a timely manner

(y) report significant unanticipated problems or complications to the Biosafety Committee through the University Biosafety Officer

(z) decontaminate and/or decommission the work area at the end of the project

4.12 Investigative staff:

(a) comply with the legislation, guidelines, and standards set by regulatory and granting agencies, University policies, and permit terms and conditions

(b) participate in training

(c) cooperate with the Department of Environmental Health and Safety, Office of Research, the Joint Health and Safety Committee, and any person including the University Biosafety Officer exercising duties as required by regulatory agencies and/or within University policies

(d) report unsafe conditions, unsafe work practices, and breaches of security to the Principal Investigator immediately

(e) notify the Principal Investigator of any incidents, spills, or confirmed or suspected illnesses resulting from a possible exposure to biohazardous materials

(f) seek advice when working with unfamiliar materials or procedures

5.0 BIOHAZARDOUS MATERIAL REGISTRATION

(a) Principal Investigators shall obtain a permit for activities involving the importation, collection, possession, use and/or storage of materials outlined within the program scope in section 1.2. Permits are obtained by submission and approval of a Biohazard Permit Application. Permits are required for biohazardous materials classified as Risk Group 2 as well as microorganisms classified as Risk Group 1.

(b) Permits for use of RG2 materials are generally issued for two years Permits involving only storage or only use of RG1 microorganisms may be approved for up to 4 years.

6.0 BIOSAFETY COMMITTEE (IBC) TERMS OF REFERENCE

The Biosafety Committee reports to the Vice-President, Finance and Operations. The committee is mandated to:

(a) Provide general oversight of the Biosafety Program

(b) Offer advice on the safe use of biohazardous materials

(c) Advise the University Biosafety Officer and Vice-President, Finance and Operations (if necessary) on matters of compliance, program, policy and/or procedure developments and/or improvements.

6.1 Membership

Biosafety Committee members are appointed by the Vice-President, Finance and Operations in consultation with the Vice-President, Research and, the Vice-President, Academic as necessary The membership shall be appointed as follows:

(a) at least one faculty member from each college in which biohazardous materials are used. To ensure appropriate committee expertise and sufficient scientific reviewers, additional faculty members may be appointed

(b) one faculty member from the Ridgetown campus if biohazardous materials are used

(c) Co-Executive Director, Laboratory Services Division, Animal Health Laboratory

(d) Manager, Research Risk, Research Services/Environmental Health and Safety

(e) Veterinarian representative from Animal Care Services

(f) Manager, Campus Animal Facilities

(g) Representative, Occupational Health and Wellness

(h) at least one staff member who works with biohazardous materials

(i) University Biosafety Officer(s), Environmental Health and Safety Department

(j) two local community members (i.e., not employed by and at arm's length from the University) knowledgeable in biohazards who represent the interest of the surrounding community with respect to health and protection of the environment

Efforts will be made for each standing member of the committee to have an alternate appointed by the Vice-President, Finance and Operations in consultation with the Vice-President, Research and the Vice-President, Academic.

Members shall be appointed such that the committee has a broad range of expertise in many types of biohazardous materials (including synthetic nucleic acids), techniques and procedures utilizing these materials, infection control and assessment of potential risk to human, animal and environmental health.

6.2 Term of Office

The University Biosafety Officer(s); Representative, Occupational Health and Wellness; Representative, Animal Care Services; Co-Executive Director, Animal Health Laboratory;

Manger, Campus Animal Facilities and the Manager, Research Risk shall be permanent members of the Committee.

The term of office for all other members and alternates shall be three years. A member or alternate may serve more than one term.

6.3 Chair and Vice-Chair

The Chair and a Vice-Chair shall be elected every 3 years from among the IBC members who are employed by the University. Neither the University Biosafety Officer(s) nor the Manager, Research Risk may serve as Chair or Vice-Chair.

6.4 Procedures

6.4.1 Voting

All members shall have voting privileges. Decisions shall normally be made by consensus. If unable to reach consensus, then the decision shall be by majority vote.

6.4.2 Meetings

Meetings shall normally be held each semester or more frequently as the Chair deems necessary to fulfil the responsibilities of the Committee. If a member is unable to attend, then the member shall arrange for his/her alternate to be present. Nothing shall preclude both the member and his/her alternate from attending the same meeting; however, the alternate may neither speak to an issue, unless requested by the Chair, nor cast a vote.

6.4.3 Quorum

Quorum shall be one-half or the smallest whole number exceeding one-half of the voting members. This must include at least one-half of the faculty members.

6.4.4 Minutes

Minutes shall be made available to members, the Vice-President, Finance and Operations and the Vice-President, Research.

6.4.5 Records

The University Biosafety Officer is responsible for maintenance of Committee records.

6.4.6 Conflict of Interest

Where a member has an actual, potential, or perceived conflict of interest, the member shall not be present during the discussion and decision.

6.5 Subcommittees

The Biosafety Committee may establish subcommittees as it deems appropriate.

7.0 APPEALS

A Principal Investigator who disagrees with the decision of the Biosafety Committee may appeal the decision. Appeals may be made on either, or both, of the following grounds:

(a) the decision was inappropriate or unreasonable in light of the evidence presented to the Biosafety Committee; and

(b) the review of the Committee lacked procedural fairness

7.1 Appeals Committee

The Vice-President, Research, shall convene an Appeals Committee. The Committee shall report to the Vice-President, Research, and shall be composed of three members as follows:

(a) one person named by the Principal Investigator;

(b) one person named by, but not currently a member or alternate of, the Biosafety Committee; and

(c) one person, mutually agreeable to the Principal Investigator and the Biosafety Committee, who shall be Chair. Failing such agreement, the person shall be appointed by the President.

Any question concerning the composition of the Appeals Committee shall be referred to the Vice-President, Academic whose decision shall be final. If the Vice-President, Academic is a party to the case or declares a conflict of interest, the question shall be heard by the Vice-President, Finance and Operations.

7.2 Appeals Committee Procedures

(a) The Committee shall meet in camera and shall maintain confidentiality;

(b) the Vice-President, Research shall forward all documentation concerning the case to the Appeals Committee;

(c) the following types of evidence shall be considered:

i. signed and dated written submissions including e-mail communications

ii. printed material with attribution

iii. published information

iv. verifiable records

v. personal testimony

(d) both parties to the appeal shall be given full opportunity to present all relevant information to the Appeals Committee

(e) the decisions of the Appeals Committee shall be by majority vote. Abstentions count as a negative vote

(f) the Appeals Committee shall deal with the appeal in a timely manner

(g) records of an appeal shall be held by the Vice-President, Research for the length of the permit or two years whichever is longer

7.3 Powers of the Appeals Committee

The Appeals Committee may confirm or modify the decision of the Biosafety Committee and may impose its own conditions in relation to the appeal including termination of the project.

8.0 GLOSSARY OF TERMS

Biohazardous Material - Includes infectious material, pathogens and toxins (produced or derived from pathogens) that are capable of causing infection, disease and/or intoxication in living organisms.

Biosafety - A program of administrative controls, medical surveillance, vaccination, and containment strategies to reduce or eliminate exposure of laboratory workers, other persons, animals, plants and the outside environment to biohazardous materials.

Biosecurity - Policies and measures taken to prevent the theft, misuse, or intentional release of biohazardous materials or to prevent the spread of disease between facilities.

Containment - The combination of physical design parameters and operational practices that protect personnel, the immediate work environment, and the community from exposure to biological material.

Containment Level - A containment classification based on level of risk or hazard to be encountered while handling biohazardous material. There are four levels of containment based on the Canadian Biosafety Standard, 2nd Edition. Containment Level 1 (CL-1) has the least level of risk; Containment Level 4 (CL-4) has the highest level of risk.

Dual use potential –Qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause harm (e.g., bioterrorism) and also including any asset related to a biological agent that could be used for nefarious purposes, including knowledge, technologies, or products that contribute to the weaponization of a pathogen or toxin.

Investigative staff **-** A person who has been authorized by the Biosafety Committee to work on a project with biohazardous materials including but not limited to faculty, staff and students.

Medical surveillance - A program designed to prevent and detect illness in people related to exposure to infectious material or toxins. The focus of the program is primarily preventive but provides a response mechanism through which a potential infection or intoxication can be identified and treated before serious injury or disease occurs.

Pathogen - Includes microorganisms, its nucleic acid(s) and/or infectious proteins capable of causing infection or disease in humans, terrestrial (including avian and amphibian) or aquatic animals and/or plants. This can include bacteria, viruses, fungi, parasites, prions, recombinant DNA, genetically modified microorganisms, viral vectors, cell lines and synthetic biological products.

Pathogen Risk Assessment – The determination of the risk group and appropriate physical containment and operational practice requirements needed to safely handle the infectious material or toxins in question.

Risk Group A system of classification of infective microorganisms by severity of individual and community risk. Risk Group 1 (RG-1) presents the least risk and Risk Group 4 (RG-4) presents the most risk.