Standard Operating Procedure

Handling of Biological Materials at PERFORM

PC-SOP-GA-002-v03

Revision History

Version	Reason for Revision	Date
01	New SOP	5-July-2012
02	• Change in management and responsibility and minor changes throughout the SOP • Responsibilities of Manager, Research Development defined • Procedure change for solid waste disposal, see Appendix II	27-Oct-2014
03	• Minor changes in sections 2 and 3 • Procedure change for biohazardous waste disposal, see Appendix II	23-Jan-2017

Summary

The content of this standard operating procedure (SOP) provides guidelines for acquisition, use, and disposal of biohazardous materials in a safe and environmentally sound manner at the PERFORM centre of Concordia University.

Table of Contents

1. Definition of Terms and Abbreviations

Biohazards	Biohazards are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or the environment. The risk can be direct through infection or indirect through damage to the environment.
Biohazardous materials	Biohazardous materials includes (but are not limited to): - Microorganisms such as viruses, fungi, parasites, bacteria and their toxic metabolites - Mammalian primary tissues, blood and body fluids; - Materials that may contain the above-mentioned agents (e.g. cell cultures, specimens from humans and animals, environmental samples); - Certain proteins, nucleic acids (siRNA, miRNA, DNA from pathogenic organisms, oncogenes).
BSO	Biosafety Officer
EHS	Concordia University Environmental Health & Safety
Laboratory worker	Individuals who operate in the clinical analysis laboratory and similar spaces containing chemical and/or potentially hazardous substances.
Principal Investigator (PI)	Head researcher that is responsible for all aspects of a given research project or program at PERFORM.
Supervisor	Person responsible for a research study or program conducted at the PERFORM Centre.
Personal Protective Equipment (PPE)	Lab coats, gloves, safety goggles, face shields, long pants, closed toe shoes etc.
MSDS	Material Safety Datasheet
PSDS	Pathogen Safety Datasheet
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.
WHMIS	The workplace hazardous materials information system (WHMIS) is a component of the hazard communication scheme in laboratory. WHMIS regulations set out requirements for workers training, hazardous materials labeling, and provision of Material Safety Data Sheets (MSDSs).

2. Introduction

2.1 Background

All users of biohazardous materials are required to follow specific rules and regulations regarding safe handling, storage, and disposal. Before working with any biohazardous materials at PERFORM all laboratory workers / users are required to have an orientation from the Clinical Analysis Supervisor or delegate at the PERFORM Centre and register to the following trainings provided by Concordia EHS:

- Introduction to Biosafety
- Safe Use of Biological Safety Cabinets
- WHMIS 1988 and WHMIS 2015
- Hazardous Waste Disposal for Lab Personnel
- Safe Handling of blood

When required, users should refer to the Laboratory Safety Manual (http://www.concordia.ca/content/dam/concordia/services/safety/docs/EHS-DOC-001_LaboratorySafetyManual.pdf) and be aware of Concordia's EHS Policies.

2.2 Purpose

This SOP defines the safe practices of acquiring, using and disposing of biohazard materials in the PERFORM Centre.

2.3 Scope

This SOP pertains to the safe acquisition, use and disposal of biohazard materials at the PERFORM Centre and to prevent worker from possible exposure to infectious materials. It does not discuss chemical or radioactive materials which are handled differently from the procedures outlined in this SOP.

2.4 Responsibility

It is the responsibility of the laboratory workers / users to use biohazardous materials in a safe and responsible manner. It is the responsibility of Principal Investigator/Supervisor to ensure any of their research team (staff, students, collaborators, etc.) obtains the necessary training, reads all the required compliance documents (SOPs / PODs) and obtains instructions and designation from the Clinical Analysis Supervisor or the delegate when required. It is the responsibility of the Clinical Analysis Supervisor or the delegate to ensure that all users of the facility have completed the proper training to be able to work in a safe manner, and have the required information available to minimize exposure.
For any protocol involving CL2 material, an additional approval from the CUBSC (Concordia University Biosafety Committee) will have to be obtained. Finally it is the responsibility of the Assistant Director, Research Development & Strategic Initiatives to

oversee the application of Biosafety program, to ensure that workplace inspections are performed on a regular basis to ensure compliance with Concordia University regulatory requirements and recommended corrections are followed.

2.5 Relevant Documents

This SOP is governed by the following Concordia University policies and SOPs:

- VPS 40 "Environment Health and Safety"
- VPS 41 "Policy on safety glasses and eye protection practices"
- VPS 52 "Biosafety Policy"
- PC-SOP-GA-001 "Guidelines for preparing Standard Operating Procedures and PERFORM Operating Documents."
- PC-SOP-CA-001 "Clinical Analysis Suite-Access, Use and Safety Rules"
  EHS-DOC-001 "Laboratory Safety Manual"
- Pathogen Safety Datasheets available online at:
  http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

Please refer to these policies and manuals, or contact Concordia EHS Department for further clarifications (ehs@concordia.ca).

3. Procedure

3.1 Acquisition of biological materials

3.1.1 Purchases or acquisitions of biological materials may only be authorized after a risk assessment has been filed with the Concordia Biosafety Officer (BSO) indicating that PERFORM can meet the containment criteria.

3.1.2 Purchases of Biological materials may only be done by people who have received the authorization from the BSO for their projects in the form of a biohazard certificate and biohazard training to purchase these products.

Items purchased or sent to PERFORM by outside sources must be logged on a biological sample / material log form by the receiver (Appendix I). Biological materials must be properly stored in easily identified boxes and must be located to a freezer and rack number. All Biological materials received must have a chain of custody indicating the origin of these samples. These forms will be filed centrally at PERFORM by the user or Clinical Analysis Supervisor.

3.1.3 For transport of biological material, sender and receiver are responsible to have the permit for importation/exportation and proper shipping documents in compliance with the Transport of Dangerous Goods regulations for class 6.2.

3.2 Use of biological products in the laboratory environment

3.2.1 This means wearing lab coats, safety glasses or face shields, gloves, closed toes shoes as described in the Biosafety Manual, PC- SOP-CA-001 and VPS-41.

3.2.2 For containment level 2, handle pathogenic under a biological safety cabinets. A solution of 70% ethanol (solution is good for 1 month) is NOT always effective against Bio Safety Level 2 microorganisms. Therefore bleach 10% solution must be used (good for 1 day). If the surface can cause corrosion, rinse with 70% ethanol or sterile water after disinfecting. Avoid creating aerosols on an open bench; use sealed cup for centrifuge, for vortex, sonicator, and stirrer work under a biosafety cabinet.

3.2.3 Wash hands following all laboratory activities, following the removal of gloves, and immediately following contact with infectious materials. Decontaminate work surfaces before and after any experiment. Do not perform mouth pipetting. It is the responsibility of the end-user to handle biological materials in a safe manner to protect themselves and those around them.

3.2.4 Human blood, body fluids and tissues are known to transmit hepatitis B virus. The risk of hepatitis B can be significantly reduced by immunization and protection from the vaccine lasts at least fifteen years. Please contact your supervisor or EHS for an appointment for vaccination at Concordia. Proof of vaccination must be sent to the supervisor and EHS. For waiver case, an exemption request must be filled out and sent to the supervisor and EHS.

3.2.5 Transportation of agent between labs and/or buildings requires safe handling procedures to reduce the risk of spills or leaks (secondary containment). Use a secondary container with the ability to hold the volume of the material in the event of a leak or a spill. Never use passenger elevators for the transport of biological and chemical materials. Always use the freight elevator at the back of the PERFORM centre (connected to the loading dock).

3.2.6 It is the responsibility of the Clinical Analysis Supervisor or the delegate to provide the appropriate waste container for handling biological waste. They will maintain an inventory on site that will handle the needs of the users.

3.2.7 For cell culture, acceptable waste containers may be a 2L side arm flask attached to a vacuum line. The vacuum setup must include 1) a primary collection flask containing an appropriate disinfectant; bleach 10% final concentration 2) a secondary overflow flask and 3) a cartridge-type in-line filter to protect the vacuum pump/central vacuum system from contamination. The vacuum pumps must be protected from the potentially aerosolized aspirated infectious substance by an in-line HEPA filter with an upstream hydrophobic filter and/or disinfectant traps. It is recommended to use Whatman™ HEPA-Vent Filter. This is a laminated hydrophobically treated glass microfiber capable of retaining 99.97% of 0.3µm particles. It repels moisture and prevents bacterial growth. Please refer to the Memo from EHS posted beside the Biological Safety Cabinets in the Clinical Analysis Suite.

3.2.8 Cell culture may only be passaged in a sterile biosafety cabinet that is operating within the yearly inspection period when in use.

3.2.9 Solid waste such as disposable or a badly soiled lab coat, gloves, sample tubes and flasks, serological pipette and pipette tips etc. should be collected in the yellow bag lined in biohazardous grey bins. Ensure to close the lid of the grey bins once finished.

3.2.10 Biologically contaminated sharps and glass blood tubes will be disposed of using specialized red or yellow sharps containers for biological contamination. Such sharps containers are not to be used for heavily contaminated chemical sharps waste.

3.2.11 Each end-user must wash their hands after handling biohazardous materials and before leaving the lab.

3.2.12 PPEs must not be worn outside the laboratory.

3.3 Disposal of biohazardous waste

3.3.1 Cell culture waste

3.3.1.1 Add an amount of bleach to the cell culture waste that gives you a final 10% bleach concentration. For example, for a 1L liquid cell culture waste container, put 100 mL of bleach just before dumping the cell culture waste in to the flask. Let it sit capped for at least 20 minutes. When the water is white or clear, you may dump the waste down the sink, and rinse well. Run the fresh cold tap water for a few minutes after dumping the bleached waste. Odors must be carefully monitored. Meanwhile replace the old flask with another with a fresh 100 mL of bleach inside or less depending on final volume.

3.3.1.2 For vessels to decontaminate, soak in 10% bleach and let it sit capped overnight before dumping it down the sink. After dumping the waste, run the fresh cold tap water for few minutes.

3.3.1.3 All reusable vessels should be washed afterwards manually or by glassware washer using Sparkleen soap, followed by rinses with type 1 water, and then autoclaved before next use.

3.3.2 Biohazardous solid waste

3.3.2.1 Biohazardous solid waste (tissues, contaminated sharps, needles, syringes, Pasteur pipettes and scalpel, etc) is disposed of in the small red biohazard waste containers only.

3.3.2.2 When a solid waste container is almost full and ready to be picked up, the user must advise the Clinical Analysis Supervisor or the delegate, and get a replacement. The user must give 24-hour notice to the Clinical Analysis Supervisor or the delegate to provide a new container from EHS. The Clinical Analysis Supervisor will remove the full containers as described in APPENDIX II

3.4 General procedure for dealing with spills

3.4.1 Training for handling a spill will be provided to all end-users by EHS during Introduction to biosafety and Safe Handling of Blood training. All spills, accidents, incidents, or exposures to infectious materials must be reported immediately to the supervisor and to EHS. Written records of incidents and investigations will be maintained by EHS.

3.4.2 The proper procedures to deal with biological spill vary depending on the agent, quantity and location. To deal with a minor biological spill, the laboratory is equipped with a spill kit which consists of the following: sorbent pads, socks, pillows, bags, nitriles gloves, goggles, emergency sheet. If it is an emergency or a spill that can cause a health danger, do not clean the spill, exit and call security at 3717.

3.4.3 When sample volumes are less than 1 ml and not dangerous for health: wipe-up with disposable wipes (Kim wipes) moistened with 10% bleach solution and dispose of in the biohazard bag in the grey bin. Soak contaminated area with a 10% bleach solution; allow 20 minutes for disinfection and wipe-up puddle and dispose of in biohazard bag in the grey bin. Avoid alcohol due to explosion hazard. Notify the PI, Clinical Analysis Supervisor or the delegate.

3.4.4 When the volumes are larger than 1 ml: use sorbent and sock from the spill kit and from the outside perimeter and soak contaminated area with a 10% bleach solution; allow 20 minutes for disinfection and wipe-up the puddle and dispose of in a biohazard waste container. Notify the PI, Clinical Analysis Supervisor or the delegate.

3.4.5 Inform the Clinical Analysis Supervisor or the delegate for help in getting the spill under control if it is safe to do so.

3.4.6 The Clinical Analysis Supervisor or the delegate will fill out an incident report on the EHS website (Appendix III) and request a subsequent follow-up if EHS so advised.

APPENDIX I

Biological Sample/Material Log Form

PERFORM Centre

Biological Sample/Material Log Form

Name: _____ **Department:** _____

Type of samples/Materials (Matrix, Anticoagulant): _____

Date of sample receipt: _____ **Total No. of samples received:** _____

Storage Temp _____ **Freezer Id:** _____ **Shelf No:** _____ **Rack No:** _____ **Box No:** _____

Participant ID #	Date Collected	No. of Sample Aliquots	Date of storage	Date of disposal	Comments	Signature

APPENDIX II

Procedure for Biohazardous Waste Disposal

Procedure for Biohazardous Waste Disposal - with Stericycle

Grey bins preparation prior to bringing to the loading dock at PERFORM Centre (grey bins with yellow lid)

1. Make sure that the internal yellow bag is sealed properly.
2. Make sure that the grey bin(s) is clean (wipe it with soap or disinfectant if required).
3. Secure (tape) the lid onto the grey bin(s).

There is a regular biohazardous waste pick-up schedule sent by EHS to the facilities coordinator, technician and supervisor of the Clinical Analysis Suite of the PERFORM Centre. They have access to the loading dock and will ensure to add the yellow sticker provided by Stericycle on the gray bins. Once Stericycle comes for the pick-up, PERFORM's staff will send the green copy by internal mail to the biosafety technician from EHS, who keeps a copy and tracks the quantity of biohazardous waste shipped.

APPENDIX III

Injury/near-miss reporting

Can be completed and submitted online at:
http://ehs.concordia.ca/services/workplace-safety/incident-reporting/

APPENDIX IV

SOP Training Record Form

Handling of Biological Materials at PERFORM

SOP Code

Ownership	Document type	Area	SOP Number	Version
PC	SOP	GA	002	03

Training Record

Full Name	
Institution/PI	
Contact (email or phone number)	

Signature

Sign here (Trainee) Date

Sign here (Clinical Analysis Supervisor) Date