

**DB440 (Containment Level 2 Facility)-Governance
Department of Chemistry**

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General Principles

This document and its appendices set the general principles and concrete regulations which govern the operation of the shared CL2 Facility (DB440), and which must be adhered to by all researchers and their teams operating in DB440. The document ensures compliance with University of Toronto's biosafety program and with associated legislations. DB440 authorized personnel accept collective responsibility for establishing a safe and collegial work environment. They recognize that all equipment in the CL2 facility is shared, and therefore must participate in the management of common equipment, common resources and other infrastructure in the facility. They also understand that consumables (plasticware, tips, solutions, etc.) do not fall under common resources that are shared.

Applicable Regulations and Guidelines

- Regulations:
 - [Occupational Health and Safety Act.](#)
 - [Human Pathogens and Toxins Act.](#)
 - [Human Pathogens and Toxins Regulations.](#)
- Guidelines:
 - [Biosafety Manual and Emergency Response Plan for Level 2 Permits.](#)
 - [DB440 CL2 Facility Biosafety Manual.](#)
 - [Operational Practices: Level 2 Biosafety Permits.](#)
 - [Best Practices to Avoid Contamination Guidelines.](#)
 - [Transportation of Dangerous Goods Guidelines.](#)
 - [DB440 SST Handout.](#)

Roles and Responsibilities

The Department of Chemistry is the Biosafety Permit Holder for this shared CL2 facility (DB440). As such, the Department shall:

- Manage access to DB440 on the basis of training and Biosafety-CL2-permit authorization.
- Ensures the completion of the DB440-Site Specific Training prior to granting access.
- Maintain a record of the names of authorized lab personnel and their completion of mandatory training requirements.
- Enforce the guidelines under the [Failure to Meet Terms and Conditions section](#) of this governance document.
- Create, update, and implement Standard Operating Procedures (SOPs) and health and safety procedures as required.
- Facilitate risk assessments when new biological agents/experimental protocols are introduced.
- Ensure biosafety cabinet (BSC) certifications are up to date.
- Administer preventative equipment maintenance when applicable.
- Track the usage of DB440 by the different research groups with the objective of cost recovery at the end of the fiscal year.
- Purchase shared equipment-related consumables (ex. CO2 compressed cylinders) using a recovery cost model where individual research teams will be charged back on the basis of usage.
- Perform routine inspections and maintain inspection records, address any infrastructure issues or deficiencies that arise from the inspections within a reasonable time.
- Investigate incidents, spills, and complaints from lab personnel, and follow up on those investigations.

Principal Investigators shall:

- Apply for a CL2 permit or amend a CL2 permit to include the use of the CL2 facility (DB440).
- Complete the EHS biosafety training.
- Ensure personnel under their supervision have completed all required training, including the LM-onboarding training (including lab-specific procedures), and the DB440-SST.
- Keep lab personnel's training records.
- Ensure lab personnel under their supervision learn and follow the SOPs in the DB440 SOP Binder and the terms of the lab personnel MOU.
- Distribute any relevant biosafety and biosecurity information to all personnel.
- Help foster a collaborative research environment in the LM CL2 facility (DB440).

- Ensure that laboratory personnel perform the assigned laboratory duties according to the schedule.
- Provide all necessary PPE.
- Maintain an accurate Biohazards inventory.
- Accept monetary responsibility to share the costs of facility operations, maintenance, and shared consumables.
 - **Model:** Cost-recovery model is based on a membership. 50% of the total annual operation costs will be covered by the department. The remaining required costs will be covered by the membership model.
- Inform the Biosafety Officer and the Department of any new Group 2 biologicals brought to your inventories, and any new protocols not previously described in the permit.
- Report to the Senior Biosafety Officer and the Department of Chemistry of any hazard, risk or any other incidents as described here.
- Possess a CL2 permit or be listed on the permit for DB440 which explicitly lists viral work in order to work with viruses. You must have previously discussed viral work with the permit holder and the Department (the CAO) and have reviewed additional safety precautions. Risk considerations must have been reviewed with the permit holder and the CAO.

Laboratory Personnel shall:

- Take all necessary training as delineated in the [on-boarding safety training](#) and the [DB440-SST](#).
- Review, understand, and follow all the SOPs available in the [DB440 SOP Binder](#).
- Follow the terms in the MOU.
- Wear mandatory personal protective equipment (PPE).
- Perform the assigned facility maintenance duties.
- Report to the Principal Investigator/Supervisor and to chem.safety@utoronto.ca of any hazards, risk, spills, incidents, or equipment/infrastructure deficiencies. Make sure that they do not operate equipment or work in a manner that may put other personnel in danger.
- Be listed on the CL2 permit for DB440 which explicitly lists viral work in order to work with viruses. You must have previously discussed viral work with the permit holder and the Department (the CAO) and have reviewed additional safety precautions. Risk considerations must have been reviewed with the permit holder and the CAO.

Training Requirements to Gain Access to DB440

Online U of T EHS training modules:

- Anyone working with biological agents (Mandatory) o EHS601: Laboratory Biosafety Training o EHS602: Biosafety Refresher.
- **NOTE:** One year after completing EHS601, EHS602 needs to be taken every year.

EHS630: Safe Use of Biosafety Cabinets

- Optional courses based on lab-specific activities o EHS603: Blood Borne-Pathogens o EHS620: SARS-CoV-2 Biosafety Training Course DB440-Site Specific Training (**Mandatory**).
- Book a training session by contacting chem.safety@utoronto.ca.
- Review [the DB440-SST handouts](#) prior to training.

DB440-Onboarding (Access)

Request for access to the facility:

Only authorized personnel are allowed to access and enter the CL2 facility. They are individuals who:

- Have a CL2 biosafety permit that includes DB440 as a working site AND/OR are included in a CL2 biosafety permit associated with DB440.
- Completed all mandatory U of T EHS training modules, as outlined above, including the DB440-Site Specific Training, have review and signed the MOU, AND have submitted proof of training and the signed MOU to chem.keys@utoronto.ca when requesting for access ([DB440 CL2 Facility Access SOP](#)).

DB440-Permanent Offboarding from the Department

- Have a CL2 biosafety permit that includes DB440 as a working site AND/OR are included in a CL2 biosafety permit associated with DB440.
- When permanently leaving Lash Miller, ensure all biological agents are transferred to an authorized new user or are disposed of following the [Biohazard Waste Disposal SOP](#).
- If the biological agents are transferred to a different research group, the EHS Biosafety Office must be contacted before doing so, as the recipient might be required to have the appropriate biosafety permit.
- Update biohazard inventories accordingly.
- Transfer or dispose of solutions and stocks.
- Leave personal shelves and bench space empty.
- Follow the [Offboarding SOP](#).

Shared CL2 Facility (DB440) Operations

DB440 does not have a safety shower, therefore the following conditions must be adhered to:

- Hazardous chemicals (stocks) cannot be stored in DB440.
- Only small volumes of already diluted solutions/reagents can be brought to/used DB440 (ex. Already prepared 70% ethanol, already prepared 1% sodium hypochlorite, and commercial bleach previously aliquoted in small volumes for daily use).
- All dilutions of concentrated stocks and aliquoting of stocks (bleach) should be performed in each research group laboratory.
- All squeeze bottles containing 70% ethanol or 1% sodium hypochlorite should be labelled with worksite WHMIS labels
- Reagents such as trypsin, PBS, cell culture media are allowed to be stored in DB440 in the quantities needed for experiments. Larger stocks should be kept in each research group lab.
- Stocks of DMSO should be kept in each research group lab and properly labelled small aliquots can be brought into DB440
- **Cardboard boxes are prohibited in DB440** (source of spores cell culture contamination)
- Larger stocks of plasticware should be stored in each research group lab. Small stocks can be brought and stored within plastic containers on the shelves available in DB440. Plastic containers must be labelled with research group name.
- Lab coats should be stored in DB440. They should have a nametag, and they should be stored one lab coat per hook (do not pile lab coats on top of each other).

Expectations When Using DB440

Authorized lab personnel are expected to follow good citizenship practices:

- Respecting other's use of the space and their samples, solutions, reagents, and consumables (plasticware).
- Being responsible for supplying and maintaining their own consumables (e.g. disinfectants, pipettes, tips, solutions, reagents, etc.).
- Booking the use of the Biological Safety Cabinets in advance following the [BSC Booking SOP](#), and not using the BSC if you have not booked it in advance.
- Booking only the amount of time necessary (not over-booking).
- Canceling bookings if they are not ready to perform the experiment.
- Ensuring biosafety cabinets are turned off with sash closed, left emptied, cleaned, and disinfected, including the BVC aspiration system (liquid waste) after each use.
- Participating in the maintenance of shared equipment, resources, and the overall housekeeping to avoid cross-contamination, fulfilling the [DB440 Lab Duties Checklist](#) (rotation schedule will be provided every six months), and the [Best Practices to Avoid Contamination Guidelines](#).
- Submitting the signed DB440 Lab Duties Checklist to chem.safety@utoronto.ca weekly.

- Maintaining all shared equipment and the overall facility in pristine condition after each use.
- Disposing of all waste (liquid, solid and sharps) as soon as containers are full, and replacing the container/bag with a new one following [Biohazard Waste Disposal SOP](#) .
- Complying with the [Best Practices to Avoid Contamination Guidelines](#).

Working with Viruses:

- Only replication-defective lentiviral particles (2nd or 3rd generation lentiviral vectors) can be used. Nevertheless, as lentiviral particles are derived from HIV and stably integrate into the genome of the infected organism, risk consideration and increased safety measures must be taken seriously. Adenovirus must be E1 and E3 deleted to render viral particles replication defective and to reduce risk upon exposure.
- If you aim to work with viruses other than lenti- and adenovirus, the SOP must be updated accordingly.

Failure to Meet Terms and Conditions

Not complying with the terms, conditions, and guidelines within this document and within the DB440 SOP Binder, or with the directions provided by your PI or the Department of Chemistry will result in consequences. The severity of the consequences will depend on the number of times (strikes) the person has committed an infraction, or the severity of the infraction as follows:

- | | |
|------------------|---|
| Strike 1: | A written/verbal warning will be given to the lab member who has committed the infraction (with a copy to the supervisor). They may also be required to read through the Biosafety Governance document and/or the specific SOP related to their infraction, if applicable. In some instances, re-training may be necessary. |
| Strike 2: | The lab member's access to the facility will be removed for two weeks. Within that timeframe, it is mandatory that the lab member complete any relevant safety training modules again. |
| Strike 3: | The lab member's access to the facility will be removed for a specified period of time, which will be decided by the Department of Chemistry in consultation with the supervisor. Based on the severity of the infraction, it may lead to a complete removal of access to the facility. |

Personnel will be supported during this process in order to help them understand the importance of fulfilling the terms and conditions for the use of DB440 in a collaborative and safe manner.

DB440 is under the Department's Biosafety permit, and the failure of the users to comply with CL2 legislation could result in the termination of this permit, which will affect the ability of all research groups using DB440 to continue with their experiments.

Inspection/Auditing

The Department of Chemistry will be responsible for performing spot-inspections and the JHSC is responsible for the yearly inspections.

Memorandum of Understanding and Agreement on Biosafety for DB440

For lab personnel working in DB440

1. I have read, understand, and will comply with the University of Toronto's Biosafety Manual, Biosafety training course(s), DB440 Biosafety Governance, all applicable SOPs, and, as applicable, HPTA, HPTR, CBS, Canadian Biosafety Guidelines – CL2, and any other regulations or standards (e.g. CFIA, ECCC).

2. I have been trained on the use of and know the exact location of the eyewash, safety shower, fire exit, spill kit and first aid kits.

3. I have been fully trained on the specifics of how to work in a shared laboratory facility and I am confident to start performing research on my own.

4. I will notify my supervisor or his/her designate, the Biosafety Officer, and the department (chem.safety@utoronto.ca), of any accident or exposure incident, and will also [complete required forms](#) as soon as possible.

5. I will notify my supervisor or his/her designate, the Biosafety Officer, and the department (chem.safety@utoronto.ca), of any missing biological agents and/or toxins, inadvertent production/release of biological agents and/or toxins, and violations of safety requirements. I will cooperate fully in any investigation of these matters.

6. I have been trained on and am able to properly operate the following equipment:
(Check all that apply).
 - _____ Autoclave
 - _____ Centrifuge
 - _____ Biosafety Cabinet
 - _____ Aspiration System

- 7. At all times when I am working, I will wear required Personal Protective Equipment, and footwear with closed toes and heels.

- 8. I know that if I have a medical condition, including a suppressed immune system, or if I have a medical concern, I must seek advice from the University's Occupational Health Nurse by calling 416-978-4467.

- 9. I recognize my responsibility and legal obligation to observe these practices and precautions while present in the facility and understand their importance for the safety and welfare of myself, all others in the facility, and the environment.

 Signature of Research Participant

 Print Name

 Date

 Signature of Permit Holder

 Print Name

 Date

Attention to: Biosafety Permit Holders

Do not submit a copy of this form along with your Biosafety permit application.

A hard-copy of this safety agreement signed by each lab worker listed under the DB440 Facility Biosafety Permit must be kept in your office/lab, and a copy must be submitted to the department (chem.safety@utoronto.ca), as a requirement for FOB access.