Laboratory Standard Operating Procedure for:

Controlled Compounds and Drugs

Description

The purpose of this procedure is to provide minimum safe work standards for personnel handling controlled compounds within a laboratory or other research areas; this includes special hazard compounds. Review this document and supply the information required in order to make it specific to your laboratory. Compounds that are considered controlled may have specific written special handling procedures or additional safe work practices. When specific procedures or work practices exist, they take precedence over the procedures in this document.

Potential Hazards

Controlled compounds being handled are often intended to have a specific medical effect as active pharmaceutical ingredients in drugs. These effects could be induced through exposure (via ingestion, dermal absorption, inhalation, etc.) Compounds in the research setting are sometimes so new that there are no toxicological studies available. Contact EHS at (313) 593-4914 to determine proper laboratory design and setup when handling these compounds.

Engineering Controls

At a minimum, a laboratory hood, vented balance enclosure, or other containment device (e.g. glove box) shall be used when handling open containers of controlled compounds. These activities include, but are not limited to:

- Weighing
- Vessel transferring of compound
- Filtrations
- Packaging and storage
- Extractions
- Sampling
    - **Note:** Drying ovens may be located outside the laboratory hood, but the drying tray must be covered both prior to placing in the oven and when removing from the oven.

An additional assessment to determine handling procedures shall be performed by the Principle Investigator (PI) and/or the Lab Manager/Director if a compound will be milled, aerosolized, or handled in a liquid readily absorbed through the skin (e.g. DMSO, DMA). All unfamiliar or potentially dangerous reactions that contain controlled compounds must initially be conducted on a small scale to evaluate the potential hazards. Reactions that may have the propensity to explode must be reviewed by EHS.

Work Practice Controls

Controlled compounds should be used only when acceptable substitutes cannot be found. Personnel working with a controlled compound must communicate the compound's identified hazard information to other personnel working nearby. No employee should handle a controlled compound without knowledge of the identified hazards.

Pressure reactions involving controlled compounds must be conducted with care. Handle the smallest quantities possible for the reaction. Handle compounds in solution when possible and minimize the amount of energy imparted to

the system to reduce aerosolization. Laboratory hood sashes shall be maintained in a closed position when not in use per the closed hood policy. Ensure any manipulation of the compound is conducted at least 6 inches inside the face of the hood or balance enclosure when handling.

Proper laboratory/area cleanliness is essential to minimize risks for exposures and contamination. Laboratory hoods perform more efficiently to protect the employee when there are limited materials blocking the air flow going into the hood and to the back of the hood baffles. Laboratory hoods should be kept free from materials and devices that are not used routinely. Items that are not used routinely should be kept on shelves, in appropriate cabinets, or in drawers. If the nature of an operation does not permit the compound to be handled in accordance with controls, the PI and/or the Lab Manager/Director shall perform an evaluation of the compound and process. Upon completion of laboratory activities, proper hand washing shall be done in accordance with good laboratory practices.

Due to the responsibilities associated with the acquisition, administration, and storage of controlled substances, the University of Michigan has established the following policy:

- To conduct animal research with controlled substances, the Principal Investigator of the associated UCUCA protocol(s) must always be appropriately licensed by State of Michigan and registered with the Drug Enforcement Administration (DEA).
- Key permanent University employees, such as laboratory managers, may also obtain separate individual state controlled substance licenses and DEA registrations if the Principal Investigator on the UCUCA protocol(s) travels frequently or is not routinely present at the registered location where controlled substances are administered.
- Only the Principal Investigator of the UCUCA protocol(s) holding the State of Michigan controlled substance license and DEA registration may be authorized to purchase and store controlled substances at their registered laboratory location. Other employees may work as authorized agents under the supervision of the licensed Principal Investigator.

Personal Protective Equipment

At a minimum, standard laboratory coats, safety glasses with integral side shields and gloves must be worn when handling controlled compounds. Disposable laboratory coats should be worn when handling powders. Flame resistant laboratory coats shall be worn when conducting operations with potential for fire. After handling controlled compounds, laboratory coats and gloves shall be removed prior to leaving the work area and must not be worn in office areas or hallways.

If the nature of an operation does not permit the controlled compound to be handled in an approved containment device, contact the PI and/or Lab Manager/Director to perform an evaluation of the compound and process. If the evaluation determines the operation can be completed outside of a containment device without additional exposure potential, a disposable laboratory coat must be worn.

Gloves, appropriate to the hazard, are required when working with controlled compounds. Refer to EHS's Glove Use Webpage for assistance with glove selection. Two sets of gloves (i.e. green nitrile gloves over purple nitrile examination gloves) should be worn whenever there is a potential for an outer glove to be impaired or damaged.

Used gloves should be carefully removed by peeling/rolling one glove inside the other. Cuffed gloves shall be utilized for skin sensitizers, compounds in liquids that are readily absorbed through the skin, and compounds denoted as having a skin exposure potential.

When operations are properly contained, respiratory protection is not required; however, respiratory protection may be worn at the discretion of the employee. All EHS training and medical surveillance must be up-to-date, before any respiratory protection may be worn.

Transportation and Storage

Transportation of any controlled compounds or other research and development materials in personal vehicles or in the shuttle vans is prohibited. For assistance with transporting compounds and other research and development materials between University of Michigan – Dearborn sites, contact EHS.

If transferring a controlled compound to another department onsite, it is the responsibility of the researcher to communicate all appropriate hazards to the receiving laboratory and personnel.

Rigid secondary storage containers must be used when transporting controlled compounds outside of the laboratory.

Waste Disposal

Because most spent, unused and expired chemicals/materials are considered hazardous wastes, they must be properly disposed of. ***Do not dispose of chemical wastes by dumping them down a sink, flushing in a toilet or discarding in regular trash containers.*** Contact EHS at (313) 593-0921 for waste containers, labels, manifests, waste collection and for any questions regarding proper waste disposal. Also, refer to EHS's Hazardous Waste Webpage for more information.

Exposures/Unintended Contact

If the employee is in need of emergency medical attention, call 911 immediately.

Contact EHS for advice on symptoms of chemical exposure, or assistance in performing an exposure assessment.

Report all work related accidents, injuries, illnesses or exposures to WorkConnections within 24 hours by completing and submitting the Illness and Injury Report Form. Follow the directions on the WorkConnections website Forms Instructions to obtain proper medical treatment and follow-up.

Complete the EHS Laboratory Incident and Near-Miss Report form.

TREATMENT FACILITIES:

Midwest Medical Center -- *Campus Employees (including student employees)*
Mon-Fri 7:30 am - 4:30 pm
9301 Middlebelt Road
Romulus, MI 48174
Phone: 734-941-1000

After hours - go to:

Midwest Medical Center
Open 24/7
4700 Schaefer
Dearborn, MI 48126
Phone: 313-581-2600

Henry Ford Medical Center-Fairlane -- *University students (non-life threatening conditions)*
19401 Hubbard Drive
Dearborn, MI 48126
Phone: 313-928-8278

Click here for more information.

Spill Procedure

- When a spill occurs, ***personal safety should always come first***.
- Alert and clear everyone in the immediate area where the spill occurred.

A **minor (small) chemical spill** is one that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel, i.e., less than 1 liter. A **major/large chemical spill** requires active assistance from emergency personnel.

For minor (small) spills:

- Alert people in immediate area of spill.
- If spilled material is flammable, turn off ignition and heat sources. Don't light Bunsen burners or turn on other switches.
- Open outside windows, if possible.
- Wear protective equipment, including safety goggles, gloves and long-sleeve lab coat.
- Avoid breathing vapors from spill.
- Confine spill to as small an area as possible.
- **Do not wash spill down the drain**.
- Use appropriate spill kits/sorbents to neutralize corrosives and/or absorb spill. Collect contaminated materials and residues and place in container. For powdered chemicals sweep carefully to avoid generation of dust or, if appropriate, use moist sorbent pads or wet the powder with a suitable solvent and then wipe with a dry cloth. Contact EHS at (313)590-0921 for proper disposal.
- Follow decontamination procedure below.

For major (large) spills:

- Attend to injured or contaminated persons and remove them from exposure.
- Alert people in the laboratory to evacuate.
- If spilled material is flammable, turn off ignition and heat sources. Don't light Bunsen burners or turn on other switches.
- **Call Public Safety at (313)593-5333 or 911 from a campus phone immediately for assistance.**
- Close doors to affected area.
- Post warnings to keep people from entering the area.
- Have person available that has knowledge of incident and laboratory to assist emergency personnel.

If a controlled compound is spilled, the proper decontamination procedure shall be followed.

For spills that involve drug conjugates use the following:

- Apply excess decontaminant (e.g. 20% bleach or specific decontaminant) to the area.
- Allow to sit for 10 - 15 minutes.
- Absorb using the plastic absorbent pads.
- Contain in a bag.
- Dispose of as Hazardous Waste.

For aqueous based solutions of drug conjugates use the following (Note: this does not involve solutions which are flammable):

- Very similar to current practices with the following deviations:
- Use the decontaminant (e.g. 20% bleach or specific decontaminant)
- Allow to sit for 24 hours (this will deactivate the API).
- Solution shall be disposed as hazardous waste.

Additional Spill Links:

- Chemical Spill Control Information

Report all emergencies, suspicious activity, injuries, spills, and fires to Public Safety by calling at (313) 593-5333 or 911 from a campus phone. Register with the University of Michigan-Dearborn Emergency Alert System.

Training of personnel

All personnel are required to complete the ***Comprehensive Laboratory Safety*** session (**BLS009** *or equivalent*) via OSEH's My LINC website. Furthermore, all personnel shall read and fully adhere to this SOP when handling controlled compounds and drugs.

Certification

I have read and understand the above SOP. I agree to contact my Supervisor or Lab manager if I plan to modify this procedure.

Name	Signature	UM ID #	Date

Prior Approval required – Is this procedure hazardous enough to warrant prior approval from the Principal Investigator? ☐ **YES** ☐ **NO**

Principal Investigator _____ **Revision Date** _____