**STANDARD OPERATING PROCEDURES**
**FOR WORK WITH TOXINS OF BIOLOGICAL ORIGIN THAT ARE NOT SELECT AGENTS**

PI Name: _____

Laboratory Location (Bldg & Room No.): _____

Animal Facility Location (Bldg & Room No.) (If not applicable, put (N/A): _____

Toxin(s): _____

Hazard(s): _____

_____

_____

Date: _____

PI's Signature: _____

***NOTE: Your signature indicates verification that your laboratory is in compliance with the following SOPs.***

1. Laboratory, support, and animal care (where applicable) personnel, ☐ have / ☐ will **(check one)** receive(d) appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel will receive annual updates, or additional training as necessary for procedural or policy changes.

   Records of all training provided are maintained, and a copy ☐ has been / ☐ will be **(check one)** provided to the EHSO.

2. An inventory control system for the toxin is in place. ☐ Yes ☐ No

3. The toxin(s) is/are stored in sealed, labeled containers that are secured in locked storage rooms, cabinets, or freezers when not in use. Refrigerators and other storage containers are clearly labeled and provide contact information for trained, responsible laboratory staff. ☐ Yes ☐ No

4. Access to areas containing toxins is restricted to those whose work assignments require access. ☐ Yes ☐ No

5. Toxin work is performed in a designated room with controlled access and at pre-determined bench areas. When toxins are in use, the room should be posted to indicate "Toxins in Use - Authorized Personnel Only." Any special entry requirements are posted on the entrance(s) to the room. Only personnel whose presence is required are permitted in the room while toxins are in use. ☐ Yes ☐ No

6. All high risk operations are conducted with two knowledgeable individuals present. Each is familiar with the applicable procedures, maintain visual contact with the other, and be ready to assist in the event of an accident.
   ☐ Yes ☐ No ☐ N/A, there are no high risk operations

7. Routine work with dilute toxin solutions, preparation of primary containers of toxin stock solutions and manipulations of primary containers of dry forms of toxins will be conducted in **(check one)**:

   ☐ a chemical fume hood ☐ a biological safety cabinet (BSC)

   a. The user verifies inward airflow of the hood or BSC before initiating work. ☐ Yes ☐ No

   b. All work is done within the operationally effective zone of the hood or BSC. ☐ Yes ☐ No

   c. When handling dry forms of toxins that are electrostatic, "static-free" disposable gloves are worn.
      ☐ Yes ☐ No ☐ N/A

8. Before containers are removed from the hood or BSC, the exterior of the closed primary container is decontaminated and placed in a clean secondary container. ☐ Yes ☐ No

9. Toxins and toxin solutions are transported only in leak/spill-proof secondary containers. ☐ Yes ☐ No

10. The interior of the hood or cabinet is decontaminated periodically, for example, at the end of a series of related experiments. Until decontaminated, the hood or BSC is posted to indicate that toxins are in use, and access to the equipment and apparatus restricted to necessary, authorized personnel. ☐ Yes ☐ No

11. Centrifugation of cultures or materials potentially containing toxins are only performed using sealed, thick-walled tubes in safety centrifuge cups or sealed rotors. The outside surfaces of containers and rotors are routinely cleaned before each use . After centrifugation, the entire rotor assembly is taken from the centrifuge to a hood or BSC to open and remove its tubes. ☐ Yes ☐ No ☐ N/A

12. Employees are expected to wash their hands after handling the toxin and/or animals; after removing gloves; and before exiting the laboratory, room where animals are housed, and the animal facility. Handwashing facilities are located in rooms_____.

13. When vacuum lines are used with systems containing toxins, they are protected with a HEPA filter to prevent entry of toxins into the lines. ☐ Yes ☐ No ☐ N/A

14. Spills and accidents which result in overt exposure should be immediately reported to _____ (the laboratory director or other appointed person). Medical evaluation, surveillance, and treatment will be provided as appropriate and written records will be maintained. Spills are to be decontaminated by: _____

    _____

    Spills and accidents which result in overt exposures to toxins will be immediately reported to the Institutional Biosafety Committee. ☐ Yes ☐ No

15. Eating, drinking, smoking, handling contact lenses, applying cosmetics and storing food for human consumption are prohibited in the lab and animal room. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only located _____.

16. Mechanical pipetting devices shall be used; mouth pipetting is prohibited. ☐ Yes ☐ No

17. Broken glassware will not be handled directly by hand. A brush and dustpan is located _____.

18. Contaminated equipment in the laboratory is decontaminated prior to servicing or shipping. ☐ Yes ☐ No

19. Use of sharps is minimized. Where needles/syringes must be used, safety needles, such as those which retract or resheath the needle are used. Glassware is replaced with plastic for handling toxin solutions wherever practical, lass Pasteur pipettes are replaced with disposable plastic pipettes, and glass chromatography columns under pressure are enclosed within a plastic water jacket or other secondary container. ☐ Yes ☐ No

20. Discarded needles/syringes (if used) are placed immediately into properly labeled, puncture-resistant sharps containers which are decontaminated as soon as practicable. ☐ Yes ☐ No ☐ N/A

21. Identify the method of disposal/deactivation of contaminated materials and remaining agent: _____

    _____.

**Personal Protective Equipment (PPE) to be Used**

PPE guidelines:

- When using an open-fronted fume hood or BSC, protective clothing, including gloves and a disposable long-sleeved body covering (gown, laboratory coat, smock, coverall, or similar garment) should be worn so that hands and arms are completely covered.
- Eye protection should be worn if an open-fronted containment system is used, or there is a potential for aerosol or splash.
- Gloves worn when handling the toxin(s) should be selected based on the hazards of both the toxin and any diluent. Toxins that are percutaneous hazards (irritants, necrotic to tissue, or extremely toxic from dermal exposure) require gloves that are known to be impervious to the toxin.
- When handling dry forms of toxins that are electrostatic, gloves that help to generate static electricity (such as latex) should NOT be worn
- Whenever a potential for airborne dust or other aerosol is present (such as in an animal room when the material is excreted into the bedding, N95 respirators should be worn by all laboratory/animal care personnel.

Based on the above guidelines, the following summarizes the work practices and PPE for anticipated tasks to be performed (add tasks as necessary):

| **Task** | **Procedure to be Performed in a BSC?** | **Type of Gloves to be Worn?** | **N95 Respirator Needed?** | **Other PPE Needed? (disposable lab coat, eye protection etc.)** |
|---|---|---|---|---|
| Preparing toxin | ☐ Yes ☐ No | | ☐ Yes ☐ No | |

| Task | Procedure to be Performed in a BSC? | Type of Gloves to be Worn? | N95 Respirator Needed? | Other PPE Needed? (disposable lab coat, eye protection etc.) |
|---|---|---|---|---|
| Administering toxin to animals (mark here if N/A □) | ☐ Yes ☐ No | | ☐ Yes ☐ No | |
| Entering animal room (mark here if N/A □ ) | N/A | | ☐ Yes ☐ No | |
| | ☐ Yes ☐ No | | ☐ Yes ☐ No | |
| | ☐ Yes ☐ No | | ☐ Yes ☐ No | |
| | ☐ Yes ☐ No | | ☐ Yes ☐ No | |

22. All protective equipment is removed after use and prior to leaving the laboratory. Disposable protective equipment is to be discarded (location) _____.

    Disposable PPE is decontaminated by _____.

23. If launderable items such as laboratory coats are allowed to be worn while working with the toxin(s), contaminated and potentially contaminated protective clothing and equipment are decontaminated using methods known to be effective against the toxin before removal from the laboratory for disposal, cleaning or repair. If decontamination is not possible/practical, materials (e.g., used gloves) should be disposed in a manner which renders the toxin inactive, such as shipping as biomedical waste for incineration or autoclaving. Materials contaminated with infectious agents as well as toxins should also be autoclaved or otherwise rendered non-infectious before leaving the laboratory. Such contaminated items are decontaminated in this manner: _____
    _____.

**If toxin is being administered to animals:**

24. Only workers trained and experienced in handling animals are permitted to conduct operations involving injection of toxin solutions using hollow-bore needles. ☐ Yes ☐ No ☐ N/A
    Name(s) of personnel performing injection: _____

25. Animals ☐ can / ☐ can not **(check one)** excrete the toxin for _____ days. Therefore, animal bedding/excreta ☐ does / ☐ does not need **(check one)** to be considered potentially hazardous requiring collection and disposal through incineration, and N95 respirators will be worn in the animal room.

26. Animal carcasses ☐ will /☐ will not **(check one)** have residual toxin present significant enough to require incineration, and will be placed in appropriate containers ☐ marked / ☐ not marked **(check one)** for incineration.

27. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building. Access to the facility is limited by secure locked doors. Doors to animal rooms open inward, are self-closing, and are kept closed when experimental animals are present. ☐ Yes ☐ No

28. Animals not involved in the work being performed are not permitted in the lab or animal room. ☐ Yes ☐ No

29. When needed, animals are housed in primary biosafety containment equipment appropriate for the animal species. Filter top cages are handled in properly designed and operating animal bio-containment cabinets recommended for rodents. ☐ Yes ☐ No ☐ N/A

30. Exhaust air is discharged to the outside without being recirculated to other rooms, and the direction of airflow in the animal facility is inward (animal rooms should be negative to the hallway). This has been verified by _____
    _____.

31. An eyewash is located (in the animal facility) _____.

32. A handwashing sink is in the animal room where animals are housed, as well as elsewhere in the facility. ☐ Yes ☐ No