

Standard Operating Procedure

Biological Toxins

Document#: BIO001.01	Distribution:
Section:	Effective Date: 2/2019
Total Pages: 9	Revision Date:

NOTES:

- *The use of Biological Toxins, including Exempt Quantity Biological Select Agents and Toxins and rDNA that encodes for toxins, must be approved by the IBC Committee and IACUC Committee (if working with animals) at Temple University.*
- *This SOP must be reviewed on an annual basis or whenever changes are made to use and/or location.*

1. **Hazard identification:**

- Toxin name:

- CAS number:

- Lethal dose 50% (LD₅₀):

- Routes of exposure:

- Target organs:

- Symptoms of acute intoxication:

- Availability of vaccine or antitoxin:

2. **Special handling procedures:**

- All work with *the biological toxin* will be performed in:
[choose from: a chemical fume hood and biosafety cabinet].
- The smallest practical quantities of the biological toxins will be used for the experiment being performed.
- The biological toxin-containing solutions will be transported and stored in secondary containment.
- When using the biological toxin working with animals:
 - IBC issued signage must be posted to the door of the room in which the toxin administration to small rodents will be performed. The signage will remain on the door for the duration of the biological toxin treatment.
 - The biological toxin may be administered to animals via [add route of administration] at dose of drug/kg animal and [add time period of animal treatment].
 - Injection of small rodents with the biological toxin-containing solution must be performed in either a certified BSC or chemical fume hood within ULAR facilities (as specified in approved ACUP).

- Toxin preparation (including locations):

- Toxin use (including *in vivo* procedures and locations):

- Toxin storage (including locations):

3. **Engineering Controls:**

- All work with the biological toxin will be conducted within the certified biosafety cabinet (BSC) or chemical fume hood. Each user should verify the inward airflow before initiating

work.

- The BSC or chemical fume hood will be decontaminated upon completion of tasks with [] [add a solution appropriate for specific toxin] for [] [add contact time].
- HEPA filter and two flask traps will be used to protect house vacuum line system.
- Safety centrifuge cups or sealed rotors will be used if centrifuging materials containing the biological toxin, and the outside surfaces will be routinely decontaminated after each use with [] [add a solution appropriate for specific toxin].
- Syringes used for the biological toxin injection will be safety engineered type (self-sheathing syringes, luer-lock syringes, etc.).
- Laboratory/Room doors will be kept closed at all times when working with the biological toxin.

[Add additional engineering control if necessary]

4. **Work Practice Controls:**

- An emergency shower and eyewash station must be easily accessible within the immediate work environment in areas where the biological toxin is used.
- A hand-washing sink must be readily available to all locations where the biological toxin is used.
- Before containers are removed from the chemical fume hood or biosafety cabinet, the exterior of the closed primary container will be decontaminated and placed in a clean secondary container.
- Until thoroughly decontaminated, the chemical fume hood or BSC should be posted to indicate that biological toxins remain in use, and access should remain restricted.
- Remove and dispose of or decontaminate protective clothing and wash hands with soap and water before leaving the work area.

5. **Personal Protective Equipment (PPE):**

The following PPE will be worn when working with *[add name of the toxin]:*

- Lab coat with long sleeves (or disposable lab coat)
- Safety glasses with side shields or chemical safety goggles
- Face protection such as a face shield
- Gloves that are impervious to the biological toxin
- Closed toed shoes and long pants

Gloves will be changed immediately if contaminated, torn, or punctured.

[Add additional PPE if necessary]

6. **Transportation and Storage:**

- Toxin containers must be labeled with the biological toxin name and hazard warnings at a minimum.
- The biological toxin will be transported in labeled and sealed non-breakable secondary containers.
- When toxins are stored in the lab, containers should be sealed, legibly labeled and secured to ensure restricted access.
- *[add the name of the toxin]* will be stored in locked *[choose from a freezer/refrigerator/cabinet]* in room *[add location room #]*.
- Refrigerators and other storage containers containing biological toxins should be labeled with contact information for trained, responsible laboratory staff.

7. Waste Disposal:

- Any biological toxin waste will be decontaminated or autoclaved as appropriate before disposal.
- Work space surfaces must be wiped down after completion of tasks with *[add appropriate inactivation agent and concentration]* during the length of the experiment. Absorbent pads will be replaced after completion of tasks or immediately if contaminated. Used and potentially contaminated absorbent pads, PPE, etc. will be placed in a hazardous waste bag and autoclaved.
- Discarded needles/syringes and other sharps should be placed directly into properly labeled, puncture-resistant sharps containers, and inactivated/decontaminated before final disposal.

8. Exposures/Unintended Contact:

- Remove contaminated clothing and/or PPE and flush mucous membranes (eyes, nose, mouth) with water from the nearest eyewash or drench hose. Intact or non-intact skin exposures should be washed immediately with soap and water.
- Report to PI and seek immediate medical evaluation if there is personnel exposure:
 - **During office hour**
 - a. **Health Science Center: Go to the Occupational Health Department, M-F, 8:00 AM to 5:00 PM.**
 - b. **Main Campus: Go to Employee Health Services, M-F, 8:30 am - noon; 1 pm - 4:40 pm.**
 - **After office hour**
 - a. **After 5 PM, go to Temple University Hospital Emergency Department.**
- Principal Investigator must immediately report the incident to the EHRS.
- Leave the area (for inhalation hazards).

Add additional information specific for the biological toxin used (if necessary)

9. Decontamination, Spills, and Emergency Procedures:

Depending upon the specific biological toxin used an autoclaving or chemical inactivation can be applied for decontamination and spill cleaning.

<i>Toxin</i>	<i>NaOCl* 30min</i>	<i>NaOH 30min</i>	<i>NaOCl+NaOH 30min</i>	<i>Steam Autoclave 1hr, 121°C</i>	<i>Comments</i>
<i>Abrin</i>	<i>No</i>	<i>No</i>	<i>No</i>	<i>Yes</i>	Heat inactivation is recommended
<i>Anthrax</i>	<i>0.5%</i>	<i>No</i>	<i>No</i>		0.5 % NaOCl is recommended
<i>Brevetoxin</i>	<i>2.5%</i>	<i>ND</i>	<i>ND</i>	<i>No</i>	2.5 % NaOCl is recommended
<i>Botulinum</i>	<i>0.1%</i>	<i>0.25N</i>	<i>ND</i>	<i>No</i>	0.1 % NaOCl or .025 N NaOH for 30 min is recommended
<i>Cholera toxin</i>	<i>0.5%</i>	<i>ND</i>	<i>ND</i>	<i>Yes</i>	0.5 % NaOCl is recommended
<i>Diphtheria toxin</i>	<i>0.5%</i>	<i>ND</i>	<i>ND</i>	<i>Yes</i>	0.5 % NaOCl is recommended
<i>Microcystin</i>	<i>0.5%</i>	<i>ND</i>	<i>0.25%+0.25N</i>	<i>No</i>	Alkalinity is the inactivation factor
<i>Palytoxin</i>	<i>0.1%</i>	<i>ND</i>	<i>0.25%+0.25N</i>	<i>No</i>	Alkalinity is the inactivation factor
<i>Pertussis toxin</i>	<i>0.5%</i>	<i>ND</i>	<i>ND</i>	<i>Yes</i>	0.5 % NaOCl is recommended
<i>Ricin</i>	<i>0.1%</i>	<i>ND</i>	<i>0.1%+0.25N</i>	<i>Yes</i>	1.0 % NaOCl is recommended
<i>Saxitoxin</i>	<i>0.1%</i>	<i>ND</i>	<i>0.1%+0.25N</i>	<i>No</i>	1.0 % NaOCl for 30 min is recommended
<i>Staphylococcal enterotoxin</i>	<i>0.5%</i>	<i>0.25N</i>	<i>ND</i>	<i>Yes</i>	SEB is heat stable. Inactivation is with 0.5% NaOCl for 30 min
<i>Tetrodotoxin</i>	<i>0.5%</i>	<i>ND</i>	<i>0.1%+0.25N</i>	<i>No</i>	1.0 % NaOCl for 30 min is recommended

<i>T-2 mycotoxin</i>	2.5%	ND	0.25%+0.25N	No	2.5 % NaOCl + .025 N NaOH for 4 hr is recommended
<i>Tetanus toxin</i>	0.5%	ND	ND	Yes	0.5 % NaOCl is recommended

* Note: NaOCl concentrations refer to Sodium hypochlorite, not household bleach. The concentration of NaOCl in household bleach is 5.25%. A dilution of 1 part household bleach in 9 parts liquid is a 0.525% solution.

Spill Procedures

- For small spills of dilute solution (inside or outside BSC):
At minimum, safety glasses, lab coat, smock, or coveralls should be worn, along with appropriate gloves to clean up a spill. If splashing may occur, safety goggles and a face shield must be worn in place of safety glasses. Cover spill with absorber paper towel or other disposable, absorbent material. Apply [add appropriate inactivation agent and concentration] to the spill, beginning at the perimeter and working towards the center, and allow [enter sufficient time in minutes] to completely inactivate the toxin.
- For any spill of toxin powder or stock solutions:
 - Inside chemical fume hood or BSC and small spill outside:
Personnel cleaning up a powder spill will wear safety glasses, lab coat, smock, or coveralls should be worn, along with appropriate gloves to clean up a spill. Gently cover powder spill with dampened absorbent paper towels to avoid raising dust. Apply [add appropriate inactivation agent and concentration], starting at the perimeter and working towards the center, allowing [enter sufficient contact time in minutes] to deactivate [add the name of the toxin]. Clean the spill area with [add appropriate inactivation agent and concentration], then soap and water.
 - Large spill outside of chemical fume hood or BSC:
Remove all personnel from the room and restrict access. As soon as possible report the spill by notifying EHRS (EHRS business hours 216-707-2520, after hours 1-1234). Tell them that a spill has occurred with [add the name of the toxin], and you are seeking guidance.

If chemical fume hood or BSC failure:

- Close or cover all toxin containers. Shut down operations, close hood sash, and evacuate room. Contact your maintenance provider to repair the BSC or chemical fume hood.

10. **Training of Personnel:**

In addition to online Biological Agent and Toxin Safety training, each laboratory employee working with biological toxins must be trained in the theory and practice of the toxins to be used, with special emphasis on the nature of the practical hazards associated with laboratory operations. This includes how to handle transfers of liquids containing biological toxin, where to place waste solutions and contaminated materials or equipment, and how to decontaminate work areas after routine operations and accidental spills. Furthermore, all personnel shall read and fully adhere to this SOP when handling the toxin.

11. **Special precautions for use of biological toxin in animals:**

- Use of toxins in animals will be documented and approved by IACUC and IBC.
- Only ready to use aliquots (with concentration of the [] *[add the name of the toxin]*) below lethal dose for humans will be transported in secondary containment into ULAR facility for animal procedures.
- Animals will be anesthetized or placed into a restraining apparatus before procedures using [] *[add the name of the toxin]* are performed. Once the animal has been properly fitted into the restraining apparatus, the syringe will be loaded just prior to injection.
- After procedures are complete, the restraining apparatus and surrounding work station will be decontaminated with [] *[add appropriate inactivation agent and concentration]*. All reusable lab equipment will be autoclaved.
- ULAR staff training with SOP for [] *[add the name of the toxin]* has to be completed before starting any experimental activities with animals.

Add additional information specific for the biological toxin used (if necessary)

12. Date of the SOP training for lab workers and animal care providers:

Name (please print)	Signature	TUID Number	Department	Position / Title