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| **BIOLOGICAL TOXIN LABORATORY STANDARD OPERATING PROCEDURE** | | | | **Procedure title: Lab fills in this part** | | |
| **Latest validation/verification completed by/date: to be filled in by OCRS Biosafety Team** | | | | | | |
| **Validation/verification method  (check all that apply):** |  | **Dry Run** |  | **Observed procedure** |  | **Other (Describe below)** |

This template is most suitable for lab procedures involving toxins such as preparation of stock solution/aliquots and administration of toxin solutions to cell cultures or in an animal model. Include sufficient detail to provide effective guidance to someone who is relatively new to your lab. **It is STRONGLY recommended that separate SOPs be developed for distinct activities.**

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| Name Biological Toxin/Venom: | | Vendor Name: |
| Product ID/Catalog Number: | Animal protocol # (if applicable): | |
| Reason for submission: (new protocol, adding personnel, annual renewal, other) | | |
| Storage Location (Room#/Building): | Location where material will be handled: | |
| Principal Investigator: | Department: | |
| Phone: | Email: | |

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| **Who will be handling this material?**  The following lab personnel are authorized toxin users and acknowledge that they have read this document and will adhere to all regulatory policies and safety procedures including completion of appropriate training. | | |
| Lab Personnel Name | Personnel ID Number | Signature |
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| **Basic Description of Research Use of Materials**  Provide a brief summary of the proposed use of toxin for your research purposes. Please provide quantity and format of toxin to be obtained and how this material is packaged as received. (NOTE: If dry toxin to be used is packaged in a screwtop vial instead of a septum vial, please provide a justification/rationale in your description.) Please describe the necessary manipulations including any need for the use of sharps or glass, manipulations involving dry powders, etc. |
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| **OPERATIONAL SAFETY DETAILS** | **REMINDERS** |
| **Where is the toxin located and how is it secured?** | Toxins must be secured and accounted for at all times. They should be stored in a locked storage unit or a locked lab at all times when unattended. |
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| **Where is the inventory log and when does it need to be completed?** | The log should be maintained in a location where all personnel authorized to access and use the toxin can get to it readily. Routine inventory checks should be done even if toxin is not used routinely to verify quantities on hand. |
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| **Which hood or BSC is designated for toxin use?** | The hood or BSC should be posted with the “toxins in use” sign; all unnecessary items removed; working surface draped with disposable drop cloth; verify proper airflow at sash before beginning work |
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| **How is the toxin secondarily contained to prevent a spill?** | Primary containers of toxin/toxin solutions should be stored in a non-breakable, rigid, leak-proof container with a secure lid for storage and movement to the hood or BSC. |
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| **What surface decontaminant can be used for treating surfaces that may have been contaminated with toxin? How is it prepared, and what is the contact time?** | Assure that you have freshly prepared decon solution available in the hood or BSC to treat a spill before you start working. Also assure that you have adequate absorbent towels and forceps or tongs readily available for spill cleanup if needed. |
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| **What personal protective equipment must be worn, for what tasks, and where do you get it?** | Disposable, fluid-resistant wraparound gown with elastic cuff and 2 pair of gloves configured to completely cover the wrist are recommended. Glove material should be compatible with diluents to be used. |
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| **What sharps will need to be used for this procedure?** | Use a vial adapter if one is available and access to a septum vial is part of the procedure. If a needle must be used, use a syringe with a fixed or luer lock needle; use a safety engineered device that allows for enclosure of the sharp end after use for reconstitution of concentrated toxin. |
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| **OPERATIONAL SAFETY DETAILS** | **REMINDERS** |
| **What specific safe sharps handling techniques apply to this procedure?** | All sharps handling steps should be carried out in such a way that your non-dominant hand is out of the “strike zone” of the sharp. Disposable sharps should be immediately discarded in a sharps container that is available within arm’s reach. |
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| **How is solid, non-sharps waste to be collected and treated for disposal? (Waste will either be treated by autoclave or submitted to OCRS Chemical Waste.)** | A receptacle for solid waste collection should be available inside the hood or BSC. The receptacle should have the same features as a secondary container and it should be lined with an appropriate bag. Biohazard bags should NOT be used for wastes that cannot be treated by autoclave. |
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| **Are there specific post-exposure actions to be followed as prescribed by Occupational Health? If YES, what are they?** | In the event of:   * a splash to the eyes, nose, mouth, or * contact with unprotected skin, or * a cut/puncture with a contaminated item   Proceed to the sink and flush the affected body area for 15 minutes. Use soap and water for unprotected skin or cut/puncture exposures. Report the exposure to your supervisor if available. Proceed to the Occupational Health Clinic (6th Floor Medical Arts Building) unless specific procedures indicate otherwise. |
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| **SUPPLIES NEEDED FOR PROCEDURE (Include or reference safety supplies mentioned in previous sections)** |
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| **SET-UP & PRE-CHECKS (This should include safety practice actions such as advance notification of lab staff, hood/BSC setup, equipment checks, etc.)** |
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| **PROCEDURAL STEPS** |
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| **CLEAN-UP & RECORDKEEPING (Include waste collection, area decon, inventory records, etc.)** |
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**PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT OF RESPONSIBILITIES RELATED TO SELECT AGENT TOXIN POSSESSION**

In order to fulfill these regulatory responsibilities, I acknowledge that:

* If there is no reason to keep the toxin, I will contact OCRS-Biosafety in order to make arrangements for destruction of the toxin.
* If the toxin is to be maintained, it must be secured at all times. The means of security will be sufficient to prevent a person who does not work in the lab from having ready access to it.
* An inventory sheet will be maintained to document how much toxin is on hand, any use of toxin-how much, for what purpose and by whom, etc. This documentation will be maintained in such a way that is readily available in the event of regulatory inspection.
* If I plan to transfer a toxin to another PI, the OCRS Biosafety Officer will be contacted to prepare a transfer letter and coordinate that transfer (provided that the party is registered with and approved by the IBC). Transfers to a party outside Vanderbilt are not permitted.
* Laboratory personnel identified as authorized toxin users will be on record with Occupational Health and complete all training and qualification actions before handling toxins.

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| Principal Investigator Signature/Date |

***Please contact OCRS Biosafety at 322-2057 for assistance with questions related to   
biological toxin safety practices.***