Requirements for Possession, Use, and Transfer of Exempt Quantities of CDC Select Toxins at all NIH Campuses

I. PURPOSE

This document outlines the National Institutes of Health's (NIH) institutional program requirements for possession, use, and transfer of exempt quantities of CDC Select Toxins

These requirements have been established to ensure safe laboratory handling, use, and storage procedures, effective inventory tracking, security measures, and compliance with federal regulations at all NIH campuses (Bethesda, RML, NCI-Frederick including Frederick National Laboratory locations, and NIEHS-NC) and locations.

Federal regulations (42 CFR 73) allow each Principal Investigator (PI) to possess up to a specified amount of toxin and remain exempt from registration with the CDC Federal Select Agent Program. The following is a list of the Select Toxins and maximum permissible quantities:

TOXIN	**Max Permissible Quantity/ PI**
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

To remain exempt from registration with the CDC, the PI must ensure the total amount of toxin possessed does not ever exceed the permissible limit. Due to the severe penalties associated with non-compliance with the Select Agent Regulations, it is required that each laboratory maintains an accurate inventory of stock, and detailed usage records for these toxins.

II. PROCEDURES

All PIs using select toxins must ensure the following requirements are met:

- Select toxin possession and use is registered with an NIH Institutional Biosafety Committee (IBC)- in Bethesda, RML, NCI-Frederick, or NIEHS-NC, PRIOR to obtaining any select toxin.
- All associated researchers in the laboratory using or having access to the toxin must be added to the applicable biological registration at your specific location and must adhere to any other specific requirements associated with the registration.

- The PI will complete and sign the Toxin Exclusion Form (TEF), or site equivalent, which may also be used for researcher attestation. The registration may be periodically amended to update the TEF.
- Develop SOPs for toxin procedures and include these in the Laboratory Biosafety Manual.
- All listed researchers attend initial Laboratory Safety Training (and annual retraining) and be provided lab specific training by the PI for exempt toxin work. At a minimum, training should include toxin-associated hazards, PPE for handling toxin, safe handling procedures, appropriate inactivation and disposal methods, inventory and recordkeeping procedures for usage, and security controls including reporting parameters.
- Inventory Controls:
    - Storage of all Select Toxins must be kept in a locked location accessible ONLY to associated researchers listed on the PRD. Toxins and/or aliquots **must be secured, with a minimum of two layers of security, with either a key or combination lock that prevents any unauthorized personnel access to the material** (e.g., keyed lockbox physically attached to inside of freezer, or within a locked freezer with a unique key or combination lock).
    - Acquire and implement an approved inventory template, such as the Division of Occupational Health and Safety (DOHS) Inventory Template, or a site- specific equivalent, which is a tool that can track usage, who accesses material, and total quantities. (Electronic inventories are acceptable)
    - A toxin usage logbook / electronic record must be maintained to track total inventory and usage in real-time, and it must also be kept in a secure location where only authorized associated researchers will access the logbook. Access to electronic logbooks must be restricted to authorized users.
    - Inventory recordkeeping must track all purchases/acquisitions of toxin, all usage and disposal of toxins as they occur. For all allocations, this may be done in terms of the number of aliquots, noting the concentration of each aliquot to track the total quantity in mg total amounts.
- All transfers of toxin require a due diligence letter to be written by the transferring (source) PI. The letter must be approved by the site-specific Biosafety Officer (BSO) prior to the transfer of any amount of select toxin. At a minimum, the letter must include the name, address, contact information (address, email, and phone) of the recipient scientist, and the intended use which details the legitimate scientific need.
- Registered users will report suspicious behavior (unauthorized attempts to access toxin storage locations, unusual prying activities, questions about toxin storage or security, etc.)
- Each registered laboratory possessing exempt quantities of select agent toxins will be inspected at least annually. At a minimum, inspections will include:
    - Review of associated researchers to verify only authorized access to toxins.
    - Verification of appropriate labeling, storage, containment, and security measures
    - Review of physical inventory with what is accounted for in the inventory logbook.
    - Verification that quantities remain below the maximum permissible limits.

Any suspicious activity regarding select toxin storage, access, or use must be reported immediately to your site-specific safety office representative at:

Bethesda (including IRF): (301) 496-2960; RML: (406) 375-9642; NCI-Frederick (301) 846-1740; and NIEHS-NC (984) 287-3393.