Standard Operating Procedure

Working With Select Toxins (Exempt Quantities)

Environmental Health & Safety

The University of Texas at Austin

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Purpose

This document outlines UT Austin's institutional requirements for possession of exempt quantities of Select Agent toxins regulated by the Centers for Disease Control and Prevention (CDC).

These requirements have been established to ensure:

- Safe laboratory handling, use, and storage procedures.
- Effective tracking and security of the regulated toxins.
- Compliance with federal regulations.

Per the federal regulations, each principal investigator (PI) may possess up to a specified amount of toxin and not be required to register with the CDC or USDA. Following is a current list of the Select Agent toxins and the maximum quantities that are allowed in order to remain exempt from federal registration.

Toxin	Maximum Allowable per PI for exemption
Abrin	100 mg
Botulinum neurotoxin	0.5 mg
Clostridium perfringens epsilon toxin	100 mg
Conotoxins	100 mg
Diacetoxyscirpenol	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Shigatoxin and Shiga-like ribosome inactivating proteins	100 mg
Staphylococcus enterotoxins	5 mg
Tetrodotoxin	100 mg
T-2 Toxin	1000 mg

The following toxins are also exempt:

- Any toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Nonfunctional toxins.

It is important to ensure that the total amount of toxin per PI is maintained below these limits **at all times** in order to remain exempt from registration with the CDC and the attendant restrictive requirements. Due to the severe penalties associated with non-compliance with the Select Agent rules,

it is imperative that each laboratory maintains current inventory information for these substances.

Failure to register a Select Agent toxin is a criminal offense, punishable by up to five years in prison and/or $500,000 in fines (Public Health Security & Preparedness Response Act of 2002).

REQUIREMENTS FOR POSSESSION OF EXEMPT QUANTITIES OF CDC SELECT AGENT TOXINS:

1. The Principal Investigator is responsible for ensuring the following:

A. Standard Operating Procedures (SOPs): Prepare written SOPs for toxin-involved research processes.

Proper PPE: Appropriate personal protection equipment is to be provided (e.g., gloves, safety goggles, lab coat or disposable lab coat). Note: if respirators are necessary, contact EHS for respirator use approval and compliance documentation.

Engineering Controls: Ensure proper use of the fume hood, biosafety cabinet, or glove box with toxin-associated procedures.

Inactivation: Use accepted inactivation procedures prior to disposal of remaining stock and/or empty containers

Disposal: After inactivation, dispose of residual wastes (liquids/solids) as follows:

- Liquids: can be disposed of in a biohazard waste container, provided there is no other characteristic of the waste that makes it a hazardous waste, such as heavy metals, flammability, etc.
- Stock vials and other materials: Deface container labeling. Collect in non-leaking container and place in biohazard waste container, with the same conditional statement as above.

B. Personnel Training: Provide initial lab-specific safety training to staff on toxin-involved processes, with updates as necessary. Ensure documentation of training is maintained. Training topics should include:

- Toxin-associated hazards
- Engineering controls used to minimize exposure (e.g., fume hood use)
- Personal protective equipment to be used when handling the toxin (PPE)
- Safe handling and storage
- Proper decontamination and disposal
- Administrative requirements (recordkeeping, inventory, security)

C. Storage/Security: Items must be

- Stored with compatible materials within secondary containment; and
- Provided one layer of physical security (e.g., toxin secured within a locked freezer or secured within a permanently fixed lockbox).

D. List of PI-Approved Users: Maintain a list of PI-approved toxin users (include those having access to toxin materials). The lab must keep track of who uses the stock (and who has access to the freezer), recording each use. Before becoming an Approved User, the PI must ensure that each person has received training under section II.B above.

E. Inventory Maintenance: Inventory of toxins must be kept current in EHS Assistant. To ensure that the exempt quantity limits are not inadvertently surpassed, inventories are to be promptly updated after every container of toxin is:

- Acquired (by purchase/intra-campus transfer)
- Depleted (by consumption /intra-campus transfer)
- Inactivated

F. IBC Registration: PIs conducting research with select agent toxins will register their research with the Institutional Biosafety Committee.

G. Self Evaluation: PIs will conduct an annual self evaluation of their select agent toxins and submit a completed form to EHS.

2. EHS is responsible for inspecting each laboratory with select agent toxins annually. The inspection will include:

- Review of approved users list to verify authorized access to toxins.
- Verification of appropriate labeling, storage, secondary containment, and security measures.
- Comparison of physical inventory with what is accounted for in the records.

3. Possession of Select Agent Toxins Above the Exempt Quantities:

Prior to possessing Select Agent toxins in quantities above the maximum allowable limits, a Principal Investigator must submit all appropriate information to the Responsible Official (EHS)for submission to the CDC and the FBI, in addition to having received CDC approval to conduct the work in an approved facility.

For any questions regarding the CDC Select Agent Program, contact the Biological Safety Officer at 471-3511.

References:

CDC Select Agent Program: http://www.selectagents.gov/

University of Iowa: https://research.uiowa.edu/ehs/files/documents/biosafety/PIexemptquantdeclaration.pdf

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Select Agent Responsible Official Date

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Biosafety Officer Date

Approved by the Institutional Biosafety Committee: 1/24/2012