

## Requirements for Possession of Permissible Amounts of Select Agent Toxins at Wellesley College

### Purpose of Document:

Select Agent Toxins are certain toxins of biological origin which are to subject to stringent regulatory requirements under 42 CFR 73 for their potential to pose a severe threat to public, animal or plant health or to animal or plant products. These toxins, along with specified biological agents (viruses, bacteria, fungi), fall under the oversight of the National Select Agents Registry (NSAR) Program

<http://www.selectagents.gov/SelectAgentsandToxinsList.html>

This document outlines Wellesley College's institutional requirements for possession of permissible amounts of Select Agent Toxins have been established to ensure:

- Safe laboratory handling, use, and storage procedures
- Effective tracking and security of the Select Agent Toxins
- Compliance with federal regulations (42 CFR Part 73)

### Possession of Select Agent Toxins above Permissible Amounts:

Possession of select agent toxins in quantities above permissible amounts requires prior approval from the Provost and the Vice President for Finance and Administration and registration with the National Select Agent Registry Program. Also note that effective 12/4/12, Botulinum neurotoxins are categorized at Tier 1 agents which trigger additional regulatory requirements. Contact EH&S for assistance.

### Permissible Amounts of Select Agent Toxins:

Possession of permissible amounts of select agent toxins requires prior approval from the Science Center Director and the Director of Environmental Health and Safety. The following Select Agent Toxins are not regulated if the amount under the control of a principal investigator does not exceed, at any time, the amounts indicated in the table below.

Select Agent Toxins/ HHS Toxins [§73.3(d)(3)]	Amount
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	5 mg
T-2 toxin	1000 mg
Tetrodotoxin	100 mg

Other Select Agents are listed, contact the EHS Office for information excluded and exempt materials as listed in 42 CFR 73.

**Severe Penalties for non-compliance:** There are severe penalties for non-compliance with the NSAR rules and it is imperative that each laboratory using and/or storing Select Agent Toxins maintain accurate and current inventory information for these substances. Failure to register with the NSAR Program is potentially punishable by up to five years in prison and/or large monetary fines. (Public Health Security & Preparedness Response Act of 2002, Section 231(c), 18 USC 175(b), & Public Law (USA Patriot Act) 107-56 Sec. 817)

## **Wellesley College Select Toxins Program Requirements:**

### **The Principal Investigator is responsible to ensure the following:**

**1) Inventory Maintenance:** Inventory of Select Agent Toxins must be kept current. To ensure PIs do not unintentionally exceed permissible amounts of Select Agent Toxins, inventories must be checked prior to purchase and be promptly updated after every container of Select Agent Toxin is:

- Acquired (by purchase and/or intra-campus transfer)
- Depleted (by consumption or by intra-campus transfer); OR
- Inactivated

**2) Storage/Security:** Select Agent Toxins must be:

- Properly stored with compatible chemicals with adequate secondary containment;  
AND
- Provided one layer of physical security (i.e., Select Agent Toxin secured within a locked freezer, or secured within a permanently fixed lockbox)

**3) Standard Operating Procedures (SOPs):** Prepare written SOPs for Select Agent Toxin involved research processes.

**4) Personnel Training:** Provide initial lab-specific safety training to staff/students involved in Select Agent Toxin related processes, with updates as necessary. Ensure documented training is maintained for at least three years. Training topics to include:

- Select Agent Toxin-associated hazards
- Engineering controls used to minimize exposure (i.e., fume hood use)
- Personal protective equipment (PPE) to be used when handling Select Agent Toxins
- Safe handling and storage
- Proper decontamination, disposal, and spill response
- Administrative requirements (recordkeeping, inventory maintenance, security)

**5) List of PI-Approved Users:** Maintain a documented list of PI-approved Select Agent Toxin users (including those having access to Select Agent Toxin storage). The lab must keep track of who uses and who has access to the stock but it is not necessary to record each use. Before becoming an approved user, the PI must ensure that each person has received training as outlined in the prior section.

**6) Engineering Controls:** Ensure proper function (i.e. current certification) and use of any fume hood, biosafety cabinet, or glove box where Select Agent Toxin-associated procedures are performed.

**7) Proper Personal Protective Equipment (PPE):** Appropriate personal protective equipment is to be provided (i.e., gloves, eye protection, lab coat) to laboratory personnel. NOTE: If respirators are necessary, contact EH&S for necessary respirator use approval and compliance documentation.

**8) Inactivation:** Use accepted inactivation procedures prior to disposal of remaining stock and/or empty containers. After inactivation, dispose of residual wastes (liquids/solids) as follows:

- **Liquids:** Collect inactivated materials in a non-leaking container constructed of compatible material, and manage as hazardous waste per Wellesley's Hazardous Waste Management procedures
- **Stock Vials and other materials:** Deface container labeling. Collect in non-leaking container and manage as hazardous waste.

**9) Inspections:**

- Self-inspections must be performed initially and at least quarterly thereafter. Inspection items include:
  - Verification that physical and online inventories are accurate
  - Review of Approved Users List to verify authorized access to Select Agent Toxins
  - Verification of appropriate labeling, storage, secondary containment, and security measures.

**Record Retention:** Documentation of self-inspections must be maintained for at least one year beyond the last date of Select Toxin use, possession, or disposal.

**Other Inspections:** EH&S will conduct periodic laboratory visits to review compliance with institutional requirements for possession of permissible amounts of Select Agent Toxins.

**10) Moving /Closing Labs:** To ensure proper safety, security, and inventory management of Select Agent Toxins during a laboratory move on campus or if a PI is closing out his/her lab, consult with EH&S.

**11) Transfer:** Transfer of the agent or toxin is prohibited unless authorized by the Provost and or Vice President of Finance and Administration that includes a review of the Rule to ensure transfer is allowed.

**12) Theft, Loss or Release:** PI must ensure that they will immediately notify a theft, loss or release to CDC and appropriate law enforcement agencies.

For any questions regarding this Policy or the Select Agent Rule, contact the Office of Environmental Health and Safety at 781-283-3882.