

Exempt Biological Select Agents and Toxins Policy

Title:	Exempt Biological Select Agents and Toxins
Last Reviewed Date:	02-05-2026
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Effective Date:	2/12/2016
Applies To:	Faculty, staff and students, others
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1 BACKGROUND

UConn does not permit the use of Select Agent Program controlled BSAT. Principal Investigators (PI) conducting research with exempt quantities of BSAT are required to register with the Institutional Biosafety Committee (IBC).

2 PURPOSE

To state the University of Connecticut’s requirements for the possession and use of exempt quantities of Biological Select Agents and Toxins (BSAT) regulated by the Centers for Disease Control and Prevention (CDC) and United States Department of Agriculture (USDA) pursuant to 42 CFR 73, 7 CFR 331, 9CFR 121..

3 APPLIES TO

This policy applies to anyone at the University of Connecticut, Storrs, Avery Point, Hartford, Stamford, or Waterbury campuses, conducting or sponsoring research or teaching activities that involve the use of exempt quantities of BSAT.

4 DEFINITIONS

Exempt BSAT: does not require entity or PI registration with the Federal Select Agent Program. The exempt BSAT are determined by the CDC and USDA Select Agent [Regulations](#). The following is a list of the toxins and the maximum quantities that are allowed in order to remain exempt from federal registration.

Toxins	Maximum Amount per PI
Abrin	1,000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	200 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1,000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

The following BSAT 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.
- Low pathogenic strains of avian influenza.
- Non-viable select agents or nonfunctional toxins.
- Certain attenuated and vaccine strains of select agents and toxins. Refer to [Notification of Excluded Attenuated Strains](#)

5 POLICY STATEMENT

To ensure compliance with local, state and federal regulations, the PI is required to follow the procedures and practices described below.

6 ENFORCEMENT

Failure to register a (non-exempt) BSAT 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).

Violations of this policy and any related procedures may result in appropriate disciplinary measures in accordance with University Laws and By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, and the University of Connecticut Student Conduct Code.

7 RESPONSIBILITIES

7.1 PRINCIPAL INVESTIGATOR

- **Request Approval:** file a Select Biological Agent Purchase /Possession Approval (SAP-I) request form at least 10 days prior to the contemplated purchase. The form SAP-I can be obtained from Environmental Health and Safety by calling 486- 3613.

Approval may also be obtained by using the Biological Agent, Clean Air Device, Radioactive Purchase Approval form in HuskyBuy. Purchase Requisitions created in HuskyBuy for BSAT will be routed to Biosafety for approval.

- **Laboratory-Specific Biosafety Manual (LSBM):** PIs are responsible for ensuring all exempt BSAT being utilized in their laboratories are incorporated into their LSBM. The [IBC Lab-specific Biosafety Manual Procedure](#) provides assistance to create a LSBM.:
 - **Standard Operating Procedures (SOPs):** Prepare written SOPs for experiments utilizing biological agents or toxins.
- **Personnel Training:** Provide initial lab-specific safety training to staff on BSAT experiments, with updates as necessary. Ensure documentation of training is maintained. Training topics should include:
 - BSAT-associated hazards
 - Engineering controls used to minimize exposure (e.g., fume hood use)
 - Personal protective equipment (PPE) to be used when handling the BSAT
 - Labeling (agent or toxin name, concentration of toxin)
 - Safe handling and storage of agents
 - Proper decontamination and disposal of undiluted stock (refer to the [Biological Health and Safety Manual](#) and [Chemical Waste Disposal Manual](#))
- **Storage/Security:** To ensure safety and security BSAT must be stored in the following manner:
 - With compatible materials within secondary containment;
 - Provided one layer of physical security (e.g., toxin secured within a locked

- freezer or secured within a permanently fixed lockbox).
 - Used only by approved staff: Before becoming an approved user, the PI must ensure that each person has received training as described above.
 - Maintain a list of PI-approved BSAT users (include those having access to BSAT materials).
 - The lab must keep track of who uses the stock (and who has access to the lockbox), recording each time the material is accessed and/or used.
- **Inventory Maintenance:** Inventory of BSAT must be kept current. To ensure that the exempt quantity limits are not inadvertently surpassed, inventories are to be promptly updated after every container of BSAT is:
 - Acquired (by purchase/intra-campus transfer)
 - Depleted (by consumption /intra-campus transfer)
 - Inactivated
- **Transfer of an exempt quantity of toxin(s):** PIs wishing to transfer an exempt quantity of a select agent toxin to another user must use due diligence and document that the receiver has a legitimate need to handle or use the BSAT.
 - An [Exempt Quantity Transfer Form](#) has been developed by the IBC for this purpose. The transfer form must be retained by the transferor as the HHS Secretary retains the right to inspect or request the submission of the due diligence documentation to the CDC.
- **IBC Registration:** PIs conducting research with BSAT must register their research with the Institutional Biosafety Committee.
- **Use of Non-Exempt BSAT:** PIs who plan to do research with these regulated agents or toxins at “off-campus institutions” must follow the procedures outlined in the [IBC’s Policies and Procedures](#).

7.2 EHS-BIOSAFETY RESPONSIBILITIES

- **Audit each laboratory with BSAT annually.**
- **Perform a security inspection annually.** The inspection will include, but is not limited to the following:
 - Review of approved users list to verify authorized access to BSAT.
 - Verification of appropriate labeling, storage, secondary containment, and security measures.

- Comparison of physical inventory with what is accounted for in the records. A copy of the current recorded inventory signed and dated by the PI, will be collected at the time of the audit by EHS Biosafety

8 FORMS/PROCEDURES

[BSAT Exempt Quantity Transfer Form](#)