I. 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.

II. Scope
This policy applies to all University personnel who use or intend to use exempt BSAT at the Storrs and regional campuses.

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

IV. Enforcement
Violations of this policy or procedure 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.

V. Definitions
Exempt BSAT do 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

<table>
<thead>
<tr>
<th>Toxins</th>
<th>Maximum Amount per PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrin</td>
<td>1,000 mg</td>
</tr>
<tr>
<td>Botulinum neurotoxins</td>
<td>1 mg</td>
</tr>
<tr>
<td>Short, paralytic alpha conotoxins</td>
<td>100 mg</td>
</tr>
<tr>
<td>Diacetoxyscirpenol (DAS)</td>
<td>10,000 mg</td>
</tr>
<tr>
<td>Ricin</td>
<td>1,000 mg</td>
</tr>
<tr>
<td>Saxitoxin</td>
<td>500 mg</td>
</tr>
<tr>
<td>Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)</td>
<td>100 mg</td>
</tr>
<tr>
<td>T-2 toxin</td>
<td>10,000 mg</td>
</tr>
<tr>
<td>Tetrodotoxin</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

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
- 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).

### VI. Responsibilities

**The Principal Investigator:**

A. **Request Approval:** University of Connecticut personnel who wish to purchase or receive exempt BSAT must 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.

B. **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 Template provides assistance to create a LSBM.
   a. **Standard Operating Procedures (SOPs):** Prepare written SOPs for experiments utilizing biological agents or toxins.
C. **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:
   a. BSAT-associated hazards
   b. Engineering controls used to minimize exposure (e.g., fume hood use)
   c. Personal protective equipment (PPE) to be used when handling the BSAT
   d. Labeling (agent or toxin name, concentration of toxin)
   e. Safe handling and storage of agents
   f. Proper decontamination and disposal of undiluted stock (refer to the Biological Health and Safety Manual and Chemical Waste Disposal Manual)

D. **Storage/Security:** To ensure safety and security BSAT must be stored in the following manner:
   a. With compatible materials within secondary containment;
   b. Provided one layer of physical security (e.g., toxin secured within a locked freezer or secured within a permanently fixed lockbox).
   c. Used only by approved staff: Before becoming an approved user, the PI must ensure that each person has received training as described above.
   d. Maintain a list of PI-approved BSAT users (include those having access to BSAT materials).
   e. 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.

E. **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:
   a. Acquired (by purchase/intra-campus transfer)
   b. Depleted (by consumption /intra-campus transfer)
   c. Inactivated

F. **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.
   a. 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.

G. **IBC Registration:** PIs conducting research with BSAT must register their research with the Institutional Biosafety Committee.
H. **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](#).

**EHS- Biosafety responsibilities:**

A. **Audit each laboratory with BSAT annually.**

B. **Perform a security inspection annually.** The inspection will include, is not limited to the following:
   a. Review of approved users list to verify authorized access to BSAT.
   b. Verification of appropriate labeling, storage, secondary containment, and security measures.
   c. 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.

**VII. Procedures/Forms**

[BSAT Exempt Quantity Transfer Form](#)

**References**