



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.12, **Possession and Use of Health and Human Services (HHS) Listed Toxins in Permissible Amounts**

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSCEP) Operating Policy and Procedure (HSCEP OP) is to establish institutional requirements for the procurement, possession, storage, use, transfer, disposal, training, and security of HHS listed toxins in permissible amounts as permitted by 42 CFR 73.3 (HHS Select Agents and Toxins). These requirements have been established to assure:

1. Safe laboratory handling, use, and storage procedures for HHS listed toxins in permissible amounts;
2. Effective tracking and security of the regulated toxins; and
3. Compliance with federal, state, and local rules, regulations, and laws.

REVIEW: This HSCEP OP will be reviewed by June 15 of every odd-numbered year (ONY) by the Director of Safety Services or designee, with recommendations for revisions submitted to the Vice President for Research (VPR) or designee by June 30.

POLICY/PROCEDURE

1. Compliance with federal, state, and local laws.

TTUHSCEP has adopted and continues the policy that all research involving permissible amounts of HHS listed toxins shall be in accordance with applicable federal, state, and local rules, regulations; including but not limited to: 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

2. Permissible Toxin Amounts:

- a. A Principal Investigator (PI) may possess no more than the published amount of a toxin defined as permissible by HHS (http://www.selectagents.gov/Permissible_Toxin_Amounts.html). Table 1 lists the specific HHS listed toxins with maximum permissible amounts.
- b. PIs shall ensure that the total aggregate quantity of a toxin (regardless of type or form) does not exceed the permissible HHS defined amount at any given time. A PI may not intentionally or accidentally exceed any permissible toxin amount so as to commit the University into registering with the Federal Select Agent Program. Exceeding HHS permissible toxin amounts may result in the revocation of purchasing privileges of any HHS listed toxin and/or institutional termination of all permissible toxin associated protocols (i.e. IBC, IACUC, IRB) and reporting of protocol termination to any applicable funding agency.

Any PI who willfully exceeds the published HHS listed toxin permissible limit and does not register with the Federal Select Agent Program may be subject to civil or criminal penalties as prescribed by law (Public Health Security & Preparedness Response Act of 2002, §231(c)).

- c. Procurement, possession, storage, use, transfer, disposal, training, and security of HHS permissible toxin amounts must meet the requirements of Attachment A of this OP; "Operational/Procedural Requirements for Possession and Use of HHS Listed Toxins in Permissible Amounts."

- d. Once a PI has fulfilled the requirements of Attachment A, an Institutional Biosafety Committee (IBC) protocol registration for the specific HHS toxin must be reviewed and approved by the IBC before HHS listed toxins may be procured. This includes purchases from vendors and transfers from other PIs or institutions.
- e. Toxins shall not be transferred to University personnel that do not have institutional approval to work with the specific HHS toxin in permissible amounts.
- f. Toxins shall not be provided or shipped to non-University individuals under any circumstance.
- g. Only paid TTUHSCEP personnel are eligible for consideration to work with HHS toxins or be included on HHS toxin protocols.

**Table 1
Maximum Permissible Amount per Toxin per PI**

SA Toxin	Exempt Quantity	SA Toxin	Exempt Quantity
Abrin	100 mg	Saxitoxin	100 mg
Botulinum neurotoxins	0.5 mg	Staphylococcal Enterotoxins (Subtypes A,B,C,D and E)	5 mg
Short, paralytic alpha Conotoxins	100 mg	T-2 Toxin	1000 mg
Diacetoxyscirpenol (DAS)	1000 mg	Tetrodotoxin	100 mg
Ricin	100 mg		

3. Audits/Inspections:

- a. Each PI possessing HHS listed toxins in permissible amounts must perform and document quarterly safety/security audits of the HHS listed toxin(s) in possession. Appendix B, "HHS Listed Toxins in Permissible Amounts Laboratory Self-Inspection Checklist" will be used to perform these audits.
- b. The Department of Safety Services will conduct quarterly laboratory audits to review compliance with this OP.

4. Toxin Quantities Exceeding Permissible Amounts

- a. IBC protocol submissions that require the use of HHS listed toxins in quantities greater than what is considered permissible by HHS will require institutional registration with the Federal Select Agent Program. Institutional participation in the Federal Select Agent Program must be approved by the VPR or designee and obtained by the University. These protocols will not be reviewed without the approval of the VPR or designee.

b. Additional Information:

Questions regarding Federal Select Agent Program regulations should be directed to the Office of Safety Services.