



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.04, **Research Involving Controlled Substances and Laboratory Apparatus**

PURPOSE: This Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) describes the use of controlled substances and laboratory apparatus in research activities at TTUHSC El Paso.

REVIEW: This HSCEP OP will be reviewed on June 1 each odd-numbered year (ONY) by the Attending Veterinarian, Assistant Managing Director of Office of Research (OR) or designee, and the Senior Director of Safety Services, with recommendations for revisions submitted to the Vice President for Research (VPR) by June 15.

POLICY/PROCEDURE:

I. OVERVIEW

Controlled substances are drugs or other substances, or immediate precursors, included in schedule I, II, III, IV, or V of the Controlled Substances Act (CSA), 21 USC, Chapter 13; and 21 CFR Part 1300-End. Drugs and substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. These materials are regulated by the U.S. Department of Justice, Drug Enforcement Administration (DEA), Office of Diversion Control, and the Texas Department of Public Safety (DPS) Controlled Substances Registration Program. Lists of controlled substances are designated in the DEA controlled substance schedules https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.

The Texas Higher Education Coordinating Board (THECB) has entered into a Memorandum of Understanding (MOU) with the DPS to establish the responsibilities of the DPS, the THECB, and the public or private institutions of higher education for implementing and maintaining a program for reporting information concerning controlled substances, controlled substance analogues, chemical precursors, and chemical laboratory apparatus used in education or research activities of institutions of higher education. [MOU](#)

II. APPLICABILITY

This policy applies to non-clinical, research use of controlled substances by Principal Investigators (PIs) employed by TTUHSC El Paso as outlined in [HSCEP OP 73.08](#).

TTUHSC El Paso does not maintain a campus-wide registration for controlled substances. Federal and state regulations require that each PI obtain appropriate licenses, permits, registrations, and adhere to applicable federal and state regulatory requirements when working with controlled substances. TTUHSC El Paso maintains a record of controlled substance(s) and authorized users through the Institutional Biosafety Committee.

Note: The guidance information in this HSCEP OP is not intended to cover all applicable parts of the DEA and DPS rules. PIs are expected to be familiar with and to comply with all DEA and DPS

rules related to obtaining, storing, using, and disposing of controlled substances. If information in this policy conflicts with DEA or DPS regulations, the federal and state rules will supersede this policy.

III. LICENSING AND REGISTRATION

PIs must register with the federal DEA to obtain the appropriate license or registration for the controlled substances to be used, prior to initially obtaining and using controlled substances.

- A. **Federal Registration:** The PI must first obtain federal licensure from the DEA. The application can be obtained from the DEA website: [DEA Controlled Substance Registration](#).

- B. **THECB MOU:** The PI must follow TTUHSC El Paso's program within his/her laboratory for reporting information concerning controlled substances, controlled substance analogues, chemical precursors, and chemical laboratory apparatus used in education or research activities. This program will address the sale, furnishings or transfer of controlled items, including glassware, covered by the MOU to any person or entity not holding a Federal DEA permit, unless the recipient is specifically exempted by law or rule. The PI must notify TTUHSC El Paso Department of Safety Services prior to any sale, furnishings or transfer of controlled items covered by the MOU ([HSCEP OP 63.11](#)).

- C. **Notification:** Copies of all registration and licensing related correspondence shall be maintained by the PI. Copies of the DEA license shall be provided to the Department of Safety Services and uploaded to the user's account via the iRIS system, prior to initial ordering of controlled substances, and following renewal or amendment to the license. A copy of the PI's license should also be stored with the Controlled Substance use records.

Compliance with all federal and state regulations is the sole responsibility of the PI as licensee. Failure to comply with applicable rules and regulations may result in loss of license, penalties, fines, or other actions.

IV. TRAINING

All licensed PIs and their authorized users shall complete the TTUHSC El Paso Controlled Substances Training Module every three (3) years. Authorized users are individuals whom the PI has designated as being allowed to conduct work with controlled substances, and who have completed all required training in the safe and compliant use of those materials. The PI is responsible for ensuring that all appropriate DEA and TTUHSC El Paso training has been completed by authorized users. This information is documented within the Institutional Biosafety Committee study application.

V. ANNUAL SAFETY EVALUATION

All licensed PIs using controlled substances will receive an annual Controlled Substances Safety Evaluation - (See Attachment A to this policy). These inspections will be completed by Safety Services and a copy of the inspection form shall be provided to the PI. This document shall be maintained by the PI for one year.

VI. **AUDITS AND INSPECTIONS**

PIs with approved IACUC protocols for use of controlled substances with animals may be audited by the IACUC twice per year and by Safety Services annually. PIs who do not have IACUC protocols for use of controlled substances may be audited by Safety Services three times per year. These audits will include reviews of recordkeeping and security related to the applicable federal and state rules and the THECB MOU.

VII. **PURCHASING**

Only licensed PIs shall be able to order DEA scheduled drugs. Before placing a first order for controlled substances, PIs shall consult with the TTUHSC El Paso Purchasing Department, Office of Research Resources, and/or Safety Services, as applicable or appropriate, to review applicable rules. The Purchasing Department will route all requisitions of controlled substances to the department of Safety Services for review and approval. This will ensure that only licensed PIs are allowed to place orders for controlled substances.

Controlled substances must be purchased by the DEA registrant, for use only by that registrant. Controlled substances may not be transferred to, or borrowed from another faculty member.

Controlled substances shall not be purchased using TTUHSC El Paso Purchasing Cards (P-Cards) ([HSCEP OP 72.15](#)) or personal credit cards. Such activities may result in loss of P-Card privileges or other administrative actions. Purchases of controlled substances shall be made through the TTUHSC El Paso Purchase Order process.

VIII. **STORAGE AND SECURITY CONTROLS**

In order to guard against theft or diversion, all controlled substances shall be kept under lock and key, with access limited only to the PI and authorized users. The number of authorized users shall be kept to the minimum essential for operation, and the stocks of controlled substances shall be limited to the smallest quantity needed for the project(s). The PI shall limit the number of keys allowing access to the controlled substances, and follow the established key control procedure for the laboratory.

Controlled substances shall be stored in a safe. This safe shall be kept locked at all times. The room in which the safe is located shall have limited access during working hours and shall be locked when unattended.

All controlled substances shall be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them. Students shall not be given unsupervised access to controlled substances.

Controlled substances possessed, kept, or otherwise stored in a manner or location not in compliance with federal or state law, are subject to seizure by and forfeiture to federal or state authorities. Failure to comply with applicable requirements may also result in suspension of purchasing privileges, suspension of the applicable research protocol, and disciplinary actions. The licensed PI is responsible for any misuse of controlled substances which occur in his/her lab.

IX. **RECORDKEEPING**

PIs shall maintain complete and accurate inventory records for all controlled substances. These records shall be kept separate from all other records and documents, in or near the primary work area, and be available for inspection as needed during regular work hours. When controlled substances are utilized as part of an IACUC-approved animal protocol, the controlled substance records will be reviewed as part of routine, semi-annual lab inspections.

The records shall be kept in English and free from codes or shorthand. All records shall be maintained by PIs for a period of at least two years from the date of the last recorded transaction.

The recordkeeping system shall include the following information:

- A. Receipt of Controlled Substances: The PI shall maintain a separate and current record of the receipt of controlled substances, indicating date received, name and address of supplier, the type, strength or concentration, and the amount of the controlled substances received. Each record shall be signed by the person receiving the controlled substance (See Appendix B— Receipt of Controlled Substance Log Form). In addition, the controlled substances shall also be recorded in the PI's hazardous materials database (SciShield) within one-week of receipt.
- B. Use of Controlled Substances: The PI shall maintain separate and current record for the storage and use of each controlled substance, indicating the date, type, strength and quantity of each controlled substance used or disposed. By noting starting volume or mass of substance in the container, each use or disposal is a subtraction from the starting quantity, and the running (decreasing) amount should equal the total amount remaining on-hand. Each record of use shall be signed by the person working with the controlled substance (See Appendix C—Use of Controlled Substance Log Form).
- C. Inventory of Controlled Substances: A complete and accurate inventory of the stock of controlled substances within each registrant's laboratory must be performed initially. The type, strength, and quantity of all controlled substances must be recorded at this time. The person conducting the inventory must also date and sign the record.
- D. Biennial Inventory: After the initial inventory is taken, a new inventory of all stocks of controlled substances on hand shall be conducted at least every two years per Federal regulations. PIs shall assure that the inventory can be reconciled to the records of receipt, use, and disposal at all times (See Appendix D—Inventory of Controlled Substance Record).

X. DISPOSAL

Controlled substances shall be disposed by notifying Safety Services who will utilize a 3rd party approved vendor. . Expired licensed materials or unused products must be stored under lock and key until properly disposed (See Appendix E—Disposal of Controlled Substance Record). The PI shall place all waste into an approved receptacle in preparation for its chemical destruction. Once the material is destroyed, the receptacle shall be disposed of, in coordination with Safety Services, through the approved waste vendor. A waste manifest verifying the final destruction of the controlled substances will be provided to the PI and Safety Services. This document shall be kept on file by both the PI and Safety Services for two years, or as otherwise mandated by the DEA. Controlled substances injected into research animals, consumed in a reaction, or irrecoverably comingled may be disposed of through the university's waste disposal procedure. In addition, the controlled substance shall be removed from the hazardous materials database (SciShield) within one week of disposal.

It is the responsibility of the PI to plan accordingly when controlled substances are expiring. Controlled substances must be disposed of no later than one month past the expiration date. If there are delays in the disposal process, upon inspection, the PI must be able to show proof that the disposal process has been initiated. No controlled substances will be approved for purchase until all expired drugs are disposed of. The sale, furnishings, or transfer of controlled items, including glassware, covered by the THECB/DPS MOU to any person or entity not holding a DPS

permit, unless the recipient is specifically exempted by law or rule, is prohibited. Sale of these items through TTUHSC El Paso Surplus Property is also prohibited.

XI. REPORTING OF LOSS, DESTRUCTION, THEFT, OR UNAUTHORIZED USE

In the event that any controlled substances are lost, destroyed, or stolen, the kinds and quantities of the materials and the date of discovery of such loss must be recorded in detail. Thefts, suspected thefts, unauthorized uses, or other losses of any controlled substance must be immediately reported [within one (1) hour of discovery] to the Texas Tech University Police Department (or appropriate local law enforcement agency) and the Department of Safety Services. Registrants must also document the incident to federal DEA and the DPS. Reporting to the DEA must be within one (1) business day using DEA Form 106, See [DEA Form https://apps.dea diversion.usdoj.gov/TLR/](https://apps.dea diversion.usdoj.gov/TLR/)

XII. TERMINATION, TRANSFER, OR SURRENDER OF DEA REGISTRATION (CLOSEOUT PROCEDURES)

Controlled substances are registered to an individual Principal Investigator (PI) and a specific registered location. Controlled substances may not remain active in a laboratory when a PI departs, relocates, retires, or surrenders their DEA registration. The following procedures apply to all controlled substance closeouts. The PI must notify Safety Services in writing as soon as departure or registration termination is known. TTUHSC El Paso reserves the right to conduct a compliance review prior to final closeout approval. No new controlled substances may be ordered once closeout procedures have been initiated.

Prior to departure or termination of registration, the PI must:

- a. Conduct a complete and accurate final inventory of all controlled substances on hand.
- b. Record the drug name, strength, dosage form, quantity on hand, and date of inventory.
- c. Sign and date the inventory record.
- d. Reconcile all inventory against receipt, use, and disposal records.
- e. Provide a copy of the final inventory to Safety Services.
- f. This inventory shall be maintained with controlled substance records for a minimum of two (2) years or longer if required by regulation.

Disposition of Controlled Substances

All controlled substances must be properly disposed of or legally transferred prior to the PI's departure or registration termination.