



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

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

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

REVIEW: This HSC OP will be reviewed on June 1 each odd-numbered year (ONY) by the Assistant Vice President for Research Integrity, and the Senior Director of Safety Services, with recommendations for revision forwarded to the Senior Vice President for Research and Innovation (SVPRI) by June 15.

POLICY/PROCEDURE:

1. 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 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 ([lists of DEA Controlled Substances](#)).

The Texas Higher Education Coordinating Board (THECB) has entered into a Memorandum of Understanding (MOU) between the Texas Department of Public Safety and the Texas Higher Education Coordinating Board 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. TTUHSC, as a public institution of higher education, will implement and maintain an appropriate reporting program as indicated in the [MOU](#).

2. APPLICABILITY.

This policy applies to non-clinical, research use of controlled substances by Principal Investigators (PIs) employed by TTUHSC ([HSC OP 73.08](#)).

TTUHSC does not maintain a campus-wide registration for controlled substances. Federal and state regulations require that each Principal Investigator (PI) obtain appropriate licenses, permits, and registrations, and adhere to applicable federal and state regulatory requirements when working with controlled substances.

Note: The guidance information in this HSC OP is not intended to cover all applicable parts of the DEA and DPS rules. Principal Investigators 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.

3. LICENSING AND REGISTRATION.

PIs must register with the federal Drug Enforcement Administration (DEA) and the Texas Department of Public Safety (DPS) to obtain the appropriate license or registration for the controlled substances to be used, prior to initially obtaining and using controlled substances.

- i. **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](#). DEA registrations remain active for a 1-year period. (State of Texas no longer issues state licenses for controlled substances.)
- ii. **THECB/DPS MOU:** The PI must implement and maintain a 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 DPS permit, unless the recipient is specifically exempted by law or rule. The PI must notify TTUHSC Department of Safety Services prior to any sale, furnishings or transfer of controlled items covered by the MOU ([HSC OP 63.11](#)).
- iii. **Notification:** Copies of all registration and licensing related correspondence shall be maintained by the PI. Copies of the DEA and DPS licenses shall be provided to the Institutional Animal Care and Use Committee (IACUC) and the TTUHSC Research Compliance Officer at TTUHSC-Lubbock Mail Stop 8146, or email a PDF to researchoffice@ttuhsc.edu prior to initial ordering of controlled substances, and following renewal or amendment to the license.

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.

4. TRAINING.

All licensed PIs and their authorized users shall complete the TTUHSC Controlled Substances Training Module every three (3) years. Authorized Users are individuals identified by the PI to conduct work with controlled substances, and who have completed all required training in the use of those materials and the applicable federal and state rules.

5. ANNUAL SELF-EVALUATION.

All licensed PIs using controlled substances shall complete a Controlled Substances Self-Evaluation at least annually (See Attachment A to this policy). These forms shall be maintained by the PI for at least one year.

6. REVIEW AND INSPECTION.

All Principal Investigators with DEA licenses for research purposes will have their use of controlled substances reviewed by the Research Compliance Officer at least once per year. The reviews will focus on recordkeeping and security related the applicable federal and state rules of the THECB/DPS MOU. Any problems noted during these reviews will be shared, in writing, with the investigator, the Senior Director of Safety Services, the TTUHSC Institutional Biosafety Committee and the SVPRI. Depending on the nature of the violation, the Texas Department of Public Safety and/or the DEA may also be notified.

Supplemental reviews may be conducted during routine semi-annual IACUC inspections for those investigators with approved IACUC protocols for use of controlled substances with animals.

PURCHASING.

Only licensed PIs shall order DEA scheduled drugs. Before placing a first order for controlled substances, PIs shall consult with the TTUHSC Purchasing Department, Office of Research, and/or Safety Services, as applicable or appropriate, to review applicable rules.

All research involving controlled substances must be approved by the appropriate institutional oversight committee prior to the start of any project. The Institutional Animal Care and Use Committee (IACUC) must approve research projects involving animals and controlled substances. The Institutional Review Board (IRB) must approve research projects involving humans and controlled substances. In addition, according to the scope of the project, approval by the Institutional Biosafety Committee (IBC) may be required.

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

7. 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. A list of Authorized Users shall be provided to the IACUC (for those PIs with approved IACUC protocols for use of controlled substances with animals) and Safety Services. Changes to the list of Authorized Users shall be provided to the IACUC and Safety Services within 30 days of the change. 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 establish key control procedures for the laboratory.

Controlled substances shall be stored in a safe (affixed to a bench or wall to prevent removal) or a substantially constructed cabinet with appropriate lock(s). This safe/cabinet shall be kept locked at all times. The room in which the cabinet 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, other than those designated as Authorized Users, 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 and disciplinary actions. The licensed PI is responsible for any misuse of controlled substances which occur in his/her lab.

8. RECORDKEEPING.

Principal Investigators 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:

- i. Receipt of Controlled Substances: A separate and current record of the receipt of controlled substances, indicating date received, name and address of supplier, and the type, strength or concentration, and amount of the controlled substances received shall be maintained. Each record shall be signed by the person receiving the controlled substance (See Attachment B—Receipt of Controlled Substance Log Form).
- ii. Use of Controlled Substances: A separate and current record for the storage and use of each controlled substance, indicating the date, laboratory building and room, specific research experiment, controlled substance's application in the research, and type, strength and quantity of each controlled substance used or disposed shall be maintained. 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 Attachment C—Use of Controlled Substance Log Form).
- iii. 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. 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. PIs shall assure that the inventory can be reconciled to the records of receipt, use, and disposal at all times (See Attachment D—Inventory of Controlled Substance Record).
- iv. Disposal: Each disposal of unused or expired controlled substances shall be documented (See Attachment E – Disposal of Controlled Substance Record).

9. **DISPOSAL.**

Controlled substances shall only be disposed by returning to a properly licensed or permitted reverse distributor or other source. PIs shall contact Safety Services for assistance with identifying authorized disposal services. Expired licensed materials or unused products must be stored under lock and key until properly disposed (See Attachment E—Disposal of Controlled Substance Record). Controlled substances injected into research animals, consumed in a reaction, or irrecoverably comingled may be disposed through the university's online [Request for Disposal of Chemicals](#).

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 Surplus Property is also prohibited.

10. **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 TTU 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, and utilize DEA Form 106 (See [DEA Theft or Loss of Controlled Substances](#)).