



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 52.17, **Controlled Substances Policy**

PURPOSE: The purpose of this Health Sciences Center Operating Policy (HSC OP) is to provide overarching guidance in the implementation of the various Texas Tech University Health Sciences Center (TTUHSC) controlled substances policies at the school and entity level for both clinical and non-clinical use. TTUHSC is committed to complying with federal and state regulations involving controlled substances and controlled items. **Any TTUHSC school or entity using or planning to use controlled substances for either a clinical or non-clinical purpose is required to have a policy and procedure which complies with the minimum requirements outlined in this policy and applicable federal and state laws, rules, and regulations.**

REVIEW: This HSC OP will be reviewed on January 15 of each odd-numbered year by the Senior Director for Safety Services, the Vice President for Institutional Compliance, and the Senior Vice President for Research with recommendations for revisions, forwarded to the President by February 1.

POLICY:

1. BACKGROUND

- a. Many substances that are used for legitimate medical and scientific research purposes are otherwise illegal. The Controlled Substances Act (21 USC Chapter 13) is the statutory framework through which the federal government regulates the lawful production, possession, and distribution of controlled substances. The Office of Diversion Control in the U.S. Drug Enforcement Administration (DEA) administers and enforces these regulations under Title 21 Code of Federal Regulations Part 1300.
- b. Use of controlled substances in Texas is considered to be within the purview of a "Controlled Substance Professional" and, as such, the user must be registered and/or licensed by the DEA (**Effective September 1, 2016 Texas Controlled Substances Registrations are no longer required. Active and current DEA registrations are still required. Contact your state licensing board for more information.**). In addition, the Texas Higher Education Coordinating Board (THECB) has entered into a Memorandum of Understanding (MOU) with the Texas Department of Public Safety (DPS) in order to establish the responsibilities of the THECB, the DPS, and the public or private institutions of higher education in Texas 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.¹
- c. Controlled substances are categorized into five "schedules" by 21 USC §812 (Schedule of Controlled Substances) depending on how dangerous and/or addictive they are and to what extent they have accepted medical uses.
- d. The Controlled Substances Act regulates use and requires users to be registered with the DEA (21 USC §§822(b), 823). Federal regulations include requirements pertaining to

¹The State of Texas publicly posts this MOU. To ensure viewing of the most recent version, visit Texas.gov (*see, e.g., <https://reportcenter.highered.texas.gov/agency-publication/policies-and-procedures/departments-of-public-safety-dps-and-texas-higher-education-coordinating-board-thecb-controlled-substance-memorandum-of-understanding-mou/>*).

secure storage; recordkeeping; inventorying; reporting loss, theft, or abuse; and safe disposal.

2. RESPONSIBILITIES

It is the policy of TTUHSC to prohibit the unlawful purchase, manufacture, distribution, possession, selling, storing or use of controlled substances in or on premises or property owned or controlled by TTUHSC. TTUHSC faculty and staff engaged in clinical or non-clinical activity that involves the use of DEA controlled substances will be responsible for registering or obtaining appropriate licensure and for assuring compliance with applicable state and federal regulations. The registrant/licensee must not allow the permit/license to lapse until all controlled substances are spent, disposed of, or transferred to another registered/licensed person. TTUHSC schools and entities preparing respective controlled substances policies and procedures must incorporate, at a minimum, the following points:

- Areas and individuals authorized to purchase and utilize controlled substances, including appropriate, required registration and/or licensing.
- Adequate physical security, containment, and internal controls to mitigate and identify potential diversions.
- Record-keeping and inventory monitoring requirement, including documentation of acquisition, usage, disposal, dates, and quantities on hand.
- Appropriate disposal procedures.
- Reporting of theft, loss, unauthorized use, or abandonment.
- Compliance with all applicable state and federal regulations addressing controlled substance usage.

The TTUHSC Safety Services and the TTUHSC Research Integrity Office will be responsible for assisting entities and individuals engaged in non-clinical (e.g., research) use of controlled substances in complying with applicable rules and regulations. This will include educating faculty and staff about the requirements, and providing regular oversight to ensure compliance. Those conducting research utilizing controlled substances should refer to [HSC OP 73.04](#), Research Involving Controlled Substances and Laboratory Apparatus. TTUHSC schools, departments, clinics, labs, and individuals engaged in clinical use, including dispensing of controlled substances, will be guided and monitored by the TTUHSC Office of Institutional Compliance.

The information in this HSC OP is not intended to cover all applicable parts of the DEA, DPS, and THECB rules and regulations. Schools, TTUHSC entities, and individuals are expected to be familiar with and to comply with all DEA, DPS and THECB rules and regulations related to obtaining, storing, using and disposing of controlled substances. If information in this policy conflicts with DEA, DPS, THECB rules and regulations, the federal and state rules and regulations will supersede this policy. Compliance with all federal and state laws and regulations is the sole responsibility of the registrant/licensee. Failure to comply with applicable rules and regulations may result in loss of license, penalties, fines or other actions, including but not limited to disciplinary action up to and including termination in accordance with TTUHSC policy.

See also: [HSC OP 73.04](#), Research Involving Controlled Substances and Laboratory Apparatus