

I. Introduction

TCU researchers may find that, in the course of pursuing knowledge, it becomes necessary to conduct lawful research using substances that are regulated by state and federal law. Due to the potential for abuse, such substances are subject to extensive licensing, storage, use, disposal, and inventorying requirements, including the federal Controlled Substances Act and its implementing regulations (collectively, the “Act”) and applicable state law

Enforced by the United States Department of Justice, Drug Enforcement Agency (“DEA”), the Act is designed to ensure a system of security and accountability in the procurement, use, storage, and disposal of Controlled Substances, as defined below. The Act requires registration holders to document the receipt of Controlled Substances once they are ordered and to continue to document use until the time of final consumption or proper disposal. Registration holders also must track all persons with access to the substances and the places in which they are stored.

The TCU Office of Research, in collaboration with TCU Environmental Management and Safety (“EMS”), oversees the TCU Controlled Substances in Research program, which assists DEA registered, researchers at TCU that are conducting research activities with Controlled Substances with compliance with the Act.

II. Applicability

This policy and supporting procedures apply to all research with Controlled Substances that is conducted under the auspices of TCU, regardless of the source of funding or location for the activities.

This policy and supporting procedures do not apply to Controlled Substances dispensed by a practitioner to a patient in the course of professional practice as authorized by the practitioners’ license. This policy does not cover teaching activity performed within a clinical environment. However, clinical teaching activities must comply with the Act.

III. Definitions

Terms used in this policy, but not otherwise defined, have the same meaning given to them in Title 21, Chapter 13 of the Code of Federal Regulations, [Part 1300 to end](#).

Authorized Individual. Research team members, and other personnel that are authorized by the DEA Registrant to access, use, store, and/or destroy Controlled Substances. All Authorized Individuals must be directly supervised by the DEA Registrant.

Biennial Inventory. A detailed inventory of all controlled substances at DEA Registrant’s location on a specified date and time.

Controlled Substance. Any substance that is listed in the Act: [List of Controlled Substances](#). Controlled substances are drugs that are further classified as Schedule I-V based on their potential to be habit forming and on their usefulness in medicine as a drug. Controlled Substances should only be lawfully obtained by individuals and institutions with a valid DEA Registration.

- Schedule I - No currently accepted medical use. Has the highest potential for abuse. (e.g., GHB, heroin, marijuana)
- Schedule II - Currently accepted medical use with restrictions. High potential for abuse with severe psychological or physical dependence. (e.g., amphetamine, methamphetamine, cocaine, codeine, morphine, meperidine, methylphenidate, pentobarbital (Nembutal))
- Schedule III - Currently accepted medical use. Abuse of drug may lead to moderate to low physical dependence or high psychological dependence. (e.g., Ketamine, Telazol, testosterone, pentothal. Euthasol is a Schedule III due to pentobarbital/phenytoin mix)
- Schedule IV - Currently accepted medical use. Low potential for abuse relative to Schedule III. (e.g., barbitol, butorphanol, chloral hydrate, diazepam)
- Schedule V - Currently accepted medical use. Low potential for abuse relative to Schedule IV (e.g., buprenorphine and Zolpidem).

DEA Registration. Registration by the DEA that authorizes a TCU employee to purchase, possess, distribute or prescribe Controlled Substances for research purposes.

DEA Registrant. A TCU employee that holds a DEA Registration for research purposes.

Disposal. Disposal of expired, excess and unwanted controlled substances. Disposal also refers to Controlled Substances that are residual (often referred to as waste) or have been contaminated through use.

Disposition Records. An accurate, continuous and current record used to track the acquisition, use and disposal of controlled substances. These are not the same as lab books that a researcher uses to record scientific findings.

Location. A room or designated area where Controlled Substances are stored or used. A location has a single address and has a DEA Registrant with which it is associated.

Principle Investigator ("PI"). The lead scientist, engineer, or researcher for a particular project.

Research. Systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge

IV. Policy Requirements

- A. All TCU employees and other individuals using Controlled Substances in TCU research must comply with all applicable TCU policies and procedures, and law, including the Act.
- B. Only DEA Registrants and Authorized Individuals identified to the Office of Research may be involved with the use of Controlled Substances in TCU Research. No person who has been convicted of a felony offense related to Controlled Substances or who has had an application for DEA Registration denied or has surrendered a DEA Registration for case may be an Authorized Individual.

- C. Any person who has knowledge of drug diversion associated with the use of Controlled Substances in TCU Research has an obligation to report such information to the DEA, and TCU Research Integrity Officer.
- D. Responsibilities.
1. Office of Research
 - Oversee the Controlled Substance Program
 - Maintain list of DEA Registrants and Authorized Individuals
 - Provide consultation regarding regulatory compliance
 2. EMS Risk Management Environmental Health and Safety
 - Provide consultation regarding safe use, storage, and disposal
 - Dispose of Controlled Substances, as necessary and authorized
 3. DEA Registrant
 - Maintain an active DEA Registration in good standing
 - Identify themselves and all Authorized Individuals to the Office of Research no less than on an annual basis
 - Manage the access, storage, use, and disposal of Controlled Substances authorized to be under the DEA Registrant's control
 - Grant "Authorized Individual" status for all staff and students that may have access to Controlled Substances under the DEA Registrant's control because of such individuals participation in the DEA Registrant's research
 - Comply with all applicable TCU policies and procedures, and law
 - Ensure compliance with all applicable TCU policies and procedures by all research team members
 - Provide appropriate secured storage of Controlled Substances
 - Restrict access to Controlled Substances under the DEA Registrant's control to only Authorized Individuals
 - Maintain usage logs, inventories, and copies of purchase orders for 3 years
 - Timely dispose of any expired or no longer needed Controlled Substances
 - Promptly notify the DEA of suspected theft, or any other incidents missing Controlled Substances
 - Comply with any inspection, inquiry, or investigation by Research Integrity Officer, and/or the DEA
 4. Research/Lab Personnel
 - Obtain "Authorized Individual" status prior to any activities associated with Controlled Substances and List/Precursor Chemicals
 - Comply with all applicable TCU policies and procedures, and law
 - Complete and submit all necessary forms to the Office of Research

- Comply with the directions for storing, using, and disposing Controlled Substances given by the PI, provided such instructions are consistent with applicable TCU policies and procedures, and law
- Assist PI with maintenance of accurate records of the acquisition, use, and disposition of controlled substances
- Use proper personal protective equipment and adhere to safe practices while using controlled substances
- Promptly notify Office of Research of suspected theft, significant volume discrepancies, or any other incidents missing Controlled Substances

V. Enforcement

Failure to comply with this Policy could result in disciplinary action, including termination of employment.

VI. Questions/Reports

If you have any questions about this Policy or would like to report a potential violation, please contact the Research Integrity Officer. Reports regarding violations of this Policy may be submitted anonymously by using the independent Ethics and Compliance Hotline at 1-877-888-0002.

VII. Related Research Policies and Procedures

Research Integrity Policy and Procedures
Use of Controlled Substances in Research Procedures

VIII. DEA Contact Information

10160 Technology Boulevard East

Dallas, TX 75220

(817) 639-2000

IX. History

Effective Date: July 19, 2018

Last Revised Date: July 19, 2018