# **DEA Controlled Substances**

#### Overview

Due to their abuse potential, items identified by the US Department of Justice, Drug Enforcement Administration (DEA) as controlled substances are subject to extensive licensing, registration, storage, security, use, and disposal requirements.

Controlled substances are materials containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and having the tendency to promote abuse or physiological or psychological dependence, as designated in state and federal controlled substance schedules. See a list of DEA controlled substances.

## **Licensing and Registration**

Since the University cannot, by law, maintain a campus wide registration for controlled substances, it is the responsibility of each individual PI to obtain appropriate licenses and registration, and to adhere to applicable state and federal regulatory requirements when working with controlled substances. PIs must register their controlled substance(s) with the federal DEA.

1. **Federal Registration:** You will need to complete the <u>DEA registration application</u>. DEA registrations remain active for a 1-year period.

## **Storage and Security Controls**

Controlled substances possessed, kept, or otherwise stored in a manner or location not in compliance with state or federal law is subject to seizure by and forfeiture to the state. Failure to comply with applicable requirements may also result in a suspension of purchasing privileges and disciplinary actions.

In order to guard against theft or diversion, all controlled substances, regardless of schedule, must be kept under lock and key, and accessible only to authorized personnel. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stocks of controlled substances to the smallest quantity needed.

All controlled substances must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

Controlled substances must be stored in a substantially constructed cabinet. This cabinet must be kept locked at all times. The room in which the cabinet is located must have limited access during working hours and provide security after hours.

## **Disposal**

Controlled substances may only be disposed by returning to a reputable pharmaceutical return company. Expired material or unused product must be accumulated and stored under lock and key until ready for disposal. Controlled substances injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures by EHS.

## Reporting of Loss, Destruction, Theft, or Unauthorized Use

Thefts, suspected thefts, unauthorized uses, or other losses of any controlled substance must be reported to the Baylor Police Department and EHS upon discovery. Registrants must also document the incident to the federal DEA. See Theft or Loss of Controlled Substances, DEA.

# Recordkeeping

PIs must maintain complete and accurate inventory records for all controlled substances. These records must be kept separately from all other records and documents, in or near the primary work area, and be available for inspection during regular work hours. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited. In the event that any controlled substances are lost, destroyed, or stolen, the kind and quantity of the material and the date of discovery of such loss must be recorded in detail. All records must be maintained by PIs for a period of at least two years from the date of the last recorded transaction.

The recordkeeping system should include the following information:

- Receipt of Controlled Substance: A separate and current record on 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. Each record must be signed by the person receiving the controlled substance.
- 2. **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 use. By noting starting volume or mass of substance in the container, each use is a subtraction from the starting quantity, and the running (decreasing) amount should equal the total amount remaining on-hand. Each record of use must be signed by the person working with the controlled substance.
- 3. 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 should be conducted at least every two years.

Note: the guidance information above is not intended to cover all applicable parts of the DEA rules. For further information on the requirements for controlled substances be sure to review the DEA website.

## MOU Controlled Laboratory Substances Fact Sheet

## PI and Lab Personnel Responsibilities

- Lock all doors/windows when the room is not occupied.
  - Establish specific locations where controlled items are utilized and/or stored.
  - Restrict access to the room to authorized personnel; establish key control so only authorized personnel can access the room.
  - Establish procedures to assure proper use of controlled items in laboratories and storerooms.
  - Beware of unauthorized personnel in the laboratory.
  - Be alert and attentive to disappearance of controlled items and report losses to the Baylor University Police department at ext. 2222
  - **Do not** send controlled items to Surplus Property.
  - Review the complete procedure, MOU-Controlled Substances.

Any person with specific authority to purchase or accept controlled items must bear full responsibility for establishing security measures regarding their purchase, acceptance, use, and ultimate disposal.

### **Controlled Apparatus**

- Condensers
- Distilling apparatus
- Vacuum dryers
- Three necked flasks
- Distilling flasks
- Tableting machines
- Encapsulating machines
- Filter funnels
- Buchner funnels
- Separatory funnels
- Erlenmeyer flask
- Two-necked flasks
- Single neck flasks
- Round bottom flasks
- Thermometer flasks
- Filtering flasks
- Soxhlet extractors
- Transformers
- Flask heaters
- Heating mantle
- Adapter tubes
- Florence Flasks

#### **Controlled Chemicals**

- Methylamine
- Ethylamine
- D-lysergic acid
- Ergotamine tartrate
- Diethyl malonate
- Malonic acid
- Ethyl malonate
- Barbituric acid
- Phenylpropanolamine
- Piperidine
- N-acetylanthranilic
- Pyrrolidine
- Phenylacetic acid
- Anthranilic acid
- Anthranilic acid
- Ephedrine
- Pseudoephedrine
- Norpseudoephedrine
- Red phosphorus (by rule, TAC)
- Hydrophosphorous acid (by rule, TAC)