

Texas A&M University
Controlled Substances Guidelines
Training Module

September 2017



DIVISION OF RESEARCH

Applicability

- Guidelines for the purchase, storage, use, and disposal of controlled substances used in research and teaching activities at Texas A&M University.

Licensing and Registration Requirements

- Investigators and teaching faculty who use, or plan to use, controlled substances in their research or teaching must register with the federal Drug Enforcement Agency (DEA) and obtain a license.
- The license/registration must be obtained prior to purchasing and using controlled substances.

Obtaining DEA registration

- You may register on-line
<https://www.dea diversion.usdoj.gov/>
- You may obtain the DEA forms at any area office of the DEA.
- Registration assistance is available at
1-800-882-9539 or at
DEA.Registration.Help@usdoj.gov

Definitions

- Authorized Agent: a co-investigator, graduate student, post doc or member of laboratory staff authorized by the registrant to access the secure storage cabinet, dispense, administer, and log controlled substances.
- Controlled Substance: A drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a controlled drug. The current official schedule of controlled substances (I, II, III, IV and V) can be found at <https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>

Definitions

- Clinical Setting: A setting where a controlled substance is used in a medical or veterinary application.
- Non-Clinical Settings: A setting where a controlled substance is used in research, teaching or testing, which is not a clinical usage of the controlled substance.
- Registrant: An individual who is registered with the DEA and whose name is on the DEA license.

Responsibilities of the Registrant

- Investigators and teaching faculty who use controlled substances in the University's non-clinical settings must obtain and keep a current DEA license/registration.
- Registrants may not allow the license/registration to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

Responsibilities of the Registrant

- All faculty, staff and students are responsible for full compliance with state, and federal law and DEA regulations governing the purchase, storage, use, and disposal of controlled substances.
- **Registrants have ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability, and disposal of their controlled substances.**

Screening and Authorizing Agents

- Registrants are responsible for all security provisions pertaining to the controlled substances in accordance with the requirements of the regulations.
- Authorized agents of the registrant may engage in approved activities under the direction of the registrant.

Purchasing

- Registrants who purchase and receive Schedule I and II controlled substances must retain DEA 222 forms, purchase orders and packing receipts for two years from the date of receipt and have them available for inspection.
- Registrants who purchase and receive Schedule III-V controlled substances must retain purchase orders and packing receipts for two years from the date of receipt and have them available for inspection.

Inventory Records

- Registrants are responsible for maintaining appropriate records and inventories of all DEA controlled substance activity for a minimum of two years from the initial receipt.
- Records must provide a complete audit trail, from purchase, receipt or acquisition to dispensing or disposal.
- Records and must be readily available for review by compliance personnel or other authorized regulatory agencies.

Inventory Records

- Registrants must maintain a real-time record of the acquisition, administration, and disposal for each DEA controlled substance included on his or her inventory.
- The registrant must document the use of each DEA controlled substance.

Inventory Records

- Records pertaining to controlled substances in Schedule I and II **must** be maintained separately from all other records of the registrant.
- Records for Schedule III, IV, and V controlled substances **may** be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records.

Storage of Controlled Substances

- Storage of controlled substances must comply with federal requirements.
- Registrants are responsible for establishing and maintaining effective controls and procedures to prevent unauthorized access, theft or diversion of controlled substances.
- The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized agents. When it is necessary for non-authorized persons to enter the storage areas, the registrant shall ensure adequate observation by an authorized person.

Storage of Controlled Substances

- Registrants are directly responsible for:
 - Establishing adequate security to prevent unauthorized access to controlled substances.
 - Establishing adequate security to prevent the diversion of controlled substances.
 - Storing controlled substances in a secure location and in a securely locked, substantially constructed cabinet, or security cabinet (i.e., not easily broken into or moved).

Disposal of Controlled Substances

- The registrant is responsible for the return or disposal of controlled substances in accordance with federal requirements.
- Texas A&M University Environmental Health and Safety Office will provide assistance and guidance in this area.
 - Environmental Health and Safety will work with a reverse distributor on an individual basis to assist registrants with disposal of controlled substances.
 - Contact Jeffery Truss (jctruss@tamu.edu) or EHS (ehsd.tamu.edu) for assistance.

Destruction and Disposal Records

- Registrants must document the disposal of controlled substances and a copy of DEA Form 41 must be maintained with the registrant's records to provide accountability for the disposal of these controlled substances.
- When a registrant leaves the University or rescinds their license, arrangements for disposal and/or transfer of all their controlled substances must be made prior to departure or license termination.

Reporting Significant Loss

- The registrant must notify the local DEA field office (Houston) in writing within **one business day** after the discovery of theft or significant loss of any DEA controlled substances. A written report to the DEA, using DEA Form 106, must be submitted within 15 days after the discovery.
- The University Police Department and Animal Welfare Office should be notified along with the DEA .
- Theft or significant losses must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

Failure to Comply

- Compliance with all federal regulations is the sole responsibility of the Registrant as the DEA license holder and may result in personal, civil, and/or criminal liability.
- Failure to comply may also result in University disciplinary action and/or suspension or termination of research.

Links to DEA forms

- DEA Registration <https://www.dea diversion.usdoj.gov/>
- DEA Form 41 (Disposal of Controlled Substances)
https://www.dea diversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf
- DEA Form 106 (Reporting a Significant Loss)
https://www.dea diversion.usdoj.gov/21cfr_reports/theft/

Texas A&M University's Controlled Substance Program

- Texas A&M University's Controlled Substance Program is housed in the Division of Research's Animal Welfare Office.
- The Controlled Substance Program provides guidance to investigators and research staff on obtaining a DEA registration/license.
- The Controlled Substance Program provides registrants with information pertaining to procurement, record keeping, storage, security, and disposal of controlled substances used in research.

Contact Information

- Animal Welfare Office
 - 979-845-1828
 - animalcompliance@tamu.edu