Texas A&M University
Controlled Substances Guidelines
Training Module

September 2017
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.deadiversion.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](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.deadiversion.usdoj.gov/](https://www.deadiversion.usdoj.gov/)
- DEA Form 41 (Disposal of Controlled Substances) [https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf](https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf)
- DEA Form 106 (Reporting a Significant Loss) [https://www.deadiversion.usdoj.gov/21cfr_reports/theft/](https://www.deadiversion.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