



Standard Administrative Procedure (SAP)

15.99.05.L0.01 Using Controlled Substances in Non-Clinical Educational and Research Activities

First Approved: September 1, 2010 *(formerly numbered as 15.03.99.L1.01)*
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April 26, 2024
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Procedure Statement and Reason for Procedure

The purpose of this SAP is to internally regulate the use of controlled substances in non-clinical educational and research activities at Texas A&M International University (TAMIU).

The Texas Department of Public Safety (DPS) and the Texas Higher Education Coordinating Board (THECB) signed a [Memorandum of Understanding](#) (MOU) that establishes responsibilities at institutions of higher education for implementing and maintaining a program for reporting information concerning controlled substances used in non-clinical educational or research activities. This document defines the requirements and procedures necessary for compliance with the MOU by TAMIU.

Procedures and Responsibilities

1. REGISTRANT RESPONSIBILITIES
 - 1.1. Individuals named as a registrant on a [Drug Enforcement Administration \(DEA\) registration](#) are responsible for all aspects of ordering, storing, recording, and using controlled substances in a non-clinical setting such as, but not limited to, a research program, sponsored project, or academic course.
 - 1.2. The registrant must obtain and keep current federal DEA registration, unless exempted by law. Registrants are responsible for full compliance with state and federal law and regulations governing procuring, maintaining security, keeping records, and disposing of controlled substances.

- 1.3. The registrant may not allow the permit to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

2. SITE AND OPERATIONAL SECURITY

- 2.1 Registrants are responsible for establishing and maintaining effective controls and procedures to prevent unauthorized access, theft, or diversion of controlled substances as per federal requirements.
- 2.2 Specific locations (e.g., a laboratory or locked storage area assigned to the registrant) should be established where controlled substances are utilized and stored.
- 2.3 Controlled substances must be secured in a manner that affords a sense of safety and accountability, for example, electronic records keeping and physical security.
- 2.4 Locked storage areas containing controlled substances must be restricted to authorized personnel. Only the registrant may access the secure storage for controlled substances.
- 2.5 When controlled substances are received, registrants should confirm order for completeness with the shipping invoice, keep records of purchase, and place in the proper storage site. Purchasing records shall be maintained by the registrant.

3. PURCHASING CONTROLLED SUBSTANCES

- 3.1 Registrants who purchase and receive controlled substances must retain appropriate forms, purchase orders, and packing receipts, as per federal regulation, and are subject to audit by DPS.

4. REPORTING THEFT, UNAUTHORIZED USE, OR SIGNIFICANT LOSS

- 4.1 Registrants and all authorized personnel must be alert and attentive to the disappearance of any controlled substances.
- 4.2 Immediately upon discovery of theft or significant loss, registrants must notify the University Policy Department (UPD), EHS, and the appropriate Chair and Dean.
- 4.3 Federal regulations require that registrants notify DEA, in writing, of the theft or significant loss of any controlled substance, disposal receptacles, or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit DEA Form 106 regarding the loss or theft. DEA Form 106 can be completed via [Theft/Loss Reporting Online \(TLR\)](#).
- 4.4 Theft or significant loss must be reported regardless of whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified, and action taken against them.

5. INVENTORY RECORDS

- 5.1 The registrant is responsible for maintaining appropriate records and inventories of all controlled substances where licensed activity is conducted at the University, as per federal regulations.
- 5.2 A full and complete inventory of all controlled substances must be completed every year by the registrant, and a list of all substances used that year may be requested by EHS.
- 5.3 Procedures must be established by each registrant to monitor their use of controlled substances. The record book must include a complete listing of all controlled substances used along with a running inventory of their usage. See Attachments below under

Appendix for examples of record keeping documents.

6. DISPOSAL

- 6.1 Disposal of controlled substances must be in accordance with federal and state regulations/rules.
- 6.2 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.

7. FAILURE TO COMPLY

- 7.1 Failure to comply with federal and state requirements may result in personal, civil, and/or criminal liability. In addition, noncompliance may result in University disciplinary action and/or suspension or termination of research.
- 7.2 Controlled substances may not be sold, furnished, or transferred except as permitted by state and federal laws and regulations.

Related Statutes, Policies, Regulations, or Rules

¹ Code of Federal Regulations, Title 21, Chapter II: Drug Abuse Prevention and Control:

<https://www.deadiversion.usdoj.gov/schedules/schedules.html>

<https://www.ecfr.gov/current/title-21/chapter-II>

² Texas Health and Safety Code, Title 6, Subtitle C, Chapter 481: Texas Controlled Substances Act:

<https://statutes.capitol.texas.gov/Docs/HS/pdf/HS.481.pdf>

[System Regulation 15.99.05, Research Compliance](#)

Memorandum of Understanding (MOU) between the Texas Department of Public Safety (DPS) and the Texas Higher Education Coordinating Board (THECB) <https://reportcenter.highered.texas.gov/agency-publication/policies-and-procedures/department-of-public-safety-dps-and-texas-higher-education-coordinating-board-theccb-controlled-substance-memorandum-of-understanding-mou/>

Definitions

Non-Clinical Setting – A setting where a controlled substance is used in research, teaching, or testing, which is not a clinical usage of the controlled substance.

Controlled Substance – A drug or other substance listed in the United States Drug Enforcement Administration (DEA) Schedules I through V¹ or Penalty Group 1 through 4 of the Health and Safety Code, Chapter 481, the Texas Controlled Substances Act².

Registrant – An individual who is named as the registrant on a DEA registration.

Appendix

Attachment A: *Order and Receipt Record for Controlled Substances*

Attachment B: *Record of Use for Controlled Substances*

Attachment C: *Inventory Record for Controlled Substances*

Contact Office

Office of Environmental Health and Safety, 956-326-2194

ATTACHMENT B:
Texas A&M International University
Record of Use for Controlled Substances

Registrant: _____

Controlled Substance Name: _____

Quantity Received: _____ Storage Location: _____

Date	Used By (Signature / Print)	Amount Used	Amount Remaining

Container Disposal Date: _____ Volume Remaining: _____

Method of Disposal: _____

Disposed By: _____
Print Name *Signature*

ATTACHMENT C:
Texas A&M International University
Inventory Record for Controlled Substances

Registrant: _____

No.	Controlled Substance Name	Form of Substance (ex: 10-mg tablet, 10-mg concentration per fl oz)	Number of Units or Volume in Each Container (ex: 100-tablet bottle or 3-mililiter vial)	Number of Commercial Containers (ex: four 100-tablet bottles or six 3-mililiter vial)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				