



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)*

Revised: July 8, 2014

March 21, 2019

Next Scheduled Review: March 21, 2024

Procedure Statement and Reason for Procedure

The purpose of this SAP is to internally regulate the use of controlled substances, controlled substance analogues, chemical precursors, and certain chemical laboratory apparatus used 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, controlled substance analogues, chemical precursors, and chemical laboratory apparatus 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. RESPONSIBLE PARTY

- 1.1 Individual faculty members are responsible for all aspects of ordering, storing, recording, and using controlled substances in their research program. If the controlled substances are to be used in conjunction with the activities in an organized research unit (e.g., centers) outside the operation of a specific sponsored project, the Director/Dean of the unit is responsible. If the controlled substances are to be used in a teaching activity, the Chair of the department through which the academic course is offered is the responsible

party. The responsible party must obtain and keep current federal Drug Enforcement Administration (DEA) and DPS registration, unless exempted by law. Registrants are responsible for procuring, maintaining security, keeping records, and disposing of controlled substances in accordance with federal and state regulations and rules.

- 1.2 The Office of Environmental Health and Safety (EH&S) shall maintain a list of all controlled substances license holders and the types of controlled substances each responsible party utilizes.

2. SITE AND OPERATIONAL SECURITY

- 2.1 Specific locations (e.g., a laboratory or locked storage area assigned to the responsible party) should be established where controlled substances are utilized and stored. Controlled substances must be stored behind a minimum of three (3) locks: in a locked cabinet, in a room that is locked after normal business hours, and in a building that is locked after hours.
- 2.2 Access to rooms and locked storage areas containing controlled substances must be restricted to authorized personnel.
- 2.3 Positions for personnel having access to controlled substances should be designated as security-sensitive and appropriate pre-employment criminal history checks must be performed.
- 2.4 When controlled substances are received, they should be immediately checked for completeness with the shipping invoice, logged in an inventory record book, and placed in the proper storage site by individual faculty members.

3. INVENTORY AND REPORTING OF LOSS

Procedures must be established by each responsible party controlled substance license holder 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 under Appendix below). Purchase records are to be maintained according to state and federal requirements and are subject to DPS audit. Authorized personnel must be alert and attentive to the disappearance of any controlled substances. Upon discovery, any loss must be reported to the appropriate Principal Investigator, the University Policy Department (UPD), EH&S, the appropriate Chair and Dean. A full and complete inventory of all controlled substances must be completed every year by the responsible party, and a list of all substances used that year must be reported to EH&S.

4. DISPOSAL

Disposal of controlled substances must be in accordance with federal and state regulations and rules.

5. NOTIFICATION

EH&S will notify each controlled substance license holder of the elements of the controlled substance policy on an annual basis. Each license holder will also be required to annually submit to EH&S a list of controlled substances they used that year and an updated list of all personnel authorized to use controlled substances.

Related Statutes, Policies, Regulations, or Rules

¹ Code of Federal Regulations, Title 21, Chapter 13: Drug Abuse Prevention and Control:

<https://www.deadiversion.usdoj.gov/21cfr/21usc>

<https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm>

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](#)

Definitions

Controlled Substance – A 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. This definition also includes controlled substance analogues with a chemical structure similar to that of a listed controlled substance and chemical precursors that may be used as a primary component in manufacturing a controlled substance. The Controlled Substances Act also cover “Chemical Laboratory Apparatus” which is defined as “...any equipment designed, made, or adapted to manufacture a controlled substance or a controlled substance analogue.”²

Appendix

Attachment A: *Precursor Chemicals and Laboratory Apparatus Inventory*

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

Attachment C: *Order and Receipt Record for Laboratory Apparatus*

Attachment D: *Record of Controlled Substances and Precursors Use and Disposal*

Contact Office

Office of Environmental Health and Safety, 956-326-2756

ATTACHMENT A:
Texas A&M International University
Precursor Chemicals and Laboratory Apparatus Inventory

Principal Investigator (PI): _____

Completed By: _____ Date: _____
















PI Signature: _____ Date: _____

Precursor Chemicals

<u>Chemical Name</u>	<u>Number and Size of Containers</u>	<u>Total Amount</u>	<u>Storage Location</u>
Anthranilic acid			
Barbituric acid			
Controlled Substance Analogue*			
D-Lysergic acid			
Diethyl malonate			
Ephedrine			
Ergotamine tartrate			
Ethylamine			
Ethyl malonate			
Malonic acid			
Methylamine			
N-Acetyl anthranilic acid			
Norpseudoephedrine			
Phenylacetic acid			
Phenylpropanolamine			
Piperidine			
Pseudoephedrine			
Pyrrolidine			

* Controlled substance analogue is a substance that is substantially similar in chemical structure to that of a controlled substance or has central nervous system activity that is substantially similar to, or greater than that of a controlled substance.

**ATTACHMENT A (continued):
Texas A&M International University
Regulated Laboratory Apparatus**

<u>Laboratory Apparatus</u>	<u>Picture</u>	<u>Number Present</u>	<u>Location (Room No.)</u>
Adapter Tubes		_____	_____
1) Buchner Funnel 2) Separatory Funnel	1)  2) 	1) _____ 2) _____	1) _____ 2) _____
1) Condenser 2) Soxhlet Extractors	1)  2) 	1) _____ 2) _____	1) _____ 2) _____
1) Distiller 2) Distilling Flask	1)  2) 	1) _____ 2) _____	1) _____ 2) _____
<u>Flasks</u> 1) Erlenmeyer 2) Filtering	1)  2) 	1) _____ 2) _____	1) _____ 2) _____
Vacuum Filters		_____	_____
1) Flask Heaters 2) Heating Mantles	1)  2) 	1) _____ 2) _____	1) _____ 2) _____
1) Round Bottom Flask 2) Three Neck Flask	1)  2) 	1) _____ 2) _____	_____ _____
Transformer		_____	_____

