

POLICY AND PROCEDURES FOR USING CONTROLLED SUBSTANCES IN NON- CLINICAL EDUCATIONAL AND RESEARCH ACTIVITIES

Texas A&M University System Health Science Center
Institute of Biosciences and Technology
Safety Office
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THE TEXAS A&M UNIVERSITY SYSTEM HEALTH SCIENCE CENTER
INSTITUTE OF BIOSCIENCES AND TECHNOLOGY

**Policy and Procedures for Using Controlled Substances in Non-Clinical
Educational and Research Activities**

I. General

This internal policy regulates the use of controlled substances, controlled substance analogues, chemical precursors and certain chemical laboratory apparatus used in non-clinical educational and research activities in The Texas A&M University System Health Science Center (HSC) Institute of Biosciences and Technology (IBT).

The Texas Department of Public Safety (DPS) and the Texas Higher Education Coordinating Board (HECB) signed a Memorandum of Understanding (MOU) that establishes responsibilities on 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 educational or research activities. This document defines the requirements and procedures necessary for compliance with the MOU by the IBT.

All procedures described herein are consistent with HSC Rule 15.99.99.Z1.03.

II. Controlled Substances Definition

Controlled Substance is defined as 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 Substance 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 Substance Acts 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

¹ Code of Federal Regulations Title 21 – Food and Drugs CHAPTER 13 – Drug Abuse Prevention and Control : <http://www.usdoj.gov/dea/pubs/csa.html> ; <http://www.usdoj.gov/dea/pubs/csa/812.htm>

² Texas Health and Safety code SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES CHAPTER 481. TEXAS CONTROLLED SUBSTANCES ACT:
<http://www.capitol.state.tx.us/statutes/hs.toc.htm>

III. Responsible Party

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 of the unit is responsible. If the controlled substances are to be used in a teaching activity, the Head of the department through which the academic course is offered is the responsible party. The responsible party individual must obtain and keep current federal Drug Enforcement Administration (DEA) and Texas Department of Public Safety (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.

The IBT Safety Office shall maintain an updated list of all controlled substances license holders and the types of controlled substances each responsible party utilizes.

IV. Site and Operational Security

- A. 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. They 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.
- B. Access to rooms and locked storage areas containing controlled substances must be restricted to authorized personnel.
- C. Positions for personnel having access to controlled substances should be designated as security sensitive and appropriate pre-employment criminal history checks must be performed.
- D. 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.

V. Inventory and Reporting of Loss

- A. 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 (please see Attachment B for example forms). Purchase records are to be maintained according to State and Federal requirements, and are subject to DPS audit.

- B. Authorized personnel must be alert and attentive to the disappearance of any controlled substances. Any losses must be reported to the appropriate Principal Investigator, IBT Security, IBT Safety Office, the appropriate Center Director, and the IBT Director upon the discovery of the loss.
- C. 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 reported to the IBT Safety Office.

VI. Disposal

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

VII. Notification

The IBT Safety Office 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 the office of the IBT Safety Office a list of controlled substances they used that year and an updated list of all personnel authorized to use controlled substances

Office of Responsibility:

IBT Safety Office

The following is a list of the controlled items including precursor chemicals, laboratory apparatus and glassware whose purchase, use, transfer and disposal must be monitored.

Precursor Chemicals

- | | | |
|-----------------------------------|-------------------------------|-------------------------|
| 1. Anthranilic acid | 7. Ergotamine tartrate | 13. Norpseudoephedrine |
| 2. Barbituric acid | 8. Ethylamine | 14. Phenylacetic acid |
| 3. Controlled Substance Analogue* | 9. Ethyl malonate | 15. Phenylpropanolamine |
| 4. D-Lysergic acid | 10. Methylamine | 16. Piperidine |
| 5. Diethyl malonate | 11. Malonic acid | 17. Pseudoephedrine |
| 6. Ephedrine | 12. N-Acetyl anthranilic acid | 18. 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.

Laboratory Apparatus

- | | |
|--|--|
| 1. Adapter tubes | 7. Filter funnels, Buchner funnels, and separatory funnels |
| 2. Condensers | 8. Flask heaters |
| 3. Distilling apparatus | 9. Heating mantles |
| 4. Distilling flasks | 10. Soxhlet extractors |
| 5. Encapsulating machines | 11. Tableting machines |
| 6. Erlenmeyer flasks, two-necked flasks, single necked flasks, round-bottom flasks, thermometer flasks, and filtering flasks | 12. Three-necked flasks |
| | 13. Transformers |
| | 14. Vacuum dryers |

NOTE: The MOU does not establish any de minimis quantities of precursor chemicals nor size of glassware or equipment.

Prescription and non-prescription medicinal formulations are exempted.

Attachment B IBT Controlled Substances Information Sheet

The following procedures and requirements are necessary for IBT to comply with the HSC Policy.

1. **MAINTAIN PURCHASE ORDER RECORDS:** Purchase orders that include controlled items should be marked with an asterisk, highlight or some other similar manner readily distinguishable from all other items appearing on the purchase order.
2. **DO NOT SELL, FURNISH OR TRANSFER** any controlled items (including surplus property) to a person or entity not holding a DPS permit or waiver, unless the recipient is specifically exempted by law or rule. Every sale, furnishing or transferring of a controlled item leaving the immediate campus (where the specific controlled item is stored and inventoried) should be reported (by the 15th day of the next month) to the DPS on a Nar-22 Form.
3. **REPORT TO IBT SECURITY** promptly upon discovery of a readily unacceptable discrepancy, pilferage or theft of a controlled item. Security is responsible for forwarding the report to DPS.
4. **SECURITY**
 - a. The Assistant Director, Security, IBT, has primary responsibility for all matters associated with security and law enforcement at IBT.
 - b. Maintain locked storage for controlled precursor chemicals and controlled substance analogues. Strictly limit access to these chemicals. Use records should be maintained.
 - c. Limit access to storerooms containing listed items to authorized personnel. Lock storage areas when unattended.
 - d. All doors into any room in which controlled items are used or stored must be locked when authorized personnel are not present.
6. **NOTIFICATION AND AWARENESS**
 - a. Departments and units affected by this Policy should post in prominent and strategic location(s), notices (this page) to inform personnel of the Policy and of the steps necessary for compliance.
 - b. Encourage personnel to be alert and attentive to the disappearance of controlled items and to report such losses as appropriate.
7. **ASSISTANCE FROM THE TEXAS DEPARTMENT OF PUBLIC SAFETY**

Upon request, the DPS will provide technical advice to the institution and will assist in investigating losses, etc. covered by the Controlled Substance Act.

If there are any questions concerning these documents, please contact Victor Pantusa, IBT Safety Coordinator (713-677-7953). Contact Rick Flores, Assistant Director of Security (713-677-7464) for assistance with security and police matters.

**Attachment C Examples of Forms to be used for the IBT Controlled
Substances Plan**

PRECURSOR CHEMICALS AND LABORATORY APPARATUS

Inventory

Principle 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.

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		_____	_____

ORDER & RECEIPT RECORD for CONTROLLED SUBSTANCES

Laboratory Principal Investigator: _____

No.	Order Date	Order By	Chemical Name	Vendor	Container Size and Number	Date Received	Received By	Storage
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

ORDER & RECEIPT RECORD for **LABORATORY APPARATUS**

Laboratory Principal Investigator: _____

No.	Order Date	Order By	Apparatus Name	Vendor	Container Size and Number	Date Received	Received By	Storage
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

