

UNIVERSITY of HOUSTON
MANUAL OF ADMINISTRATIVE POLICIES AND PROCEDURES

SECTION: Safety
AREA: Specific Area Guidelines

Number: 06.04.01

SUBJECT: Clinical and Research Use of Controlled Substances and Dangerous Drugs
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I. POLICY AND SCOPE

- A. The University of Houston strives to provide every opportunity for its employees and students to attain excellence in their educational and employment experiences, and thereby further the mission of the institution. The university recognizes that to help employees and students realize these goals, it must provide safe environments conducive to employment and educational activities. The university shall seek ways to minimize the hazards of working with controlled substances and dangerous drugs in the university's clinical and non-clinical settings while meeting federal and state laws.
- B. It is the policy of the University to prohibit the unlawful purchase, manufacture, distribution, possession, selling, storing, or use of a controlled substance or dangerous drug, in or on premises or property owned or controlled by the University.
- C. Nothing in this policy is to be construed as authorizing any individual to engage in any act that such individual is not authorized or permitted to do under federal or state laws or rules. Compliance with this policy is not to be construed as compliance with all applicable federal or state laws or rules.
- D. Personal medication is exempt from the requirements of this guide if the drug was obtained in accordance with the Texas Health and Safety Code, chapters [481](#) and [483](#).
- E. University registrants who use controlled substances and dangerous drugs in the university's clinical and non-clinical settings must obtain and keep current United States Drug Enforcement Administration (DEA) and Texas Department of Public Safety (DPS) registrations, unless exempted by law. Registrants are responsible for procuring, maintaining security, keeping records, and disposing of controlled substances and dangerous drugs in accordance with federal and state regulations and rules. The registrant may not allow the permit to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

II. DEFINITIONS

- A. Clinical setting: A setting where a controlled substance or dangerous drug is used in a medical application.
- B. Controlled substances: A Substance, including a drug, an adulterant, and a dilutant, listed in Schedules I-V or Penalty Groups 1, 1-A, 2 through 4 of the Texas Health and Safety Code, [chapter 481](#). The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance.
- C. Dangerous drug: Device or drug that is unsafe for self-medication and that is not included in Schedules I-V or Penalty Groups 1-4 of the Texas Health and Safety Code,

Chapter 481. The term includes a device or a drug that bears, or is required to bear, either of the following labels:

1. "Caution: Federal law prohibits dispensing without prescription" or "Rx only" or another label that complies with federal law; or
 2. "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."
- D. DEA: United States Drug Enforcement Administration.
- E. DPS: Texas Department of Public Safety.
- F. Non-Clinical settings: A setting where a controlled substance or dangerous drug is used in research or education which is not a clinical usage of the controlled substance or dangerous drug.
- G. Registrant: Practitioner, physician, dentist, nurse, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Texas.

III. PROCEDURES

University faculty or staff members who work with controlled substances and dangerous drugs must obtain and keep current DEA and DPS registrations, unless exempted by law. Registrants are also responsible for procuring, securing, maintaining records, and disposing of controlled substances and dangerous drugs in accordance with federal and state guidelines.

A. Registration Process

1. A university faculty or staff member who qualifies as a registrant must obtain a DEA registration application by calling (713) 693-3660, or 1-800-743-0595 or visit the web site below for more information:
<http://www.deadiversion.usdoj.gov/drugreg/index.html>.
2. Apply for a DEA registration number using DEA Form 225. The certifying signature on the form must be the registrant's supervisor. The business address should be listed. The link to the application is found at the following web site:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm.
3. After receipt of a DEA registration number, apply for a DPS Registration.
 - a. Application forms for a DPS registration may be obtained from:

Department of Public Safety
Controlled Substances Registration Section
P.O. Box 4087
Austin, Texas 78773-0001
(512) 424-2188
E-mail: tppcsr@txdps.state.tx.us
 - b. Registrants must furnish their DEA registration numbers on the DPS application.

- c. Apply for a DPS registration using DPS Form NAR-77. The certifying signature on the form must be the registrant's supervisor. The business address should be listed. Please visit the following web site for additional information:

http://www.txdps.state.tx.us/criminal_law_enforcement/narcotics/narccsr.htm.

B. Procurement Process

1. Registrant must use a DEA Form 222 to order controlled substances in Schedules I and II. A DEA Form 222 is issued only to a registrant who has a DEA registration number, and can be obtained from the local DEA office.

Drug Enforcement Administration
1433 W. Loop South, Suite 600
Houston, TX 77027
(713) 693-3660

The List of Controlled Substances and Schedules can be reviewed at
<http://www.deadiversion.usdoj.gov/schedules/index.html>.

2. A DEA Form 222 is not required to order controlled substances in Schedules III – V.
3. Complete university purchasing documents and DEA form 222 if required. The certifying signature on DEA Form 222 must be the registrant's supervisor. Registrant must order through the Purchasing Department per UH MAPP [04.01.01](#).
4. A Dispensing Record Form (sample provided in Addendum B) must be used as the controlled substance is dispensed.

C. Security Controls

Registrants are responsible for establishing and maintaining effective controls and procedures to safeguard against controlled substances and dangerous drugs being diverted from legitimate sources to the illicit market. Controlled substances and dangerous drugs may only be used for a legitimate purpose as authorized by appropriate university official(s). Registrants are directly responsible for:

1. Establishing adequate security to prevent unauthorized access to controlled substances and dangerous drugs.
2. Establishing adequate security to prevent the diversion of controlled substances and dangerous drugs.
3. Not allowing any unauthorized individual access to controlled substances and dangerous drugs storage areas.
4. Storing controlled substances listed in Schedules I-V in a locked office and in a securely locked, substantially constructed cabinet, or security cabinet (i.e., not easily broken into or moved; see [21 CFR 1301.71](#)).
5. The registrant shall notify the local DEA office, in writing, of the theft or loss of any controlled substances within one business day of discovery of such loss or

theft. The registrant shall also complete, and submit to local DEA office, DEA Form 106 regarding the loss or theft. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

The registrant is also required to notify University of Houston Department of Public Safety (UHDPS) of the theft or loss of any controlled substances and dangerous drugs. This does in no way supersede notification to DEA.

6. Dangerous Drugs must be secured in a locked area per [21 CFR 1301.71](#).

D. Maintenance of Records of Inventories

Records and inventories are required to be maintained as part of the registration requirements as detailed in 21 CFR [Section 1304.04](#) and [Section 1304.11](#). Every inventory and other records required to be kept under this part must be kept by the registrant and made available, for at least two years from the date of such inventory or records, for inspections and copying by authorized employees of the DEA, UHDPS, Internal Auditing, DPS, or appropriate state regulatory agency.

1. Controlled substances Schedules I-V

- a. The registrant shall take an initial inventory of all stocks of controlled substances on hand on the date he/she starts newly registered storage location. Each registrant must then complete an inventory of all Controlled Substances (Schedules I-V) every six months after the initial inventory is taken, using the EHS Inventory Form. The University Health Center pharmacy will follow Texas State Board of Pharmacy regulations.
- b. The regulations require that an inventory of controlled substances must be conducted on a biennial basis for each registered location. Biennial inventories of all controlled substances Schedules I-V must be kept by each registrant, and must include the following information:
 - i. The name of the substance;
 - ii. Each formulation of the substance (e.g., liquid, tablet), and
 - iii. The number of units or volume of each formulation in each commercial container.
- c. Inventories of controlled substances Schedules I and II require an exact count or measurement of contents. Schedules III, IV, and V require an estimated count or measure of contents, unless the commercial container holds fewer than 1,000 tablets or capsules.
- d. Inventory records must be kept for two years from the date of the inventory in accordance with the regulations outlined in the Texas Controlled Substances Act, Health and Safety Code, [Chapter 481](#).

2. Dangerous Drugs

Each registrant must conduct and maintain an inventory of all dangerous drugs annually, using the sample inventory form in Addendum A or any other form deemed acceptable. The University Health Center pharmacy will follow Texas State Board of Pharmacy regulations.

E. Records

1. Persons registered under the Federal and Texas Controlled Substances Acts to manufacture, distribute, analyze, or dispense controlled substances or dangerous drugs, or to conduct research with controlled substances or dangerous drugs must keep and maintain inventories and records required for two years from the date such inventories and records are made. A “record” is any notification, order form, statement, invoice, prescription, inventory information, or other document for the acquisition or disposal of controlled substances or dangerous drugs in conformance with record keeping and inventory requirements of federal law and the [Texas Controlled Substances Act](#).
2. Inventories and records shall be available for inspection and copying by authorized employees of UHDPS, Internal Auditing, DPS, DEA, or appropriate state health regulatory agency.
3. Registrants must also maintain complete and accurate records of purchases (to include samples received from pharmaceutical manufacturer representatives), transfers, and disposals of controlled substances listed in Schedules I-V and dangerous drugs.
4. Records of purchases, transfers, acquisitions, and disposals of controlled substances and dangerous drugs must include the following information:
 - a. Name, quantity, and strength of drug;
 - b. Invoice number or purchase order number;
 - c. Date of purchase or acquisition;
 - d. Date and quantity administered disposed or transferred; and
 - e. Reason for administering, disposing or returning of the controlled substance.
5. Records of purchases, acquisitions, transfers, and disposals of dangerous drugs are to be maintained by the registrant for two years beyond acquisition or disposal.

Record keeping requirements and reporting requirements are detailed in [21 CFR 1304.21](#) and [22](#).

F. Disposal Process

The registrant is responsible for the return or disposal of controlled substances and dangerous drugs in accordance with procedures listed in Title 21, Section 1307.21 of the regulations.

Registrants requiring disposal of controlled substances and dangerous drugs may request assistance from the Special DEA Agent in the Houston area. A listing of controlled substances on [DEA Form 41](#) is required of registrants and the Special Agent may recommend disposal through any of the following:

1. Transfer to person registered under the Act and authorized to possess the substance.
2. Destruction in the presence of an agent of the Administration or other authorized persons; or
3. By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.
4. The registrant 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 and dangerous drugs.

G. Employee Screening Procedure

The registrant is responsible for managing the controlled substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions. However, agents of the registrant may engage in approved activities under the direction of the registrant, in which case the registrant is required to screen those employees prior to authorization. One questionnaire is required for each employee (non-practitioner) who is authorized by the registrant to handle DEA controlled substances under his or her direction.

A questionnaire which includes the following questions in [21 CFR 1301.90](#) must be completed for each non-practitioner having access to DEA controlled substances as part of the screening process:

- Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial). If the answer is yes, furnish details of conviction, offense, location, date, and sentence.
- In the past three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician? If the answer is yes, furnish details.

H. Compliance Review

1. The Environmental Health and Safety Department may conduct periodic reviews of each registrant to verify compliance with regulations and the provisions of this policy. A list of all registrants will be requested annually. Any changes to researcher status can be reported to Environmental Health and Safety at 713-743-5858.

2. The UH Internal Auditing Department may perform periodic reviews to ensure compliance with the provisions of this policy. Also, other institutional committees may impose additional requirements on the use of controlled substances and dangerous drugs in a manner that will not jeopardize the institutional requirements and personnel safety.

IV. REVIEW AND RESPONSIBILITY

Responsible Party: Assistant Vice President for Public Safety

Review: Every three years on or before August 1

V. APPROVAL

Carl Carlucci
Executive Vice President for Administration and Finance

Renu Khator
President

Date of President's Approval: May 25, 2011

VI. REFERENCES

[Title 21 Code of Federal Regulations - Part 1300](#) Food and Drugs; Texas Health and Safety Code, chapters 481 and 483

[Title 37 of Texas Administrative Code, Part 1, Chapter 13 – Controlled Substances](#)

Index Terms:

Controlled substances
Dangerous drugs
Drug Enforcement Administration
Texas Department of Public Safety
Registrant

REVISION LOG

Revision Number	Approved Date	Description of Changes
1	09/22/1999	Initial version
2	10/25/2004	Removed "In Non-Clinical Settings" from title of MAPP. Applied new MAPP template. Emphasis is made throughout the document when a non-clinical setting is part of the procedure. Added definition for Clinical Setting and removed definition for SRM. Organization change from Safety and Risk Management (SRM) Department to Environmental Health and Risk Management (EHRM) throughout document. In Section III.B.1, registrants must order a controlled substance through the Purchasing Department. A copy of DEA Form 222 is sent to EHRM for non-clinical settings. Section III.B.6 was removed. Schedules III – V controlled substances and dangerous drugs must be ordered through the Purchasing Department. In Section III.E.1, an inventory is performed every year using the EHRM Inventory Form (Attachment A). In Section III.G.8, a more detailed procedure was documented for registrants leaving university employment and the laboratory checkout procedure with UH DPS and EHRM. EHRM conducts periodic reviews of each registrant to verify compliance with regulations and MAPP 06.04.01, in addition to the Internal Auditing Department. Review schedule was changed from two years to three years. Responsible party was changed to AVP for Plant Operations
3	01/28/2005	In Section III.B, #6 was added to indicate that for clinical settings, the registrant will use the normal procurement process.

Revision Number	Approved Date	Description of Changes
4	08/31/2006	The definition for controlled substances was expanded in Section II.A. The “caution” labels in Section II.B were quoted and expanded. In Section II.A.2, a website for DEA registration was added. The DPS Registration forms address removed “Registration Section” and Narcotics Service.” Section III.A.4.c added information on applying for DPS registration using DPS Form NAR-77. Section III.A.5 added details on copies of current registrations and subsequent renewal registrations from DEA and DPS being provided to EHRM at mail code EHRM 1005. Section III.B was changed to emphasize non-clinical setting and clinical setting procurement processes for all controlled substances, removing a specific section for a procurement process for schedules III-V substances and dangerous drugs. A note was added to Section III.C.4.c on EHRM requirements for a small non-removable safe in a secure area to comply with all documentation in Section III.C.4. The formatting of information was changed in Section III.C.5, and Section III.C.6 was added to indicate that dangerous drugs must be secured in a locked area. Section III.D was expanded to emphasize controlled substances in schedules I-V, and dangerous drugs. Section III.F was documented to emphasize the disposal process for all controlled substances and dangerous drugs. Addendum B, UH Controlled Substances and Dangerous Drugs Dispensing Record, was added.
5	03/10/2010	A note was added to the beginning of the procedure to indicate that the document was being revised to comply with U.S. Drug Enforcement Agency Regulations
6	05/25/2011	Applied revised MAPP template and added new Revision Log. Revised title from “Controlled Substances and Dangerous Drugs” to current title. Added statement in Section I to prohibit unlawful possession of a controlled substance or dangerous drug on property owned or controlled by the University. Updated the registration process and procurement process with web site forms and revised examples in Addendums A and B. Removed information on security cabinet specifications. Added information on maintenance of inventory and records. Removed information on record keeping, referencing 21 CFR 1304.21 and 22. Updated the disposal process to current operating practices. Replaced compliance review with employee screening procedure. Changed the responsible party, and added a reference to Title 37 of the Texas Administrative Code, Part 1, Chapter 13. Updated Index terms

APPENDIX B
University of Houston
Controlled Substances and Dangerous Drugs
Dispensing Record

Drug: _____

Finished form: _____

Units per Vials/Bottles: _____

Pl.: _____

Inventory#: _____

Expiration Date: _____

[illegible]

Note: Sample Dispensing Record form provided by EHS Department to assist CS&DD Registrants with Record keeping requirements.

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