

### Controlled Substances in Research Use

**General:** The University of Texas Health Science Center at Houston requires that all individuals conducting activities with DEA controlled substances be registered with the DEA, DPS, and FDA (where appropriate) and comply with state and federal regulations regarding the acquisition, storage, use and disposal of those substances.

#### 1. Registration

Both the state and federal law classify controlled substances into five categories according to their medical use and potential abuse. For example, Schedule I substances are categorized as having no medical value and having the highest potential for abuse. Schedule V is categorized as having the least potential for abuse.

Registration forms are available on the web at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov) and [www.txdps.state.tx.us/criminal\\_law\\_enforcement/narcotics/Controlled\\_Substances/](http://www.txdps.state.tx.us/criminal_law_enforcement/narcotics/Controlled_Substances/).

##### A. Research use

Every person conducting research activities with a controlled substance is required to register with the Drug Enforcement Agency (21 CFR 1301.11). Re-registration is required annually. State employees are exempt from the registration fee (see 21 CFR 1301.21 or instructions on application Form 225).

For Schedule II-V Substances, complete and submit DEA Form 225 or DEA Form 224 (see Instructional Use below).

For Schedule I substances, in addition to DEA Form 225, the applicant is required to submit three copies of the research protocol (see 21 CFR 1301.18 or instructions on application Form 225).

##### B. Instructional Use

Every person conducting instructional activities with a controlled substance is required to register with the Drug Enforcement Agency (21 CFR 1301.11). For Schedule II-V substances, use DEA Form 224 to register (can be used for both research and instructional activities). Re-registration is required every three years. State employees are exempt from the registration fee (see 21 CFR 1301.21).

##### C. Notes

- For Schedule I substances, a copy of the DEA Application and research protocol must be submitted to EH&S. Following review, EH&S will provide institutional approval as appropriate.
- DEA Form 222 must be used for procurement of Schedule I and II substances (Order DEA Form 222 by checking 'Indicate here if you require order form books' on application form.)
- On August 12, 1999, Ketamine was included into the Federal Drug Enforcement Regulations. Purchase, use and disposal of Ketamine requires a Schedule III permit.

## **2. 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.

Agents of the registrant may engage in approved activities under the direction of the registrant. The registrant is required to screen those employees prior to authorization. As part of the screening process, a questionnaire which includes the following questions (21 CFR 1301.90) must be completed for each non-practitioner having access to DEA controlled substances:

- Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense?
- In the past three years, have you knowingly used narcotics, amphetamines or barbiturates other than those prescribed to you by a physician?

Fill out one questionnaire for each employee (non-practitioner) who is authorized by the registrant to handle DEA controlled substances under his or her direction.

## **3. Record Keeping**

To ensure accountability, a complete and accurate continuing record (e.g. real-time inventory) is required for each substance and must be maintained on a current basis. Continuing records should be kept for two years after the substance is spent. It should include:

- Date of receipt
- Name of the substance
- Each finished form of the substance (e.g. 10 mg tablet or 10 mg concentration./mL)
- Number of units or volume of each finished form in each container
- Number of containers of each finished form (e.g. six 3-mL vials)
- Date of dispensing, units or volume dispensed, units or volume remaining in container, name or initials of the individual who dispensed or administered the substance
- If substance is acquired from, or distributed to another person, their name, address and DEA registration number must be recorded along with date and number of units acquired or distributed
- If substance is disposed of, include date, manner of disposal, and quantity of substance disposed (Keep disposal records for at least two years)

Initial and biennial inventories are required for Schedule I and II substances. An initial inventory shall include:

- Name of substance
- Each finished form of substance (e.g. 10 mg tablet or 10 mg concentration / mL)
- Number of units or volume of each finished form in each container
- Number of containers of each finished form (e.g. six 3-mL vials)

Damaged, defective, expired or impure substances awaiting disposal must also be inventoried including name, total quantity, and the reason why the substance is being maintained.

After the initial inventory, a new inventory must be taken at least every two years. The biennial inventory date must be within two years of the last inventory. Inventories and records for Schedule I and II substances are required to be maintained separately from all other records of the registrant. Records and inventories of all controlled substances must be maintained at the registered location.

Inventories (biennial and real-time/continuing records) and other records including copy of certificate of registration, purchase orders, copy of DEA Form 222 (if applicable), loss records and screening questionnaires must be kept at the registered location and made available to EH&S and compliance officer review.

#### **4. Security**

Registrants shall provide effective controls to guard against the theft or diversion of controlled substances. Substances are required to be stored in securely locked, substantially constructed cabinets or safes (i.e. not easily broken into or moved; see 21 CFR 1301.71).

Registrants are required to report any significant loss or thefts to the local DEA office by using DEA Form 106. 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.

#### **5. Disposal**

All DEA controlled substances must be accounted for upon their disposal. Please contact EH&S Environmental Protection Program (713-500-8100) for information concerning the disposal of Schedule I-V DEA controlled substances. A current certification of registration will be required. Keep all disposal records for at least two years.

#### **6. Surveillance**

As a service, EH&S Chemical Safety Program will survey all controlled substance researchers annually to assist with verification of recordkeeping, security and disposal. A list of all registrants will be requested annually with the assistance of UTPD and the DEA. Any changes to researcher status can be reported to Chemical Safety at 713-500-5832.

## APPENDIX



**QUESTIONNAIRE FOR EMPLOYEES OR AFFECTS WHO WILL HAVE ACCESS TO  
SUBSTANCES REGULATED BY THE DRUG ENFORCEMENT AGENCY OF THE UNITED  
STATES OF AMERICA**

The Drug Enforcement Agency requires that any person who will have access to controlled substances as a result of his or her status as an employee or agent of the University of Texas Health Science Center at Houston answer the following questions. Any false information or omission of information may jeopardize your position with respect to employment. Information revealed by this questionnaire will not necessarily preclude employment, but will be considered as part of an overall evaluation of your qualifications. The responses on this questionnaire will be held in the strictest confidence.

1. In the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently charged with committing a criminal offense? (Do not include 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.

Yes\_\_\_\_ No\_\_\_\_

2. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Yes\_\_\_\_ No\_\_\_\_

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Signature (Employee)

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Printed Name

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Signature (Principal Investigator)

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Printed Name

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Date

Reference: 21 CFR 1301.90





**University of Texas Health Science Center at Houston  
Environmental Health and Safety  
Controlled Substances Evaluation Record**

**REGISTERED USER INFORMATION:**

Registered User:	_____	Authorized personnel:	_____
Campus Mailing address:	_____		_____
Office Phone:	_____		_____
Surveyed by:	_____		_____
Date surveyed:	_____		_____

		Y	N	Comments
<b><u>SECURITY</u></b>	Cabinet of "substantial construction"?			_____
	Cabinet locked?			_____
	Cabinet affixed?			_____
	Cabinet secure?			_____
<b><u>RECORDS</u></b>	DEA License # : _____			Expiration date: _____
	DPS License # : _____			Expiration date: _____
	FDA License # : _____			Expiration date: _____
	Ledger available?			_____
	Name, quantity & strength?			_____
	Invoice/PO #?			_____
	Purchase date?			_____
	Administration dates & quantities?			_____
	Disposal dates & quantities?			_____
	Reason for administering or disposing documented?			_____
	Records maintained for two years beyond acquisition or disposal?			_____
<b><u>INVENTORY</u></b>	Biennial inventory kept?			_____
	Name of substance?			_____
	Substance formulation?			_____
	Units/volume of each formulation per container?			_____

**COMMENTS**

\_\_\_\_\_

\_\_\_\_\_

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**SIGNATURES**

Performed by: _____	Date Performed: _____
Reviewed by: _____	Date Reviewed: _____



## The University of Texas Health Science Center at Houston Environmental Health and Safety Guidance Document

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**Title:** Controlled Substances Surveillance Program

**Original Date:** May 28, 2003

**Program:** Chemical Safety

**Revised Date:** May 28, 2003

**Section:** Laboratory Surveillance

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**General:** This guidance document defines the scope of each category in the Chemical Safety Program's Controlled Substances Evaluation Record to ensure that controlled substances inspections are performed consistently and completely.

Controlled substances surveys are to be completed to ensure that state and federal regulations are being met and that a high level of safe working practices is maintained at the University of Texas Health Science Center at Houston while minimizing disruptions to the research activities. The surveys will be assigned per Principal Investigator (PI) who is a registered user with a license to distribute, dispense, analyze, conduct research to, or administer a controlled substance in the course of professional practice or research in Texas.

Always be polite and courteous to PI's and lab workers. Initiate the survey process by asking about the agents and processes involved in their research. This survey is a tool with which Environmental Health and Safety can provide a safe working environment for all University employees while ensuring compliance with applicable rules and regulations.

### Controlled Substances Evaluation Record questions and background

#### SECURITY

##### 1. Cabinet of "substantial construction"?

A "substantially constructed cabinet" is a structure of wood or metal so constructed as to resist easy entry by simple tools such as screw drivers, crow bars, tire tools, or pry bars. Hinges should not be mounted with bolts or screws on outside of doors.

*Deficiency Response:* Storage cabinet is not of substantial construction. The cabinet should be constructed of wood or metal so as to resist easy entry by simple tools such as screw drivers, crow bars, tire tools, or pry bars

**2. Cabinet locked?**

The locking devices should be installed internally as deadbolt type, or the device should be of a type that has protected mounting screws or bolts to make removal difficult.

*Deficiency Response:* The locking device on the storage cabinet is insufficient or not in use. The locking device should be installed internally as deadbolt type, or the device should be of a type that has protected mounting screws or bolts to make removal difficult.

**3. Cabinet affixed?**

The cabinet should be permanently constructed or attached to the building structure or fixtures so as to prevent the cabinet from being physically removed from the premises. If the cabinet is a metal file cabinet type, it should be permanently attached to prevent easy removal and have an external locking bar that secures the drawers.

*Deficiency Response:* The storage cabinet should be permanently affixed to the building or fixtures so as to prevent physical removal from the premises.

**4. Cabinet secure?**

A cabinet less substantially constructed may meet security requirements provided the cabinet is located in a room or an area where the entrance has been so constructed that the hinge mounting inhibits removal and a limited number of employees have keys or combinations to the locking device. If combination locks are used, the combination must be changed upon termination of employees who have knowledge of the combination.

*Deficiency Response:* The storage cabinet is not kept in a secure location with limited access.

**RECORDS**

**5. License expiration date?**

Registrant should be aware of the license expiration date to assure that the proper paperwork for renewal is submitted, avoiding attempted purchases on expired licenses.

*Deficiency Response:* The (DEA, FDA, etc.) license for this controlled substance has expired.

**6. Ledger available?**

The records must be maintained in a bound record book, ledger, or other device equal in durability and capacity to record the required data. The record-keeping device shall have a numbered page for each drug by drug strength.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances.

**7. Name, quantity & strength?**

The names, quantity and strengths of each drug purchased, transferred, acquisitioned and disposed of must be maintained within the ledger.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances. The names, quantity and strengths of each drug purchased, transferred, acquisitioned and disposed of must be maintained within the ledger.

**8. Invoice/PO #?**

The invoice or purchase order number for each drug purchased, transferred, acquisitioned and disposed of must be maintained within the ledger.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances. The invoice or purchase order number for each drug purchased, transferred, acquisitioned and disposed of must be maintained within the ledger.

**9. Purchase date?**

The date of purchase or acquisition of each drug purchased, transferred, acquisitioned and disposed of must be maintained within the ledger.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances. The date of purchase or acquisition of each drug purchased, transferred, acquisitioned and disposed of must be maintained within the ledger.

**10. Administration dates & quantities?**

The administration dates and quantities of each drug must be maintained within the ledger.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances. The administration dates and quantities of each drug must be maintained within the ledger.

**11. Disposal dates & quantities?**

The disposal dates and quantities of each drug must be maintained within the ledger.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances. The disposal dates and quantities of each drug must be maintained within the ledger.

**12. Reason for administering or disposing documented?**

The reasons for administering or disposing of each drug must be maintained within the ledger.

*Deficiency Response:* A proper ledger must be maintained regarding the use of controlled substances. The reasons for administering or disposing of each drug must be maintained within the ledger.

**13. Records maintained for two years beyond acquisition or disposal?**

All records regarding the purchases, acquisitions, transfers and disposals of controlled drugs are to be maintained by the registrant for two years beyond acquisition or disposal.

*Deficiency Response:* All records regarding the purchases, acquisitions, transfers and disposals of controlled drugs are to be maintained by the registrant for two years beyond acquisition or disposal.

**INVENTORY**

**14. Biennial inventory kept?**

Each registrant must conduct an inventory of all controlled substances every two years. Inventory records must be kept for two years from the date of the inventory.

*Deficiency Response:* An inventory of all controlled substances must be conducted every two years. Inventory records must be kept for at least two years from the date of the inventory.

**15. Name of substance?**

Each biennial inventory record must contain the name(s) of each substance in inventory.

*Deficiency Response:* The biennial inventory record must contain the name(s) of each substance in inventory.

**16. Substance formulation?**

Each biennial inventory record must contain the formulation (e.g. liquid, tablet) of each substance in inventory.

*Deficiency Response:* The biennial inventory record must contain the formulation (e.g. liquid, tablet) of each substance in inventory

**17. Units/volume of each formulation per container?**

Each biennial inventory record must contain the number of units or volume of each formulation in each commercial container.

Deficiency Response: The biennial inventory record must contain the number of units or volume of each formulation in each commercial container.