UNT Health Science Center

Office of Research Compliance

Controlled Substance Manual

Standard Operating Procedures

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# PREFACE

The University of North Texas Health Science Center requires that all persons conducting activities with DEA controlled substances in basic and applied research settings shall be registered with the DEA and licensed with the Department of Public Safety. All persons shall comply with state and federal regulations regarding the acquisition, record keeping, inventory, storage, use, and disposal of those substances.

**Office of Research Compliance (ORC)**

Questions about procurement, secured storage, use, disposal, required documentation, or regulatory questions regarding controlled substances in research should be directed to the ORC. The ORC offers controlled substances education sessions for faculty, staff, and students.

Chapter

1

# Chapter 1: Licensing and Registration

Since the UNTHSC cannot, by law, maintain a campus wide registration for controlled substances, it is the responsibility of each individual PI to obtain appropriate annual licenses and registrations, and to adhere to applicable state and federal regulatory requirements when working with controlled substances. Registrants shall not allow the permit to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

1. Federal Registration: You will need to complete the DEA registration application. <http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm>

DEA registration remains active for a 1 year period.

1. State Licensing: Once you complete your DEA Registration, you will need to complete a DPS Controlled Substance Registration. DPS licensing is for a 1 year period.

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

1. Reminders: Submit a copy of each license to the Director of Research Compliance.

Notices of registration renewals will be sent out by UNTHSC’s Research Compliance several weeks prior to expiration.

Chapter

2

# Chapter 2: Approval

No individual who has been convicted of a felony for any State or Federal law regarding controlled substances should be allowed access to controlled substances.

Chapter

3

# Chapter 3: Ordering or Procurement

Controlled substances must be ordered on-line using UNTHSC procurement system (ePRO).

Vendors

#### Authorized Principal Investigator may use any vendor that is authorized to supply requested substances.

Stocks of controlled substances must be kept to the smallest quantity needed.

Each PI will be initially notified when the order is ready to be picked up from the UNTHSC Central Receiving department.

Research Compliance will be notified if the PI is not available for pick-up, from the UNTHSC’s Receiving department.

Only the PI or authorized personnel may pickup controlled substances from the Receiving department or Research Compliance, as needed.

Persons picking up from central receiving should be sure to get necessary receiving records to be maintained with required documents.

CHAPTER

4

# Chapter 4: Storage and Security Controls

All Principal Investigators using controlled substances are responsible for establishing and maintaining effective controls and procedures against unauthorized access to controlled substances.

All controlled substances shall be stored in a substantially constructed, securely locked, cabinet (safe) as per Federal regulations. The cabinet should be permanently constructed or attached to a building structure to prevent physical removal.

Access to locked storage cabinets containing controlled substances shall be restricted to limited authorized personnel.

All controlled substances shall be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

Principal Investigators shall rekey a key lock if a key is lost or upon termination of an employee having possession of a key.

Principal Investigators shall change a combination lock code if a record of the combination is lost or stolen or upon termination of an employee having knowledge of the combination.

At least two authorized persons shall co-sign for initial storage of a sealed vial of bulk compound and subsequent laboratory use.

The Director of Research Compliance is available to assist in evaluating and making recommendations regarding site security.

Chapter

5

# Chapter 5: Labeling, Storage, and Security

All containers of controlled substances must be properly labeled. If the laboratory re-packages compounds or dilutes controlled substances, appropriately label the re-packaged, compounded or diluted substance and store it in the safe.

The label on diluted or combined controlled substances that will be stored at least overnight in the safe must include the following information:

1. Name of controlled substance
2. Final concentration of controlled substance
3. Volume per container
4. Expiration date
5. NDC code
6. Lot number
7. Manufacturer

Chapter

6

# Chapter 6: Disposal

Expired or unused product(s) must be labeled, separated, and stored under lock and key until ready for proper disposal.

You should contact the Office of Research Compliance, Ext # 2458, to request disposal of controlled substances. You must provide a copy of your DEA license for disposal.

Disposal of controlled substances should be documented in the spiral bound binder labeled as “*Scheduled Drug Inventory Record Year* ”.

You should maintain all additional records documenting each disposal for two years.

The Director of Research Compliance is available to assist in proper disposal.

Chapter

Chapter

7

# Chapter 7: Required Documentation

Drug accountability records shall be completed upon receipt of controlled substances, after each use, disposal, or loss. PIs must maintain complete and accurate inventory records for all controlled substances.

All records shall be kept separately from all other records, in or near the primary work area, and be available for inspection.

All records shall be maintained for at least two years from the date of the last recorded transaction or use.

The recordkeeping should include the following information:

1. **Receipt of Controlled Substance**: Open and verify contents. Each receiving record must be signed and dated upon receipt by the authorized person receiving the controlled substance. Also document in “*Scheduled Drug Inventory Record Year \_\_\_\_\_\_\_\_\_\_”* yellow spiral bonded log book*.*
2. **Use of Controlled Substance**: A separate and current record for the use of each controlled substance, indicating the **name of substance**, **date dispensed**, laboratory building/room, **finished drug form**, **total amount on hand and remaining after each use**, **amount used**, **authorized user’s signature**, and authorized witness’s signature must be documented in the “Scheduled Drug Inventory Record Year” spiral bonded log book.
3. **Disposal of Controlled Substance via Reverse Distributor**: Current record indicating the **number of commercial containers, quantity per container, date of disposal, how disposed, name, address, and registration number of person to whom distributed**.
4. **Initial Inventory of Controlled Substance**: A complete and accurate inventory of the stock of controlled substances within each authorized registrant’s laboratory must be performed initially upon receipt of DEA license. You must record zero inventories at this time on the “Research Control Substance Bi-Annual Inventory Record”. The authorized person conducting the inventory and authorized witness must also sign the “Research Control Substance Bi-Annual Inventory Record”.
5. **Biennial Inventory**: After the initial inventory is taken, a new inventory of all stocks of controlled substances on hand should be conducted every two years. The **inventory date** and **opening or close of business**, **drug name**, **strength**, **quantity**, **drug form (tablet, capsule, etc)**, **number of units/volume**, **total quantity**, expiration date, *name of Principal Investigator*, *and location* must be recorded on the “Research Control Substance Bi-Annual Inventory Record” at this time. The authorized person conducting the inventory and authorized witness must also sign the “Research Control Substance Bi-Annual Inventory Record”.
6. Authorized Users Signature Log as designated by PI: date signed, printed name, title, signature, initials, and date departed.

**NOTE**: **Bolded** words indicate required data per Federal Regulations.

Chapter

8

# Chapter 8: Loss or Theft

Authorized personnel must be alert and attentive to the disappearance of any controlled substances. Thefts, suspected thefts, unauthorized uses, or any significant loss of controlled substances must be immediately reported (within the next business day) to the Office of Research via the Director of Research Compliance and the University Police upon the discovery of the loss.

In addition, the DEA requires that theft or significant loss of controlled substances be reported on DEA Form 106 Report of Theft or Loss of Controlled Substances. The form is available at <http://www.deadiversion.usdoj.gov/>

If a container of a controlled substance is inadvertently broken or damaged, document this on the disposition record and have an authorized witness sign and date it. Complete a DEA Form 41 for the amount of the substance lost and write "unintentional destruction" on the form. This form is available at <http://www.deadiversion.usdoj.gov/index.html> . Signatures of the authorized person who broke the bottle, the authorized witness and the Registrant are required on Form 41. Mail the original to the DEA and file a copy with your controlled substance records.

Chapter

9

# Chapter 9: Diversion

An employee who has knowledge of a drug diversion associated with the actions of a fellow employee, supervisor, or Principal Investigator has an obligation to report such information to the Office of Research at 817.735.2458 or the EthicsLine at 877-606-9187.

Reporting compliance violations is strongly encouraged, and it is the Health Science Center's policy to immediately establish an inquiry and follow up each report to its conclusion. The inquiry process is conducted according to a standardized Report and Response Protocol.

The Texas Whistleblower Act protects anyone who, in good faith, reports unlawful activity from retaliation for making such a report.

Chapter

10

# Chapter 10: Inventory

Principal Investigators or authorized persons must conduct inventory reconciliation every two years. This inventory must be documented, dated, signed, and an authorized witness needs to sign.

Refer to chapter 6: Required Documentation.

The Director of Research Compliance will verify the inventory during post approval monitoring.

Chapter

11

# Chapter 11: Inspections

The DEA or TXDPS or their authorized designees may enter your lab at reasonable times and inspect your use, storage, documentation, and your adherence to all applicable laws regarding controlled substance. Inspections may be unannounced.

The Director of Research Compliance will conduct post approval monitoring (PAM) of laboratories to verify compliance with applicable state and federal regulations.

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Chapter

12

# Chapter 12: **Modifications**

Each PI must notify the DEA and TXDPS before the seventh day after any change in name, address, telephone, schedules, or any information required on the application or registration.

Chapter

13

# Chapter 13: **Forms**

* 1. Research Control Substance Biennial Inventory Record
  2. Authorized Users Signature Log
  3. Scheduled Drug Inventory spiral bonded logbook
  4. Disposal record, if applicable

Refer to the [Office of Research Compliance](http://www.hsc.unt.edu/Sites/OfficeofResearchCompliance) for the current forms.

Chapter

14

# Chapter 14: References

1. Title 21 CFR 1300

<http://www.deadiversion.usdoj.gov/index.html>

2. Texas Controlled Substance Act: <http://www.dshs.state.tx.us/dmd/control_subst_sched.shtm>

<http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.481.htm>

<http://www.txdps.state.tx.us/criminal_law_enforcement/narcotics/DPSDrugRules.pdf>

**Modifications to ORC-Controlled Substances Manual**

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| --- | --- | --- |
| Date | Chapter/Section | Description of Modification(s): |
|  |  |  |
| 3/24/11 | Chapter 5 | Added text: “5. NDC code and 6. Lot number and 7. Manufacturer” |
| 6l16/11 | All | Changed color; added name; adjusted format |
| 6/16/11 | Chapter 7 | Bolded required records per DEA regulations |
| 6/16/11 | Chapter 3 | Revised text to indicate authorized PI may purchase controlled substances from any authorized vendor |
| 6/16/11 | Chapter 9 | Added text to indicate reporting compliance violations is policy; proper established procedures will be followed in investigating reported incidents; Whistleblower Act |