THE UNIVERSITY OF TENNESSEE
HEALTH SCIENCE CENTER

UT Health Science Center: RS202 - Controlled Substances in Research	
Version 2	**Publication Date: 05/13/2024**

Objective

This policy is to ensure that Researchers planning work with controlled substances are aware of and understand their responsibility for complying with the relevant state and federal statutes and regulations governing the use of these substances.

Scope

This Policy applies to the use of controlled substances in research conducted under the auspices of UTHSC, and all in vivo research under IACUC-approved protocols and in vitro research. It extends only to controlled substance licensees/registrants engaged in research at UTHSC.

Roles

I. **DEA Registrant**: The responsibility for controlled substance compliance rests with the DEA Registrant (often the Principal Investigator). The DEA Registrant retains all liabilities for loss, theft, or misuse of any controlled substance acquired through his/her registration. The DEA registrant is responsible for:

- Obtaining and renewing both the DEA registration and the TN State Board of Pharmacy license,
- Assuring that all acquisition, storage, security, use, inventory, disposal, and record-keeping requirements are met.
- Ensuring that only appropriate individuals are designated as Authorized Users and that they have been appropriately trained.

II. **Authorized User**: The DEA Registrant may authorize members of his or her staff to work with controlled substances under the DEA Registrant's license/registration ("Authorized Users"). However, the DEA Registrant retains overall responsibility for meeting all regulatory requirements. Authorized Users must be listed on the DEA Registrant's controlled substance protocol submitted with the license application.

DEA Registrants may not name as Authorized Users any person who: (i) has been convicted of a felony offense relating to controlled substances; or (ii) at any time, has had an application for registration with the DEA denied, a DEA registration revoked or has surrendered a DEA registration for cause.

Authorized Users are responsible for completing training in and complying with requirements for the proper use, handling, storage, security, documentation, and reporting of diverted controlled substances.

III. **Office of Research Safety Affairs (RSA)**: The Office of Research Safety Affairs is responsible for establishing and maintaining this policy, making training available for Authorized Users, and auditing controlled substance records as part of the Laboratory Inspection Program.

Definitions

Administer: means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject

Authorized User: A university employee authorized to use Controlled Substances by a DEA Registrant.

Controlled Substances: Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end) and the Tennessee Controlled Substance Act. Controlled substances are identified in the schedules contained within the "List of Scheduling Actions, Controlled Substances, Regulated Chemicals" published by the DEA.

DEA: U.S. Drug Enforcement Administration

DEA Registrant: A University Member who holds DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of Controlled Substances.

Disposal: Relinquishment of contaminated, expired, excess, residual (or waste), or unwanted Controlled Substances.

Drug Diversion ("Diversion"): is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

Expired and/or Unusable Substances: Controlled substances for which the expiration date has passed. Or tablets, injections, liquid, or preparations compounded in error that contain Controlled Substances that can no longer be used due to contamination.

Principal Investigator (PI): The individual with final responsibility for the conduct of research or other activity described in a proposal or an award.

Registration: Formal grant of specific authority for Controlled Substances activities by the DEA and by the Tennessee Board of Pharmacy. Often referred to as a license or certificate.

Schedule I: Drugs or other substances that have no currently accepted medical use and a high potential for abuse.

Schedule II: Drugs or other substances that have a high potential for abuse, currently have an

accepted use in medical treatment in the United States or have a currently accepted medical use with severe restrictions. Abuse may lead to severe psychological or physical dependence.

Schedule III: Drugs or other substances that have a lower potential for abuse than Schedule I or II drugs and have an accepted use in medical treatment in the United States. Abuse is associated with moderate or low potential for physical or psychological dependence.

Schedule IV: Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III and currently have an accepted medical use in the United States. Abuse may lead to limited physical or psychological dependence.

Schedule V: Drugs or other substances that have an accepted medical use in the United States and contain limited quantities of certain narcotics. Abuse may lead to limited physical or psychological dependence relative to those in Schedule IV.

Procedure

I. Researcher Licensing and Registration:

The University does not hold an "institutional license" for use of controlled substances in research. Any individual who uses or synthesizes controlled substances for research under the auspices of the UTHSC must be: (a) licensed with the Tennessee State Board of Pharmacy (TBOP) and registered with the US DEA (a "DEA Registrant"); or (b) authorized under the license of a DEA Registrant. No person shall manufacture, obtain, possess, administer, or dispense a legend drug or controlled substance for the purpose of scientific research or chemical analysis without having first secured a license to do so. Physician investigators that maintain appropriate licensure for controlled substances used in his/her medical practice must obtain research licensure from the Tennessee State Board of Pharmacy to use these substances in research involving animals and/or must modify his/her state license to include the use of controlled substances in the research setting.

A copy of current DEA and Tennessee Board of Pharmacy registrations must be shown or provided to RSA.

II. Procurement of Controlled Substances:

Vendors of controlled substances will require verification of proper registration and licensure prior to the sale of controlled substances. Registrants may only order or purchase controlled substances within a given class specified on their registration. For example, if the registrant is approved for the use/purchase of schedule II non-narcotic drugs (e.g. Nembutal) that does not mean that he/she can also purchase a schedule II narcotic drug (e.g. Fentanyl) not specified on the DEA application. The registrant would need to go through the DEA and the TN State Board of Pharmacy first to get this approved. For the purchase of Schedule I and II drugs, the purchaser must compete DEA form 222.

The registrant must verify the accuracy of a shipment of Controlled Substances from a supplier immediately upon receipt. These controlled substances must then be entered into the inventory maintained by the registrant. Discrepancies must be reported to the DEA, UTHSC Police, the Office of Research, and the supplier upon discovery.

III. Storage of Controlled Substances

Controlled substances must be stored separately from other chemicals and reagents. For example, ketamine, a schedule III controlled substance, must be stored separately from xylazine, a non-controlled substance. Controlled substances shall at all times be properly safeguarded and securely kept at the address on file with the DEA and which corresponds with the information indicated in the ordering of the controlled substances. Adequate security and storage must be provided and access to such storage must be limited to Licensed and/or Other Authorized Individuals. Each registrant must have access to their own means of securing controlled substances and may not share a storage device with other registrants.

Security requirements vary depending on: (1) whether the storage is for working stocks or reserve or main stocks; and (2) the schedule of controlled substance.

A. Working Stocks – appropriate for most individually licensed Principal Investigators.
    1. Schedule I-IV controlled substances shall be kept in stationary (typically built in a wall), locked double cabinets. Both cabinets must have key-locked doors with separate keys; spring locks or combination locks are not acceptable.
    2. Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.

IV. Authorized Users

To minimize the possibility of diversion, the registrant must limit access to the controlled substance storage areas to a minimum number of authorized employees. Access must not be provided to any individual who has been convicted of a felony offense related to controlled substances. Prior to being allowed authorization to handle DEA-controlled substances, each employee must be involved in a screening process that identifies eligibility for such authorization. The Registrant must have the following questions answered in writing by any Authorized Users:

A. 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.
B. 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.

Controlled Substance Program Form 1: Employee Screening Statement is the required form for this purpose. Copies shall be provided to the employee, and originals must be maintained on file at the registered location for a minimum of two years following the cessation of controlled substance activity. Registrants must also maintain a log of all Authorized Users that have access to controlled substances. Controlled Substance Program Form 2: Access Log Is the required form for this purpose.

V. Training

All DEA Registrants and persons working under the licensee shall be familiar with and adhere to all federal and state controlled substances rules and regulations. All Licensed Individuals and other Authorized Users must complete an initial Controlled Substances Acquisition, Use and Disposal training. The training must be renewed every three years. This training is available through the Office of Research Safety training resources website.

VI. Theft or Loss

Registrants must notify the DEA Memphis Resident Office of the theft or significant loss of any controlled substances in writing within one business day of discovery of such loss or theft.

Reports of theft or loss can be emailed to tntheftorloss@usdoj.gov. The registrant must then promptly complete and submit the DEA Form 106 to the DEA Diversion Office. The Memphis Resident Office is located at 50 N. Front Street, Suite 500, Memphis, TN 38103 and can be called at (901) 969-3518. Suspected theft of controlled substances must also be reported to the UTHSC Police Department by calling (901) 448-4444.

VII. Destruction and Disposal

Damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances must be disposed of through reverse distribution or a destruction method that complies with applicable regulations. Acceptable methods of destruction include:

A. Prompt delivery of controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location. A copy of DEA Form 41 must be completed and added to the records of the registrant.
B. On-site destruction. Destruction can be facilitated by RSA utilizing an on-site method of destruction. The following procedures shall be followed:

    1. The DEA registrant or an Authorized User of the registrant shall handle the controlled substance and treat it in a manner that will it non-retrievable. An example of such a treatment method is the use of Rx Destroyer™, Cactus Smart Sink™ or a comparable product. The Office of Research Safety maintains a supply of Rx Destroyer to use for such purposes.
    2. Two employees of the registrant shall witness the destruction of the

controlled substance in a manner that renders it non-retrievable. The witnesses will attest to this destruction by providing appropriate documentation in the Use Log for each container of controlled substance. A copy of DEA Form 41 must be completed and added to the records of the registrant.

Contact the RSA at labsafety@uthsc.edu for additional information or to arrange for disposal of unwanted controlled substances.

Recordkeeping

The controlled substances regulations require significant record keeping at every point, including initial receipt, use, and disposal. The licensed individual is responsible for maintaining this documentation with respect to controlled substances used for his or her research. The records must be maintained at the premises where the licensed activity is conducted and easily produced in the event of an inspection by the TN State Board of Pharmacy or the DEA.

Inventories and records of controlled substances listed in Schedules I and II must be maintained separately from all other records maintained by the DEA registrant. Likewise, inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or in such a form that they are readily retrievable from the ordinary business records of the registrant. All records related to controlled substances must be maintained and be available for inspection for a minimum of three years. All signatures in the inventory and records must be legible and dated. All records must be maintained by Licensed Individuals for a period of at least two years from the date of the last recorded purchase, transfer, use, or other transaction.

The RSA provides a series of required forms to assist investigators with the maintenance of necessary documentation. These forms have been adopted to ensure that all researchers provide the information and documentation necessary to safeguard their liability as a DEA registrant. Any other format of documentation must be approved by the Office of Research Safety.

The following documentation must be maintained by the Registrant:

I. Authorized User Screening Form (*Controlled Substance Program Form 1: Employee Screening Statement)*
II. Log of Authorized Users (*Controlled Substance Program Form 2: Access Log)*
III. Initial Inventory (*Controlled Substances Program Form 3: Controlled Substances Inventory)*
IV. Biennial Inventory (*Controlled Substances Program Form 3: Controlled Substances Inventory)*
V. Use Logs (*Controlled Substances Program Form 4: Use Log*)
VI. DEA Form 222 – Schedule I or II Order Form
VII. DEA Form 106 – Diversion Report Form
VII I. DEA Form 41 – Registrants Inventory of Drugs Surrendered (or destroyed)

Initial Inventory

An initial inventory must be performed at the time that the Registrant takes controlled substances into their possession. *Controlled Substances Program Form 3: Controlled Substances Inventory* must be used for maintaining these records. The inventory shall include:

I. DEA Form 222 for Schedule I or II controlled substances.
II. Whether the inventory was taken at the beginning or close of business.
III. The name of each substance.
IV. Each finished form of the substance (e.g., 10-milligram tablet or 10milligram concentration per fluid ounce or milliliter).
V. The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
VI. The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter 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. In determining the number of units of a controlled substance in a commercial container that has been opened, the registrant shall, if the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, the registrant may make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, he/she must make an exact count of the contents.

Biennial Inventory

After the initial inventory, a new inventory must be taken by the registrant at least every two years. The biennial inventory date must be within two years of the last inventory. *Controlled Substances Program Form 3: Controlled Substances Inventory* must be used for maintaining these records. Initial and biennial inventories must be maintained by each registrant and kept at the location where the substances are stored. Initial and biennial inventories must be kept for three years from the date the inventory was conducted.

Use Documentation

Use documentation must include the name of the Licensed Individual, the date, type and quantity of drug and signature of the Licensed Individual or other Authorized User handling the controlled substance. If necessary, each container and corresponding log form will be marked with a unique identifier for tracking purposes. The registrant will record all administration or disposal of controlled substances in a log. *Controlled Substances Program Form 4: Use Log* must be used for this purpose.

A separate log form must be maintained for each container of controlled substance. Any use of controlled substance including losses incurred during administration (e.g. syringe loss) or waste disposal must be noted on the log form for that container. This must be done in a manner that the total volume used from that container equals the total quantity received at the time of purchase.

DEA Form 106

In the event of loss or diversion of controlled substances a copy of DEA Form 106 must be retained with controlled substance documentation.

DEA Form 41

This form is required to document the loss of controlled substances due to breakage, spillage, or intentional destruction. DEA Form 41 must be completed following any of the above incidents and retained with controlled substance documentation. The wastage of partial doses, container residue or similar aliquots generated in during controlled substance administration do not need to be documented on this form but must be recorded in the controlled substance use log.

Penalties/Disciplinary Action for Non-Compliance

The State of Tennessee and the DEA can impose administrative, civil, and criminal actions against a controlled substance licensee and DEA registrant for noncompliance and/or theft or loss associated with storage, administration, recordkeeping, and other aspects of controlled substances. Failure to comply with UTHSC Controlled Substance Policy, state regulations, or federal regulations may result in termination of any controlled substance authorization or disciplinary action from the Office of Research.

Responsible Official & Additional Contacts

Subject Matter	Office Name	Telephone Number (xxx) xxx-xxxx	Email/Web Address
Policy Clarification and Interpretation	Research Safety Affairs	901-448-6114	labsafety@uthsc.edu
Policy Training	Research Safety Affairs	901-448-6114	labsafety@uthsc.edu
Controlled Substances in Research	Research Safety Affairs	901-448-6114	labsafety@uthsc.edu

Related Policies/Guidance Documents

I. Controlled Substances Act, 21 United States Code (USC), Drug Abuse Prevention and Control, Chapter 13
II. 21 CFR 1300-1399, Drug Enforcement Administration, Department of Justice
III. Tennessee Controlled Substances Act
IV. Tennessee Legend Drug and Controlled Substance Research Act of 1984, Title 53, Chapter

14

V. DEA Practitioner's Manual, 2023 Edition
VI. HM5202 – Controlled Substances Policy
VII. SA0100 – Safety and Environmental Health Program
VII I. SA0700 – Safety and Environmental Health Responsibilities

Appendices

I. Controlled Substance Program Form 1: Employee Screening Statement
II. Controlled Substance Program Form 2: Access Log
III. Controlled Substances Program Form 3: Controlled Substances Inventory
IV. Controlled Substances Program Form 4: Use Log

Controlled Substance Program Form 1:

UTHSC Authorized User Screening Statement

(based on 21 CFR 1301.90)

UTHSC requires that all employees who have access to controlled substances used in research as a part of their work duties complete the following questionnaire in order to ensure compliance with the federal regulations governing controlled substances found at 21 CFR Section 1301.90. The U.S. Drug Enforcement Agency requires the collection of this information in order to "fairly assess the likelihood of an employee committing a drug security breach." The information collected on this form will only be used by UTHSC to assess an employee's security risk with respect to working with controlled substances.

1. Question. 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.)

   _____Yes _____No

   If the answer is yes, furnish details of conviction, offense, location, date, and sentence.

2. Question. In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician?

   _____Yes _____No

   If the answer is yes, furnish details.

Statement of Employee:

If I have knowledge of drug diversion from UTHSC (e.g., by a colleague, fellow employee, etc.), I agree that it is my obligation to report such information to a responsible individual, the DEA Memphis Resident Office and the UTHSC Police Department. This information will be treated as confidential and UTHSC shall take all reasonable steps to protect the confidentiality of the information and my identity, as the employee furnishing information. I understand that failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area.

_____

Signature Date

Print Name_____

Controlled Substances

Authorized User Access Log

THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Registrant Name: _____

Department: _____

Registrant Location: _____

Instructions:

List below all persons to whom Registrant has issued a key, key code or other access device to enter room or area, housing controlled substances.

Recipient's Name	Recipient's Title	Date Access Device Issued	Recipient's Initial	Registrant's Initials	CS Screening Date (Form 1)	Controlled Substances Training Date	Date Access Device Returned or Terminated	Registrant's Initials	Recipient's Initials

Controlled Substances Program Form 3
Controlled Substances Inventory

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Initial Inventory: ___Yes ___No **OR** **Biennial Inventory:** __ Yes ___No

Instructions: A separate copy of this form should be used for baseline controlled substances inventory for subsequent biennial inventories. A complete physical inventory should be completed of all controlled substances at the beginning or close of business. Separate inventory sheets must be maintained for Schedule I & II Controlled Substances and Schedule III, IV & V Controlled Substances.

Registrant's Name: _____ **Department:** _____

Registration Number: _____ **Registration Location:** _____

Complete Physical Inventory? ___Yes ____No **Date:** _____

Time: _____ **Beginning of Business** _____ **Close of Business**

Line No.	Name of substance	Identification Number or Manufacturer's Lot Number	Product Form / Concentration	Schedule	Volume or Quantity per Container	Number of containers
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
12						

***List opened/partially used containers individually.**

Make an exact count of C-I or C-II contents. Make an exact count if a C-III, -IV or -V container held more than 1,000 tablets or capsules. Count or measure the contents if the container holds less than 1,000 tablets or capsules.

At least two (2) people must together perform, sign and date this inventory: 1) _____ **2)** _____

Reviewed by Registrant: _____ Date: _____

(Signature)

Controlled Substances Program Form 4

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CONTROLLED SUBSTANCE CURRENT USE LOG

One log sheet should be completed for each container of a Controlled Substance. Controlled Substance usage must be tracked on a per dose (use) basis. Record the total quantity of the substance to the nearest metric unit weight or the total number of units finished form.

Drug Name: _____ **Schedule Invoice No:** _____ **CS Storage Location:** _____

Finished Form: _____ **(e.g.: tablet, powder, liquid) Strength**: _____**(eg:10mg/mL) Container Type:** _____**(glass, plastic) Registrant's Name:**

_____**Department:** _____**DEA Registration No.** _____**Registration**

Location: _____

Tracking No: _____ **Date Added to Inventory:** _____

Date	Amount Received	Amount Used	Balance (unit)	Printed Name of Person who Dispensed/Administered Drug	Reason for Use/Protocol #/Species (if applicable)

Log continued onto attached page. □ Y □ N

- This log must be kept in the controlled substance storage container. The log balance must match the physical balance of CS at all times.
- Any log discrepancies, or other circumstances that indicate significant loss or theft of controlled substance must promptly be reported to Research Safety Affairs.
- When this controlled substance is no longer needed, use a reverse distributor for disposal or contact Research Safety Affairs (ext. 8-6114) for disposal.
- When this controlled substance is completely used up, retain this log in your records for two years, deface empty container label and throw in regular trash.