



UT Health Science Center: HM5202 - Controlled Substances Policy	
Version 1	Publication Date: 06/14/2022

No./Title: HM5202 – CONTROLLED SUBSTANCES POLICY	Resp. Office: Campus Safety and Emergency Management	Effective Date: 5/14/2021
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Related Policies: UT System Safety Policy SA0100 UT System Safety Policy SA0700		
Forms:		

PURPOSE, SCOPE, AND APPLICABILITY

The University of Tennessee Health Science Center (UTHSC) is committed to complying with federal and state regulations involving controlled substances and controlled items. Due to their abuse potential, controlled substances are subject to licensing, registration, storage, security, use, and disposal requirements.

The purpose of this policy is to ensure that campus entities 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.

The scope of this document extends only to controlled substance licensees/registrants engaged in research, medical and clinical activities at the UTHSC Memphis campus.

This Policy applies to the use of controlled substances on campus, including in research conducted under the auspices of UTHSC, and all in vivo research under IACUC-approved protocols and in vitro research.

The acquisition, use and disposal of controlled substances in the state of Tennessee is regulated by the Tennessee State Board of Pharmacy and the United States Department of Justice Drug Enforcement Administration (US DEA). Individuals who use, manufacture or synthesize controlled substances under the auspices of the University 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.

The University does not hold an “institutional license” for use of controlled substances in research. Even if an individual has a practitioner’s (clinical) license and DEA registration for treatment of patients with controlled substances, if he or she will also be conducting laboratory or non-therapeutic research involving controlled substances, a separate research license from

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the Tennessee State Board of Pharmacy is required. In addition, for research with Schedule I-A drug, a separate registration with the DEA is required.

ABBREVIATIONS, ACRONYMS AND DEFINITIONS:

1. **Administer:** The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner or (in his presence) by his authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means.
2. **Authorized Official:** The individual(s) formally authorized to be the “approver” of DEA registration applications on behalf of the institution.
3. **Authorized User:** A University Member authorized to use Controlled Substances by a DEA Registrant.
4. **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.
5. **DEA:** U.S. Drug Enforcement Administration
6. **DEA Registrant:** A University Member who holds DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of Controlled Substances.
7. **Dispense:** To deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery;
8. **Dispenser:** An individual practitioner, institutional practitioner, pharmacy or, pharmacist who dispenses a controlled substance
9. **Disposal:** Relinquishment of contaminated, expired, excess, residual (or waste), or unwanted Controlled Substances.
10. **Drug Diversion (“Diversion”):** 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.
11. **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.
12. **HIPAA:** Health Information Portability Accountability Act. HIPAA is a US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.

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- 13. Individual Practitioner:** A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.
- 14. Mid-level Practitioner:** An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice.
- 15. Prescriber:** means an individual licensed as a medical doctor, podiatrist, dentist, optometrist, veterinarian, osteopathic physician, or physician assistant who has the authority to issue prescriptions for controlled substances, or an advanced practice nurse with a certificate of fitness to prescribe and the required supervisory relationship with a physician
- 16. PI:** Principal Investigator. The individual with final responsibility for the conduct of research or other activity described in a proposal or an award.
- 17. PII:** Personally Identifiable Information. PII is any data that could potentially identify a specific individual. Any information that can be used to distinguish one person from another and can be used for de-anonymizing anonymous data can be considered **PII**.
- 18. Precursor Chemicals:** Precursor chemicals are chemicals used in the course of legitimate research that can potentially be used in the illicit production of controlled substances, such as methamphetamine, cocaine, heroin, and MDMA (ecstasy). The mission of the Precursor Chemicals Control Programs is to disrupt the illicit production of controlled substances by preventing diversion of precursor chemicals.
- 19. Reverse Distributor:** A person or entity registered with the DEA and authorized to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction. Reverse distributors must destroy controlled substances received for the purpose of destruction within 30 calendar days of receipt. Day 1 is the day the substances are physically acquired through pick-up or delivery.
- 20. 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.
- 21. Schedule I:** Drugs or other substances that have no currently accepted medical use and a high potential for abuse.

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- 22. 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.
- 23. 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.
- 24. 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.
- 25. 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.
- 26. Teaching Activity:** Activities that include classroom demonstrations, laboratory exercises and research projects which are required for completion of a course at the undergraduate, graduate, or professional level.
- 27. University Member:** All UTHSC full- and part-time faculty, classified employees, administrative staff, paid student assistants, students, volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by program agreements or other contractual arrangements are considered university members for purposes of this Policy. Only full time faculty members can be DEA Registrants under this policy.

RESPONSIBILITIES:

- 1. DEA Registrant:** The responsibility for controlled substance compliance rests with the DEA Registrant. The DEA registrant is responsible for obtaining and renewing both the DEA registration and the TN State Board of Pharmacy license and for assuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met.
- 2. 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.

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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

Employee Questionnaire:

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:

1. Question. 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.
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? If the answer is yes, furnish details.

Copies of the form 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.

Controlled Substances Monitoring Database (CSMD)

All healthcare practitioners with DEA numbers who prescribe or dispense controlled substances in a practice providing direct care to patients in Tennessee on more than fifteen (15) days in a calendar year must be registered in the CSMD. Licensed veterinarians who never prescribe or dispense a controlled substance in an amount intended to treat a non-human patient for more than five (5) days are not required, but are encouraged to register.

STORAGE OF CONTROLLED SUBSTANCES:

Storage of Controlled Substances

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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.

1. Working Stocks – appropriate for most individually licensed Principal Investigators.

a. 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.

b. Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.

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:

1. 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.
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.

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[Controlled Substance Program Form 1: Employee Screening Statement](#) may be used 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.

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.

DISPOSAL OF CONTROLLED SUBSTANCES

This section sets forth the rules for the destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances within Title 21 Code of Federal Regulations, Part 1317 that are lawfully possessed by [Registrants \(subpart A\)](#), [Non-registrants \(subpart B\)](#), and [Destruction of Controlled Substances \(Subpart C\)](#). The purpose of such rules is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

At all times, disposal and destruction must abide by all regulatory procedures (e.g. forms, witnesses, logs, etc). All documentation record retention shall follow prescribed Federal, State, Local, and University requirements.

1. All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to §1317.95(c), shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable; or
2. Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual

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substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present; or

The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

General Destruction Methods and Procedures

In accordance with Title 21 Code of Federal Regulations, Part 1317.90 (Methods of Destruction) and 1317.95 (Destruction Procedures), the destruction of any controlled substance shall be in accordance with the following requirements:

1. Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction. If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.
2. Transport to a registered location. If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be followed:
 - a) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur);
 - b) Two employees of the transporting registrant shall accompany the controlled substances to the registered location;
 - c) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete;
3. Transport to a non-registered location. If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed:
 - d) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

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- e) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location;
 - f) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;
 - g) Two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and
 - h) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.
4. On-site destruction. If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed:
- a) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and
 - b) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

Practitioner inventory. Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

- (1) Promptly destroy that controlled substance in accordance with Title 1317, subpart C (Disposal) using an on-site method of destruction;
- (2) Promptly deliver that 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;
- (3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or
- (4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.
- (5) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (4) of this section, without prior application in each instance, on the condition that the practitioner keep records of such

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disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances.

Non-practitioner inventory. Any registrant that is a non-practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

- (1) Promptly destroy that controlled substance in accordance with Title 1317, subpart C (Disposal) of this part using an on-site method of destruction;
- (2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;
- (3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or
- (4) Promptly transport that controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall as described in paragraph (3) of this section.

GENERAL TRAINING AND INFORMATION REQUIREMENTS

General 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.

DEA Registrants, or their designees, shall provide appropriate training to all Authorized Users working under the license.

Effective July 1, 2014, all prescribers who hold a current federal drug enforcement administration (DEA) license and who prescribe controlled substances shall be required to complete a minimum of two (2) hours of continuing education related to controlled substance prescribing.

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RECORDKEEPING:

DEA registrants must maintain the following records at the registrant's location as identified on the registration:

- Employee questionnaire and authorization records
- Executed order forms
- Inventory records (must be kept for a minimum of two years from the date of record)
- Drug dispensing records (must be kept for a minimum of two years from the date of record).
- Key/Combination authorizations for access to controlled substances storage locations.

NOTE: A registrant who wishes to maintain records at a location other than the registered location must notify the DEA. Refer to [21 CFR 1304.04](#) for guidance.

Controlled Substance Tracking/Inventory

For each container of controlled substances, tracking records must be kept that note every time that these substances are used. Every mL or mg of a controlled substance must be accounted for in the dispensing records. The drug control record should have an entry for each time material was removed from the container.

An inventory must be performed to document controlled substances in the registrant's possession. The inventory must be performed initially upon receipt of controlled substances into the registrant's inventory for the first time and at least every two years thereafter. The inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location.

A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of CFR Title 21, Part 1304.

In the event that controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

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Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

Each inventory must contain the following information:

1. Whether the inventory was taken at the beginning or close of business
2. Names of controlled substances
3. Each finished form of the substances (e.g., 100 milligram tablet)
4. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
5. The number of commercial containers of each finished form (e.g., four 100 tablet bottles)
6. Disposition of the controlled substances

Control of PII and HIPAA

In part, the DEA states that “A registered practitioner is required to keep records of controlled substances that are dispensed to the patient, other than by prescribing or administering, in the lawful course of professional practice.” These usage logs may contain the patient full name, address, medication and the dosage received. Therefore, the DEA registrant (and subsequently Authorized Users) shall ensure that these logs are controlled and prevent disclosure or release to unauthorized personnel.

ASSOCIATED STANDARDS:

- Controlled Substances Act, 21 United States Code (USC), Drug Abuse Prevention and Control, Chapter 13
- 21 CFR 1300-1399, Drug Enforcement Administration, Department of Justice
- Tennessee Controlled Substances Act

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- Tennessee Legend Drug and Controlled Substance Research Act of 1984, Title 53, Chapter 14
- DEA Practitioner's Manual, 2006 Edition,
<https://www.deadiversion.usdoj.gov/pubs/manuals/pract/>