THE UNIVERSITY OF MEMPHIS®

Controlled Substances Program

June 2017

This Controlled Substances Program was approved by the Chemical Hygiene Committee on June 19, 2017, for use by University of Memphis personnel who use controlled substances in research.

University personnel creating, using, storing, or disposing of controlled substances for research purposes are expected to comply with the procedures contained herein. Personnel failing to abide by these procedures or the associated laws and regulations promulgated by the United States of America or the State of Tennessee are at risk for disciplinary action by the University and imposition of significant civil and/or criminal penalties.

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The University of Memphis
Controlled Substances Program

Purpose

The acquisition, use, and disposal of controlled substances in the State of Tennessee are strictly regulated by the Tennessee State Board of Pharmacy and the United States Department of Justice Drug Enforcement Administration (US DEA).

The purpose of this program is to ensure that researchers working with, or planning work with, controlled substances are aware of and understand their responsibility for complying with the relevant state and federal statutes, regulations governing the use of these substances, and University policy.

Scope and Application

This Program applies to the use of controlled substances in research conducted under the auspices of the University of Memphis (the "University"), including all *in vivo* research under IACUC-approved protocols and *in vitro* research.

The University does not hold an "institutional license" for use of controlled substances in research; therefore, any individual who possesses, uses, or synthesizes controlled substances for research under the auspices of the University must be: (1) licensed with the Tennessee State Board of Pharmacy and registered with the US DEA to conduct such research, or (2) authorized under the license of a Licensed Individual with respect to such research.

Individual clinical practitioners already licensed and registered with DEA for treatment of patients with controlled substances must have a separate research license from the Tennessee State Board of Pharmacy if he or she will also be conducting laboratory or non-therapeutic research involving controlled substances. In addition, a separate registration with the DEA is required for research with a Schedule I drug.

Definitions

Controlled Substance – A Controlled substance is a drug that is regulated by state and federal laws designed to control the danger of addiction, abuse, physical and mental harm, the trafficking by illegal means, and the dangers from actions of those who have used the substances.

Licensed Individual – The Licensed Individual is the person ultimately responsible for controlled substance research compliance. Typically, the Licensed Individual is the PI of a research protocol.

Other Authorized Individual – An Other Authorized Individual is a member of the Licensed Individual's staff, authorized to work with controlled substances under the Licensed Individual's license/registration.

Drug Schedules

Drugs, substances, and certain chemicals used to make drugs are classified by the DEA into five (5) distinct categories, or schedules, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a factor in the scheduling of drugs. Schedule I drugs

represent the highest potential for abuse and severe psychological and/or physical dependence; abuse potential decreases for each successive schedule number (i.e., Schedules II through V).

A list of controlled substances and associated schedules is available from the US DEA; however, the list only shows basic or parent chemicals and does not necessarily describe salts, isomers and salts of isomers, esters, ethers, and derivatives which may also be classified as controlled substances. Therefore, the list is intended as a general reference and is not a comprehensive listings of all such substances.

Controlled substances and analogs need not be listed as such to be treated as a Schedule I substance for criminal prosecution.

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are defined as the most dangerous drugs, with potentially severe psychological or physical dependence. Some examples of Schedule I drugs are:

- Heroin
- Lysergic acid diethylamide (LSD)
- Marijuana (cannabis)
- 3,4-methylenedioxymethamphetamine (ecstasy)
- Methaqualone
- Peyote

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, but less abuse potential than Schedule I drugs, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are:

- Cocaine
- Methamphetamine
- Methadone
- Hydromorphone (Dilaudid)
- Meperidine (Demerol)
- Oxycodone (OxyCotin)
- Fentanyl
- Dexedrine
- Adderall
- Ritalin

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:

- Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin)
- Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine)
- Ketamine
- Anabolic steroids
- Testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are:

- Xanax
- Soma
- Darvon
- Darvocet
- Valium
- Ativan
- Talwin
- Ambien

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are:

- Cough preparations with less than 200 milligrams of codeine or per 100 milliliters (e.g., Robitussin AC)
- Lomotil
- Motofen
- Lyrica
- Parepectolin

Some of the controlled substances used in research and their schedule numbers and DEA codes are:

Substance	Schedule	Narcotic?	DEA Code
Ketamine	III	N	7285
Pentobarbital (e.g., Nembutal)	II	N	2270
Buprenorphine	III	Y	9064
Fentanyl	II	Y	9801
Diazepam	IV	N	2765
Pentobarbital & non-controlled active ingredients (e.g., Beuthanasia)	III	N	2271

Responsibilities

Licensed Individual

The responsibility for controlled substance research compliance rests with the Licensed Individual. In addition, the Licensed Individual shall:

- Obtain, and renew in a timely manner, both the TN State Board of Pharmacy license and DEA registration;
- Pay all required registration and licensure fees;
- Ensure that all acquisition, storage, security, inventory, disposal, reporting, and record-keeping requirements are met; and

- Pay all fees associated with disposal of controlled substances associated with his or her research.

Other Authorized Individual

Other Authorized Individuals shall comply with all applicable federal and state laws/regulations, conditions of the Licensed Individual's license and registration, and with this program.

Environmental Health and Safety

Environmental Health and Safety (EH&S) shall assist researchers and PIs in maintaining compliance with this program. EH&S responsibilities include maintaining this written program; providing University personnel with guidance on licensing, registration, decommissioning, waste disposal, and related tasks; and performing periodic reviews of each Licensed Individual's management of controlled substances and compliance with this program.

Procedures

Researcher Licensing and Registration

Authorization for acquisition and use of controlled substances for research requires both licensing with the Tennessee State Board of Pharmacy and registration with the US DEA. Note that licensing requirements for research are separate from, and in addition to, requirements that apply to medical practice; therefore, MDs and MD/PhDs conducting laboratory or non-therapeutic human subject research involving controlled substances must obtain licensure/registration for laboratory use of controlled substances in addition to licensure for their practice.

The online appendices include a link to instructions for obtaining a state license and DEA registration.

Authorizing Other Users

A Licensed Individual may designate additional University employees under his or her supervision as Other Authorized Individuals to use controlled substances for approved activities at the registered physical location; however, the Licensed Individual retains overall responsibility for meeting all regulatory requirements.

Prior to authorization, the Licensed Individual shall screen these employees as described at 21 CFR 1301.90. Therefore, Licensed Individuals may not name as Other Authorized Individuals any person who has (1) been convicted of a felony offense relating to controlled substances, or (2) has had at any time an application for registration with the DEA denied, a DEA registration revoked, or has surrendered a DEA registration for cause. This information should be documented on the screening form included in the online appendices or on an equivalent form. Names of Other Authorized Individuals shall be listed on the Licensed Individual's controlled substance protocol submitted with the license application. The Licensed Individual shall maintain appropriate records of who has access to controlled substances in their lab, including the substances and amounts used, using the form included in the online appendices or on an equivalent form.

Procurement of Controlled Substances

Procurement and Contract Services may require additional information from a Licensed Individual for initial orders and amendments to initial orders for use of controlled substances in research (see 21 CFR 1301.18 and 1301.32). For Schedule I and II drugs, the request must include a completed DEA Form 222.

Licensed Individuals may only order/purchase controlled substances within the class(es) specified on their license and registration. For example, if the Licensed Individual is approved for the purchase/use of Schedule II non-narcotic drugs (e.g., Nembutal), that **does not** mean that he or she can also purchase a Schedule II narcotic drug (e.g., Fentanyl) not specified on the DEA application.

All orders for controlled substances shall list the "ship to" address as the address listed on the license and registration of the Licensed Individual ordering the material.

Receipt of Controlled Substances

A Licensed Individual shall verify the accuracy of a shipment of controlled substance(s) immediately upon receipt. Discrepancies shall be reported to the DEA, UofM Police, EH&S, and the supplier within one hour of discovery.

Storage and Security

Controlled substances shall at all times be properly safeguarded and securely kept at the address on file with the State Board of Pharmacy and 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 Individuals and Other Authorized Individuals. Security requirements vary depending on the schedule of controlled substance as noted below.

General Requirements for Storage

All controlled substances shall be stored behind at least two differently keyed locks at all times.

- Keyed lockboxes shall not have keys stored near the lockbox, and all such keys shall be stored separately from other keys giving access to the controlled substance(s).
- Combination lock lockboxes shall conform to the following:
    - Only the Licensed Individual and a minimal number of designated Other Authorized Individuals shall know the combination.
    - A request to change the combination shall be submitted within ten (10) business days after a Licensed Individual or Other Authorized Individual knowing the combination leaves the employ of the University, or is no longer licensed, or is no longer an Other Authorized Individual. If the combination cannot be changed immediately, additional security measures shall be implemented until such time as the combination is changed.

Schedule I and II Controlled Substances

- Schedule I and II substances shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V Security Container.

- A safe or cabinet weighing less than 750 lbs. must be secured to something of substantial construction (e.g., bolted to wall or floor, or base imbedded in concrete).

Schedule III, IV, and V Controlled Substances

These substances shall be stored using one of the following methods*:*

- A wall mountable, controlled substance lockbox with two doors and two locks (each lock shall be keyed differently)
- A single-lock lockbox that is stored in a drawer or cabinet that is secured at all times with a hasp and padlock (The drawer and cabinet shall be substantially constructed (e.g., in a drawer that is part of either a bench or cabinet that is mounted to the wall or floor).)
- A single-lock lockbox, stored in a drawer or cabinet in a room that is inaccessible to the public and the door kept locked at all times
- A safe or steel cabinet meeting the requirements for storage of Schedule I and II substances
- A single-lock lockbox in a refrigerator or freezer that can also be locked and is within a room that is also lockable (This is only permitted where storage at 4°C or colder is required.)

Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss shall be documented by the Licensed Individual and a witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g., tablets), must be placed in the disposal waste stream. If the spilled controlled substance is not recoverable (e.g., liquids); the Licensed Individual and a witness shall document the circumstances in the inventory record.

Disposing of Controlled Substances

Licensed Individuals should make every effort to limit the amount of controlled substances requiring disposal. This can be accomplished by monitoring expiration dates, ensuring use of controlled substances within the appropriate timeframe, and limiting purchase/storage of controlled substances to appropriate quantities (e.g., sufficient to support the equivalent of 3-months research).

If controlled substances expire or otherwise require disposal, the Licensed Individual shall contact EH&S for assistance; this may be accomplished by submitting an Unwanted Chemical Declaration Form. While awaiting removal by EH&S or University hazardous waste contractor, all controlled substances shall remain securely stored in accordance with the “Storage” section of this Program.

Reporting Diversion, Theft, or Loss of Controlled Substances

Anyone having knowledge or reasonable suspicion of inventory irregularities or diversion, theft, or loss of controlled substances from a registered location shall report such information to UofM Police, EH&S, and the Licensed Individual (if the licensed individual is not the person reporting). The Licensed Individual shall, within one business day of discovery, report the incident to the TN State Board of Pharmacy and US DEA using the procedures promulgated by each respective agency.

Recordkeeping

The Licensed Individual is responsible for maintaining all required records of controlled substances associated with his or her research. These records shall be maintained at the premises where the licensed activity is conducted and be readily available for inspection by EH&S, TN State Board of Pharmacy, or the US DEA. All signatures in the inventory and records must be legible and dated.

Initial Inventory Documentation

On the day after DEA registration is received, when research with/possession of controlled substances begins, and upon receipt of a controlled substance, an initial inventory shall be performed using the "Initial Controlled Substance Inventory Form" included in the online appendices or on an equivalent form containing at least the same information.

Use Documentation

Use of controlled substances shall be documented on the "Controlled Substance Use Form" included in the online appendices or on an equivalent form containing at least the same information.

Inventory Documentation

An inventory of the stock of controlled substances at all locations where controlled substances are present shall be recorded at least annually. Annual inventory date must be within one year of each previous inventory. Document the inventory using the "Annual Controlled Substance Inventory Form" included in the online appendices or on an equivalent form containing at least the same information.

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.

Inventories and records of controlled substances listed in Schedules I and II, including DEA Form 222, shall be maintained separately from other controlled substance records of the Licensed Individual.

Records Retention

All records shall be maintained by Licensed Individuals for a period of at least **five (5) years** from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance.

Disposal and Transfer of Controlled Substances

Licensed Individuals needing to dispose of controlled substances shall notify EH&S and submit an Unwanted Chemical Declaration Form found in the online appendices. Licensed Individuals shall also document disposal of controlled substances by maintaining written records containing:

a. Date of transfer to EH&S or disposal contractor;

b. Name, form, and quantity of the substance transferred;

c. Name, address, and registry number of the person from whom transferred; and

d. Name, address, and registry number of the supplier or manufacturer to whom the substances are transferred.

If a Licensed Individual transfers a controlled substance to another Licensed Individual, the transfer must also be documented, with a copy to EH&S, and all inventory records and other records pertaining to the inventory must be transferred to the next Licensed Individual responsible for the controlled substance.

Licensed individuals disposing of or transferring a controlled substance to another licensed individual shall remain licensed until all such transactions are complete.

In the event of death or extended absence of a Licensed Individual, the Licensed Individual's supervisor shall notify EH&S, which will arrange for disposal or transfer of controlled substances to another Licensed Individual who will assume responsibility for them.

Abandonment

Abandonment of controlled substances is prohibited. Licensed Individuals leaving the University of Memphis shall initiate the decommissioning process and notify EH&S 30 days prior to termination of employment; this will allow records to be reconciled and unused controlled substances properly disposed of or transferred in a timely manner to the inventory of another Licensed Individual at the University of Memphis. However, should a Licensed Individual depart the University without appropriately disposing or transferring all controlled substances associated with their activities, the department chair shall be responsible for appropriate disposition of the controlled substances as part of the required decommissioning process.

Online Appendices

Controlled Substance Licensing and Registration Instructions

Initial Controlled Substance Inventory Form

Annual Controlled Substance Inventory Form

Controlled Substance Use Log

Screening Form for Other Authorized Individuals

Other Authorized Individuals Log

Laboratory Decommissioning Form

Unwanted Chemical Declaration Form