

I. Introduction

These procedures supplement the Use of Controlled Substances in Research Policy (the "Policy").

II. Definitions

All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

III. Procedures

- A. Authorized Individual. Individuals must obtain authorization from a DEA Registrant prior to ordering, possessing, using, or storing Controlled Substances on the DEA Registrant's behalf.
1. To become an Authorized Individual:
 - a. Complete the following forms:
 - i. DEA Personnel with Access to Controlled Substances form
 - ii. Authorized Personnel Screening Statement
 - iii. Authorization and Consent to Release Confidential Information
 - b. Submit completed forms with original signatures to the DEA Registrant.
 2. DEA Registrant.
 - a. A DEA Registrant must authorize in writing all staff and students who will be working on the registrant's project involving Controlled Substances. Authorizations should be kept in the Registrant's lab records and maintained.
 - i. Authorized Individuals may engage in approved activities under the direction of the registrant. The activities must be delegated by the registrant to Authorized Individuals in writing. The registrant can authorize any individual who has been successfully screened and directly reports to him/her, works under his/her direction and is directly involved with a research project related to the specific DEA registration.
 - ii. The registrant must performed security and background checks for all individual(s) prior to granting authorization as an authorized user.
 - iii. A registrant may not allow any individual to have access to controlled substances if an application for registration was submitted by the individual and denied or revoked by the DEA.

- b. Research involving the use of Controlled Substances with animals must have an approved IACUC protocol with the substances listed. Research involving human subjects and controlled substances must have an approved IRB protocol with the substances listed.
- c. The DEA Registrant is responsible for managing Controlled Substances in accordance with applicable law, including inventory, record keeping and security provisions.
 - i. Assure that unauthorized user(s) do not have access to the storage cabinet and/or controlled substances
 - ii. Assure that only the registrant or Authorized Individuals are allowed to reconcile Controlled Substance shipments from outside vendors into the inventory logs
 - iii. Provide written documentation to each Authorized Individuals related to his/her specific responsibilities and authorization. This includes conducting inventories, receiving packages, having access to storage locations, administering drugs, etc.
 - iv. Ensure that all Authorized Individuals are properly trained and are aware of all applicable regulations.
 - v. Ensure current familiarity with DEA regulations and change in category of controlled substances

B. Acquisition and Delivery.

1. Controlled Substances. All Controlled Substances must be legally acquired. Only DEA Registrants can purchase Controlled Substances for use in research. NOTE: A clinical practitioner (i.e. physician, veterinarian, etc...) shall not issue a prescription to themselves to obtain controlled substances to be stored or dispensed for research purposes.
2. Delivery of Controlled Substances
 - a. Controlled Substances must be delivered directly to the address on the holder of the DEA registration.
3. The registrant for each registered location must maintain complete, current and accurate purchasing records if Controlled Substances are stored, delivered or administered at that location. The following information should be recorded when receiving a Controlled Substance shipment:
 - a. Name, address, and DEA registration number of the supplier.
 - b. Name, concentration or weight, dosage form, and quantity of Controlled Substance received
 - c. Signature of the person receiving the shipment (this must be either the registrant or an Authorized Individual)
 - d. Date received

4. For schedule I and II Controlled Substances, copy 3 of the triplicate DEA Form 222 must be completed, maintained and kept separate from all other records.
5. Invoice and acquisition records of Controlled Substances listed in schedule I and II must be maintained separately from all other records. Invoice and acquisition records of Controlled Substances listed in schedules III-V must be maintained either separately from other records or in a form such that the information is readily retrievable. All invoice and acquisition records must be kept for at least two years from the date of record.
6. Schedule I or II. Any person registered to conduct research with schedule II Controlled Substances must send, in triplicate, DEA order form #222. This form can only be obtained through the DEA. Researchers must contact the DEA directly at 1-800-882-9539 or submit an [online request through the DEA](#). Schedule I and II Controlled Substances can only be ordered by the registrant.
7. Schedule III-V Controlled Substances may be purchased by contacting a commercial supplier. Schedule III-V Controlled Substances can only be ordered by the registrant or an Authorized Individuals of the registrant.

C. Transfers

1. Import/Export. Special procedures, authorization and reporting forms are required. This may include interstate activities. DEA Registrants intending to engage in these activities must thoroughly research applicable procedures and requirements before proceeding. Information from the DEA on the import/export of controlled substances for scientific purposes can be found at http://www.deadiversion.usdoj.gov/imp_exp/index.html
2. Transfer between Registrants/Research Groups. Registrants may only transfer Controlled Substances to other registrants. Each registrant must be approved to possess the scheduled drug or chemical that is transferred. The following information must be included and maintained in the records of both the supplier and the recipient of the transferred Controlled Substances. The following information must be included in any document used to transfer a Controlled Substance:
 - a. Name, address, and DEA registration number of the recipient
 - b. Name, address, and DEA registration number of the supplier
 - c. Name, concentration, and quantity of Controlled Substance transferred
3. Transfer Date. A [DEA Form 222](#) must be used for transfers of Schedule I and II substances. The recipient must submit attached copies one and two to the supplier. The supplier must retain one and submit copy two to the DEA.

4. Any documentation must be signed and dated by both the supplier and recipient upon delivery. The form\document should be filed with inventory records and kept for at least two years.
5. Secure and log the newly received Controlled Substance into the current inventory upon delivery. The recipient must complete copy three of DEA Form 222 if the substances received are in schedule I or II.

Note: Registrants can only transfer up to 5 percent of their annual total controlled substance dosage units to other registrants without having to acquire a separate distributor registration.

D. Security.

Controlled Substances must be stored in securely locked, substantially constructed drug cabinets or safes in locations where access is limited. Any PI who has concerns with security locations should contact the Office of Research to ensure the cabinets or safes used to store Controlled Substances conform to applicable requirements. Generally, acceptable storage includes safes and steel cabinets cemented or bolted to the floor or wall, as well as locking storage drawers that are inaccessible from the upper or lower drawers in the stack. Portable, locked safety cabinets, standard file cabinets, and open spaces (e.g. corridors) are not sufficient for the storage of Controlled Substances.

All Controlled Substances must be kept locked in their storage location except when it is necessary for Authorized Individuals to remove, legitimately work with and replace the Controlled Substances. Controlled Substances must not be left unattended, and when they are not being used for research, they must be securely stored in the drug cabinet or safe.

Keys and/or combinations to the cabinet or safe should be secure and under the direct control of the DEA Registrant and their associated Authorized Individuals at all times. Combinations to safes must be changed whenever an authorized user, with access to the safe, departs the unit or is no longer authorized access.

E. Reporting of Loss, Destruction, Theft, or Unauthorized Use.

Thefts, suspect thefts, unauthorized use, or other losses of any Controlled Substance must be reported immediately to the DEA within one (1) business day upon discovery. In addition to phone reporting, a Report of Theft or Loss of Controlled Substances (DEA Form 106) must be completed and submitted to the Dallas Field Division Office. The DEA recommends that the form be submitted electronically by completing the [online version of Form DEA-106](#).

Any unauthorized persons who gain access to Controlled Substances for the purpose of diversion or theft must be reported to the DEA.

A copy of all reports and/or investigations must be kept by the registrant.

Additional information on the DEA requirements for the reporting of theft or loss of controlled substances can be found at

http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

F. Recordkeeping.

1. General. Controlled Substance records and inventories must be maintained in conformity with federal regulations ([21 CFR-Part 1304](#)). All documents related to Controlled Substances must be readily retrievable and available for any audit. "Readily retrievable" means that specific records are kept in such a manner that they can be separated from all other records and retrieved in a reasonable time frame. Registrants must maintain all records at the address listed on one's DEA registration. The registrant must maintain complete and accurate accounting of all Controlled Substances from the time they are ordered until they are completely used or otherwise disposed in accordance with regulations.
2. Records and inventories must be maintained for at least two years. A separate logbook should be kept containing the Controlled Substance information. All records must be stored in a secure location, preferably locked in the cabinet or safe containing the controlled substances.
3. All records of schedule I and II Controlled Substances must be kept separately from those of schedule III-V substances.
4. All records of Controlled Substances in schedule III-V must be kept separately from all other records of the registrant in such a form that the records are retrievable.
5. The following records must be maintained and be readily available:
 - a. DEA Registration
 - b. Authorized Individual background checks and authorized user log
 - c. Acquisition and ordering invoices
 - d. Signed and dated supplier invoices or packing slips
 - e. DEA Form 222s
 - f. Used, voided and unused Form 222s
 - g. Inventory records
 - h. Initial inventory
 - i. Biennial inventory

- j. General inventory
- k. Usage and administration records
- l. Multiple dose usage log
- m. Diluted drug solution log
- n. Transfer records of controlled substances between registrants
- o. Disposal records
- p. DEA Form 106-Report of Loss or Theft

6. Inventories.

- a. General. All inventories must be kept at the registered site. Inventories must be maintained in a written, typewritten, or printed form at the registered location (or approved DEA location) for at least two years from the date the inventory was completed. Inventories (initial, biennial and general) must include the following information:
 - i. Name, address and DEA registration number of the registrant
 - ii. Date and time the inventory was performed (at the beginning or the end of the day)-Initial and Biennial
 - iii. Signatures of the registrant or Authorized Individuals responsible for taking the inventory.
 - iv. Initial and Biennial
- b. For each controlled substance in finished form the inventory must include:
 - i. Name of substance
 - ii. Each finished form of the substance (ex. 5-mg tablet or 5-mg concentration per fluid ounce)
 - iii. Number of units of volume of each finished form in each commercial container (ex. 100-tablet bottle or 5-mL vial)
 - iv. Number of commercial containers of each finished form (ex. 5 100-tablet bottles or 6 5-ml vials)
- c. For damaged, defective or impure substances, substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounds, the inventories must include:
 - i. Name of substance
 - ii. Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form.
 - iii. Reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.
- d. When determining the number of units of each finished form of a Controlled Substance in a commercial container which has been opened, do the following:

- i. If the substance is listed in schedule I or II, make an exact count or measure of the contents.
 - ii. If the substance is listed in schedule III-V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which the exact count of the content must be made.
- e. Schedule I and II Controlled Substance inventories must be separated from inventory records of schedule III-V substances.
- f. Initial Inventory. A separate inventory must be performed on the date the registrant first engages in any activity covered by his or her registration. It is advised that this be done when the registrant receives their initial DEA registration.
An initial inventory must be taken for any newly scheduled substance that was not previously listed on any schedule.
- g. Biennial Inventory. The DEA requires a physical inventory of all Controlled Substances be conducted every two years. The inventory may be taken on any date within two years of the previous inventory date. The inventory must be kept at the registered site for at least two years after completion of inventory.
- h. General Inventory. A continuous general inventory log is required to track acquisitions, current on-hand stocks, administration, transfer to usage logs transfers to other registrants and disposal. A separate general inventory log should be created for each stock of drug and its associated strength or container size.
- i. Schedule I and II records must be separate from schedule III-V records.

G. Disposal and Destruction of Controlled Substances.

1. The DEA Registrant is responsible for the proper disposal of any Controlled Substance in their possession. The preferred method of disposal of Controlled Substances is complete use of the substance. The registrant must properly dispose of any Controlled Substance in their possession prior to retiring, leaving TCU or allowing their registration to expire. Failure to do so is a violation of DEA regulations and the registrant may be subject to penalty that may include fines and imprisonment.
2. Controlled Substances consumed in a reaction or converted into a hazardous waste mixture from which a Controlled Substance is not recoverable may be disposed of through routine waste disposal with TCU EHS. If a Controlled Substance has expired, is no longer needed, or if the registrant is discontinuing research due to retirement or new employment, then the registrant should contact EHS in a timely manner for disposal procedures.

To schedule a pickup of hazardous waste, submit the Request for Disposal through TCU EHS.

Empty bottles from controlled substances must be triple-rinsed with tap water then disposed of in any appropriate waste container.

3. The registrant may dispose of out-of-date, damaged, or otherwise unusable or unwanted Controlled Substances, including samples, to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The registrant should contact the Dallas DEA Field Division Office for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III-V controlled substances may be transferred via an invoice. All disposal records must be kept at the registrants' location for a period of two years. Refer to [DEA Drug Disposal Information](#) for additional information.

H. Inspections. Any of the following parties may conduct random inspections of any lab located on TCU's premises that uses, stores, or otherwise possess Controlled Substance. Such inspection may be unannounced.

- The Office of Research may conduct inspections, including proper storage, recordkeeping procedures, and all other aspects of the Policy and this procedure.
- The DEA may conduct random audits and inspections.
- The Institutional Animal Care and use Committee (IACUC) will conduct biannual inspections of all laboratories approved for animal research. This inspection includes a check of proper storage of Controlled Substances.

IV. Related Research Policies and Procedures

Research Integrity Policy
Research Integrity Procedures
Use of Controlled Substances in Research Policy

VI. Effective Date

Effective Date: July 19, 2018