UNIVERSITY OF
NORTHERN COLORADO

Environmental Health and Safety

Controlled Substance Management Plan for Researchers

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I. Introduction

The Drug Enforcement Administration (DEA) enforces the controlled substances laws and regulations of the United States. The Controlled Substances Act (CSA) places all substances which were in some manner regulated under existing federal law into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. More information can be found in Title 21 United States Code (USC) Controlled Substances Act. The CSA also provides a mechanism for substances to be controlled (added to or transferred between schedules) or decontrolled (removed from control). The procedure for these actions is found in Section 201 of the Act (21U.S.C. §811). Through the DEA, it is possible to conduct business with controlled substances.

This manual describes the procedures for complying with the United States Drug Enforcement Administration (DEA).

All Principal Investigators (PIs) involved in the use of controlled substances for research must know and comply with all state and federal regulations regarding the procurement, recordkeeping, inventory, storage, use, and disposal of those substances.

PIs using DEA controlled substances in research must obtain a DEA individual researcher registration and the PI is ultimately responsible for all activities occurring under their registration.

II. Definitions

Authorized User
An authorized user is an individual authorized by a PI to use controlled substances under the PIs direction. Completion of appropriate training is required.

Certificate of Registration
A certificate of registration is a form issued by the DEA (DEA Form 223). The certificate must be maintained and displayed at the registered location in a readily retrievable manner and must be available for DEA and UNC inspection.

Controlled Substance
A controlled substance is any substance listed in the Controlled Substances Act (21 CFR, part 1300 to end), Lists of Scheduling Actions, Controlled Substances, and Regulated Chemicals published by the DEA.

Dispense
The term "dispense" means 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 and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who delivers a controlled substance to an ultimate user or research subject. (21 USC §802(10))

Disposal
Disposal is the proper relinquishment of contaminated, expired, excess, residual (or waste), or unwanted controlled substances.

Drug Enforcement Administration (DEA)
The agency within the United States Department of Justice that enforces the controlled substances laws and regulations is called the Drug Enforcement Administration.

Expired and/or Unusable Substances
Controlled substances for which the expiration date has passed, along with tablets, injections, liquid, or preparations compounded in error that contain controlled substances that can no longer be used for research due to contamination, etc. are called expired and/or unusable substances.

Principal Investigator (PI)
The Principal Investigator is the individual with overall responsibility for the conduct of research or other activity described in a proposal, protocol, or an award, and/or the individual with fiduciary responsibility for award management.

Recordkeeper
The recordkeeper is an individual who provides only data entry services and is assigned by the registrant to assist with the registrant’s records. The recordkeeper is not authorized to dispense substances, enter new substances into inventory, or dispose of substances. The registrant is responsible for all actions and records of the recordkeeper.

Registrant
The registrant is a UNC faculty member who holds a DEA license and is responsible for ordering, storing, using, recordkeeping, and disposing of controlled substances or controlled substances research protocols.

Registration
Registration is the formal grant issued by DEA to an individual for specific authority for controlled substances activities. Often referred to as a license or certificate.

Research
Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research may be defined in additional detail in certain contexts.

Transfer
To move controlled substances from the inventory of one DEA registrant to another DEA registrant is known as a transfer.

Usage Log
The usage log is a document completed by each registrant and authorized user tracking usage of controlled substances. The registrant must keep a controlled substance usage log for a minimum of two (2) years from the date of the last entry.

III. Controlled Substance Definitions

According to the DEA Diversion Control Division, “drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and the likelihood of causing dependence when abused.” Definitions of controlled substance schedules can be found here: https://www.deadiversion.usdoj.gov/schedules/#define.

IV. DEA Exempt Chemical Preparations

There are certain diluted substances available for purchase that have been approved by the DEA for vendors to sell for use in research, including use as testing standards. This commercial process and dilution have been vetted through the DEA for that purpose, and the resulting substances do not require a DEA registration for use. Labs cannot make their own diluted standards to avoid DEA regulations.

V. Who Must Register

UNC faculty who store, administer, or order-controlled substances for controlled substance research protocols on which they are a contributing investigator, must register with the DEA (for Controlled Substance Schedules I-V. To be a registrant, the individual must have oversight of the research protocol.

VI. Separate Registrations for Separate Locations

Registrations must be for the specific location where the controlled substances are stored. This means that a registrant seeking to work with controlled substances in multiple locations (labs) must have multiple registrations, registration for each location.

VII. Registrants Holding a Clinical Practitioner Registration

A practitioner registration from the DEA allows for clinical research and instructional activities with the controlled substances for which registration was granted. Practitioner registration does not authorize the use of controlled substances for animal research or chemical analysis. A separate researcher registration is required for these activities. Those individuals who wish to use a controlled substance in research must register independently with the DEA. Individual registration can be processed by submitting DEA Form 225 to the DEA.

VIII. Registration and Inspection

It is the responsibility of each registrant to obtain the required registrations and to comply with applicable state and federal regulatory requirements when working with controlled substances. Registrants must maintain current registrations until all their controlled substances are spent or disposed of properly.

Registrations must be for a specific location where controlled substances are stored. When registering, use the street address, department name, building name, and room number where the controlled substances will be stored. A registrant seeking to store controlled substances in multiple locations (labs) must have multiple registrations, a registration for each location (lab).

Registrations should cover the schedules needed for approved research protocols.

To Obtain a DEA Certificate of Registration

For Controlled Substance Schedule I, registration application for DEA cannot be completed online, researchers must print and complete DEA Form 225, along with the following required attachments. The application and required attachments must be mailed to the DEA:
The researcher must attach 3 copies of protocol, including curriculum vitae to conduct research with Schedule 1 controlled substances.

- Name, address, DEA registration number (if any)
- Institutional or company affiliation
- Qualifications, including Curriculum Vitae (CV) with a list of publications
- Research Project:
    - Title of project
    - Statement of purpose
    - Name of controlled substance(s) (CS) involved amount (with justification) of each needed and source.
    - Research protocol (detailed description of procedures), including number and species of research subjects, dosage to be administered, route and method of administration, and duration of the project.
    - The location where research will be conducted.

- Statement of security provisions for storing and dispensing the CS(s) in order to prevent diversion.
- If investigator plans to manufacture or import the CS(s), statement of quantity to be manufactured or imported and sources of chemicals to be used or substance to be imported.
- Authority (if applicable):
  - Institutional approval
  - Approval from Environmental Health and Safety (EHS) Department.
  - Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number).
  - Indication of an approved funded grant (number) if any.

For Controlled Substance Schedules II-IV, registration application for DEA must be completed***.*** The online application allows the applicant to obtain an electronic receipt of the application as soon as it is complete. A copy of the original application must be kept by the PI.

Information concerning the DEA registration process can be obtained from the DEA field office by contacting the Registration Call Center at 1-800-882-9539, or online. The DEA Call Center is staffed from 8:30 a.m. to 6:00 p.m., EST. During non-business hours, information is available through an automated Call Center Menu.

Termination from the University

If the registrant leaves, retires, or is terminated from the university, please notify Environmental Health and Safety department (EHS) as soon as possible, preferably 30 days before termination. EHS will need to discuss transferring or disposing of the registrant's DEA controlled substance(s). The registrant is responsible for the management of their DEA controlled substances as long as they have their license.

DEA Inspections

The DEA local Special Agent will coordinate the scheduling of DEA inspections. Prompt responses to requests for availability are not only appreciated but also may expedite the inspection process.

The Registration applicant must be present for the inspection.

Registration applicants must be prepared to answer questions regarding the entire path of the controlled substance listed in the application. Questions may include when and where the controlled substance is ordered to, how it is safely brought to that location/lab and secured in the location/lab.

IX. After Receiving the Registrations

As each registration is received, send a copy to EHS and Human Resources. EHS maintains a database of all researcher registrations of controlled substances.

DEA registrations are active for a one (1) year period or less.

X. Changes to Registrations

If any aspect of the registration changes, the DEA must be notified as outlined below.

For changes to a DEA registration, registrants must submit a DEA Registration/Application Update Request online. The link to the “Registration Changes” form can be accessed online.

After submitting a request for changes to your registration, notify EHS.

Examples of changes may include:

- Address
- Schedule
- Change in location of where the controlled substance(s) is stored. The controlled substance(s) cannot be moved to the new location until after the DEA has inspected the new location and approved the change.

XI. Adding Controlled Substances to Already Approved Registrations

If a registrant is already approved for a specific schedule (Schedules II-VI) and would like to add controlled substances within the same schedule to his/her research protocol, no additional submissions/requests need to be made to the DEA for changes in specific controlled substances under those schedules. However, the registrant should ensure that their research protocols and inventory have been updated to reflect any changes in controlled substances.

Any changes in controlled substances for a Schedule I Registration requires the submission of supplemental research protocols and DEA Headquarters approval. Registrants must log in to their DEA registrations online and request a modification to their current Schedule I researcher registration by adding the needed/requested drug codes. Supplemental research protocols are processed the same way as original research protocols. If needed, the DEA will request additional information regarding the supplemental research protocol.

After submitting a request for changes to your registration, notify EHS.

XII. Registration Renewals

For DEA registration renewals, complete Form 225a online.

Make sure that registrations are renewed in a timely manner. Expired registrations are inactivated by the DEA after one (1) month. If registrations are inactivated by the DEA, the registrant will need to re-apply for a new registration.

It is recommended that registrants place a renewal reminder on their calendar a few months prior to expiration. DEA reminder notices are inconsistent.

Once PIs receive their renewed certificate of registration, DEA form 223, send one (1) copy of the renewed registration to EHS.

If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.

Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances for any period of time under an expired registration.

XIII. Authorized Users

The registrant is individually responsible for adhering to federal and state regulations and to university policies pertaining to the possession and use of controlled substances. If needed, the registrant may identify individuals to be authorized users.

Please note that the PI cannot authorize the use of DEA products to anyone other than one who directly reports to the PI. Therefore, the PI with the registration cannot allow another PI or their staff to use or buy products under the DEA registration unless the registered PI is in a direct supervisory role of the individual(s) or is working as a co-PI on a research project.

A PI may formally authorize specific staff members under their supervision, or a co-investigator on the research project, to have access to the regulated pharmaceutical substances, including controlled substances regulated by the DEA. The completed authorization form should be kept by the PI for the length of each individual's employment (or for co-investigators, the duration of their project affiliation), plus an additional three (3) years.

XIV. Personnel Screening Form – Authorized User

To comply with DEA guidance, all authorized users shall complete the Personnel Screening Form– Authorized User prior to the handling of any controlled substances and on a yearly basis (such as at the time of renewal of the DEA Registration). (21 CFR 1301.90)

The registrant must retain this completed form in a secure confidential file.

XV. Roles and Responsibilities

Office of Research:

- Increase awareness of and accountability for compliance when using controlled substances in research.

Registrants:

- Comply with federal and state regulations and university policy pertaining to the possession and use of controlled substances. The Registrant is individually responsible for adherence to DEA regulations.
- Maintain a copy of the original DEA controlled substance application and any documents of modifications or changes made to the registration.
- Obtain and maintain DEA registrations.
- Retain a record of training completion.
- If needed, identify and document individuals as authorized users.
- Complete an annual review of the Personnel Screening Form– Authorized User for each authorized user.
- Maintain documentation for current authorized users.
- Provide and maintain documentation on training in laboratory-specific operations involving controlled substances.
- Ensure proper storage of controlled substances.
- Maintain strict control over the security of the location of the controlled substances along with the inventory of records.
- Obtain DEA approval for schedule changes prior to ordering, inventorying, dispensing, or disposing of such substances.
- Schedule I, Schedule II, and Schedule III-V controlled substances **cannot** be stored together! For each of these three categories, the registrant must maintain a separate storage area and a separate set of drug logs (inventory, usage logs, etc.).
- Receive, store, use, and dispose of controlled substances properly.
- Complete all drug logs contemporaneously as controlled substances are received, used, and disposed of.
- Retain drug logs (Inventory Record, Dispensing Record, Usage Log, Wastage Record, and Disposal Log) for three (3) years after the complete use or disposal of controlled substances.
- Exercise signature authority for purchases and disposal of controlled substances.
- Conduct an initial inventory.
- Conduct a biennial inventory.
- Report the theft or loss of any controlled substance to the DEA Field Division (using DEA Form 106), Department of Public Safety, and EHS within one (1) business day of discovery of such loss or theft.
- Dispose of unwanted controlled substances in accordance with DEA regulations.
- Dispose of controlled substances no longer supported by an approved protocol.

- Upon receipt, send copies of current DEA registrations to EHS.
- Report lapse of DEA registration to EHS immediately.
- Report DEA audits to EHS immediately.

Authorized Users:

- Complete the Personnel Screening Form–Authorized User before commencing the use of controlled substances. Thereafter, annually review Personnel Screening Form–Authorized User, as needed.
- Sign the Authorized Users Signature Log (Note: separate logs are kept for Schedule I and Schedule II-V controlled substances).
- Maintain usage log according to proper procedures.
- Always maintain the security of drugs.
- Keep accurate inventory and usage records for all controlled substances related to research projects.
- Complete usage log sheets—Controlled Substance Usage Log and Wastage Record.
- Store controlled substances in a lockbox, a laboratory-level lockbox, or in a locked cabinet.
- Return any unused controlled substances and the usage log sheets to the registrant after each day.
- Immediately report to the registrant any discrepancy or suspected theft.
- Receive laboratory-specific training from the registrant or other authorized user before using controlled substances. Immediately report to the registrant any felony violations/convictions.

XV. Training

Prior to working with a controlled substance, researchers are required to develop a DEA lab-specific SOP.

PIs are responsible for training authorized users in the following:

- The nature of controlled substance hazards including local and systemic toxicity.
- Specific research procedures that could result in an exposure.
- The importance of properly securing controlled substances, usage logs, and incident procedures for lost and/or missing drugs and inventory.
- Conditions and situations that could result in personal exposure.
- Lab-Specific DEA Controlled Substance SOP (provided by the PI that holds the DEA registration). All authorized users must read and be allowed to ask questions about the Lab Specific DEA Controlled Substance SOP. Once training is complete, authorized users must sign and date the training log that is kept with the DEA Controlled Substance SOP.

XVI. Purchasing Controlled Substances

Registrants (or their authorized users) can order only the controlled substances used in their research—the registrations should cover only the schedules needed for the registrants' approved research protocols.

Stocks of controlled substances must be kept to the smallest quantity needed. Controlled substances can be ordered through the standard procurement process with the following additional requirements:

Schedule I or II

Any person registered to conduct research with controlled substances in Schedule I or II must send, in triplicate, DEA Form 222.

Along with the order request and the DEA Form 222, a copy of the DEA Registration must be included.

Schedules III-V

Schedules III-V controlled substances may be ordered by a registrant through the standard procurement process.

XVIII. Recordkeeping and Inventory Requirements

21 CFR 1304.21 21 United States Code (USC)§ 827(a)(3) and CFR 1304.04 21 USC§ 827(b)

The following records must be maintained at the DEA Registrant's location (the address that appears on the DEA Registration):

- Personnel Screening Form—Authorized User for each authorized user(s).
- Executed order forms.
- Receiving record or purchase receipt that is verified, signed, and dated.
- Inventory records (must be kept a minimum of two (2) years from date of last transaction).
- Controlled Substance Usage Logs (must be kept a minimum of two (2) years from the date of last transaction).

All controlled substance records must be kept separate from all other records, in or near the primary work area, and must be available for inspection at any time by EHS, DEA, or state inspectors.

The controlled substances tracking requirements can be found on 21 CFR 1304.

Controlled Substances Log: a controlled substances log will be maintained at each location where controlled substances are stored. Dedicated notebooks are strongly recommended for maintaining records for all controlled substances. A separate page

shall be maintained for each controlled substance. Inventories and records for Schedule I and II drugs must be kept separate from all other records maintained by the licensed researcher. Records for Schedule III-V drugs must be kept separate from all other records. Alternatively, a folder for controlled substances records can be created so they are easily and “readily retrievable” from other records.

Basic recordkeeping includes:

- Records of receipt
- Records of use (including loss or theft)
- Records of disposal of controlled substances

The following information will be kept in the receiving log:

- The date the substance was received at the storage location.
- The substance name assigned by the manufacturer.
- The manufacturer of the substance or vendor.
- The quantity and strength of the substance added to the storage area.
- Name of an individual adding product to the inventory.

Dispensing controlled substances: whenever drugs are dispensed either for teaching purposes, research, or surrendered for disposal, the following information must be logged:

- The date used or the disposal of waste.
- The quantity dispensed for aliquots or dilution.
- Strength dispensed (concentration and volume).
- Name of person (authorized user).
- Quantity remaining in inventory.

Labeling Containers: controlled substances that are removed from their original packaging and compounded, diluted, or combined, must be labeled with a new control number, the final concentration, the amount per container and the expiration date.

Inventory Audits: the licensed researcher must maintain a complete and accurate accounting of all controlled substances from the time they are ordered until they are used up or properly disposed of.

- These inventories and records should be kept at the location where the licensed activity is conducted and must be readily available for inspections.
- Chemical inventories of controlled substances must be kept up-to-date, and discrepancies reconciled at least annually.
- The licensed researcher should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of at least two years.

Training

Training completion documentation for Registrant and Authorized User(s).

Usage Logs

The PI and their staff are required by federal and state law to document the use of controlled substances. Records must include “details” from the date of order throughout

the controlled substance's life cycle, i.e., until containers are empty or disposed of in accordance with proper disposal procedures.

Records must be kept secure, preferably in the same secure storage as the controlled substance. Records must include the order invoice sheet, all usage logs for that order, and any disposal records. Usage logs (see Appendix B) must include the name and strength of the drug, the amount received, name of the PI, and date when controlled substances were delivered. Usage logs must indicate the amount of each use, date of use, name, and signature of the authorized user using the drug, and a balance remaining each day. Initials can be utilized after the first time a name and signature are entered on a usage log. Typically, the usage logs provide a legally defensible paper trail for the controlled substance while it is in the responsible PIs possession. Without the usage logs, there would be no record of the controlled substances proper vs. improper use.

Usage Logs for Diluted/Mixed Controlled Substances
All actions taken with a controlled substance, including diluting/combining/mixing must be recorded. Per the DEA, a dilution solution log is needed.

When controlled substances are accidentally destroyed*, damaged, or contaminated; there should be a line entry in the usage logs. In the case the controlled substance is damaged or contaminated, send a request for disposal by emailing EHS.

*If a controlled substance is destroyed, a witness (one listed on the Controlled Substance Authorized Personnel Log and who is aware of all the program requirements) is needed. A description of how the controlled substance was destroyed must be listed in the usage log, along with the signatures of both the witness and the individual who accidentally destroyed the controlled substance.

Biennial Inventory
The DEA requires an inventory to be conducted and documented every two (2) years. PIs must declare their inventory status even if there is zero controlled substance in stock when biennial inventory is taken. The Biennial Inventory is a snapshot of the department's on-hand controlled substance inventory at the "close of business" for that day.

Inspections
Included in an inspection of the proper storage and recordkeeping of controlled substances. Among the items checked on these visits will include, but may not be limited to:

- The list of authorized controlled substance users.
- Completion of authorized user screening form.
- Proper security of controlled substances.
- Controlled substance use logs.
- Controlled substance inventories.
- Verification of lab personnel who have access to controlled substances.
- Expiration status of controlled substances.

- Verification of proper security of controlled substances.
- Completion of use logs and inventories.

The local DEA may conduct random audits and inspections of controlled substances. An inspection by the DEA may be conducted in coordination with EHS.

Controlled Substance Receiving
Controlled substances must be shipped directly to the registrant, to the address that appears on the registration. Once received, the controlled substances must be opened, and the contents verified by the person receiving the controlled substance. Any discrepancies must be rectified with the supplier and/or shipper. If discrepancies cannot be rectified, the registrant must contact the DEA.

Once the registrant has verified that the shipment is correct, the registrant must sign and date the purchase receipt and file it with the Registrant's Controlled Substances records and report the controlled substance to EHS.

Controlled Substance Dispensing and Tracking
The DEA Registrant is the only individual that can dispense a controlled substance from inventory. From the time a controlled substance is received on campus until it is fully used or disposed of, a record of the chain of custody and usage must be kept. At any point, the controlled substance changes hands or is used, it must be documented by the registrant dispensing the controlled substance. The documentation must include the quantity, date dispensed, and the recipient's initials.

Each quantity of a controlled substance must be accounted for in the Dispensing Records. Controlled Substance Dispensing Record, Controlled Substance Usage Log, and Disposal Record forms.

Controlled Substance Transfer
DEA regulation does not allow the transfer of a controlled substance between PIs. Please note that it is a felony to provide/possess a controlled substance that is not registered with the DEA in your name.

In addition, PIs may not transfer controlled substances to or from other institutions whether within state lines or across state lines.

Diluted/Mixed Controlled Substances
Controlled substances must not be left unattended on the countertops and/or lab benches. Dilutions and mixtures of the stock drug concentration must also be secured (same as pure concentration), labeled properly, and never left unattended. The diluted/mix or transferred product should be marked with the name of the drug, drug's lot number, expiration date, and the date when the drugs are diluted or opened. Controlled substances must never be used after their expiration date in animal research.

When controlled substances are diluted or combined, each new container must be labeled and tracked.

- The label must include the name of the controlled substances, lot number (or tracking number), date opened, final concentration, amount per container and expiration date if this is applicable.

- When syringes are filled and stored in the controlled substance cabinet, a label with the above information must be attached to the syringe.

Inventory Procedures
After a DEA Registration is first issued, a registrant must take an initial inventory (see Appendix A). An inventory is a count of all controlled substances in the registrant's possession. The inventory must reflect a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count. ***On the initial inventory, a registrant should start by recording a zero inventory. On the initial inventory, the table will be blank because the registrant should have zero inventory. Once controlled substances are ordered and received, a new inventory must be created and then created again every two (2) years.***

Each DEA Registrant must maintain an inventory. The inventory must be:

- Maintained at the registered location.
- Available for two (2) years after the controlled substance is used or disposed of.
- Completed every two (2) years (biennially) to comply with DEA regulations. (21 CFR 1304.11) The biennial inventory may be taken on any date within two (2) years of the previous biennial inventory date and must show whether it was performed at the opening or closing of the day.
- Updated on the effective date when a controlled substance is added to any schedule (list of controlled substances). Inventories of Schedule I and Schedule II Controlled Substances must be maintained separately from those for all other controlled substances, i.e., a Registrant with Schedules I-V Controlled Substances must keep three separate inventories—one for Schedule I, one for Schedule II, and one for Schedules III-V.

The inventory must contain the following information:

- Date of inventory
- Exact time of inventory and whether at the start or close of the business day
- Name of DEA Registrant and DEA Registration number
- Location of inventory

The person conducting the inventory and a witness must sign and date the Inventory Record.

For Controlled Substances, the Inventory Record must include**:**
Name of a controlled substance
Lot #
Schedule

Drug Form
Number of units/volumes
Supplier
Date Acquired

For the Controlled Substances Diluted Form, the Inventory Record must include:

- The name of the controlled substance
- Each concentration (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or mL)
- The number of units or volume in each container (e.g., 100-tablet bottle or 3-milliliter vial)
- The number of containers

For each controlled substance that is expired, damaged, defective, or impure awaiting disposal; or held for quality control purposes; or maintained for extemporaneous compounding, the Inventory Record must include:

- Name of a controlled substance
- The total quantity of the substance to the nearest metric unit weight or the total number of units (e.g., fifty 10 mg tablets or 10 ml of 50 mg/ml)
- Reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance.
- The best practice is to store substances in this category separately within the registrant's inventory, i.e., a separate compartment, box, or bag within the storage area.

Labeling Requirements
All containers of controlled substances must be properly labeled. If the laboratory repackages, compounds, or dilutes controlled substances, appropriately label the repackaged, compounded, or diluted controlled substance and store it in the safe. The label on diluted or combined controlled substances that are stored in the safe overnight or longer must include the following information:

- Name of controlled substance
- Final concentration of controlled substance
- Volume per container
- Expiration date (must be no more than 30 days after dilution

XIX. Storage and Security

All controlled substances must be stored in accordance with the DEA's Diversion Control Division's Controlled Substance Security Manual.

Storage of controlled substances must provide for the effective prevention of theft. Federal regulations require registrants to store controlled substances in a securely locked and substantially constructed cabinet. As mandated by the Drug Enforcement Administration (DEA), all controlled substances listed in Schedules I-V must be stored

in a securely locked box within a substantially constructed locked cabinet or double lock safe with limited access.

DEA Registrants are responsible for establishing and maintaining effective controls and procedures against unauthorized access to Controlled Substances.

Although these guidelines were developed to be consistent with DEA guidelines, unique situations may cause DEA inspectors to require alternative storage solutions.

General storage rule

- At all times, controlled substances must be stored behind at least two differently keyed locks.
- For keyed lockboxes
  - Do not store the keys near the lockbox; and
  - Do not store the keys together.
- For combination lock lockboxes
  - Only the registrant, and as few responsible individuals as possible, should know the combination.

Whenever anyone who knows the combination is terminated from employment, the combination(s) must be changed

Schedule I and II substances (e.g., Pentobarbital is a Schedule II drug)

- Must be stored in a safe or steel cabinet of substantial construction.
  - If the safe or cabinet is less than 750 lbs., it must be mounted or secured to something of substantial construction (e.g., bolted to a wall or the floor, or the base embedded in concrete).
  - The safe/cabinet should have an inner and outer door with the locks for each door keyed differently.

Schedule III, IV, and V controlled substances (e.g., Ketamine and Buprenorphine, are Schedule III controlled substances)

- Should be stored using one of the following methods:
  - Preferred method: a wall-mountable controlled substance lockbox with two doors and two locks (with each lock keyed differently).
  - A single-lock lockbox stored in a drawer or cabinet that is secured with a hasp and padlock. The drawer and cabinet should be substantially constructed such as in a drawer that is art of either a bench or cabinet that is mounted to the wall or floor.
  - If a lab is not accessible to the public, then an option is to use a single-lock lockbox, stored in a drawer or cabinet in a room that is always kept locked.

- Schedule III, IV and V substances can also be stored with Schedule I and II substances.

Cold storage for controlled substances

- For storage at 4°C or colder, a single-lock lockbox in a refrigerator or freezer that can also be locked is permitted. The room must also be lockable and locked after hours.

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

All controlled substance shipments must be processed and stored in a secure cabinet as soon as possible after receipt. The controlled substances must be opened, and the contents verified by the person receiving the controlled substance. The Inventory Record also must be updated at this time.

XX. Carrying Controlled Substances between University Buildings

Moving controlled substances between laboratories in a licensed researcher's location requires documentation for receiving controlled substances for daily use by the authorized daily user. Transportation of controlled substances between registrant laboratories must be in a locked storage container (or safe) and transported by the registrant or authorized agent with appropriate dispensation/custody forms. However, researchers must not leave the controlled substances unattended. Unless a controlled substance is in the process of being used for research, it must be securely stored in a safe or vault. The authorized researcher is responsible for ensuring any transport is conducted in a secure manner to prevent any diversion.

XXI. Disposal

A DEA Registrant must dispose of out-of-date, damaged, or otherwise unusable or unneeded controlled substances. The disposal of controlled substances is the final action necessary to ensure proper management of controlled substances.

When disposing of Schedule I and II Controlled Substances, DEA Form 222 must be used. Schedules III-V Controlled Substances may be transferred via invoice. Expired or unusable substances must be labeled, separated, and stored in a cabinet or safe that meets DEA requirements for the highest-level security until ready for disposal. Maintaining these substances in a separate box or container within the same cabinet or safe where inventory is stored is acceptable.

The Controlled Substances Inventory Record must be updated and copies of the records documenting the transfer and disposal of controlled substances must be

maintained for a period of two (2) years from the last recorded transaction. The Controlled Substances Disposal Log can be used for documentation purposes.

The DEA strictly regulates the disposal of unwanted controlled substances. If controlled substances are mixed with radioactive waste, the drugs are not eligible for disposal under these guidelines. They should be disposed of as radioactive materials. The disposal of the controlled substance vial must be recorded in the respective controlled substances accountability record. For disposal contact EHS.

Upon permanent closure of a researcher's lab or termination of employment, disposal of all controlled substances in accordance with university policies and procedures is required. Controlled substances may not be transferred to another institution. Records of disposal and all usage logs of closed labs must be forwarded to EHS.

XXII. Handling Abandoned/Orphaned Controlled Substances

"Orphan" DEA controlled substances: Occasionally, a controlled substance is found but the 'owner' is not known or has left the university. The substances may have been purchased before they were classified as controlled substances, may have been abandoned during the process of closing a laboratory, or may have had some other extenuating circumstance. In these types of situations, the controlled substance is called an "Orphan" controlled substance.

An official from the responsible department must take temporary possession of "orphan" controlled substances and work to ensure it is properly stored prior to their destruction. The department must contact EHS for the proper destruction of the abandoned/orphaned controlled substances by providing the following information:

- registrant's name (if known)
- DEA Registration number (if available)
- location where the Orphan was found (lab number, building, and originating department)
- name of the controlled substance
- controlled substance content in each individual container
- supplier
- number of containers
- size of each container

In these kinds of circumstances, Department Chairs must contact EHS to arrange for the appropriate disposal and notification to the DEA.

Any person who is registered with the DEA who violates recordkeeping requirements or abandons controlled substances will be subject to civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Please note that abandoning substances is equivalent to distributing a controlled substance to an unauthorized person.

XXIII. Theft or Significant Loss

The DEA Registrant of the stolen or lost controlled substance shall complete the following:

- Notify EHS immediately.
- Within one (1) business day of discovery of loss or theft, notify the DEA Field Division Office in the area, in writing, of the theft or significant loss of any controlled substance. This is a Federal regulation.
- Complete and submit DEA form 106 online to the Field Division Office in the area, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss. (21 C.F.R. § 1301.76(b)).
- Registrants must report suspected thefts or significant losses to the local DEA within one (1) business day. Call the local DEA Office.
- Submit a completed copy of the DEA Form 106 to EHS.

In order to better track controlled substances reported as lost or stolen, DEA has incorporated the use of the National Drug Code (NDC) number in the DEA Form 106. The NDC number identifies the manufacturer, product, dosage form, and package size. Entry of the NDC number will prompt the system to auto-populate additional fields such as the name of the product, dosage form, dosage strength, and quantity per container.

If a container of a controlled substance is broken, it must be documented in the Inventory Record, and a witness must sign and date the record.

XXIV. Monitoring Inspections

The DEA can inspect an existing registrant at any time. Contact EHS if an inspector arrives on campus.

XXV. Close Out of Registration

Registrants wishing to terminate their active registration(s) must inform the DEA and EHS of their intent to terminate.

Under no circumstances are controlled substances to be abandoned by a DEA Registrant. Registrants are expected to properly dispose of controlled substances no longer required or prior to departure from a university position.

Any person who is registered with the DEA who violates recordkeeping requirements or abandons controlled substances will be subject to the civil penalties outlined in the United States Code (USC): 21USC Sec. 842. Abandoning substances is equivalent to distributing a controlled substance to an unauthorized person.

XXVII. References

For more information regarding the DEA Controlled Substance, visit the DEA.

Appendix A.

University of Northern Colorado

DEA Controlled Substance Inventory Form

For the use of Controlled Substances in Research

DEA Registration Holder (first and Last):	DEA Registration Number:	Building and Room Number:	DEA Schedule
Date:	Authorized users:		
Signature:			

Line Number	Drug Information		Controlled Substance Name and manufacture/Vendor	Unopened Containers		Opened Containers			Finished Form
	DEA #	Schedule		Qty.	Container Size	Qty.	Container Size	Remaining Amount	
1									
2									
3									
4									
5									

6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

(1) Cross out the unused lines. Keep the inventory record at the licensed-registered location.
(2) Schedule I and II drugs must be separated from all other drugs or placed on a separate form.
(3) Unopened containers of same substance, manufacturer, volume, and concentration can be listed together.
(4) List open containers as separate line items.
(5) Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules).
(6) For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents.
(7) Finished form refers to the strength and form of the item as commercially prepared.

Appendix B.

University of Northern Colorado

DEA Controlled Substance Usage log

DEA Registration Holder (first and Last):	DEA Registration Number:	Building and Room Number:	DEA Schedule
Controlled Substance Name:	National Drug Code (NDC):	Container size:	
Date Received:	Date Disposed of:	Destruction Documentation Received	Lot/Serial #
Notes:			

Date:	Activity used for:	Amount removed (ml, mg, tables, etc.)	Amount Remaining (ml, mg, tables, etc.)	Authorized Individual
		Starting Amount:		

University of Northern Colorado

DEA Controlled Substances Usage Log

Continuous Sheet

Date	Activity used for	Amount removed (ml, mg, tables, etc.)	Amount Remaining (ml, mg, tables, etc.)	Authorized Individual

Appendix C.

University of Nothern Colorado

DEA Controlled Substance Authorization Log

DEA Registration Holder (first and Last):	DEA Registration Number:	Building and Room Number:	DEA Schedule
Controlled Substance Name:	National Drug Code (NDC):	Container size:	
Date	Address:		Lot/Serial #
Notes:			

Date Signed	Name (print)	Signature	Initails	Date Departed

Appendix D.

University of Northern Colorado

Waste Recording Form and Disposal Log

DEA Registration Holder (first and Last):	DEA Registration Number:	Building and Room Number:	DEA Schedule
Date:	Container #:		
Signature:			

Date Added	Added by (Name)	Signature	Amount	Waste description	Container

Contact Environmental Health and Safety at (970) 351-1149

Disposer Signature: _____

Date Container Emptied: _____

Appendix E.

University of Northern Colorado Dilution Log

DEA Registration Holder (first and Last):	DEA Registration Number:	Original Container #:	DEA substance name and Schedule
Date:	Volume or weight used for dilution:		
	Dilution Solution and volume:		
Final ratio/concentration:	Expiration date	Dilution Unique container #	

Date	Amount withdrawn	Balance(mL, mg, etc)	User Initials	Comments