

USE OF DEA CONTROLLED SUBSTANCES IN RESEARCH

The Drug Enforcement Agency has specific registration and management requirements for researchers using Controlled Substances. This document provides a summary of these requirements, as well as other requirements for use of Controlled Substances in research by employees of The University of Alabama in Huntsville.

Revised: 5/10/21

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Introduction

Any individual who uses or synthesizes Controlled Substances (CS) for research under the auspices of The University of Alabama in Huntsville must be: (a) licensed with State of Alabama, and registered with the US DEA (a “Licensed Individual” or DEA registrant) to conduct such research; or (b) authorized under the license of a Licensed Individual with respect to such research. The University does not hold an “institutional license” for use of CS in research.

- Both the State of Alabama and the United States federal government regulate CS (CS) used in Research. It is the responsibility of the individual who uses or synthesizes CS for research to be aware of and to comply with all federal and state laws regarding CS. This document is based on state and federal regulations, but the DEA registrant is also required to follow any additional state and federal regulation over and above this policy.
- The drugs that are considered to be CS are listed in the following laws/regulation: Schedules I to V of Title 21 of the Code of Federal Regulations (CFR) Section 1308. Scheduled drugs are listed at <http://www.dea diversion.usdoj.gov/schedules/index.html>
- Registration must be maintained at all times while CS are being used in Research or in the user’s possession.
- Researchers must use the CS they order exclusively for their own Research. These drugs cannot be shared or transferred to others not supervised directly by the researcher.
- Researchers must supervise their employees, students, and other agents who assist them in their CS research. Supervising personnel includes: explaining what and how CS will be used in the Research; ensuring personnel are trained in CS security and record-keeping procedures; and actively monitoring personnel’s use of CS in Research to ensure that all applicable laws/regulations are being followed.
- Researchers must keep CS in a secure locked cabinet or safe and control access to the CS. The Researcher is responsible for supplying and ensuring the locked cabinet is purchased and installed.
- Researchers must keep accurate records on the purchase, receipt, use and disposal of CS. Researchers also must keep an initial and biennial inventory of their CS.
- Records for Schedule I and II CS must be kept separately.
- Researchers must immediately report any theft or significant loss of CS to DEA, the OEHS, and the UAH PD.

Authorizing Users

21 C.F.R. § 1301.76 specifies that a DEA registrant “shall not employ, as an agent or employee who has access to CS, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause”. In other words, the DEA requires that any individual with even limited access to CS must complete a DEA screening certification and undergo a background check.

The form in Appendix 3 may be used by researchers to assist in complying with the paragraph above. This form must be completed and signed by both the employee or student affected and the DEA registrant before giving access to CS. Once both the parties sign the screening form, the DEA registrant must take custody of this form for filing with other documents related to the DEA registration.

Purchasing

DEA registrants or their authorized agents must determine the need for the CS and sign all requisitions for CS, regardless of the amount of purchase. Compliant manufacturers and suppliers require that all purchase orders for schedule I and schedule II substances be submitted using a DEA form 222. You are required to use a reverse distributor unless you can show that one is not available. A reverse distributor will handle any remaining amounts of product when you have completed the research. Please check with your distributor before ordering to be sure they offer this service. For ordering schedule I and schedule II CS, a copy of the DEA registrant's DEA number and her/his registration must be submitted using a signed DEA form 222. DEA forms 222 are provided to the individual licensed researchers by DEA by an online request.

Receiving

Office of Environmental Health & Safety (OEHS) personnel are NOT DEA registered, and cannot collect, hold, or dispose of CS. DEA registrants are the only people allowed to receive CS packages. Delivery must be directly to the Authorized Agent and not to the Central Shipping and Receiving personnel. If a CS is routed to Central Shipping and Receiving, the package will be rejected unless the DEA Registrant can collect the package while the truck driver is present

Labeling

If CS are removed from their original packaging and compounded, diluted or combined, each new container must be labeled and tracked. The label must include: the name of the CS, the lot number, the final concentration, the amount per container and the expiration date.

Storage

CS possessed, kept, or otherwise stored in a manner or location not in compliance with state or federal law is subject to seizure by and forfeiture to the state. Failure to comply with applicable requirements may also result in a suspension of purchasing privileges and disciplinary actions by DEA.

In order to guard against theft or diversion, all CS - regardless of schedule - must be kept under lock and key, and accessible only to authorized personnel. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stocks of CS to the smallest quantity needed.

- All CS must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.
- All CS stored in the researcher's lab must be stored in a safe, vault, locked steel cabinet, or other secure storage container, which if weighing less than 750 pounds, must be bolted or cemented to the floor. This storage container must be kept locked at all times. Lab storage locks may consist of a key lock, pad lock, or combination lock
- Drugs in Schedules I and II may not be stored with drugs in other CS Schedules or substances not on the CS list.
- The room in which the storage container is located must have limited access during working hours and provide security after hours. The CS should not be located near a glass panel where they are visible from the outside.
- This access list must be updated at least annually and as persons are added or removed.

When possible, only authorized personnel should be allowed in the areas where CS are used or stored.

Storage Restrictions

- Do not share CS storage facilities.
- Do not transfer CS from its original container for storage purposes.
- Do not store other chemicals or supplies in a CS storage unit.
- Do not store CS in a corridor.

Security

Access Control

Restrict access only to authorized personnel on your CS Use Authorization List and follow these precautions:

- Keep storage key(s) in the physical custody of authorized personnel at all times. You can make multiple key copies and assign them to authorized personnel.
- Do **not** store keys in a drawer or on the wall.
- When maintenance work is done in the controlled substance storage area, the research staff must maintain adequate observation.

Personnel Changes

When authorized personnel leave their position in the lab:

- Change combinations or retrieve the individual's keys.
- Contact Facilities and Operations to change the locks at the researcher's expense in the event of lost or missing keys.

Disposing of CS

If you are a DEA registrant, you must dispose of your controlled substance per DEA regulations. The UAH OEHS will not pick up or dispose of any controlled substance that belongs to a DEA registrant. OEHS personnel are NOT DEA registered and therefore cannot collect, hold, or dispose of CS.

Empty vials of CS (injectable drugs) can be disposed of in red bag biohazardous waste containers, although the label should be removed or rendered unreadable. In addition, the disposal of the empty vial must be recorded in the respective CS accountability record.

Report of Theft or Loss of CS

If a theft is suspected, immediately notify the DEA Registrant, the UAH Police, the DEA, Alabama State Board of Pharmacy and OEHS. Online theft and reporting requirements for DEA can be found here: [DEA website link](#).

Spill

Federal regulations require that DEA registrants notify the DEA Field Division Office in their area, in writing, of the loss of any controlled substance within one business day of discovery of such loss. The registrant shall also complete and submit to the Field Division Office in their area, DEA Form 106, "Report of Theft or Loss of CS" regarding the theft or loss. ([21 C.F.R. § 1301.76\(b\)](#)) You must document, in the CS accountability record, the volume of the DEA-controlled substance that was lost, and submit a [DEA form 106 detailing the loss to the DEA](#) just like in the case of theft. You do not need to use a reverse distributor to dispose of the materials used to clean up the spill. Materials from such a spill should be packaged for collection by OEHS as a chemical waste spill (hazardous waste). Please reference uah.edu/oehs for instructions on waste pickups.

Disposal

The DEA Office of Diversion Control regulates the disposal of DEA CS. Proper use and disposal of DEA CS is the responsibility of the DEA registrant. The form can be found here: https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf must be completed prior to disposing of any DEA controlled substance. Three (3) copies of the form must be sent to the local DEA branch and the registrant should retain one (1) copy for at least two years. The DEA registrant must submit a photo copy off all the documents to OEHS within one week of contacting DEA.

The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

- (1) By transferring to a person registered under the Act and authorized to possess the substance (original supplier or a reverse distributor);
- (2) By delivery to an agent of the Administration or to the nearest office of the Administration;
- (3) By destruction in the presence of an agent of the Administration or other authorized person;

Reverse Distribution:

These are commercial operators referred to as reverse distributors. Schedule I and schedule II CS should be transferred via the DEA form 222, while schedule III–V substances may be transferred via invoice. The licensed researcher must maintain copies of the records documenting the transfer and disposal for a period of at least two years after disposal of a controlled substance. There is a charge for the use of a reverse distributor. The cost of waste disposal depends on the type and quantity of the substance.

Licensed researchers wanting to dispose of CS that are mixed with hazardous chemical waste should *reference the uah.edu/oehs website for waste pickup instructions. Current phone numbers are available on the page.*

Orphan CS

It is the responsibility of DEA registrant to dispose of all CS before they terminate employment with the University. If the original DEA registrant is not available and DEA is not able to determine who in your department is registered, then you, the current owner, are responsible for contacting OEHS office. The OEHS office can assist you in surrendering the CS to a DEA approved reverse distributor for the proper disposal of “orphaned” CS. Please reference uah.edu/oehs for contact information.

A responsible individual from OEHS shall then contact the DEA Special Agent in Charge of the state and provide any necessary information and forms in writing. The following information should be documented before calling :

- The name and address of the person writing the letter;
- The name and quantity of each controlled substance to be disposed of;
- How the applicant obtained the substance, if known; and
- The name, address, and registration number, if known, of the person who possessed the CS prior to the applicant, if known.

The Special Agent in Charge shall authorize and instruct OEHS to dispose of the CS safely.

Record Keeping

All individuals conducting research and/or teaching activities with CS must document all actions taken with the CS. This includes receiving, using, diluting/combining, transferring and disposing of expired, excess, or unwanted CS.

DEA registrants must maintain complete and accurate inventory records for all CS. These records must be kept separately from all other records and documents, in or near the primary work area, and be available for inspection during regular work hours. The use of codes, symbols, or foreign languages in identifying CS or person in the record is prohibited. In the event that any CS are lost, destroyed, or stolen, the kind and quantity of the material and the date of discovery of such loss must be recorded in detail. All records must be maintained by DEA registrant for a period of at least two years from the date of the last recorded transaction.

1. Schedule I and II CS must be maintained separately from all other records of the DEA registrant. Schedule III, IV, and V CS must be maintained either separately from all other records of the D E A registrant or in such form that the information required is readily retrievable from the ordinary business records of the DEA registrant.
2. **Whiteout may not be used** on any forms or documents associated with CS ordering, storage, use, transfer, disposal, etc. Simply draw a line through the incorrect information, initial the correction, and write in the correct information.
3. All required records shall be **maintained for at least two years** for inspection and copying by authorized employees of the Alabama Board of Pharmacy, DEA or OEHS. However, it is recommended that these records be maintained for five years.

The recordkeeping system should include the following information:

Purchasing Record:

- The following types of documentation may be used as purchasing records:
 - Schedules I and II: only DEA Form 222 may be used as a purchasing record.
 - Schedules III, IV, or V: a copy of the invoice, a copy of the shipping document, or copy of the packing slip.
- Purchasing records must contain:
 - The handwritten date of receipt;
 - The name, address, and DEA number of the company from which the CS was purchased;
 - The name of the CS purchased;
 - The size and strength of the CS purchased;
 - The amount purchased (which should match the amount received). The DEA registrant must sign each record.

Receipt of Controlled Substance:

- A separate and current record on the receipt of CS indicating:
 - date received,
 - name and address of supplier,
 - the type, strength or concentration, and amount of the CS received.

The person receiving the CS must sign each record.

Use of CS:

- A separate and current record for the use of each CS indicating (sample usage form, Appendix 1)
 - the date,
 - laboratory building and room,
 - specific research experiment,
 - controlled substance's application in the research,
 - and type, strength and quantity of each controlled substance use.

By noting starting volume or mass of substance in the container, each use is a subtraction from the starting quantity, and the running (decreasing) amount should equal the total amount remaining on-hand. The person working with the controlled substance must sign each record of use.

Disposal Records:

- Disposal records must contain:
 - Copy of the filled DEA Form 41;

- Your DEA number, name, and address;
- The reverse distributor's DEA number, name, and address;
- The number of units (in finished forms and/or commercial containers) disposed of in any manner, including the manner of disposal.

The disposal record must be dated to reflect when the products were sent for destruction and left your inventory.

Inventory Procedures

At least once a year, DEA registrants must complete an inventory to compare the actual count of CS in the safe to the amount in the written disposition records. More frequent inventories are recommended for laboratories using Schedule I or Schedule II drugs, higher volumes, multiple CS or with many Authorized Users. The recommended inventory form (Appendix 2) contains all the required information to meet the DEA regulations. DEA registrants must send a copy of the inventory annually to the OEHS. The inventory should be:

- Maintained at the registered location (unless a notification has been sent to DEA notifying that records will be maintained at a specified central location);
- Available for 2 years after the substance is used or is disposed;
- Repeated every 2 years (annually recommended to remove expired substances from inventory);
- Updated on the effective date of a rule (from the DEA) when a substance is added to the Schedule (list of CS).

During an inventory, if a discrepancy is found or any of the material is unusable (i.e. damaged, defective or impure substances), an exact count of the dosage units must be made, or the container must be graduated to reflect its content. Inventory shall include the following:

1. Name, address, and DEA registration number;
2. Date the inventory was taken and whether it was at the beginning or end of the day;
3. Name of substance;
4. Total volume of substance or total number of units (i.e. 50 10mg tablets);
5. Reason for the substance being maintained by the researcher;
6. Sign and date form.

Inventory and Location Audits:

The DEA registrant must maintain a complete and accurate accounting of all CS; from the time they are ordered until they are used up or 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 CS are up-to-date and discrepancies reconciled at least annually. Authorized employees of the Alabama Board of Pharmacy, DEA and OEHS may audit inventory and the facility at any time without a notice.

Transportation

CS must be shipped to the DEA registrant's address, as indicated in the DEA registration. Once

received, the controlled substance should be opened to verify the contents and any discrepancies should be rectified with the supplier. If discrepancies cannot be rectified, DEA should be contacted.

Transferring CS between laboratories in a DEA registrant's location requires documentation for receiving CS for daily use by the authorized daily user. The transport between laboratories of the registrant must be in a locked storage container (or safe) and transported by the DEA registrant or authorized agent with appropriate dispensation/custody forms. However, researchers must not leave the CS unattended. Unless a CS 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.

Please note that it is a felony to provide a CS to a person who is not registered with the DEA. All transfers of CS can only occur between two DEA registrants. Transfers of schedule I or II CS must be accompanied by a DEA Form 222 completed by the DEA registrant receiving the substance(s).

Closing a Laboratory with CS

Abandonment of CS is a violation of the DEA regulations.

To close a laboratory that contains CS:

- Dispose of all CS following the above disposal directions.
- Keep the CS locked in the safe until they are picked up for disposal.
- Cancel the DEA registration.
- If applicable, send all unused DEA Forms 222 to the DEA Regional Office via certified or registered mail. In your cover letter to the DEA list the unique numbers on the Forms 222 and save a copy of the letter in your CS records.
- Notify OEHS that the laboratory is no longer using CS for research.

Regulations

- Title 21 United States Code (USC), [sections 1300 to 1308](#)
- Title 21 USC, [CS Act, section 801](#) et seq.
- [Title 20 Chapter 2, Alabama Uniform CS Act](#) 1407, Alabama Legislature 1971
- Alabama Board of Medical Examiners and Medical Licensure website

Appendix 1 Controlled Substance Usage Log

The University of Alabama in Huntsville

Office of Environmental Health & Safety

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

Drug name:

Schedule#:

CS Storage Location:

Finished form (eg: tablet, powder, liquid):

Strength:(eg: 10mg/mL)

Container type: (glass, plastic)

Principal Investigator:

Registration #:

PO Number:

Date added to PI inventory:

Department:

Container ID:

Date	Amount Received	Amount Used		Balance (unit)	Dispenser's Printed Name	Reason for Use/ Animal Protocol #/ Species

- This log must be kept in the controlled substance storage drawer or safe. The log balance must match the physical balance of CS at all times.
- This log must be retained in the lab for 2 years from either the date of disposal or date of complete use. **Retain until:** _____
- Any log discrepancies, suspected misuse, or theft of controlled substance must be reported to DEA and OEHS immediately.
- Any breakage of containers must be initialed by the individual responsible for breakage and co-signed by the PI.

Log Continuation Page: _____

Drug Name: _____ Schedule #: _____ Container ID#: _____

Note: in grey box below, list the amount carried over from previous log sheet.

Date	Amount Used	Balance	Dispenser's Printed	Reason for Use/ Animal Protocol #/ Species

- This log must be kept in the controlled substance storage drawer or safe. The log balance must match the physical balance of CS at all times.
- This log must be retained in the lab for 2 years from either the date of disposal or date of complete use: **Retain until:** _____
- Any log discrepancies, suspected misuse, or theft of controlled substance must be reported to DEA and OEHS immediately.
- Any breakage of containers must be initialed by the individual responsible for breakage and co-signed by the PI.

Appendix 3

EMPLOYEE QUESTIONNAIRE FOR ACCESS TO CONTROLLED SUBSTANCES

The Drug Enforcement Agency requires that any person who will have access to controlled substances as a result of his or her status as an employee or agent of The University of Alabama in Huntsville answer the following questions. Any false information or omission of information may jeopardize your position with respect to employment. Information revealed by this questionnaire will not necessarily preclude employment, but will be considered as part of an overall evaluation of your qualifications. The responses on this questionnaire will be held in the strictest confidence and maintained by the DEA Registrant in locked files.

1. In the past five years, have you been convicted of a felony or within the past two years of any misdemeanor or are you presently charged with committing a criminal offense? (Do not include 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.

Yes _____ No _____

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.

Yes _____ No _____

Signature

Name (Print)

Signature (Principal Investigator)

Name (Print)

Date _____

Reference: 21 CFR 1301.90