Guidelines for the use of dea controlled substances

The Drug Enforcement Agency has specific registration and management guidelines for researchers using controlled substances. This document provides a shortened guideline for the use of these materials by employees of the University of Alabama in Huntsville.

*Effective Date: November 2013*

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# Introduction

Any individual who uses or synthesizes controlled substances for research under the auspices of the University of Alabama at Huntsville must be: (a) licensed with State of Alabama, and registered with the US DEA (a “Licensed Individual”) 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 controlled substances in research.

* Both the State of Alabama and the United States federal government regulate Controlled Substances used in Research.
* The drugs that are considered to be Controlled Substances 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.deadiversion.usdoj.gov/schedules/index.html>
* Registration has to be maintained at all times while Controlled Substances are being used in Research or in the user’s possession.
* Researchers must use the Controlled Substances they order exclusively for their own Research. These drugs can’t be shared or transferred to others not supervised directly by the researcher
* Researchers have to supervise their employees, students and other agents who assist them in their Controlled Substances research. Supervising personnel includes: explaining what and how Controlled Substances will be used in the Research; ensuring personnel are trained in Controlled Substances security and record-keeping procedures; and actively monitoring personnel’s use of Controlled Substances in Research to ensure that all applicable laws/regulations are being followed.
* Researchers must keep Controlled Substances in a secure locked cabinet or safe and control access to the Controlled Substances.
* Researchers must keep accurate records on the purchase, receipt, use and disposal of Controlled Substances. Researchers also must keep an initial and biennial inventory of their Controlled Substances.
* Records for Schedule I and II Controlled Substances must be kept separately.
* Researchers must immediately report any theft or significant loss of Controlled Substances to DEA and the OEHS.

# Authorizing Users

Section 1301.76 of the United States Drug Enforcement Administration (DEA) manual for registrants specifies that a DEA registrant “shall not employ, as an agent or employee who has access to controlled substances, 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 controlled substances must complete a DEA screening certification and undergo a background check.

To make this DEA requirement easier for principal investigators to screen laboratory personnel who will have access to controlled substances, OEHS has developed a form (Appendix 1). This form must be filled and signed by both the employee (student) and the DEA registrant before giving access to controlled substances. Once both the parties sign the screening form, DEA registrant must take custody of this form for filing with other documents related to the DEA registration.

# Purchasing

PIs with a DEA license or their authorized agents must determine the need for the controlled substances and sign all requisitions for controlled substances, regardless of the amount of purchase. Manufacturers and suppliers such as Sigma-Aldrich require that all purchase orders for schedule I and schedule II substances be submitted using a DEA form 222. It is highly recommended that you use a reverse distributor. A reverse distributor will handle any remaining amounts of product when you have completed the research. Please check with your distributor before ordering. For ordering schedule I and schedule II controlled substances, a copy of the licensed researcher’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 upon an online request.

# Receiving

Office of Environmental Health & Safety personnel are NOT DEA registered and therefore cannot collect, hold, or dispose of controlled substances. 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.

# Labeling

If controlled substances 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 controlled substances, the lot number, the final concentration, the amount per container and the expiration date.

# Storage

Controlled substances 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 controlled substances - 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 controlled substances to the smallest quantity needed.

* All controlled substances 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 controlled substances are used or stored.

### Storage Restrictions

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

SecurityAccess Control
Restrict access only to authorized personnel on your Controlled Substances 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 ChangesWhen authorized personnel leave their position in the lab:

* Change combinations or retrieve the individual's keys.
* Locks on boxes within will be changed at the researcher’s expense in the event of lost or missing keys.

# Disposing of Controlled Substances

 If you are a registered user with the DEA, you must dispose of your controlled substance per DEA policy. The UAH OEHS may not pick up or dispose of any controlled substance that belongs to a DEA registered user. Office of Environmental Health & Safety personnel are NOT DEA registered and therefore cannot collect, hold, or dispose of controlled substances.

Empty vials of controlled substances (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 controlled substances accountability record.

### Report of Theft or Loss of Controlled Substances

If a theft is suspected, immediately notify the DEA Registrant, UAH Police, the DEA, Alabama State Board of Pharmacy, and OEHS. The unit registrant must then complete DEA Form 106, <http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html> Report of Theft or Loss of Controlled Substances. Four copies must be made of the report. The DEA registrant shall keep a duplicate copy for its records, forward two copies, the original and duplicate copy, to the Field Division Office of DEA, and provide one duplicate copy of the Alabama State Board of Pharmacy. The unit registrant will send a photocopy of the report to OEHS.

### Spill

Federal regulations require that 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 Controlled Substances" regarding the theft or loss. ([**21 C.F.R. § 1301.76**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm)(b))You must document, in the controlled substances accountability record, the volume of the DEA-controlled substance that was lost, and submit a [DEA form 106 detailing the loss to the DEA](https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp) 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 contact OEHS at 2171 for waste pick-ups.

### Disposal

The Drug Enforcement Agency’s (DEA) Office of Diversion Control regulates the disposal of DEA controlled substances. Proper use and disposal of DEA controlled substances is the responsibility of the individual holding the DEA registration used to obtain them. A [Registrants Inventory of Drugs Surrendered (DEA Form 41)](http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_blank.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 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 controlled substances 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 controlled substances that are mixed with hazardous chemical waste should *contact OEHS at 2171.*

### Orphan Controlled Substances

It is the responsibility of DEA- licensed researchers to dispose of all controlled substances before they leave the University. If the original licensed researcher 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 to surrender the controlled substances to a DEA approved reverse distributor for the proper disposal of “orphaned” controlled substances. *Please contact OEHS at 2171.*

A responsible individual from OEHS shall then submit to the DEA Special Agent in Charge of the state a letter stating:

* 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 controlled substances prior to the applicant, if known.

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

# Record Keeping

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

PIs must maintain complete and accurate inventory records for all controlled substances. 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 a controlled substance or person in the record is prohibited. In the event that any controlled substances 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 PIs for a period of at least two years from the date of the last recorded transaction.

1. Schedules I and II must be maintained separately from all other records of the registrant. Schedule III, IV, and V must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the 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. It is recommended that these records be maintained for five years.

**The recordkeeping system should include the following information:**

### A purchasing record:

* The following types of documentation may be used as purchasing records:
* Schedules I and II: only [DEA Form 222](https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp) 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 controlled substance purchased
* The size and strength of the controlled substance 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 controlled substances indicating:
* date received,
* name and address of supplier,
* the type, strength or concentration, and amount of the controlled substances received.

The person receiving the controlled substance must sign each record.

### Use of Controlled Substances:

* A separate and current record for the use of each controlled substance indicating (sample usage form, Appendix 2)
* 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 controlled substances 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 controlled substances or with many Authorized Users. The recommended inventory form (Appendix 3) contains all the required information to meet the DEA regulations. Registrants must send a copy of the inventory annually to the Office of Environmental Health and Safety. 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 controlled substances).

For each substance not listed above (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 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 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 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

Controlled substances must be shipped to the licensed researcher’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 controlled substances between laboratories in a licensed researcher’s location requires documentation for receiving controlled substances 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 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.

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

# Closing a Laboratory with Controlled Substances

Abandonment of controlled substances is a violation of the DEA regulations.

To close a laboratory that contains controlled substances:

* Dispose of all controlled substances following the above disposal directions
* Keep the substances locked in the safe until they are picked up for disposal.
* If there is no other DEA laboratory in the same building, 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 controlled substances records.
* Notify OEHS that the laboratory is no longer using controlled substances for research.

# Regulations

* Title 21 United States Code (USC), [sections 1300 to 1308](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title21/21cfrv9_02.tpl)
* Title 21 USC, [Controlled Substances Act, section 801](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html) et seq.
* [Title 20 Chapter 2, Alabama Uniform Controlled Substances Act](http://www.albop.com/actsprovisions/Act1407%20-%20Nov%202011.pdf) 1407, Alabama Legislature 1971

**Appendix 1**

**Controlled Substance Usage Log**

**University of Alabama, 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** |
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* 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.*

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| **Date** | **Amount Used** | **Balance (unit)** | **Dispenser’s Printed Name** | **Reason for Use/ Animal Protocol #/ Species** |
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* 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 2**

**INVENTORY OF CONTROLLED SUBSTANCES**

**University of Alabama, Huntsville**

**Office of Environmental Health and Safety**

|  |  |
| --- | --- |
| **Registrant:** | **Current Date:** |
| **DEA Reg. No #:** | **Last Inventory Date:** |
| **Building#** | **Room#** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Substance:** | **Finished****Form:** | **Number of****Units in each Container:** | **Number of****Containers:** | **Total****Units:** |
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**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, 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