



UNIVERSITY OF OREGON

DEA Controlled Substances Program Manual

ENVIRONMENTAL HEALTH & SAFETY



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I. Purpose

This manual addresses compliance with federal regulations, in accordance with UO Safety Policy 08.00.02, regarding registration, acquisition, use, storage, and disposal of U.S. Drug Enforcement Agency (DEA) Controlled Substances (CS) being used in University of Oregon research laboratories.

II. Background and Applicability

Pursuant to UO Policy 08.00.02, safety is the responsibility of all employees. Under the authority of the University of Oregon President, this policy was developed to provide a safe teaching, research, service, housing, and recreational environment. The University requires its employees to cooperate fully and as promptly as possible with all applicable regulations issued under state, federal and local authorities.

Due to their abuse potential, drugs identified by the U.S. Department of Justice, Drug Enforcement Administration (DEA), or the Oregon State Board of Pharmacy, as Controlled Substances (CSs) are subject to registration, storage, security, use, and disposal requirements. At the University of Oregon, Enterprise Risk Services' Environmental Health and Safety office (EHS) has the responsibility for assisting researchers comply with these requirements.

In conducting research and teaching activities involving CS, the following individuals must comply with the procedures set out below and applicable federal and state regulations relating to CS:

- University employees
- Any other individuals using University resources or facilities, or receiving funds administered by the University
- Volunteers, individuals and entities contracting with the University, and other individuals who may represent or speak for the University

Failure to comply with the procedures found below may be grounds for discipline by the University, suspension or termination of research, referral for misconduct proceedings, reporting to external licensing authorities by the University, and/or any other corrective action. Any disciplinary action imposed will follow the applicable laws, agreements, policies, and procedures for the individual's employment.

This procedure does not apply to prescription CS dispensed by a medical practitioner to a patient in the course of professional practice as authorized by his or her license.



III. Definitions

Authorized Users

Members of a research group or other employees of the University who are directly supervised by a DEA Registrant and are formally authorized to access secured CS storage.

Controlled Substance (CS)

Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR Part 1300 to end). This includes, specifically, any substance included in the definition of “Controlled Substance” under 21 U.S.C. § 802(6).

DEA Registrant

Often, but not always, the Principal Investigator, the DEA Registrant is a University employee designated to hold DEA registration who is responsible for ordering, storing, using, and disposing of CS within his or her inventory. Registrants must first be approved by (1) the head of the unit responsible for the space where work is occurring, and (2) the Institutional Official.

Disposal

Disposal of expired, excess, and unwanted CS. This term also refers to the disposal of residual CS (often referred to as waste) or those that have been contaminated through use.

Drug Enforcement Agency (DEA)

The agency within the United States Department of Justice that enforces the CS laws and regulations.

Environmental Health and Safety (EHS)

The University unit responsible for working with academic, research, and administrative units to promote compliance and responsible behavior as required by health, safety, and environmental standards, codes, regulations, and University programs.

Institutional Animal Care and Use Committee (IACUC)

The University committee charged with oversight of the use of vertebrate animals in research and instruction.

Institutional Official

Signatory authority for DEA Registrations on behalf of the Office of the President. The Associate Vice President for Research will serve as Institutional Official.

Location

A room or designated area where CS are stored or used. A storage location has a single address and has one DEA Registrant with which it is associated.

Registration

Formal grant of specific authority by the DEA to use CS. This grant of authority is evidenced



by a Certificate of Registration issued by the DEA. This also includes obtaining a letter of confirmation from the Oregon State Board of Pharmacy indicating that DEA Registrant is exempt from registration requirements for the State of Oregon.

Research

Systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes, but is not limited to, research involving animals and non-therapeutic research involving human subjects.

IV. Authority and Responsibilities

DEA Registrants who work with or use CSs in their research must do the following:

- Be aware of and comply with University, federal, and state statutes, regulations, policies, and procedures pertaining to proper registration, acquisition, storage, use, and disposal of CS. This also includes proper maintenance of records.
- Apply for and maintain DEA registration, including maintaining compliance with renewals.
- Maintain accurate records related to inventory, use, storage, and disposal of CS under his or her purview.
- The DEA Registrant may delegate responsibilities for maintaining all records regarding inventory use, handling, storage, and disposal of CS to authorized users.
- Identify authorized users within their lab, properly screen authorized users and directly supervise CS use by authorized users.
- Conduct inventory reconciliation of CS under his or her control at least biennially.
- Report inventory discrepancies to EHS.
- Report theft, loss, diversion, or significant inventory discrepancies to EHS, the UO Police Department, DEA, and all other relevant authorities as required by the federal law (including DEA administrative rules), state law, and University policies and procedures.
- Notify EHS of inspections and notifications of inspections by the DEA or the State of Oregon.
- Make arrangements with DEA for the transfer or disposal of any remaining CS before leaving the University or canceling or surrendering a registration.
- Comply with all other applicable requirements set forth in these procedures.

Authorized Users who work with or use CS must do the following:

- Refrain from using, storing, disposing, or otherwise working with CS until he or she is formally recognized as an authorized user, including the successful completion of an employee questionnaire, criminal background check, and other appropriate employee screening procedures.



- Comply with University, federal, and state statutes, regulations, policies, and procedures pertaining to proper registration, acquisition, storage, use, and disposal of CS under the direct supervision of a DEA Registrant.
- Report theft, loss, diversion, or significant inventory discrepancies to the DEA Registrant, and, if necessary, EHS, the UO Police Department, DEA, and all other relevant authorities as required by the federal law (including DEA administrative rules), state law, and University policies and procedures.
- Use, handle, store, and dispose of CS only as directed by his or her DEA Registrant.

Environmental Health & Safety will do the following:

- EHS staff will be responsible to aid all DEA Registrants in maintaining compliance with the applicable laws, policies and procedures through training sessions, guidelines, consultations, and audits. This includes maintaining and tracking all registration applications, registration certificates, and renewals.
- EHS staff will provide other assistance and oversight that the University deems necessary and appropriate to ensure compliance with applicable laws and University policies and procedures.
- EHS staff will escort DEA inspectors during their inspections of labs and act as a liaison between the inspectors and the DEA Registrant or authorized users.
- EHS staff will report periodically to the Institutional Official with status information about DEA registration submissions and renewals.

Institutional Official will do the following:

- Provide oversight over the use of CS in research conducted in University controlled facilities.
- Serve as a signatory authority on DEA registration forms.
- Facilitate counsel, assistance and representation by the University, including by EHS, Vice President for Research and Innovation, General Counsel or others, as appropriate, should compliance with applicable laws and University policy and procedures be questioned or inspected by the DEA or the Oregon State Board of Pharmacy.

V. Initial Registration with UO

The researcher responsible for projects involving CS (often the Principal Investigator) will initiate registration and is referred to as the “DEA Registrant.”

The first step for new DEA Registrants is to submit the *New Registrant Application* to UO Environmental Health & Safety. Please note that signatures must be obtained from the Department Chair/Institute Director (or other individual directly responsible for the space in which CS work is conducted) AND the UO Institutional Official, currently Cassandra Moseley. Electronic signatures are not permitted because originals are needed to verify signatures appearing in CS usage forms.



The Registrant must also submit the Background Check Permission Form to EHS unless the background check has been performed within the last five years during the hiring process. EHS will determine the date of last background clearance and instruct the registrant accordingly.

The DEA Registrant may proceed with steps 5.2 and 5.3 below while awaiting background check clearance, but may not go any further. The screening and background check process is repeated every ten years for the duration of the individual's work with CS.

All forms are found on the UO EHS website: <http://safety.uoregon.edu/controlled-substances>. Once submitted to EHS, please allow up to one week for background check processing.

VI. Establishing Authorized Users

Simultaneously, the DEA Registrant can identify Authorized Users within his/her research. Authorized Users are individuals who are directly supervised by the DEA Registrant, *and* who must have access to CS storage within the lab. If a lab member is handling or administering CS in research but does not need access to the storage location, they do not need to be named an Authorized User. When identifying authorized users within your group, please minimize those who have access to the storage areas. Registrants should not employ as an agent or employee who has access to CS:

- Any person who has been convicted of a felony offense related to CS
- Any person who has been denied a DEA registration
- Any person who has had a DEA registration revoked
- Any person who has surrendered a DEA registration for cause

Each proposed Authorized User must complete and submit a *Personnel Screening Form* to UO EHS. The form must be signed by the DEA Registrant. EHS will arrange for a background check if the individual was hired more than two years ago. EHS will notify the Registrant when the lab member can be designated an "authorized user." The University must provide initial approval for each lab member to serve as an authorized user upon the successful completion screening form and background check. However, after the University's initial approval is given, the Registrant must make a final determination of whether he or she will accept responsibility for supervising the lab member by designating him or her as an authorized user. Documentation of each authorized user's background clearance must be kept in the CS files for two years past the individual's departure date. The DEA Registrant and Authorized Users must resubmit the Screening Form every two years for the duration of their involvement in CS work.

Note: A DEA Registrant may only designate authorized user if the employee reports directly to the DEA Registrant. Therefore, the Registrant cannot allow another Registrant or their faculty/staff to use or buy CS under his or her registration.

Removal of Authorized Users



When the need arises for a DEA Registrant to remove Authorized Users from his/her Registration, the effective termination date is to be entered at the bottom of the individual's signed *Screening Form* and send a copy to EHS. Please change the location of the key or change the code to the keybox whenever an authorized user is removed from the DEA license. Maintain the individual's records for at least two years past the termination date.

VII. Training

While the DEA Registrant awaits background check approval, training should be scheduled for the DEA Registrant and any Authorized Users under his/her purview. Following the outline of the Training Manual, this session includes a review of the users' responsibilities, an overview of processes, technical instructions on completing the forms, and an opportunity to ask questions. Training must be conducted before a Registrant takes possession of a CS.

VIII. Registration with DEA

Federal law requires each Registrant using CS to possess an individual DEA registration that corresponds to one location where CS are stored. The State of Oregon Board of Pharmacy may require notification or a letter of exemption for work with Controlled Substances, though this is obtained separately from the federal DEA registration.

DEA Registrants using CS for research will use Form 225 for their application to the DEA. Use of CSs in teaching should be registered using Form 224.

EHS will provide assistance with completing these forms. Please enter the name of the UO Associate Vice President for Research in the field requesting an "official's" name. UO researchers are exempt from the DEA registration fees.

Once the DEA registration certificate is received by the Registrant, the certificate should be filed in a secure location, such as the CS logbook described in Section 5.2 below. The Registrant must provide a copy of the DEA registration to EHS.

Amending the Registration

If any changes occur pertaining to the use or registration of the CS (including, for example, the lab changing locations where CSs are used/stored), the DEA Registrant may need to update their registration with DEA. Licenses for Schedules III and IV do not require addition of new Schedule III or IV drugs to be itemized individually. The researcher should maintain a copy of their protocol as they would need to make it available if ever requested by a DEA Investigator.

If the DEA Registrant or lab is moving from the University of Oregon to another university, the CS cannot be transferred. The DEA Registrant must dispose of all CS as described below before the move and buy new CS once at the new location under a new DEA registration with the new university.



To determine whether an amended license must be obtained, contact the local field office for guidance:

Twillia Miller
Drug Enforcement Administration
Registration Program Specialist – ID & OR
Office: 503-721-6553
Fax: 503-721-6602

Mail To:
Drug Enforcement Administration
Portland District Office – Diversion
100 SW Main St, Suite 500
Portland, OR 97204

Annual Renewals

DEA registration is valid for one year and must be renewed annually. Generally, the DEA will contact the Registrant prior to the expiration of the registration and provide instructions on submitting a renewal application.

If registration is allowed to expire, the DEA Registrant must start the registration process over again. This, unfortunately, will also put the Registrant into non-compliance with the Federal regulations. The DEA Registrant and his or her authorized users will not be able to use, buy, or dispose of any DEA products during any period in which the DEA Registrant does not have a valid registration.

IX. Oregon Board of Pharmacy Exemption

Researchers are required by the state of Oregon to possess a practitioner's license (physician, veterinarian, or pharmacist) if they wish to store and use controlled substances. In lieu of such a license, researchers may request a Letter of Exemption from the Oregon Board of Pharmacy. The following are instructions on obtaining a Letter of Exemption: First, the DEA Registrant must obtain a DEA controlled substance registration as a researcher.

Second, the Registrant needs to submit a letter to the Oregon Board of Pharmacy. The title of the letter should be: "Letter Requesting an Exemption of Licensing." The letter needs to explain who they are, the research they are performing, and how controlled substances are used. The researcher must already have a DEA license to obtain an exemption. To submit a request, contact Rachel Melvin, Executive Support Specialist, Rachel.melvin@state.or.us.

Information on the Oregon Board of Pharmacy can be found at www.pharmacy.state.or.us.



X. Recordkeeping

DEA Registrants must maintain complete and accurate inventory records for all CS. A disposition usage log must be started for each bottle as soon as it is received. Each DEA Registrant's recordkeeping must include the following records:

Receipt of CS

When a CS is received from a manufacturer or vendor, the accompanying paperwork (order form, shipping documents, and invoices) must be retained as part of the CS official record.

You must maintain a record of the receipt of each CS, indicating date received, date opened, name and address of supplier, and the type, strength or concentration, and amount of the CS received. If the product is a Schedule I or II (C-I or C-II) use the DEA 222 form to log this into the lab as initial inventory.

When a delivery of CS is received from a vendor, it must be issued an internal inventory number. The following numbering convention must be used for consistency within UO and to avoid accidental duplications:

MMDDYY of receipt + First & Last Initials of DEA Registrant

(Example: a receipt of Ketamine for a DEA Registrant named Howard Hughes on February 14, 2020 would be listed as 021420HH.)

Beyond this convention, you have leeway with further distinguishing the substance. For instance, an order of 10 vials of one CS may more easily tracked by issuing inventory numbers such as 021420HH-A, 021420HH-B, etc.

The inventory number must be clearly and indelibly marked on the vial itself. A label-making machine is ideal; if a marker is used please write legibly and ensure it will not erase with alcohol.

A Controlled Substance Disposition Log shall be initiated for the substance, immediately upon receipt. Because the Disposition Log also serves as a chain of custody, this will track the CS's initial receipt and possession. In the example above, if 10 vials are received, it may be most logical to initiate 10 separate Disposition Logs, one for each vial.

Usage (Disposition) of CS

A record for the storage and use of each vial or container of a CS ("use" meaning to administer, dispense, professionally use, or otherwise dispose of), indicating the date, building and room, specific research experiment, CS application in the research, and type, strength and quantity of each CS use. The record must also include the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the



substances were administered or dispensed. 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. Each record of use must be made and signed by the authorized user working with the CS. The inventory should also include a detailed list of any CS lost, destroyed, or stolen, including the type, strength, and quantity of such substances, and the date of the discovery of such loss, destruction, or theft.

Mixtures and Dilutions

Mixtures and dilutions of CS should be issued a new internal inventory number consisting of the original (parent) inventory number plus a suffix. Following is the recommended method of identification:

MMDDYY of receipt + First & Last Initials of DEA Registrant + .01

(Example: a dilution of Ketamine in the Howard Hughes lab, which produced ten more vials, could be identified as 021420HH.01, 021420HH.02, 021420HH.10, etc.) A fresh Disposition Log should be created to pair with each vial created.

If you have diluted a product for use, and uses it all during one application, there is no need to create a disposition/usage log for that dilution.

Inventory of CS

A complete and accurate inventory and reconciliation of the stock of CS within each DEA Registrant's laboratory must be recorded:

- when he or she first receives a DEA license, noting "no drugs on hand"
- again when the first receipt of drugs occurs, then
- at least every two years thereafter.

The inventory can be taken either as of the opening of business or the close of business on the inventory date and this, along with the date, should be noted on the inventory. Any product that is in the lab at that time must be inventoried, even if it has not been in the lab's possession for the full two years. The type, strength, and quantity of all controlled substances must be recorded at this time in the manner prescribed in DEA regulations. The DEA Registrant or authorized user conducting the inventory must date and sign the record.

Transfers

Transfer of Schedule II CS must be conducted using DEA Form 222. This form may be requested at the DEA website:

<https://apps.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>. The form is not available online, but must be requested using the Official Order Form. A Form 222 must be completed for every Schedule II transfer of ownership. The current owner should be listed



as the “supplier” on the form. The form is in triplicate; one copy stays with the supplier, one goes to the recipient, and the third must be mailed to the DEA.

Transfer of Schedule III-V CS can be conducted between DEA Registrants within UO only. Please complete the Schedule III-V Transfer Form to initiate this:

The Transferor (current Registrant possessing the CS) must enter his/her:

- Full name
- DEA-issued registration certificate number
- Current storage location
- Date of transfer
- Signature (electronic is permissible)

The transferor should fill out the information for each CS to be transferred to the listed recipient. The CS Schedule and 4-digit National Drug Code number can be found on the DEA Controlled Substance List.

The Recipient should then enter his/her:

- Full name
- DEA-issued registration certificate number
- New storage location
- Date of transfer
- Signature (electronic is permissible)

A copy of the completed form should be maintained in each Registrant’s file for at least two years. The Transferor should write an entry in the current Disposition Log indicating the transfer transaction, and update the Balance Remaining column accordingly.

The Recipient must initiate a fresh Disposition Log to track usage of the material from the transfer going forward.

Loss

If any CS has been stolen, misplaced, or lost from the lab’s control, it must be reported to EHS, UOPD, the DEA (DEA Form 106, “Drug Theft/Loss”), and any other relevant authorities. This includes required reporting for unauthorized uses, unauthorized destruction, and a significant explained loss (e.g., dropped and broken bottle) of CS. Any discrepancies or losses of the product must be noted on the CS’s disposition log.

Record Maintenance

The recordkeeping forms must be up-to-date and readily available for inspection by DEA and EHS. All records must be kept for a minimum of two years after the last recorded date of use, order, transfer, disposal, or other recorded transaction involving the CSs.

All vendor records including orders, shipping, and receiving forms are also required to be



kept for inspection purposes.

XI. Inspections

The DEA Diversion Control Officers may come for a site visit before granting your DEA license. They may also make unannounced inspections at any time to any registration holder or applicant. Whether an inspection is scheduled or unannounced, the University requires the DEA Registrant and authorized users to notify EHS immediately.

EHS and the Institutional Official request to be present to serve as professional experts to help answer questions or concerns about UO policies, procedures, and guidelines.

XII. Handling and Transport

The University requires DEA Registrants and authorized users to adhere to DEA requirements related to handling and transport of CS. Neither the DEA Registrant nor her or his authorized users are permitted to transport CS from one location to another unless both locations are identified on the DEA registration.

Labs and individuals cannot dilute any CS to a lower concentration in order to eliminate the need to have any product registered. Once a product is a CS, it is always a CS, regardless of how the lab alters or dilutes it.

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 has 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 the DEA regulations.

A DEA Registrant cannot give her or his CS to another researcher to have it compounded, diluted, tested, disposed, etc., unless the CS are formally transferred as described above.

XIII. Disposal

Unwanted drugs must be disposed of using a specific approved method; DEA has permitted UO to utilize the following process for disposal of CS:

1. Transfer the drug to Dr. Kathy Snell in TeACS using the Transfer Form. Maintain a copy of this transfer form with your files until 2 years after the date of transfer.
2. Dr. Snell will dispose of the CS into the SmartSink device in the presence of a witness.
3. Dr. Snell will dispose of the SmartSink cartridges on a periodic basis via



incineration, per DEA requirements.

EHS cannot take possession of DEA CS, including for purposes of disposal.

CS injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures available from UO EHS and UO Animal Welfare Services.

The lab may not combine CS waste into one bottle for consolidation. Each individual container of CS must be maintained and tracked separately until disposal; at the time of disposal an entry shall be made on each container's usage log documenting disposal.

Empty drug vials/containers may be disposed in the standard lab waste stream, after defacing the label.

For disposal of non-controlled pharmaceuticals, UO procedures for chemical waste disposal apply.

XIV. Termination of License

If the DEA Registrant desires to terminate his/her work with CS (e.g., the lab is closing or the DEA Registrant is retiring), the DEA Registrant must notify EHS immediately for assistance in properly concluding CS work. The Registrant must dispose of or transfer the CS prior to closing the lab or before allowing the DEA registration to expire. DEA should be notified to cancel the registration, and will inform the Registrant of any additional requirements.

XV. Associated Forms

- New Registrant Application
- Authorized User Screening Form
- Disposition Log (UO template)
- Mixture/Dilution Disposition Log (UO template)
- DEA Form 222 for transfer of Schedule I and II drugs
- DEA Form 41 for documenting disposal/destruction
- DEA Form 106 for documenting drug theft/loss
- Schedule III-V Transfer Form (UO template)
- Inventory Log (UO template)