



Safety Instruction

DEA Controlled Substance Program

Overview:

This safety instruction addresses the use of any pharmaceutical grade product in Oregon State University research laboratories, including drugs classified as “controlled substances” by the [US Drug Enforcement Administration](#) (DEA). This is written for Principal Investigators (PI) or supervisors, as they are ultimately responsible for the use and storage of the substances registered to them.

Registration

- Each PI must have an individual DEA Research registration. DEA Controlled Substances cannot be shared between PIs unless both PIs are co-researchers on the same grant and the second PI is listed as an authorized user under the PI with the registration.
- A practitioner registration (DM, DVM) cannot be used for both patient/animal care and research. A separate researcher registration must be obtained.
- Researchers will use the Office of Diversion Control [Form 225](#) to register the controlled substance. OSU is a Government Funded Research Facility and is therefore exempt from registration fees.
- Registrations must list the storage location of material, applicable schedules, and not be expired.
- A copy of the registration must be sent to Environmental Health and Safety (EH&S) Ehs@oregonstate.edu.
- Registration is valid for one year and must, therefore, be renewed annually

DO NOT let the registration expire! If expired, the PI will need to start the process again. The PI or researchers will not be able to use, buy or dispose of any DEA products without a valid registration and the PI will potentially be in violation of the DEA regulations, as the lab will be in possession of DEA controlled substance(s) that the PI would not have a valid registration for.

Ordering

- The registration holder must order controlled substances.
- For Schedule I:
 - Incorrectly filled out Form 222's must be voided and kept as part of the recordkeeping requirements.
 - Form 222's cannot be pre-signed.
- At least two people should verify receipt of the controlled substances.

Storage/Use Location

- Controlled substance containers must be in good condition, labeled, and not expired.
- Storage must be at the registration location.
- Schedule 1 and 2 controlled substances must be stored separately from schedule 3, 4, and 5 controlled substances.
- Non-controlled substances cannot be stored with controlled substances without approval from the DEA.
- Registration holder can transport material (within university boundaries) from the storage location for use at a different location from the address on the DEA registration. When at a different location material cannot be left unattended. Controlled substances must be returned, secured, and stored at the registered location by the end of the day.
 - Usage log must reflect the transfer and initial inventory completed.
 - Transfer Form must be completed and kept with the substance from the time it leaves the authorized storage location to when it is returned to the authorized storage location.
- Sharing locked cabinets by multiple registration holders needs to be approved by the DEA.

Security

- A double secured system must be in place.
 - Common hallway badge access doors cannot count as security.
 - Storage cabinets must be non-transportable and substantially constructed. Cabinets must be secured to the floor or wall by facilities.
- Storage must be at the registration location.

Inventory

- An Initial inventory must be completed for all registrations, once you received your Registration. This should be zero. An initial/biennial inventory template can be downloaded from EH&S Website
- Usage log is required for all controlled substances.
 - Mixed/diluted controlled substances must have a log if the mixture is not used within a business day.
 - Usage logs cannot be kept with controlled substances.
- Biennial inventory must be completed every two years. An initial/biennial inventory template can be downloaded from EH&S Website
- All paperwork must be readily available for audits.

Recordkeeping

- Controlled substance stock containers must be added to the online chemical inventories systems (EHS Assistant@).
- All DEA forms and paperwork must be retained for 2 years.

Diversion, Theft or Loss of Controlled Substances

- Must be reported immediately to the local DEA, Department of Public Safety and EH&S.
- DEA form 106 must be completed.

Audits

- Audits are conducted by EHS annually for all DEA registration holders.
- DEA can audit any registration holder at any time.

DEA Exempt Chemical Preparations List:

Before applying for a registration with the DEA, investigators should review the [DEA Exempt Chemical Preparations List](#) to check if the substances they plan to use are exempt from DEA approval. Controlled substances in the form(s) described on the DEA exempt chemical preparation list may be lawfully purchased and used in research without a DEA registration. Use of exempt chemical preparations is intended for laboratory, industrial, or educational purposes and not for immediate or subsequent administration to a human being or other animal.

User Authorization and Usage Log:

Please note that the PI cannot authorize anyone who is not directly reporting to them to use the DEA products they are registered to use. Therefore, the PI with the registration cannot allow another PI or their staff to use or buy products under the registration unless the registered PI is in a direct supervisory role of these individuals or are working as a co-PI on a research project.

A PI may formally authorize specific staff members under their control, or a co-investigator on the research project, to have access to the regulated pharmaceutical substances, including controlled substances regulated by the DEA. The EH&S [Authorized Users Signature Log](#) documents such permissions. 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 3 years.

Disposal:

Registrants and authorized agents should only purchase and store those quantities of controlled substances needed for current research or instructional activities. Damaged, expired, unwanted, unusable, or nonreturnable controlled substances must be accounted for, stored, and disposed of in accordance with applicable state and federal regulations. If the lab is closing or the PI is retiring, the PI must dispose of those controlled substances prior to closing the lab or before allowing the DEA registration to expire.

Disposal Options:

There are three disposal options for expired or unwanted Controlled Substances. Environmental Health and Safety (EH&S) should be contacted to help determine the correct disposal method.

1. Contact the Supplier:

Some suppliers will take back pharmaceuticals for credit. If possible, this is the best means of Controlled Substance disposal.

2. Reverse distribution:

For large quantities or volumes of controlled substances, contact a reverse distributor. This option transfers ownership of the controlled substance to a DEA-approved pharmaceutical returns processor for re-use, re-sale, or destruction at a hazardous waste incinerator. This process may involve the completion of [DEA Form 222](#) or [DEA Form 41](#) depending on the reverse distributor and the substances involved.

If returning controlled drugs to the distributor where they were purchased is not an option, disposal of unused stocks of controlled drugs is usually accomplished using "Reverse Distributors." The DEA will no longer accept drugs for disposal but has licensed private companies to receive controlled substances that are expired or no longer wanted. These companies charge a fee for the service. A [complete list of reverse distributors](#) is available.

3. Contact EH&S for other options of disposal.

If the container is empty per the usage log, the cap can be removed, the label defaced, and the container disposed of in regular trash.

If abandoned controlled substances are found contact EHS for disposal.

Other Resources:

- Title 21 Code Federal Regulations, Part 1300-END: <http://www.deadiversion.usdoj.gov/21cfr/cfr/>
- List of [DEA Controlled Substances](#)
- EH&S DEA Controlled Substance webpage: <https://ehs.oregonstate.edu/controlled-substances>
- DEA Diversion Control webpage: <http://www.deadiversion.usdoj.gov/schedules/index.html>
- Office of Diversion Control Controlled Substance Security Manual : http://www.deadiversion.usdoj.gov/pubs/manuals/sec/sec_non_prac.htm.

