



# 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.

Oregon State University requires each PI to have an individual DEA 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.

List of [DEA Controlled Substances](#)

### 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.

### DEA Controlled Substance Registration Information:

Principal Investigators should contact EH&S for a consultation before registering for a controlled substance.

Researchers will use the online Office of Diversion Control Form 225 to register the controlled substance (<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>). OSU is a Government Funded Research Facility, and is therefore exempt from registration fees.

The US DEA registration is valid for one year and must therefore be renewed annually. The registered person will be contacted by the DEA, usually three months prior to its expiration, to renew it. The DEA will send only one reminder, and is usually done via email.

**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.

Contact EHS:  
[safety@oregonstate.edu](mailto:safety@oregonstate.edu)  
[oregonstate.edu/ehs/](http://oregonstate.edu/ehs/)  
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If the PI allows their substance registration to expire and still are in possession of the expired chemicals, contact EH&S to help set a plan to discard of expired chemicals. **There are serious consequences for being in possession of controlled substances that have an expired registration.**

### **Storage Requirements:**

All controlled substances must be stored in accordance to the Office of Diversion Control Controlled Substance Security Manual which can be found at: [http://www.deadiversion.usdoj.gov/pubs/manuals/sec/sec\\_non\\_prac.htm](http://www.deadiversion.usdoj.gov/pubs/manuals/sec/sec_non_prac.htm). Registrants and authorized agents may only receive and store the minimum amount of controlled substances needed for current research. All controlled substances **must** be stored in a locked steel cabinet or a locked substantially constructed cabinet. Controlled substances should not be located near a glass panel where they can be visible from the outside.

Registrants and authorized agents using and storing controlled substances must provide effective controls to guard against theft. This includes, but is not limited to, restricting the number of keys that access the controlled substances and limiting the number of employees who will have access to these keys. Keys for locked cabinets must be kept in secure locations when not in use. If controlled substances are locked using a combination or numerical coded lock, combinations/codes must be changed upon turnover of an employee who has knowledge of the combination/code. In addition to locked access control, only authorized personnel should be permitted to access a university laboratory where controlled substances are used or stored. For any storage related questions please contact Environmental Health and Safety.

Non-laboratory personnel/visitors entering areas where controlled substances are used or stored must always provide identification and a rationale for access. Controlled substances must never remain unlocked or unattended during laboratory maintenance work or other required access by individuals who are not the registrant or authorized agent.

### **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.

Accurate tracking of a controlled substance inventory is one of the most important aspects of the DEA program. Up to date inventory maintenance is the key to the loss detection, theft, and the diversion of controlled substances. PIs need to maintain a [Controlled Substance Usage Log](#) for each controlled substance on hand. The usage log balance must match physical balance at all times, and all discrepancies must be documented with explanations.



## 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. All controlled substances that are to be disposed of must have an **OSU Hazardous Waste Label that includes the material name, quantity, date, and license number**

Disposal of a controlled substance must render it non-retrievable. Though the DEA does not specify destruction methods, it does state, "the process utilized to render a substance 'non-retrievable' shall permanently alter the substance's physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes. A substance is considered 'non-retrievable' when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue."

Sharps used for allocating controlled substance must be segregated from other waste streams. A control substance contaminated sharps' label must contain the material used, date, and licenses number.

### 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. On-site Disposal:**

Small quantities (less than one (1) pound) can be disposed onsite by the DEA registrant using the following six-step Controlled Substance disposal procedure:

- I. Contact Environmental Health and Safety at [ehs@oregonstate.edu](mailto:ehs@oregonstate.edu) to place a Controlled Substance disposal request.
- II. Complete the Registrants Inventory of Drugs Surrendered (DEA Form 41) prior to disposal.
- III. Inform Environmental Health and Safety when DEA Form 41 has been completed and is ready for review.
- IV. EH&S will forward this form to the DEA with a projected two (2) week disposal date.
- V. At the end of the waiting period an EH&S representative will set an appointment time with the Registrant and an officer from the Department of Public Safety (DPS) to be present as witnesses to the disposal of the controlled substance(s), verify that the DEA Form 41 is complete, and inventory records. The destruction of the controlled substance will occur in a fume hood at the location the material is stored.
- VI. Three copies will be made of the DEA Form 41; one will be mailed to the DEA, one will be sent to EH&S and one will be saved for the Registrant's records



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### 3. 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. Contact EH&S for assistance finding a reverse distributor.

### Theft or Loss:

**Registrants must notify the appropriate DEA field office and EH&S of theft or significant loss of any controlled substance.**

The registrant must then promptly complete and submit the DEA Form 106 regarding such losses or thefts. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties identified and action taken against them.

### Other Resources:

- Title 21 Code Federal Regulations, Part 1300-END: <http://www.deadiversion.usdoj.gov/21cfr/cfr/>
- Oregon State University Hazardous Waste Disposal: <http://oregonstate.edu/ehs/waste>



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