**Standard Operating Procedure**

**DEA Controlled Substances Use**

***This is an SOP template and is not complete until:*** *1) lab specific information is entered into the box below 2) lab specific protocol/procedure is added to the protocol/procedure section and
3) SOP has been signed and dated by the PI and relevant lab personnel.*

 Print a copy and keep with your
*Chemical Hygiene Plan* and/or *Lab Safety Resources Binder*

|  |  |
| --- | --- |
| **Department:** | Click here to enter text. |
| **Date SOP was approved by PI/lab supervisor:** | Click here to enter a date. |
| **Principal Investigator:** | Click here to enter text. |
| **Lab Safety Coordinator/Lab Manager:** | Click here to enter text. |
| **Lab Phone:** | Click here to enter text. |
| **Office Phone:** | Click here to enter text. |
| **Emergency Contact:** | Click here to enter text. |
| *(Name and Phone Number)* |
| **Location(s) covered by this SOP:** | Click here to enter text. |
| *(Building/Room Number)* |

**Type of SOP:** x☐ Process x☐Hazardous Chemical ☐Equipment

1. **Purpose**

[Identify the intended use of a process/equipment/chemical]

1. **Procedure/Scope:**

[List or otherwise identify procedures that involved controlled substance use]

**Physical & Chemical Properties/Definition of Chemical Group**

CAS#: [Insert CAS Number]

[Important safety information regarding accidental exposure]

1. **Safety Data Sheet (SDS) Location**

Online SDS can be accessed at (<http://oregonstate.edu/ehs/sds>). A hard copy can be found at Oak Creek Building with Environmental Health & Safety.

1. **Personal Protective Equipment (PPE) (Describe the correct PPE for working with the chemical or needed during the process)**

Laboratory personnel must always wear a lab coat when working in a lab. Closed-toed shoes are also required at all times.

**Hand Protection**

**Eye Protection**

**Skin and Body Protection**

**Respiratory Protection**

**Hygiene Measures**

1. **Security and Access Control**

[Describe the type of locking structure and how it meets DEA security requirement (i.e. double locked safe, lock both tethered inside a cabinet/refrigerator, locked refrigerator, etc.)]

Only Authorized users shall have access to DEA Controlled Substances. Authorized User Form available upon request.

Procedure for access and returning controlled substances from different locations: [Example: Authorized users needing to use a controlled substance will request the key to the lock box and locked cabinet from the lab manager. The user will retrieve the drug needed, lock the box and cabinet, and return the keys to the lab manager before proceeding to perform their experiment. Upon completion of an experiment, the authorized user will request the keys from the lab manager, return the stock bottle to the lock box, and return the keys to the lab manager].

1. **Lost or Stolen Controlled Substances**

**Procedures for reporting lost or stolen controlled substances (all thefts or losses of controlled substances must be reported to Public Safety and EH&S immediately upon discovery):**

Significant losses or theft must be reported immediately to the DEA. In addition, OSU Public Safety and Controlled Substance Program Coordinator must be contacted.

The registrant should provide initial notification in writing of the loss or theft to the DEA Portland field office. Immediately fax to the DEA Portland field office.

PORTLAND DISTRICT OFFICE

100 SW MAIN STREET
SUITE 500
PORTLAND, OR 97204

Phone 1: (888) 219 4261
Fax 1: (503) 721 6602

* Use online DEA Form 106: Report of Loss or Theft to follow up with the faxed report.
* All in transit losses and lost DEA Form 222s must be reported to the DEA.

During initial inquiries into the incident, registrants must complete an online DEA Form 106: [Report of Theft or Loss of Controlled Substances Form 106](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html). A report must still be filed if lost or stolen material is recovered.

Minor discrepancies in inventory **that are not attributed to theft or loss** can be reconciled on the inventory report with proper notation. A DEA Form 106 does not need to be submitted for this purpose. However, the DEA should be contacted for guidance on how to proceed with such matters. The DEA recommends a registrant should determine significant loss in relation to controlled substance activity, patterns or trends of loss, and loss of controlled substances with high risk of diversion. Refer to the [DEA Office for Diversion Control](http://www.deadiversion.usdoj.gov/fed_regs/rules/2003/fr0708.htm) for more information.

1. **Record Keeping**

Describe the process for tracking usage of controlled substances on usage logs. E.g. authorized user will note their name and date when obtaining a drug from secured storage. Upon completion of an experiment and return of the stock bottle to secure storage, they will note the volume of drug used.)

A Controlled Substance Usage Log will be used to log the physical balance of the CSs at all times, and all discrepancies will be documented with explanation. This form will be kept for the duration of the project plus an additional 3 years. An up-to-date inventory will be kept through OSU’s EHS Assistance inventory log online.

A dilution log will be used to log a dilution, and each dilution will have its individual dilution log. These forms will be kept for the duration of the project plus an additional 3 years.

Only authorized users on the “Authorized Users Signature Log” will be able to conduct research with the CSs. The user(s) will be trained on the proper procedures on handling, storage, and the “CS Usage Log.”

* **Other Record Keeping requirements:**
* All records must be kept on hand for at least 2 years from the date of record (the date on which you received the substance).
* All completed order forms
	+ - A copy of the invoice
		- A copy of the purchase order
		- A copy of the shipping document
		- A copy of the packing slip
		- The name, address, and DEA number of the company from which the Controlled Substance 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)
* Inventory forms: (All inventory forms must be kept on file in the lab where the substance is used)
* Controlled Substance Use Log - Every container of controlled substance in your possession must have an associated use log that is kept in the same locked and secure place.
* Containers of concentrated or solid - A controlled substances must each have a log sheet to record the amount removed to make dilutions or solutions.
* Dilutions and solutions - if the staff has diluted a product for use, and uses it all during one application, there is no need to create an inventory for that dilution. If any diluted material remains for intended use at a later date, a new inventory page must be created, as it is considered a “new product” and dilution.
* Transfer Log - To track the transfer of controlled substances from one authorized person or location to another.
* Biennial Inventory Form - A full inventory of all DEA controlled substances must be completed every two years. 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.
	+ - Entries are made when the substance is dispensed and are hand-written in ink.
		- Waste bottles: If the lab makes a dilution of the product and does not use all of it in their work, the remaining portion is now considered waste. A new inventory form for the dilution must be initiated and kept for any amounts of that same dilution. Lab staff cannot add different dilutions to this waste bottle.
* Record of destruction of a lab’s DEA materials will be recorded by the DEA program manager on the DEA Form 41. This form will be sent to the DEA regional manager and a copy sent to the individual PI.
* A Lab Specific [**SOP for DEA Controlled Substance Use**](https://ehs.mit.edu/site/sites/default/files/documents/BSP-DEA-DEA_SOP_template.docx) and record of training completions must be on file.
* **Authorized User**
* Screening Form, if a Registrant wishes to grant a lab member access to the CS storage area as an Authorized User Screening must be completed.
* Authorized User Form, if a Registrant wishes to grant a lab member access to the CS storage area as an Authorized User Form must be completed.
1. **Transporting DEA Controlled Substances** (fill this out if you will be transporting the substances outside of the laboratory where the substances is stored)

[Include information for handling and documentation of the transportation of the DEA Controlled Substance.]

1. **Spills**

The breakage, spillage, or other witnessed controlled substance losses do not require the immediate notification of DEA if the breakage or spillage is not recoverable. The registrant must document the circumstances of the breakage in the inventory records and the Controlled Substance Use Log. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed.

1. **Disposal Procedure**

DEA Controlled Substances will be properly disposed of prior to DEA registration expires and prior to the lab closing (if applicable).

Controlled substances will be disposed of one of two ways:

1. *Contact the Supplier:*

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

1. *Reverse Distribution:*
* Contact a [Reverse Distribution Vendor](https://vetboard.az.gov/sites/default/files/documents/files/DEA%20Registered%20Reverse%20Distributors%20-%202016.pdf) to register.
* Complete the vendor’s application for approval to ship material – either in paper form and sent by mail / fax or in electronic form (both require current DEA registration).
* Additional Forms – Completing DEA D-222 form if necessary (for Schedule I & II controlled substances)
* Payment – payment or payment information is required with application.
* Shipping – once authorized, items are packaged and shipped by you via an approved shipper (Fed-Ex or UPS usually). Contact EH&S via the “Intent to Ship” form to ensure shipping is done properly. Allow 3-5 business days before item is to be shipped.
* Always request documentation of return/disposal/destruction.
1. **References**

DEA List of Controlled Substances & Exemption List: <https://www.deadiversion.usdoj.gov/schedules/>

DEA Forms and Applications: <https://www.deadiversion.usdoj.gov/online_forms_apps.html>

1. **Training Requirements**

Training to new authorized users will be done by the Registered Agent, which will include this completed SOP.

All authorized users will read and be allowed to ask questions about this SOP with the registered agent. Once training is complete, authorized users must sign and date the training log that is kept with this SOP (see last page of this document)

**Principal Investigator SOP Approval**

By signing and dating here the designee certifies that the Standard Operating Procedure (SOP) for *DEA Controlled Substance Use* is accurate and effectively provides standard operating procedures for laboratory personnel.

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Signature Printed Name/Title Date

I have read and understand the content of this SOP:

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
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