Animal Care and Use Program
Policy

Controlled Substances Acquisition, Storage, Inventory and Disposal

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BACKGROUND

Federal regulations restrict the use of certain substances with abuse potential (controlled substances). The Drug Enforcement Administration (DEA) is the principle Federal agency responsible for the enforcement of regulations pertaining to the acquisition, storage, inventory, and disposal of controlled substances.

SCOPE

This policy pertains to the use of all controlled substances in animals on OHSU Central and Waterfront Campus, and West Campus.

POLICY

The procedures outlined in this document, as per DEA regulations, must be followed when using controlled substances in animals (see the following website for schedules of substances: http://www.deadiversion.usdoj.gov/schedules/index.html).

PROCEDURES

I. ACQUISTION
- **A.** DEA Registration
  1. Medical Practitioners (Medical Doctors or Veterinarians) possessing an individual DEA registration may use that registration to acquire controlled substances for research.'
  2. Investigators who do not hold an MD, DVM, or equivalent degree must acquire a DEA registration for researchers using Form 225. See the following website to apply for DEA registration: http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm
- **B.** Oregon State Requirements
  1. Medical Practitioners may possess controlled substances without being required to register with the Oregon Board of Pharmacy.
  2. Non-Medical practitioners are required by the Oregon Board of Pharmacy to seek a letter of exemption from registration by submitting a letter of research intent, along with verification of DEA registration, to the following:

     Executive Director
     Oregon Board of Pharmacy
     800 SE Oregon Street, Suite 150
     Portland, Oregon 97232
- **C.** Purchasing controlled substances

1. Investigators, Department of Comparative Medicine Central and Waterfront Campus (DCM-C) and Division of Comparative Medicine West Campus (DCM-W) may purchase controlled substances from
   i. OHSU Central Pharmacy
      a) Purchasing requires a DEA registration and completion of the appropriate order form.
      b) Some agents, e.g. veterinary specific drugs are not available from the Central Pharmacy.
   ii. Approved veterinary supply distributor
      a) Purchasing requires a DEA registration.
      b) A Letter of Exemption from the Oregon Board of Pharmacy may be required.
   iii. Laboratory supply company
      a) Purchasing requires a DEA registration.
      b) Use of non-pharmaceutical grade agents in animal studies is subject to limitations and conditions of the OHSU IACUC Policy on Non-Pharmaceutical-Grade Drug Use in Laboratory Animals.
   iv. Purchasing agents that are on DEA Schedule I and II also requires the submission of DEA Form 222. This form may be obtained directly from the DEA at https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp .

II. STORAGE

A. Keep controlled substances in a lockable container, (e.g. cabinet, safe, drawer). Secure the container to the floor, counter, or wall.

B. Keep the container in a room with a door that locks. Keep the room locked after hours or at other times when no one is around. Alternatively, if the entire building is locked at all times, this can also satisfy this requirement.

C. Keep the container locked at all times, unlocking it only to retrieve or store the drugs.

D. Limit access to the controlled substances container. Issue keys (or combination codes) to as few people as possible. Alternatively, keep one key in a secure location and limit access to the key to as few people as possible.

III. INVENTORY

A. Federal law requires that researchers maintain records including the following information:

1. When acquiring controlled substances:
   i. Name of the substance (e.g. Ketamine)
   ii. Form and quantity per container (e.g. 100 mg/ml, 10 ml vials)
   iii. Number of containers acquired
   iv. The date the controlled substance was acquired
   v. The name and address from where the substance was acquired
2. When dispensing controlled substances:
   i. Name of individual to whom it was dispensed
   ii. Date of dispensing
   iii. Volume or quantity dispensed
   iv. Name or initials of dispenser
3. Controlled substances not dispensed or used – Controlled substances that are lost, stolen, spilled, arrive in damaged container, or are otherwise unusable must be documented and reported. See Section D. General Questions and Answers for more information

B. Biennial inventory – DEA registrants are required to conduct an inventory of any controlled substances they have on hand. This inventory must be conducted at least every two years. The following information should be included in the inventory:

1. Name of the substance (e.g. Ketamine)
2. Form and quantity per container (e.g. 100 mg/ml, 10 ml vials)
3. Number of containers on hand

If any impure or unusable substances are on hand (e.g. cocktail or expired drugs), they should also be included in the inventory. List the name of the substance, the quantity, the

reason it is being kept, and whether the substance could be used in the manufacture of any controlled substance.

IV. DISPOSAL

A. Federal law and the DEA have strict regulations governing the disposal of controlled substances. Investigators may not dispose of any unused controlled substances without authorization from the DEA.

1. If investigators have any controlled substances that require disposal, they may contact a Reverse Distributor to arrange disposition.

Reverse Distributor Registrants Drug Disposal Companies For Pacific NW Locations	
California	Washington
Exp Pharmaceutical Services Corp. 48021 Warm Springs Blvd Fremont, CA 94539-7497 1-800-350-0397 or 510-476-0909 Schedules 2, 3, 3N, 4, 5	P. S. Industries, Inc. 1100 2nd Avenue, Suite B1 Seattle, WA 98101-3425 206-749-0739 Schedules 2, 3, 3N, 4, 5

2. Alternatively any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration. (CFR Section 1307.21)

3. Correspondence with the Special Agent in Charge regarding instructions on disposal of controlled substances should be documented. Documentation should include the mode of correspondence (e.g. phone call, email, in person, etc.), date of correspondence, name of the Special Agent in Charge as well as the research or DCM personnel, and the method of disposal authorized by the Special Agent in Charge.

Special Agent in Charge
Drug Enforcement Administration
Portland District Office
1220 SW 3rd Avenue, Room 1525
Portland, OR 97204
503-326-2447
http://www.deadiversion.usdoj.gov/

DEFINITIONS

PER TITLE 21 UNITED STATES CODE (USC) CONTROLLED SUBSTANCES ACT SECTION 802.

Controlled substance - The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

Inventory - *Inventory* means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

Practitioner - The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research,

to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Dispense - The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

AUTHORITY

Code of Federal Regulations, Title 21, Part 1300-1399
Oregon Regulatory Statutes (ORS) 475.940 to .999
Oregon Administrative Rules 855-080-0022

REFERENCES

Guide for the Care and Use of Laboratory Animals (Guide) 8th edition, 2011; p 115, All those involved in animal care and use must comply with federal laws and regulations regarding human and veterinary drugs and treatments.