



Campus Administrative Policy

Policy Title: Management of Controlled and Prescription Drugs in Laboratories on Campus

Policy Number: 6007 Functional Area: Research

Effective: January 1, 2016
Date Last Reviewed: January 1, 2016
Date Scheduled for Review: July 1, 2023
Supersedes: N/A (New Policy)

Approved by: Richard Traystman
Vice Chancellor for Research

Prepared by: Office of University Counsel
Reviewing Office: Vice Chancellor for Research
Responsible Officer: Vice Chancellor for Research

Applies to: CU Anschutz Medical Campus
CU Denver Campus
CU South Denver Location

A. INTRODUCTION

The University has an obligation to ensure that Controlled Substances and Prescription Drugs are properly ordered, inventoried, transferred and disposed. In order to prevent and manage Controlled Substances and Prescription Drugs on campus, the university has created a series of mandatory requirements for departments and Principal Investigators (PI) to implement in laboratories across campus.

B. POLICY STATEMENT

This Policy was created to address the need to order, inventory, and properly dispose of Drug Enforcement Administration (DEA) Controlled Substances and Prescription Drugs used in laboratories on campus for the purpose of furthering scientific research. This Policy is intended to provide guidance to maintain compliance in University laboratories.

In order to remain compliant with DEA and other state and federal regulations, PIs in each laboratory on campus are responsible for lab management. These management

responsibilities include the ordering, inventory, use and disposal of DEA Controlled Substances and Prescription Drugs that are used for research protocols.

C. DEFINITIONS

For the purpose of this policy, the following terms shall be defined as outlined below:

"Controlled Substance" shall mean any drug or substance that is considered controlled under the federal Controlled Substances Act, or the Colorado Uniform Controlled Substance Act. All Controlled Substances are divided into five schedules. A substance is assigned to its respective schedule based on whether it has a currently accepted medical use for treatment in the United States, its relative potential for abuse, and the likelihood of its causing dependence when abused. Marijuana continues to be listed and considered by the federal government as a Schedule I Controlled Substance.

"Prescription Drug" shall mean any drug that is available only with written instructions from a medical provider, including a veterinarian, from a pharmacist or pharmaceutical provider.

D. PROCESSES FOR COMPLIANCE

1. DEA Licensing Procedures

All active laboratories using Controlled Substances must comply with the following:

- a. Only the PI in the laboratory may apply for and hold a DEA license to order Controlled Substances for approved lab protocols. To properly inventory Controlled Substances that enter laboratories, no additional laboratory personnel may obtain and use a DEA license.
- b. If the PI is not a current DEA license holder, the PI must file an application with the DEA Office of Diversion Control by filling out Form 225 for researchers. If the PI is an MD or a Pharm D and holds a personal DEA license for their clinical practice, they *may not* use that license to order Controlled Substances for animal/biologic research purposes. The PI may contact the Environmental Health and Safety department (EHS) with any questions about this process.
- c. All PIs must notify EHS with the details of their license. The EHS Controlled Substance website (ucdenver.edu/dea) has downloadable forms and additional information on how to apply for a license, and how to manage inventory and disposal.

2. Ordering Schedule and Prescription Drugs

- a. Each laboratory on campus must institute a process for ordering Controlled Substances and Prescription Drugs wherein one individual is responsible for

placing the order, a second individual is responsible for receiving the order, and a third individual is responsible for paying for the order. One person may not perform multiple functions in the ordering process unless prior approval is obtained from EHS, the Office of Regulatory Compliance, and the Officer of University Counsel.

- b. A Controlled Substance or Prescription Drug cannot be ordered using a personal procurement card (e.g., A-Card or P-Card), even if the total amount of the order is under \$5,000.
- c. All orders for Controlled Substances or Prescription Drugs must be completed through the Procurement Service Center (PSC) only. Purchases may be made using a standing purchase order or through the CU Marketplace; which method shall be determined by each individual laboratory.

3. Inventory, Control, and Audit of Controlled Substances and Prescription Drugs

- a. All laboratories on campus must have an inventory process for all Controlled Substances, Prescription Drugs, and on-controlled non-prescription materials. The number of controls and level of detail will be determined by the category of drug or material.
- b. All PIs are responsible for knowing of and logging the substances brought into, used in, and transferred out of the laboratory.
- c. An inventory control plan must consist of a monthly audit of Controlled Substances and Prescription Drugs in each laboratory. Each control plan must include physical or electronic documentation of all Controlled Substances and Prescription Drugs currently in the laboratory, their use levels, and whether or not they have been marked for disposal.
- d. The PI for each laboratory must provide EHS with the inventory control and audit plan to ensure it meets the minimum requirements contained in this Policy.
- e. All Controlled Substances and Prescription Drugs must be kept in a locked area which only authorized individuals within the laboratory are able to access.

4. Transfer of Schedule and Prescription Drugs

The use of Controlled Substances is approved for individual researchers, and only for the research location(s) described in that researcher's DEA application. Therefore, a PI may only transfer Controlled Substances in accordance with DEA rules and regulations.

5. Disposal of Schedule and Prescription Drugs

- a. Controlled Substances must be disposed of in coordination with EHS. Submit an inventory of the Controlled Substances along with the name of the PI holding the DEA registration to ehs.hazmat@ucdenver.edu, making sure to include for each container the name of the Controlled Substance, the National Drug Code (NDC) number found on the label of the container, the size of the container, and the amount of the Controlled Substance left in the container, per the running inventory.
- b. After EHS verifies that there is a current DEA registration on file, personnel from the reverse distributor group in EHS will fill out the necessary forms and make an appointment to pick up the Controlled Substances for disposal.
- c. Per DEA requirements, the pickup of the Controlled Substances will be done by two members of EHS.
- d. After the Controlled Substances are destroyed, EHS will provide copies of the destruction paperwork, which must be kept by the DEA registration holder for a period of two years and must be made available during any inspection.
- e. Prescription Drugs must be disposed of by submitting a Chemical Waste Disposal Request Form to ehs.hazmat@ucdenver.edu. As Prescription Drugs are not regulated by the DEA, no additional forms are required for their disposal.

Notes:

1. Dates of official enactment and amendments:

January 1, 2016: Adopted/Approved by the Vice Chancellor for Research

2. History:

December 5, 2019: Modified to reflect a campus-wide effort to recast and revitalize various Campus policy sites into a standardized and more coherent set of chaptered policy statements organized around the several operational divisions of the university.

3. Initial Policy Effective Date: January 1, 2016

4. Cross References/Appendix: