



# University of California Business and Finance Bulletin

Office of the Executive Vice President  
Business Operations

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**Controlled Substances Program**

*<http://www.ucop.edu/ucophome/policies/bfb/bus50.html>*

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Safety Director

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**Responsible Officer:** EHS Director  
**Responsible Office:** Risk Services

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## I. PURPOSE

The purpose of this document is to define the roles and responsibilities for establishing and maintaining a Controlled Substances Program. This document allows University locations to tailor their programs to meet local expectations based on the various state jurisdictions of the Drug Enforcement Administration (DEA). The policy establishes the minimum regulatory requirements and provides a Best Practices Guide to aid in program implementation. University locations are expected to implement the program using the Best Practices Guide or equally effective procedures. University locations are also expected to develop detailed written procedures to implement this policy and to demonstrate compliance with federal and state regulations (US Department of Justice, DEA (CFR Title 21, Food and Drug Act §1300-1316) and California regulations (California Health and Safety Code §11100-11700)) on acquiring, maintaining, storing, using, and disposing of controlled substances.

## II. DEFINITIONS

Authorized University Activities – University approved research, veterinary care associated with research, and teaching uses of Dangerous Drugs and Devices, including Controlled Substances, and Precursor and Listed Chemicals.

Authorized Individual – A Principal Investigator or laboratory member who is authorized to possess or use Controlled Substances by the University or Laboratory. See section IV.E.

Clinical Setting – A setting where a controlled substance or dangerous drug is used in a human or animal patient care application not associated with research.

Controlled Substances – Narcotic and non-narcotic drugs under the jurisdiction of the federal Controlled Substances Act and the California Uniform Controlled Substances Act, including but not limited to those substances listed in 21 CFR §1308.11-1308.15.

Drug Enforcement Administration (DEA) – the agency responsible for enforcing the controlled substances laws and regulations of the United States.

Dangerous Drug or Device – The terms “Dangerous Drug” and “Dangerous Device” are defined in California Business and Professions Code Chapter 9, Division 2, Article 2 §4022 and includes the following:

- (a) Any drug that bears the legend “Caution: federal law restricts this device to sale by or on the order of a physician, pharmacist, veterinarian, etc.” “Rx only” or words of similar import.
- (b) Any device that bears the statement “Caution: federal law restricts this device to sale by or on the order of a physician, pharmacist, veterinarian, etc.” “Rx only” or words of similar import.

(c) Any other drug or device by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 (of the California Business and Professions Code).

University investigators engaged in Authorized University Activities are permitted to purchase dangerous devices without a prescription as defined by California Business and Professions Code Chapter 9 Division 2 Article 3 §4059 and §4059.5.

Environment, Health and Safety (EHS) Department – The administrative unit that manages the location’s Environment, Health and Safety programs.

Investigational New Drug (IND) – A drug that has not been approved for general use by the Food and Drug Administration but is under investigation in clinical trials regarding its safety and efficacy first by clinical investigators and then by practicing physicians using subjects who have given informed consent to participate.

Institutional Review Board (IRB) – The respective location’s Committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.

Listed Chemicals – Under federal law, any List I or List II chemical including a List I chemical specifically designated by the DEA Administrator in 21 CFR §1310.02(a), that in addition to legitimate uses, can be used in manufacturing a controlled substance in violation of the federal Controlled Substances Act, and any List II chemical specifically designated by the DEA Administrator in 21 CFR §1310.02(b), that in addition to legitimate uses is used in manufacturing a controlled substance in violation of the Act.

Materiel Manager – See section IV.D.

Non-Clinical Setting – A setting where a controlled substance or dangerous drug is used in a teaching, research, or veterinary care associated with research. This includes human subject research protocols.

Precursor Chemical – Under California pharmacy law, a precursor chemical is any chemical that may be used to create controlled substances, including but not limited to catalysts, direct precursors or crucial ingredients used in the production of controlled substances (see also California Health and Safety Code §11100).

Program Administrator – The position with operational responsibility for the location’s Controlled Substance Program. See section IV.C.

Research Advisory Panel of California – A function of the California Attorney General’s office which, pursuant to California Health & Safety Code §11480 & 11481, must review and authorize proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances.

Responsible Official – The position with responsibility for oversight of the location’s Controlled Substance Program. See section IV.B.

### III. SCOPE

This policy does not apply to University clinical activities. Clinical care activities performed by a University Medical Center, veterinary teaching hospital, pharmacy, or clinic are governed by federal and state accrediting and regulatory agencies and are subject to review and audit by those agencies. Medical practitioners in University facilities are required to maintain appropriate state and federal licensure with respect to dispensing controlled substances.

Except as cited in the preceding paragraph, this policy applies to all authorized campus research and teaching activities which involve dangerous drugs, including controlled substances, listed and/or precursor chemicals, and dangerous devices. Based on feedback and the need for continuous improvement, this policy will evolve to incorporate updates that are identified to support scientific research or to address the needs of clinical activities.

### IV. RESPONSIBILITIES

#### A. Chancellor or Laboratory Director

Each Chancellor or Laboratory Director is responsible for providing resources to effectively administer a Controlled Substances program and for designating, in writing, a Responsible Official to establish and oversee the program.

#### B. Responsible Official

As designated by the Chancellor or Laboratory director, the Responsible Official shall:

1. Establish and oversee the Controlled Substances Program in accordance with DEA regulations and best practices;
2. Sign all DEA registrations on behalf of the UC Regents; and
3. As appropriate, grant a Power of Attorney to managers to enable them to obtain and execute order forms for controlled substances. The Responsible Official may designate one or more individuals to implement and manage the program.

#### C. Program Administrator

The Responsible Official's designee (such as personnel from Environment, Health and Safety) charged with implementing and managing the Controlled Substances Program on a day-to-day basis. The Program Administrator shall be either (i) a California licensed pharmacist or California licensed medical professional who is legally authorized by California and federal law to order, prescribe, or dispense dangerous drugs and devices, including Controlled Substances; or (ii) a person with training and experience in California and federal laws governing dangerous drugs, including Controlled Substances, and dangerous devices.

#### D. Materiel Management

The Materiel Manager or designee is responsible for procuring Controlled Substances,

Listed and Precursor chemicals for Authorized University Activities in compliance with DEA registrations, the location's Controlled Substances Program, and University/Laboratory policies.

E. Authorized Individuals

A Principal Investigator or laboratory member (e.g. staff and/or students) who are authorized to possess or use Controlled Substances by the University or Laboratory. Authorized Individuals are responsible for understanding their responsibilities within the program and complying with DEA regulations, program requirements, and University/Laboratory policy governing the acquisition, use, storage, and disposition of controlled substances.

V. GENERAL PROGRAM REQUIREMENTS

Each University location is responsible for complying with the following general requirements.

A. DEA Registration

1. Obtaining and maintaining the appropriate types of DEA Controlled Substance Registrations. 21 CFR §1301.13 lists the scope of activities authorized within each category; DEA registration categories, applications for registration, and instructions are available online at <http://www.dea diversion.usdoj.gov/drugreg/index.html>.
2. Establishing written procedures for:
  - a. Filing of new applications;
  - b. Application management;
  - c. How University research personnel shall individually maintain separate registrations with the DEA (such as licensed healthcare professionals);
  - d. How University employees engaged in an Authorized University Activity with Schedule I Controlled Substances shall obtain an individual DEA registration for each such project.

B. Authorization Process and Training

Each location must develop an authorization process and establish a training program for those who require access to Controlled Substances. Training shall occur prior to authorizing an individual and at a minimum, must include:

1. Storage site controls and security;
2. Ordering, delivery, and receipt;
3. Usage logs and biennial inventory requirements;
4. Transfers of Controlled Substances;
5. Import and export policies;

6. Disposal of Controlled Substances;
7. Diversion and loss reporting; and
8. Illicit activities and repercussions.

C. Power of Attorney

Each Responsible Official may designate additional individuals to sign official Controlled Substances order forms and to procure Controlled Substances for Authorized University Activities. A sample Power of Attorney form and Notice of Revocation is available at CFR Title 21 §1305.05.

D. Complying with Import, Export, Interstate and Intrastate Use Requirements

1. Imports

It is unlawful to import Dangerous Drugs, including Controlled Substances, into the United States unless: (i) the DEA grants an import permit to the University; or (ii) in the case of other Dangerous Drugs that are not Controlled Substances, the drug is subject to FDA regulation and may require an Investigational New Drug Permit (IND) issued by the FDA.

2. Exports

The University does not permit the export of Dangerous Drugs including Controlled Substances, federal List I and II chemicals, or California-listed chemicals acquired under a University DEA registration or using University funds without first obtaining explicit permission from the DEA Office of Diversion Control Import/Export Unit and institution's Responsible Official.

3. Interstate and Intrastate Use

A DEA registration may need to be obtained in the State or location within California that the research is being conducted. Transfers between DEA registrants may be permitted with the permission of the Program Administrator.

E. Documentation of Local Controlled Substances Program Compliance

Each campus must develop and publish written procedures that address the following federal or state requirements:

1. Controls with regard to ordering, procurement and distribution of Controlled Substances for Research Purposes. Minimally, these must address:
  - a. Prohibits any individual the ability to order, receive, distribute, and dispose of controlled substances;
  - b. General requisition, procurement, and distribution requirements and approval processes; this includes identification of orders of unusual size, orders deviating

- substantially from a normal pattern, and orders of unusual frequency;
- c. The approval process and requisition information for Investigational New Drugs;
  - d. Orders for Schedule I and II drugs using DEA Form 222;
  - e. Orders for Schedules III, IV, and V and other Dangerous Drugs;
  - f. Orders for Federal List I Chemicals/Precursor Chemicals
  - g. Orders for California Listed Chemicals/Precursor Chemicals;
  - h. Orders for Dangerous Drugs and Devices (Material requiring a Prescription).
2. Controls, Storage, and Security safeguards to prevent unauthorized acquisition, access, use, theft, or a diversion of Controlled Substances, List I chemicals, California Precursor Chemicals, and other Dangerous Drugs and Devices.
  3. Personnel Screening Requirements to ensure that no individual has access to controlled substances who has been convicted of a felony offense relating to controlled substances or whose application for registration with the DEA has been denied, or whose registration was revoked or surrendered for cause. See 21 CFR §1301.76 and 1301.90.
  4. Record-Keeping and Inventory Requirements, including:
    - a. Power of Attorney forms;
    - b. Purchasing and associated records;
    - c. Distribution and chain-of-custody records;
    - d. Proper retention schedules for acquisition, use, and disposition records;
    - e. Adequate recordkeeping by investigators or authorized personnel:
      - i. Usage log and inventory and biennial inventories;
      - ii. Separation of records by location;
      - iii. Purchase records for Dangerous drugs and Devices. (See 21 CFR §1304.04, 1304.11, 1310)
  5. Diversion, Loss, or Theft Reporting of Controlled Substances, Precursors, and List I chemicals. Location-specific procedures must include details on which campus office should be notified of and report to DEA within 24 hours about each theft or significant loss of controlled substances. See 21 CFR §1301.91.
  6. Disposal or Destruction of any controlled substance must be in accordance with DEA policies, procedures, and regulations. See 21 CFR §1307.21.
  7. California Research Advisory Panel Requirements for Principal Investigators to obtain and submit applications to the Research Advisory Panel.

California law requires that certain studies involving Schedule I and II Controlled

Substances be submitted and approved by the Research Advisory Panel of California. Principal Investigators must follow the guidance on the Research Advisory Panel (<http://ag.ca.gov/research/index.php>) website.

F. Required Auditing and Monitoring

Each location must develop and implement a routine auditing and monitoring program that includes unannounced inspections of investigator-maintained substances and records for compliance with state and federal laws governing the use of dangerous drugs and controlled substances in Authorized University Activities.

G. Illicit Activities

The University complies with federal and state law which makes it a criminal activity for employees to illegally possess, sell, use, or divert controlled substances, but shall also immediately become the subject of independent action regarding their continued employment. Any member of the University community who suspects another member of such illicit activities should follow campus or laboratory reporting policy.

H. Complying with State Licensure Requirements for Research Involving Human Subjects

Only California licensed medical personnel and investigators engaged in Authorized University Activities and acting within the scope of their authorized professional practice and consent of all applicable Institutional Review Boards (IRB) may prescribe, furnish, dispense or administer Dangerous Devices and Dangerous Drugs, including Controlled Substances, to human research subjects. .

References:

Food and Drug Act of 1906 (as amended) (21 USC §§1300-1316)

Controlled Substances Act of 1970

California Uniform Controlled Substances Act, Health and Safety Code §§11100-11700

California Research Advisory Panel (<http://ag.ca.gov/research/index.php>)

California Business & Professions Code Chapter 9, Division 2, Article 2 §4022+-