



OFFICE OF RISK SERVICES

OFFICE OF THE PRESIDENT  
1111 Franklin Avenue, 6<sup>th</sup> Floor  
Oakland, California 94607-5200

January 10, 2024

CHANCELLORS  
ACADEMIC COUNCIL CHAIR STEINTRAGER  
LABORATORY DIRECTOR WITHERELL  
ANR VICE PRESIDENT HUMISTON

**Re: Systemwide Review of Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching**

Dear Colleagues:

Enclosed for systemwide review are proposed revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching.

Substantive revisions to this Policy are proposed to incorporate changes to (1) specifically describe the scope of duties of the Campus Controlled Substances Program and the Controlled Substances Program Officers (CSPOs); (2) define the Campus Designation form of DEA Registration; (3) specifically address requirements applicable to DEA Registrations other than Campus Designation DEA Registrations, such as individual schedule I DEA Registrations; (4) provide more specific procedures regarding Powers of Attorney; (5) provide additional guidance as to import, export, interstate and intrastate use, transfer and transport of Controlled Substances, as well as Controlled Substances Analogues and DEA-exempt chemical preparations; and (6) establish responsible units and individuals for patient care and clinical Controlled Substances Programs.

The proposed revisions were drafted by a subcommittee of the UC Controlled Substances Program Officers Workgroup, which is composed of CSPOs from each UC campus, as well as representatives from UC Legal, UCOP Research Policy Analysis and Coordination (RPAC), and UCOP Risk Services (OPRS). During the management consultation process, drafts of the proposed changes were shared with the full CSPO Workgroup, including UC Legal, RPAC, and OPRS, as well as with the UC Environment, Health & Safety Leadership Council. The major area of discussion was regarding whether to include use of controlled substances in patient care settings. Ultimately, it was determined the scope of this policy should not apply to those environments other than to establish the unit and positions responsible for such activities because such uses are more heavily regulated, including more specifically prescribed program structures, than the uses for research and teaching.

### **Systemwide Review**

Systemwide review is a public review distributed to the Chancellors, the Chair of the Academic Council, the Director of the Lawrence Berkeley National Laboratory, and the Vice President of Agriculture and Natural Resources requesting that they inform the general University community, especially affected employees, about policy proposals. Systemwide review also includes a mandatory, 90-day full Senate review.

Employees should be afforded the opportunity to review and comment on the draft policy. Attached is a Model Communication which may be used to inform non-exclusively represented employees about these proposals. The

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Labor Relations Office at the Office of the President is responsible for informing the bargaining units representing union membership about policy proposals.

We would appreciate receiving your comments no later than **April 9, 2024**. Please submit your comments to Ken Smith at [ehs@ucop.edu](mailto:ehs@ucop.edu). If you have any questions, please contact Ken Smith at [ehs@ucop.edu](mailto:ehs@ucop.edu) or (510)882-3499.

Sincerely,

DocuSigned by:



Kevin Confetti, Risk Services

Associate Vice President & Chief Risk Officer

Enclosures:

- 1) Draft Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching (clean copy)
- 2) Draft Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching (tracked-changes copy)
- 3) Model Communication

cc: President Drake

Provost and Executive Vice President Newman

Executive Vice Chancellors/Provosts

Executive Vice President and Chief Operating Officer Nava

Executive Vice President Rubin

Senior Vice President Bustamante

Vice President and Vice Provost Gullatt

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Executive Director Smith

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Chief of Staff Kao

Chief of Staff Levintov

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Associate Director Dicaprio

Associate Director Garcia

Associate Director Teaford

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Associate Director Woolston

Assistant Director LaBriola

Manager Crosson

Analyst Durrin

Administrative Officer Babbitt

Policy Advisory Committee

Controlled Substances Program Officers



## BFB-BUS-50: Controlled Substances Use In Research and Teaching

<b>Responsible Officer:</b>	Chief Risk Officer
<b>Responsible Office:</b>	RK - Risk / EH&S
<b>Issuance Date:</b>	5/5/2009
<b>Effective Date:</b>	5/5/2009
<b>Last Review Date:</b>	
<b>Scope:</b>	<p>This Policy applies to University of California (UC) faculty, staff, and Authorized Individuals who use Controlled Substances, DEA Listed Chemicals, and/or California Precursor Chemicals in UC research and teaching activities.</p> <p>This Policy does not apply to Controlled Substance use in connection with patient care activities performed by a UC health system, veterinary teaching hospital, pharmacy, or clinic except to establish the units and positions responsible for such activities (see section IV). Controlled Substance use conducted in connection with patient care activities is governed by federal and state laws regarding Controlled Substances and/or California Precursor Chemicals and also is governed by federal and state licensing, accrediting and regulatory agencies and subject to such agency rules as well as review and audit by those agencies. Each UC entity using Controlled Substances in connection with patient care activities as described in this Policy is responsible for the monitoring and oversight of the Controlled Substances program.</p>

<b>Contact:</b>	Ken Smith
<b>Title:</b>	Executive Director of EH&S
<b>Email:</b>	<a href="mailto:Ken.Smith@ucop.edu">Ken.Smith@ucop.edu</a>
<b>Phone:</b>	(510) 987-0170

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### I. POLICY SUMMARY

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The purpose of this document is to define the roles and responsibilities for establishing and maintaining a Controlled Substances Program within the University of California. This document allows University locations to tailor their programs to comply with practices of local Drug Enforcement Agency (DEA) field division offices, as well as DEA regulations. University locations must develop detailed written procedures to implement this Policy and to document compliance with federal and state laws on acquiring, maintaining, storing, using, and disposing of Controlled Substances. (See the Federal Controlled Substances Act, 21 U.S.C. §§801 – 971 and implementing regulations at 21 C.F.R. §§1300 – 1399; and the California Uniform Controlled Substances Act, California Health and Safety Code §1100 – 11651 and implementing regulations at 11 California Code of Regulations §§800 – 810.7)

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### II. DEFINITIONS

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**Authorized Individual** – A Principal Investigator (PI) or laboratory member who is authorized by the University or National Laboratory to possess or use Controlled Substances.

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

**California Precursor Chemical** – Any substance listed under California Health and Safety Code §11100 et seq.

**Campus Controlled Substance Program** – A program established by each UC location to facilitate compliance with applicable requirements and procedures associated with the procurement, storage, use, transfer, disposal, and inspection of schedule II-V Controlled Substances for Authorized University Activities.

**Campus Designation** – DEA Authorization to include specific Controlled Substance storage locations and/or business activities on a campus under a single applicable DEA

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Researcher registration. Extension of additional storage locations and/or business activities of Controlled Substances require collaboration with the local DEA field office and approval by the DEA Diversion Control Division.

**Controlled Substance** – 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 C.F.R. §1308.11-1308.15.

**Controlled Substance Analogue** – Defined under Section 802(32)(A) of the Controlled Substances Act as follows:

Except as specified by Section 802(32)(C) the term “Controlled Substance Analogue” means a substance

- (i) the chemical structure of which is substantially similar to the chemical structure of a Controlled Substance in schedule I or II;
- (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a Controlled Substance in schedule I or II; OR
- (iii) with respect to a particular person, where such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a Controlled Substance in schedule I or II.

Under section 802(32)(C), such term does not include:

- (i) a Controlled Substance;
- (ii) any substance for which there is an approved new drug application;
- (iii) with respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, under section 355 of Title 21 of the U.S. Code governing food and drugs to the extent conduct with respect to such substance is pursuant to such exemption; or
- (iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

**Controlled Substance Controls** - Controls related to ordering, receiving, prescribing, dispensing, administering, and documenting of Controlled Substances, including theft/loss and diversion monitoring.

**Controlled Substance Program Officer (CSPO)** – The position with operational responsibility for each location’s Campus Controlled Substance Program.

**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 include 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 that 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).

**Drug Enforcement Administration (DEA)** – The agency responsible for enforcing the Controlled Substances laws and regulations of the United States.

**DEA Listed Chemicals** – A collective term that includes any DEA List I or List II chemical. Under 21 C.F.R. §1300.02, a List I chemical is one specifically designated by the DEA Administrator in 21 C.F.R. §1310.02(a), and that, in addition to legitimate uses, is used in manufacturing a Controlled Substance in violation of the federal Controlled Substances Act, and is important to the manufacture of a Controlled Substance. A DEA List II chemical is one specifically designated by the DEA Administrator in 21 C.F.R. §1310.02(b) and that, in addition to legitimate uses, is used in manufacturing a Controlled Substance in violation of the Controlled Substances Act.

**DEA Registration** – A DEA Registration pursuant to which business activity and coincident activity related to Controlled Substances is either required or permitted by 21 C.F.R. §1301.

**Environment, Health and Safety (EHS) Department** – The administrative unit that manages the location’s Environment, Health and Safety programs. Actual name of the departments may vary at each location.

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

**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.

**Materiel Manager** – The position at each University location responsible for the procurement of Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals for Authorized University Activities in compliance with DEA registrations,

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University or Laboratory policies, and the requirements of the location's Campus Controlled Substance Program.

**Non-Patient Care Setting** – An environment in which a Controlled Substance or Dangerous Drug and/or Device is used in teaching, research, or veterinary care associated with research.

**Officer of the University** – As defined by UC Regents Bylaw 32, individuals who are Level One Senior Management Group (SMG) members, which includes the position of President, all SMG positions that directly report to the Regents and/or the President, and the Chief Executive Officers of the medical centers.

**Patient Care Setting** – An environment in which Controlled Substances or Dangerous Drugs and/or Devices are used in a human or animal patient care applications not associated with research.

**Power of Attorney** – An official document in which a DEA registrant authorizes one or more individuals to act for the registrant either (a) in issuing orders for schedule I or II Controlled Substances, executed in a form substantially similar to the sample Power of Attorney form at 21 C.F.R. §1305.05, or (b) in signing registration applications for an entity in compliance with 21 C.F.R. §1301.13.

**Research Advisory Panel of California (RAPC)** – A review body of the California Attorney General's office established pursuant to California Health and Safety Code §11480 and §11481, which reviews and authorizes proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as schedule I and schedule II Controlled Substances that require review under California Health and Safety Code §11213.

**Responsible Official** – The position at a UC location with responsibility for oversight of the location's Campus Controlled Substance Program. This responsibility falls to the Chancellor unless the Chancellor or other individual who is an Officer of the University delegates this role through a Power of Attorney.

**Transfer** – "Distribution" (as defined in 21 U.S.C. Section 802) of Controlled Substances from one practitioner who is registered to dispense a Controlled Substance to another such practitioner.

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### **III. POLICY TEXT**

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All individuals associated with the University of California who use Controlled Substances in connection with patient care, research, veterinary care, and teaching activities must comply with federal and state laws in addition to University Policies and procedures governing Controlled Substances. To assist University of California personnel in complying with these regulations and with this University Policy, specific institutional requirements have been established for the management of Controlled Substances.



## **A. Activities under the Campus Controlled Substance Programs**

The University, through Campus Controlled Substance Programs, maintains institutional and/or departmental registrations with the DEA for research involving schedule II-V Controlled Substances. Researchers conducting Authorized University Activities must obtain schedule II-V Controlled Substances through the Campus Controlled Substance Program.

Although there is not a regulatory or systemwide Policy requirement that Campus Controlled Substance Programs oversee activities conducted under individual DEA registrations, individuals who plan to apply for, seek modifications to, or terminate an individual DEA registration for Controlled Substances that will be used on campus and/or in connection with Authorized University Activities, or who plan to import or export Controlled Substances to be used on campus and/or in connection with Authorized University Activities, should notify and consult the campus CSPO (see sections III(C)(5) and III(D)(2)(a) below). In addition, individual locations may choose to adopt local policies or procedures placing some or all aspects of such activities (including applications and management of individual DEA registrations) into the purview of the Campus Controlled Substance Program. Campus Controlled Substance Programs may provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices in the form of checklists, guidance documents, and FAQ materials.

The Campus Controlled Substance Programs and institutional and/or departmental DEA registrations do not cover:

1. Activities conducted under an individual schedule II-V DEA registration obtained outside of the Campus Controlled Substance Program. In accordance with their individual DEA registration, such persons conducting activities under their personal DEA registration are responsible for proper purchasing, recordkeeping, disposal, and other regulated practices;
2. Use of any schedule I drug. Consistent with federal law, researchers independently obtain individual DEA registrations for use of any schedule I drug in research;
3. Use of Controlled Substances in Patient Care Settings at the University. Pharmacists, physicians, and other providers supporting UC health systems, Student Health Services and other University clinics must solely operate under their own individual DEA registrations. Roles and responsibilities for use of Controlled Substances in Patient Care Settings are covered in Section IV. Compliance Responsibilities.
4. Use of Controlled substances at non-University of California institutions. When performing research at a non-University of California facility, UC

researchers will be subject to the host institution's Campus Controlled Substances Program. If there is no program, researchers will need to register independently for an individual DEA registration.

5. Authorized Individuals working in a research laboratory conducting Authorized University Activities with the use of Dangerous Drugs and/or Devices. Researchers are responsible for procuring, maintaining security of, keeping records for, and disposing of Dangerous Drugs and/or Devices in accordance with federal and state regulations. Dangerous Drugs and/or Devices may be ordered without a prescription as defined by California Business and Professions Code Chapter 9, Division 2, Article 3 §4059 and §4059.5; and
6. Use of DEA-exempt chemical preparations. A researcher need not obtain a DEA registration to purchase and use DEA-exempt chemical preparations that meet the requirements of 21 C.F.R. §1308.24 and as listed [Exempt Chemical Preparations List published by DEA's Diversion Control Division \(see Section VI. Related Information for the URL\)](#). For additional information, see section III(D)(4) of this Policy (Complying with DEA-exempt Chemical Preparation Requirements for Working with DEA-exempt Preparations).

## **B. Campus Controlled Substance Program Requirements**

The following requirements apply to schedule II-V institutional and/or departmental research registrations obtained through the Campus Controlled Substances Program.

1. **Campus Designations of a DEA Registration:** DEA regulations require that every location at which Controlled Substances are received or stored must obtain its own DEA registration. UC locations may seek and the DEA may grant a Campus Designation request or other form of approval, which permits the University to receive or store Controlled Substances at different physical addresses or buildings on a contiguous campus or as otherwise authorized by the DEA. Campus Designations shall be in the name of the campus or a campus department or school (or combinations or parts of those units). Any Campus Designation request must be evidenced by a written letter from the DEA Diversion Control Division approving the Campus Designation. No Controlled Substances may be received or stored under a schedule II-V institutional and/or departmental research registration without written approval by the CSPO while a Campus Designation request is pending.
2. **Authorization Process and Training:** Each University 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:

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- a. Storage site controls and security;
  - b. Ordering, delivery, and receipt;
  - c. Usage logs and biennial inventory requirements;
  - d. Transfers;
  - e. Import and export policies;
  - f. Disposal;
  - g. Diversion and loss reporting; and
  - h. Illicit activities and repercussions.
3. **Power of Attorney:** Each UC location may, through a Power of Attorney executed by the Chancellor or other individual who is an Officer of the University, authorize the Responsible Official, CSPO, or other individual to sign institutional DEA registrations on behalf of a University location or issue orders for schedule I or II Controlled Substances for Authorized University Activities. Unless restricted from doing so by the Power of Attorney executed by the Chancellor or Officer of the University, authorized personnel may authorize, through a Power of Attorney, additional individuals to sign such registrations or issue such orders.
4. **Documentation of Campus Controlled Substance Program Compliance:** Each location must develop and publish written procedures that address the following federal or state requirements:
  - a. **Ordering, procurement and distribution of Controlled Substances for research purposes.** At minimum, these must address:
    - i. Restrictions on any individual's capacity to perform all of the following activities related to Controlled Substances: placement of an order with a supplier, receipt of a shipment from a supplier, distribution, and disposal;
    - ii. General requisition, procurement, and distribution requirements and approval processes, including the identification of orders of unusual size or frequency or orders deviating substantially from a normal pattern;
    - iii. The approval process and requisition information for Investigational New Drugs and schedule II drugs using DEA Form 222;

- iv. Orders for schedules III, IV, and V;
  - v. Orders for DEA List I and List II Chemicals; and
  - vi. Orders for California Precursor Chemicals.
- b. **Controls, storage, and security safeguards** to safeguard against unusual or suspicious acquisition and prevent unauthorized acquisition, access, use, theft, or a diversion of Controlled Substances, DEA List I Chemicals, and California Precursor Chemicals.
- c. **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, whose application for registration with the DEA was denied, or who registration was revoked or surrendered for cause (as required by 21 C.F.R. §1301.76 and §1301.90).
- d. **Recordkeeping and Inventory Requirements**, including:
- i. Power of Attorney forms;
  - ii. Purchasing and associated records;
  - iii. Distribution and chain-of-custody records;
  - iv. Proper retention schedules for acquisition, use, and disposition records;
  - v. Adequate recordkeeping by investigators or authorized personnel:
    - 1. Usage log and inventory and biennial inventories; and
    - 2. Separation of records by location.
- e. **Diversion, loss, or theft reporting of Controlled Substances, DEA List I and List II Chemicals, and California Precursor Chemicals:** Individual Campus Controlled Substance Program procedures must specify which division or office is responsible for notifying (1) the local DEA field division office within one business day about each theft or significant loss of Controlled Substances as well as the subsequent submission of DEA Form 106 (as required by 21 C.F.R. §1301.91), (2) the local DEA field division officer about any unusual or excessive loss or disappearance of a DEA List I or List II Chemical (if required by 21 C.F.R. § 1310.05(b)(1)), or (3) the California Department of Justice about any theft or loss of

any California Precursor Chemical in writing within three days after the discovery (if required by California Business & Professions Code § 11103).

- f. **Disposal or destruction of Controlled Substances** must be in accordance with DEA policies, procedures, and regulations (as required by 21 C.F.R. §1307.21).

- 5. **Required Auditing and Monitoring:** A routine auditing and monitoring program must be established and include inspections of researcher-maintained Controlled Substances and records for compliance with state and federal laws governing the use of Controlled Substances in Authorized University Activities.

### **C. Responsibilities of Individual / Other DEA Registrants**

The following requirements apply to researchers with an Analytical Laboratory DEA registration, individual schedule II-V DEA research registration as permitted by the relevant university location, or individuals who are conducting research with the use of any schedule I drug. No individual may use Controlled Substances for any research in a Non-Patient Care setting at any location without notice to the CSPO.

- 1. **DEA Registration:** In consultation with the CSPO, individuals must file and obtain approval for the appropriate DEA registration prior to undertaking any activities with respect to controlled substances.
- 2. **Authorization and Training:**
  - a. Ensure necessary researcher authorization for and training of individuals in the laboratory who are assigned work with Controlled Substances; and
  - b. Maintain documentation to verify currently authorized researchers.
- 3. **Security, Storage, Inventory, Inspections, and Recordkeeping:**
  - a. Maintain strict control over inventory and security of Controlled Substances;
  - b. Ensure that Controlled Substances covered under an individual DEA registration are not intermingled in any manner with Controlled Substances covered under separate DEA registrations and/or owned by the University or by other individuals or entities.
  - c. Ensure authorized researchers receive, store, use, dispose of, and continually maintain Controlled Substance usage logs;

- d. Under California BPC § 4105, maintain usage logs for three (3) years after the full use or disposal of Controlled Substances; and
  - e. Complete and retain biennial inventory records as required by regulations.
4. **Potential Loss or Diversion Reporting:** Individual registrants must notify the CSPO and report to the local DEA field office within twenty-four hours of the discovery of any theft or significant loss of Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals. Individual registrants must also complete and submit DEA Form 106 “Report of Theft or Loss of Controlled Substances (and disposal receptacles)” or DEA Form 107 “Report of Theft or Loss of Listed Chemicals,” as applicable.
5. **Required Notification of CSPO Regarding DEA Registration Applications and Changes:** Individual registrants must notify the CSPO when applying for, transferring, modifying, or terminating a registration with the DEA that pertain to Controlled Substances used on campus and/or in connection with Authorized University Activities.

#### D. Additional Requirements for All DEA Registrants

1. **Illicit Activities:** Consistent with federal law, the University prohibits unlawful possession, sale, use, or distribution of illicit drugs by students and employees on University property or as part of any University activity. Illegal possession, sale, use, or distribution of Controlled Substances is subject to criminal sanctions under federal and state law. In addition, the University may pursue discipline, including employment action, against any employee found to have violated University policy prohibiting unlawful activities involved Controlled Substances on campus or as part of any University activity. Any member of the University community who suspects another member of such illicit activities should follow local reporting policies and procedures.
2. **Import, Export, Interstate and Intrastate Use, Transfers, and Transport:**
  - a. **Imports and Exports:** Importation or exportation of Controlled Substances, DEA List I and II Chemicals, or California Precursor Chemicals, including under an individual registration, requires prior written approval by the CSPO and must comply with federal and state laws, including but not limited to DEA regulations, state law and U.S. Food and Drug Administration (FDA) regulations. Such laws could require completion or approval of a permit or registration or could impose reporting requirements.
  - b. **Interstate and Intrastate Use:** A separate DEA registration and/or state license or registration may need to be obtained for use of

Controlled Substances in research conducted outside of California or at a non-UC location within California. For this reason, any such use requires prior written approval by the CSPO.

- c. Transfer:** Transfers of Controlled Substances, DEA Listed Chemicals, or California Precursor Chemicals, must comply with federal and state laws, including but not limited to DEA regulations. Such laws and regulations could apply to interstate or intrastate transfer or even transfer between University DEA registrations or within a University DEA registration. Such laws and regulations could limit the transferred amount or type of drug or chemical, require completion or approval of a permit or an order form request, or could impose reporting or registration requirements. For transfer of substances under the purview of the Campus Controlled Substance Program, prior written approval by the CSPO is required, except for transfers of DEA List II Chemicals or transfers between authorized locations covered by an institutional and/or departmental DEA designation.
  - d. Transport:** Movement of Controlled Substances off of University property in support of an Authorized University Activity, such as field research, requires prior approval from the CSPO.
- 3. Controlled Substance Analogues:** Research involving Controlled Substance Analogues, including but not limited to dispensing, manufacturing, transferring, importing or exporting, is subject to federal DEA regulations and other laws. Controlled Substance Analogues must commonly be treated as schedule I or II Controlled Substances absent applicability of an exception which depends on a number of factors, including but not limited to the chemical structure of the compound and whether the compound is intended for human consumption. Due to the complexity of this analysis, the CSPO should be contacted prior to Controlled Substance Analogues being obtained, dispensed, manufactured, transferred, imported or exported.
- 4. DEA-Exempt Chemical Preparations:** Exemptions are applicable only to the precise preparation or mixture described in the application submitted and approved by the DEA and only for those sections of the Controlled Substances Act and the Code of Federal Regulations specifically identified in the application. Any change in the quantitative or qualitative composition of the preparation or mixture or change in trade name or other designation of a preparation or mixture may result in loss of exempt status. Once a preparation or mixture is no longer exempt under 21 C.F.R. §1308.24, the preparation or mixture is a Controlled Substance, and the CSA and the DEA's implementing regulations apply.

- 5. State Licensure for Research Involving Human Subjects:** Only California licensed medical personnel and researchers engaged in Authorized University Activities and acting within the scope of their authorized professional practice and with the approval of all applicable Institutional Review Boards (IRB) may prescribe, furnish, dispense or administer Dangerous Drugs and/or Devices, including Controlled Substances, to human research subjects.
- 6. Research Advisory Panel of California (RAPC):** Consistent with California law, Principal Investigators planning to conduct research projects in California using schedule I and/or II Controlled Substances must obtain and submit an application to the RAPC and obtain RAPC's review and approval. Guidance regarding the process for obtaining RAPC review and approval can be found on the RAPC website (see Section VI. Related Information for the URL).

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## **IV. COMPLIANCE / RESPONSIBILITIES**

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### **A. Campus Controlled Substance Programs**

#### **1. Chancellor or National Laboratory Director**

- a. Provide resources to effectively administer a Campus Controlled Substance Program;
- b. Designate, in writing, a Responsible Official to establish and oversee the program; and
- c. If appropriate, execute a Power of Attorney to authorize the Responsible Official to sign institutional DEA registrations on behalf of the University location or to issue orders for schedule II Controlled Substances for Authorized University Activities. Any such authorization must be further evidenced by a Delegation of Authority.

#### **2. Responsible Official**

- a. Establish and oversee the Campus Controlled Substance Program in accordance with DEA regulations and best practices, as well as this Policy;
- b. As designated by the Chancellor or National Laboratory Director, the Responsible Official shall:
  - i. Designate one or more individuals, such as the CSPO, to implement and manage the program and ensure that any such designee receives training and/or has experience in



California and federal laws governing Controlled Substances;

- ii. If authorized through a Power of Attorney, sign all DEA registrations on behalf of the UC or National Laboratory location of the UC Regents or sign a Power of Attorney to authorize the CSPO or additional individuals to sign such DEA registrations; and
- iii. If authorized through a Power of Attorney, obtain and execute order forms for schedule II Controlled Substances or sign a Power of Attorney to authorize the CSPO or additional individuals to obtain and execute such order forms.

The authorization by the Responsible Official for other individuals to sign registrations or obtain and execute order forms set forth in section IV(A)(2)(b)(ii-iii) above must be further evidenced by a Delegation of Authority.

Notwithstanding the foregoing, nothing shall restrict the Chancellor or National Laboratory Director from directly assigning to the CSPO the authority to take the actions set forth in section IV(A)(2)(b)(ii-iii) above through a Power of Attorney, rather than assigning such authority to the Responsible Official.

### **3. Controlled Substance Program Officer (CSPO)**

- a. Implement and manage the Campus Controlled Substance Program on a day-to-day basis as the Responsible Official's designee (such as personnel from Environment, Health and Safety).
- b. If delegated the authority through a Power of Attorney, the CSPO may sign registrations and/or obtain and execute order forms as described above in section IV(A)(2)(b)(ii-iii).
- c. The CSPO shall receive training and/or have experience in California and federal laws governing Controlled Substances.

### **4. Materiel Management / Procurement**

- a. Procure Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals for Authorized University Activities in compliance with DEA registrations, University or National Laboratory policies and procedures, and the location's Campus Controlled Substance Program.

- b. The task of procuring Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals for Authorized University Activities may be delegated to department purchasers with approval from the CSPO.

## **5. Authorized Individuals**

- a. Understand their responsibilities within the Campus Controlled Substances Program; and
- b. Comply with DEA regulations, Campus Controlled Substances Program, and University or National Laboratory policies governing the acquisition, use, storage, transfer, and disposition of Controlled Substances.

## **B. Patient Care and Clinical Controlled Substance Programs**

### **1. Chief Executive Officer for Each UC Health System**

- a. Designate the Chief Pharmacy Officer to establish Controlled Substance Controls in the University hospital pharmacies and in any other University hospital licensed spaces, including provider-based clinics, affiliated with that UC Health location.
- b. Designate an individual or individuals to establish Controlled Substance Controls with respect to any other facility affiliated with that UC Health location where Controlled Substances are stored. Such facilities include but are not limited to clinics that are not listed on the hospital license.

### **2. Chief Pharmacy Officer for Each UC Health System**

- a. Establish Controlled Substance Controls in the University hospital pharmacy and in any other University hospital licensed space, including provider-based clinics.

### **3. Medical Affairs & Governance Office at Each UC Health System**

- a. Ensure that physicians that require DEA practitioner registrations provide evidence of such registrations to the Medical Affairs & Governance Office.
- b. Ensure that physicians using the hospital's institutional practitioner electronic prescribing application submit verification of identity as required by 21 C.F.R. §1311.

### **4. Controlled Substance Practitioner**

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- a. Every individual who orders, prescribes, administers or dispenses Controlled Substances for clinical use or human subjects research is individually responsible for compliance with their DEA registration and federal and state laws and University policies.

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## V. PROCEDURES

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Each UC location is responsible for developing procedures for the Campus Controlled Substance Program that align with this Policy and applicable federal and state regulations.

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## VI. RELATED INFORMATION

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Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301-399i Federal Controlled Substances Act of 1970, 21 U.S.C. §§801- 971 and implementing regulations at 21 C.F.R. §§1300-1399

(<https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter13/subchapter1&edition=prelim>)

DEA's Diversion Control Division's Exempt Chemicals Preparation List

([https://www.deadiversion.usdoj.gov/schedules/exempt/exempt\\_chemlist.pdf](https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf))

California Business & Professions Code Division 2, Chapter 9, Article 2 §4021, 4022, 4059, and 4059.5.

([https://leginfo.legislature.ca.gov/faces/codes\\_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=9.&article=2.](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=9.&article=2.))

California Uniform Controlled Substances Act, Health and Safety Code §11100-11651, and implementing regulations at 11 California Code of Regulations §§800-810.7

([https://leginfo.legislature.ca.gov/faces/codes\\_displayexpandedbranch.xhtml?tocCode=HSC&division=10.&title=&part=&chapter=&article=](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=HSC&division=10.&title=&part=&chapter=&article=))

Research Advisory Panel of California ( <https://oag.ca.gov/research>)

University of California Board of Regents Bylaw 32. Officers of the University

(<https://regents.universityofcalifornia.edu/governance/bylaws/bl32.html>)

U.S. Safe and Drug-Free Schools and Communities Act (20 U.S.C 1145g; 1011i; 34 C.F.R. Part 86)

U.S. Drug-Free Workplace Act of 1988 (41 U.S.C. §8101 et seq.)

UC guidance on use and possession of marijuana on UC property

(<https://www.ucop.edu/safety-and-loss-prevention/environmental/program-resources/uc-smoke-free/marijuana-and-drug-policy.html>)

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University of California Contract and Grant Manual, Chapter 3-600 (Controlled Substances & Drugs and Narcotics (<https://www.ucop.edu/research-policy-analysis-coordination/resources-tools/contract-and-grant-manual/chapter3/chapter-3-600.html>))

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## **VII. FREQUENTLY ASKED QUESTIONS**

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Not applicable.

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## **VIII. REVISION HISTORY**

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This Policy was revised to incorporate changes effective XX, 2023 to (1) specifically describe the scope of duties of the CSPO and the Campus Controlled Substances Program; (2) define the Campus Designation form of DEA Registration; (3) provide more specific procedures regarding Powers of Attorney; (4) specifically address requirements applicable to DEA Registrations other than Campus Designation DEA Registrations, such as individual schedule I DEA Registrations; (5) provide additional guidance as to import, export, interstate and intrastate use, transfer and transport of Controlled Substances, as well as Controlled Substances Analogues and DEA-exempt chemical preparations; and (6) establish responsible units and individuals for patient care and clinical Controlled Substances Programs.

This Policy was reformatted into the standard University of California Policy template effective June 1, 2012.

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## **IX. APPENDIX**

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Not applicable.



# BFB-BUS-50: Controlled Substances

<b>Responsible Officer:</b>	Chief Risk Officer
<b>Responsible Office:</b>	RK - Risk / EH&S
<b>Issuance Date:</b>	5/5/2009
<b>Effective Date:</b>	5/5/2009
<b><u>Last Review Date:</u></b>	<u>6/5/2023</u>
<b>Scope:</b>	<p><del>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.</del></p> <p>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.</p> <p><u>This Policy applies to University of California (UC) faculty, staff, and Authorized Individuals who use Controlled Substances, DEA Listed Chemicals, and/or California Precursor Chemicals in UC research and teaching activities.</u></p> <p><u>This Policy does not apply to Controlled Substance use in connection with patient care activities performed by a UC health system, veterinary teaching hospital, pharmacy, or clinic except to establish the units and positions responsible for such activities (see section IV). Controlled Substance use conducted in connection with patient</u></p>

	<p><u>care activities is governed by federal and state laws regarding Controlled Substances and/or California Precursor Chemicals and also is governed by federal and state licensing, accrediting and regulatory agencies and subject to such agency rules as well as review and audit by those agencies. Each UC entity using Controlled Substances in connection with patient care activities as described in this Policy is responsible for the monitoring and oversight of the Controlled Substances program.</u></p>
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<b>Contact:</b>	Ken Smith
<b>Email:</b>	<a href="mailto:Ken.Smith@ucop.edu">Ken.Smith@ucop.edu</a>
<b>Phone #:</b>	510-987-0170

## I. POLICY SUMMARY

The purpose of this document is to define the roles and responsibilities for establishing and maintaining a Controlled Substances Program within the University of California. This document allows University locations to tailor their programs to ~~meet to comply with practices of~~ local ~~expectations based on the various state~~ Drug Enforcement Administration Agency (DEA) field division offices, as well as DEA regulations. ~~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~~ must develop detailed written procedures to implement this ~~policy~~ Policy and to ~~demonstrate document~~ compliance with federal and state ~~regulations-laws on acquiring, maintaining, storing, using, and disposing of Controlled Substances. (See the Federal Controlled Substances Act, 21 U.S.C. §§801 – 971 and implementing regulations at US Department of Justice, DEA (CFR Title 21 C.F.R., Food and Drug Act §§1300 – 13161399); and the California regulations Uniform Controlled Substances Act, (California Health and Safety Code §11100 – 1170011651)) and implementing regulations at 11 California Code of Regulations §§800 – 810.7.)~~ acquiring, maintaining, storing, using, and disposing of controlled substances.

## II. DEFINITIONS

Authorized Individual – A Principal Investigator (PI) or laboratory member who is authorized by the University or National Laboratory to possess or use Controlled Substance.s by the University or Laboratory. (See Section IV)

**Authorized University Activities** – University approved research, veterinary care associated with research, and teaching uses of Controlled Substances, including Dangerous Drugs and/or Devices, Listed Chemicals, including Controlled Substances, and California 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)~~

**California Precursor Chemical** – Any substance listed under California Health and Safety Code §11100 et seq.

**Campus Controlled Substance Program** – A program established by each UC location to facilitate compliance with applicable requirements and procedures associated with the procurement, storage, use, transfer, disposal, and inspection of schedule II-V Controlled Substances for Authorized University Activities.

**Campus Designation** – DEA Authorization to include specific Controlled Substance storage locations and/or business activities on a campus under a single applicable DEA Researcher registration. Extension of additional storage locations and/or business activities of Controlled Substances require collaboration with the local DEA field office and approval by the DEA Diversion Control Division.

~~**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 C.F.R. §1308.11-1308.15.

**Controlled Substance Analogue** – Defined under Section 802(32)(A) of the Controlled Substances Act as follows:

Except as specified by Section 802(32)(C) the term “Controlled Substance Analogue” means a substance

- (i) the chemical structure of which is substantially similar to the chemical structure of a Controlled Substance in schedule I or II;
- (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a Controlled Substance in schedule I or II; OR
- (iii) with respect to a particular person, where such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a Controlled Substance in schedule I or II.

Under section 802(32)(C), such term does not include:

- (i) a Controlled Substance;

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- (ii) any substance for which there is an approved new drug application;
- (iii) with respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, under section 355 of Title 21 of the U.S. Code governing food and drugs to the extent conduct with respect to such substance is pursuant to such exemption; or
- (iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

**Controlled Substance Controls** - Controls related to ordering, receiving, prescribing, dispensing, administering, and documenting of Controlled Substances, including theft/loss and diversion monitoring.

**Controlled Substance Program Officer (CSPO)** – The position with operational responsibility for each location’s Campus Controlled Substance Program.

**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.~~

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

**DEA Listed Chemicals** – Under federal law~~A collective term that includes any DEA List I or List II chemical. Under C.F.R. §1399.92, including a List I chemical specifically designated by the DEA Administrator in 21 C.F.R. §1310.02(a), and that, in addition to legitimate uses, can be~~is used in manufacturing a eControlled sSubstance in violation of the federal Controlled Substances Act, and is important to the manufacture of a Controlled Substance. A DEA any List II chemical is one specifically designated by the DEA Administrator in 21 C.F.R. §1310.02(b), and that, in addition to legitimate uses, is used in manufacturing a eControlled sSubstance in violation of the Controlled Substances Act.



**DEA Registration** – A DEA Registration pursuant to which business activity and coincident activity related to Controlled Substances is either required or permitted by 21 C.F.R. §1301.

**Environment, Health and Safety (EHS) Department** – The administrative unit that manages the location’s Environment, Health and Safety programs. Actual name of the departments may vary at each location.

**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.

**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** – The position at each University location responsible for the procurement of Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals for Authorized University Activities in compliance with DEA registrations, University or Laboratory policies, and the requirements of the location’s Campus Controlled Substance Program. See Section IV

**Non-Clinical Patient Care Setting** – An environment in which a Controlled Substance or Dangerous Drug and/or Device is used in teaching, research, or veterinary care associated with research. 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).~~

**Officer of the University** – As defined by UC Regents Bylaw 32, individuals who are Level One Senior Management Group (SMG) members, which includes the position of

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President, all SMG positions that directly report to the Regents and/or the President, and the Chief Executive Officers of the medical centers.

**Patient Care Setting** – An environment in which Controlled Substances or Dangerous Drugs and/or Devices are used in a human or animal patient care applications not associated with research.

**Power of Attorney** – An official document in which a DEA registrant authorizes one or more individuals to act for the registrant either (a) in issuing orders for schedule I or II Controlled Substances, executed in a form substantially similar to the sample Power of Attorney form at 21 C.F.R. §1305.05, or (b) in signing registration applications for an entity in compliance with 21 C.F.R. §1301.13.

**Program Administrator** – The position with operational responsibility for the location's Controlled Substance Program (Section IV)

**Research Advisory Panel of California (RAPC)** – A ~~function~~ review body of the California Attorney General's office ~~which, established~~ pursuant to California Health & ~~and~~ Safety Code §11480 & 11481, ~~must~~ which ~~reviews~~ and ~~authorizes~~ proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as ~~Schedule~~ schedule I and ~~Schedule~~ schedule II Controlled Substances that require review under the California Health and Safety Code §11213.

**Responsible Official** – The position at a UC location with responsibility for oversight of the location's Controlled Substance Program. ~~See Section IV~~ This responsibility falls to the Chancellor unless the Chancellor or other individual who is an Officer of the University delegates this role through a Power of Attorney.

**Transfer** – “Distribution” (as defined in 21 U.S.C. Section 802) of Controlled Substances from one practitioner who is registered to dispense a Controlled Substance to another such practitioner.

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### **III. POLICY TEXT**

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All individuals associated with the University of California who use Controlled Substances in connection with patient care, research, veterinary care, and teaching activities must comply with federal and state laws in addition to University Policies and procedures governing Controlled Substances. To assist University of California personnel in complying with these regulations and with this University Policy, specific institutional requirements have been established for the management of Controlled Substances.

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

## **A. Activities under the Campus Controlled Substance Programs**

The University, through Campus Controlled Substance Programs, maintains institutional and/or departmental registrations with the DEA for research involving schedule II-V Controlled Substances. Researchers conducting Authorized University Activities must obtain schedule II-V Controlled Substances through the Campus Controlled Substance Program.

Although there is not a regulatory or systemwide Policy requirement that Campus Controlled Substance Programs oversee activities conducted under individual DEA registrations, individuals who plan to apply for, seek modifications to, or terminate an individual DEA registration for Controlled Substances that will be used on campus and/or in connection with Authorized University Activities, or who plan to import or export Controlled Substances to be used on campus and/or in connection with Authorized University Activities, should notify and consult the campus CSPO (see sections III(C)(5) and III(D)(2)(a) below). In addition, individual locations may choose to adopt local policies or procedures placing some or all aspects of such activities (including applications and management of individual DEA registrations) into the purview of the Campus Controlled Substance Program. Campus Controlled Substance Programs may provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices in the form of checklists, guidance documents, and FAQ materials.

The Campus Controlled Substance Programs and institutional and/or departmental DEA registrations do not cover:

1. Activities conducted under an individual schedule II-V DEA registration obtained outside of the Campus Controlled Substance Program. In accordance with their individual DEA registration, such persons conducting activities under their personal DEA registration are responsible for proper purchasing, recordkeeping, disposal, and other regulated practices;
2. Use of any schedule I drug. Consistent with federal law, researchers independently obtain individual DEA registrations for use of any schedule I drug in research;
3. Use of Controlled Substances in Patient Care Settings at the University. Pharmacists, physicians, and other providers supporting UC health systems, Student Health Services and other University clinics must solely operate under their own individual DEA registrations. Roles and responsibilities for use of Controlled Substances in Patient Care Settings are covered in Section IV. Compliance Responsibilities.
4. Use of Controlled substances at non-University of California institutions. When performing research at a non-University of California facility, UC researchers will be subject to the host institution's Campus Controlled Substances Program. If there is no program, researchers will need to register independently for an individual DEA registration.

5. Authorized Individuals working in a research laboratory conducting Authorized University Activities with the use of Dangerous Drugs and/or Devices. Researchers are responsible for procuring, maintaining security of, keeping records for, and disposing of Dangerous Drugs and/or Devices in accordance with federal and state regulations. Dangerous Drugs and/or Devices may be ordered without a prescription as defined by California Business and Professions Code Chapter 9, Division 2, Article 3 §4059 and §4059.5; and
6. Use of DEA-exempt chemical preparations. A researcher need not obtain a DEA registration to purchase and use DEA-exempt chemical preparations that meet the requirements of 21 C.F.R. §1308.24 and as listed Chemical Preparations List published by DEA's Diversion Control Division (see Section VI. Related Information for the URL). For additional information, see section III(D)(4) of this Policy (Complying with DEA-exempt Chemical Preparation Requirements for Working with DEA-exempt Preparations).

## **B. Campus Controlled Substance Program Requirements**

The following requirements apply to schedule II-V institutional and/or departmental research registrations obtained through the Campus Controlled Substances Program.

- 1. Campus Designations of a DEA Registration:** DEA regulations require that every location at which Controlled Substances are received or stored must obtain its own DEA registration. UC locations may seek and the DEA may grant a Campus Designation request or other form of approval, which permits the University to receive or store Controlled Substances at different physical addresses or buildings on a contiguous campus or as otherwise authorized by the DEA. Campus Designations shall be in the name of the campus or a campus department or school (or combinations or parts of those units). Any Campus Designation request must be evidenced by a written letter from the DEA Diversion Control Division approving the Campus Designation. No Controlled Substances may be received or stored under a schedule II-V institutional and/or departmental research registration without written approval by the CSPO while a Campus Designation request is pending.
- 2. Authorization Process and Training:** Each University 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:
  - a. Storage site controls and security;
  - b. Ordering, delivery, and receipt;
  - c. Usage logs and biennial inventory requirements;
  - d. Transfers;

- e. Import and export policies;
- f. Disposal;
- g. Diversion and loss reporting; and
- h. Illicit activities and repercussions.

**3. Power of Attorney:** Each UC location may, through a Power of Attorney executed by the Chancellor or other individual who is an Officer of the University, authorize the Responsible Official, CSPO, or other individual to sign institutional DEA registrations on behalf of a University location or issue orders for schedule I or II Controlled Substances for Authorized University Activities. Unless restricted from doing so by the Power of Attorney executed by the Chancellor or Officer of the University, authorized personnel may authorize, through a Power of Attorney, additional individuals to sign such registrations or issue such orders.

**4. Documentation of Campus Controlled Substance Program**

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

**a. Ordering, procurement and distribution of Controlled Substances for research purposes.** At minimum, these must address:

- i. Restrictions on any individual's capacity to perform all of the following activities related to Controlled Substances: placement of an order with a supplier, receipt of a shipment from a supplier, distribution, and disposal;
- ii. General requisition, procurement, and distribution requirements and approval processes, including the identification of orders of unusual size or frequency or orders deviating substantially from a normal pattern;
- iii. The approval process and requisition information for Investigational New Drugs and schedule II drugs using DEA Form 222;
- iv. Orders for schedules III, IV, and V;
- v. Orders for DEA List I and List II Chemicals; and
- vi. Orders for California Precursor Chemicals.

**b. Controls, storage, and security safeguards** to safeguard against unusual or suspicious acquisition and prevent unauthorized acquisition, access, use, theft, or a diversion of Controlled Substances, DEA List I Chemicals, and California Precursor Chemicals.

c. 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, whose application for registration with the DEA was denied, or who registration was revoked or surrendered for cause (as required by 21 C.F.R. §1301.76 and §1301.90).

d. Recordkeeping and Inventory Requirements, including:

i. Power of Attorney forms;

ii. Purchasing and associated records;

iii. Distribution and chain-of-custody records;

iv. Proper retention schedules for acquisition, use, and disposition records;

v. Adequate recordkeeping by investigators or authorized personnel:

1. Usage log and inventory and biennial inventories; and

2. Separation of records by location.

e. Diversion, loss, or theft reporting of Controlled Substances, DEA List I and List II Chemicals, and California Precursor Chemicals: Individual Campus Controlled Substance Program procedures must specify which division or office is responsible for notifying (1) the local DEA field division office within one business day about each theft or significant loss of Controlled Substances as well as the subsequent submission of DEA Form 106 (as required by 21 C.F.R. §1301.91), (2) the local DEA field division officer about any unusual or excessive loss or disappearance of a DEA List I or List II Chemical (if required by 21 C.F.R. § 1310.05(b)(1), or (3) the California Department of Justice about any theft or loss of any California Precursor Chemical in writing within three days after the discovery (if required by California Business & Professions Code § 11103).

f. Disposal or destruction of Controlled Substances must be in accordance with DEA policies, procedures, and regulations (as required by 21 C.F.R. §1307.21).

5. Required Auditing and Monitoring: A routine auditing and monitoring program must be established and include inspections of researcher-maintained Controlled Substances and records for compliance with state and federal laws governing the use of Controlled Substances in Authorized University Activities.

C. Responsibilities of Individual / Other DEA Registrants

The following requirements apply to researchers with an Analytical Laboratory DEA registration, individual schedule II-V DEA research registration as permitted by the relevant university location, or individuals who are conducting research with the use of any schedule I drug. No individual may use Controlled Substances for any research in a Non-Patient Care setting at any location without notice to the CSPO.

**1. DEA Registration:** In consultation with the CSPO, individuals must file and obtain approval for the appropriate DEA registration prior to undertaking any activities with respect to controlled substances.

**2. Authorization and Training:**

**a.** Ensure necessary researcher authorization for and training of individuals in the laboratory who are assigned work with Controlled Substances; and

**b.** Maintain documentation to verify currently authorized researchers.

**3. Security, Storage, Inventory, Inspections, and Recordkeeping:**

**a.** Maintain strict control over inventory and security of Controlled Substances;

**b.** Ensure that Controlled Substances covered under an individual DEA registration are not intermingled in any manner with Controlled Substances covered under separate DEA registrations and/or owned by the University or by other individuals or entities.

**c.** Ensure authorized researchers receive, store, use, dispose of, and continually maintain Controlled Substance usage logs;

**d.** Under California BPC § 4105, maintain usage logs for three (3) years after the full use or disposal of Controlled Substances; and

**e.** Complete and retain biennial inventory records as required by regulations.

**4. Potential Loss or Diversion Reporting:** Individual registrants must notify the CSPO and report to the local DEA field office within twenty-four hours of the discovery of any theft or significant loss of Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals. Individual registrants must also complete and submit DEA Form 106 “Report of Theft or Loss of Controlled Substances (and disposal receptacles)” or DEA Form 107 “Report of Theft or Loss of Listed Chemicals,” as applicable.

**5. Required Notification of CSPO Regarding DEA Registration Applications and Changes:** Individual registrants must notify the CSPO when applying for, transferring, modifying, or terminating a registration

with the DEA that pertain to Controlled Substances used on campus and/or in connection with Authorized University Activities.

**D. Additional Requirements for All DEA Registrants**

- 1. Illicit Activities:** Consistent with federal law, the University prohibits unlawful possession, sale, use, or distribution of illicit drugs by students and employees on University property or as part of any University activity. Illegal possession, sale, use, or distribution of Controlled Substances is subject to criminal sanctions under federal and state law. In addition, the University may pursue discipline, including employment action, against any employee found to have violated University policy prohibiting unlawful activities involved Controlled Substances on campus or as part of any University activity. Any member of the University community who suspects another member of such illicit activities should follow local reporting policies and procedures.
  
- 2. Import, Export, Interstate and Intrastate Use, Transfers, and Transport:**
  - a. Imports and Exports:** Importation or exportation of Controlled Substances, DEA List I and II Chemicals, or California Precursor Chemicals, including under an individual registration, requires prior written approval by the CSPO and must comply with federal and state laws, including but not limited to DEA regulations, state law and U.S. Food and Drug Administration (FDA) regulations. Such laws could require completion or approval of a permit or registration or could impose reporting requirements.
  
  - b. Interstate and Intrastate Use:** A separate DEA registration and/or state license or registration may need to be obtained for use of Controlled Substances in research conducted outside of California or at a non-UC location within California. For this reason, any such use requires prior written approval by the CSPO.
  
  - c. Transfer:** Transfers of Controlled Substances, DEA Listed Chemicals, or California Precursor Chemicals, must comply with federal and state laws, including but not limited to DEA regulations. Such laws and regulations could apply to interstate or intrastate transfer or even transfer between University DEA registrations or within a University DEA registration. Such laws and regulations could limit the transferred amount or type of drug or chemical, require completion or approval of a permit or an order form request, or could impose reporting or registration requirements. For transfer of substances under the purview of the Campus Controlled Substance Program, prior written approval by the CSPO is required, except for transfers of DEA List II Chemicals or transfers between authorized locations covered by an institutional and/or departmental DEA designation.



d. **Transport:** Movement of Controlled Substances off of University property in support of an Authorized University Activity, such as field research, requires prior approval from the CSPO.

3. **Controlled Substance Analogues:** Research involving Controlled Substance Analogues, including but not limited to dispensing, manufacturing, transferring, importing or exporting, is subject to federal DEA regulations and other laws. Controlled Substance Analogues must commonly be treated as schedule I or II Controlled Substances absent applicability of an exception which depends on a number of factors, including but not limited to the chemical structure of the compound and whether the compound is intended for human consumption. Due to the complexity of this analysis, the CSPO should be contacted prior to Controlled Substance Analogues being obtained, dispensed, manufactured, transferred, imported or exported.

4. **DEA-Exempt Chemical Preparations:** Exemptions are applicable only to the precise preparation or mixture described in the application submitted and approved by the DEA and only for those sections of the Controlled Substances Act and the Code of Federal Regulations specifically identified in the application. Any change in the quantitative or qualitative composition of the preparation or mixture or change in trade name or other designation of a preparation or mixture may result in loss of exempt status. Once a preparation or mixture is no longer exempt under 21 C.F.R. §1308.24, the preparation or mixture is a Controlled Substance, and the CSA and the DEA's implementing regulations apply.

5. **State Licensure for Research Involving Human Subjects:** Only California licensed medical personnel and researchers engaged in Authorized University Activities and acting within the scope of their authorized professional practice and with the approval of all applicable Institutional Review Boards (IRB) may prescribe, furnish, dispense or administer Dangerous Drugs and/or Devices, including Controlled Substances, to human research subjects.

6. **Research Advisory Panel of California (RAPC):** Consistent with California law, Principal Investigators planning to conduct research projects in California using schedule I and/or II Controlled Substances must obtain and submit an application to the RAPC and obtain RAPC's review and approval. Guidance regarding the process for obtaining RAPC review and approval can be found on the RAPC website (see Section VI. Related Information for the URL).

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 website (<http://ag.ca.gov/research/index.php>)~~

~~**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.~~

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## **IV. COMPLIANCE / RESPONSIBILITIES**

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### **A. Campus Controlled Substance Programs**

#### **1. Chancellor or National Laboratory Director**

- a. Provide resources to effectively administer a Campus Controlled Substance Program;
- b. Designate, in writing, a Responsible Official to establish and oversee the program; and

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a.c. If appropriate, execute a Power of Attorney to authorize the Responsible Official to sign institutional DEA registrations on behalf of the University location or to issue orders for schedule II Controlled Substances for Authorized University Activities. Any such authorization must be further evidenced by a Delegation of Authority.

~~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.~~

**2. Responsible Official**

a. Establish and oversee the Campus Controlled Substances Program in accordance with DEA regulations and best practices, as well as this Policy

~~B.b.~~ As designated by the Chancellor or National Laboratory Director, the Responsible Official shall:

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

~~— Establish and oversee the Controlled Substances Program in accordance with DEA regulations and best practices;~~

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

- i. Sign all DEA registrations on behalf of the UC Regents; and Designate one or more individuals, such as the CSPO, to implement and manage the program and ensure that any such designee receives training and/or has experience in California and federal laws governing Controlled Substances;
- ii. If authorized through a Power of Attorney, sign all DEA registrations on behalf of the UC or National Laboratory location of the UC Regents or sign a Power of Attorney to authorize the CSPO or additional individuals to sign such DEA registrations; and
- iii. If authorized through a Power of Attorney, obtain and execute order forms for schedule II Controlled Substances or sign a Power of Attorney to authorize the CSPO or additional individuals to obtain and execute such order forms.

The authorization by the Responsible Official for other individuals to sign registrations or obtain and execute order forms set forth in section IV(A)(2)(b)(ii-iii) above must be further evidenced by a Delegation of Authority.

4. Notwithstanding the foregoing, nothing shall restrict the Chancellor or National Laboratory Director from directly assigning to the CSPO the authority to take the actions set forth in section IV(A)(2)(b)(ii-iii) above

through a Power of Attorney, rather than assigning such authority to the Responsible Official.

~~2. 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.~~

### 3. Controlled Substance Program Officer (CSPO)

- a. Implement and manage the Campus Controlled Substance Program on a day-to-day basis as the Responsible Official's designee (such as personnel from Environment, Health and Safety).
- b. If delegated the authority through a Power of Attorney, the CSPO may sign registrations and/or obtain and execute order forms as described above in section IV(A)(2)(b)(ii-iii).
- c. The CSPO shall receive training and/or have experience in California and Federal laws governing Controlled Substances.

#### D.4. Materiel Management / Procurement

- a. The Materiel Manager or designee is responsible for procuring Procure Controlled Substances, DEA Listed Chemicals, and California Precursor chemicals-Chemicals for Authorized University Activities in compliance with DEA registrations, University or National Laboratory policies and procedures, and the location's Controlled Substances Program, and University/Laboratory policies.
- b. The task of procuring Controlled Substances, DEA Listed Chemicals, and California Precursor Chemicals for Authorized University Activities may be delegated to department purchasers with approval from the CSPO.

#### E.5. Authorized Individuals

- a. Understand their responsibilities within the Campus Controlled Substances Program; and
- b. ~~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~~ Comply with DEA regulations, Campus Controlled Substances program requirements, and University/ or National Laboratory policy governing the acquisition, use, storage, transfer, and disposition of controlled substances.

## **B. Patient Care and Clinical Controlled Substance Programs**

### **1. Chief Executive Officer for Each UC Health System**

- a. Designate the Chief Pharmacy Officer to establish Controlled Substance Controls in the University hospital pharmacies and in any other University hospital licensed spaces, including provider-based clinics, affiliated with that UC Health location.
- b. Designate an individual or individuals to establish Controlled Substance Controls with respect to any other facility affiliated with that UC Health location where Controlled Substances are stored. Such facilities include but are not limited to clinics that are not listed on the hospital license.

### **2. Chief Pharmacy Officer for Each UC Health System**

- a. Establish Controlled Substance Controls in the University hospital pharmacy and in any other University hospital licensed space, including provider-based clinics.

### **3. Medical Affairs & Governance Office at Each UC Health System**

- a. Ensure that physicians that require DEA practitioner registrations provide evidence of such registrations to the Medical Affairs & Governance Office.
- b. Ensure that physicians using the hospital's institutional practitioner electronic prescribing application submit verification of identity as required by 21 C.F.R. §1311.

### **4. Controlled Substance Practitioner**

- a. Every individual who orders, prescribes, administers or dispenses Controlled Substances for clinical use or human subjects research is individually responsible for compliance with their DEA registration and federal and state laws and University policies.



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## V. PROCEDURES

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Each UC location is responsible for developing procedures for the Campus Controlled Substance Program that align with this Policy and applicable federal and state regulations.

See Appendix A, Best Practices Guide

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## VI. RELATED INFORMATION

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Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301-399i Federal Controlled Substances Act of 1970, 21 U.S.C. §§801- 971 and implementing regulations at 21 C.F.R. §§1300-1399 (<https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter13/subchapter1&edition=prelim>)

DEA's Diversion Control Division's Exempt Chemicals Preparation List ([https://www.deadiversion.usdoj.gov/schedules/exempt/exempt\\_chemlist.pdf](https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf))

California Business & Professions Code Division 2, Chapter 9, Article 2 §4021, 4022, 4059, and 4059.5. ([https://leginfo.legislature.ca.gov/faces/codes\\_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=9.&article=2.](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=2.&title=&part=&chapter=9.&article=2.))

California Uniform Controlled Substances Act, Health and Safety Code §11100-11651, and implementing regulations at 11 California Code of Regulations §§800-810.7 ([https://leginfo.legislature.ca.gov/faces/codes\\_displayexpandedbranch.xhtml?tocCode=HSC&division=10.&title=&part=&chapter=&article=](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=HSC&division=10.&title=&part=&chapter=&article=))

Research Advisory Panel of California ( <https://oag.ca.gov/research>)

University of California Board of Regents Bylaw 32. Officers of the University (<https://regents.universityofcalifornia.edu/governance/bylaws/bl32.html>)

U.S. Safe and Drug-Free Schools and Communities Act (20 U.S.C 1145g; 1011i; 34 C.F.R. Part 86) (<https://www.govinfo.gov/content/pkg/USCODE-2011-title20/html/USCODE-2011-title20-chap70-subchapIV.htm>)

U.S. Drug-Free Workplace Act of 1988 (41 U.S.C. §8101 et seq.) ([https://uscode.house.gov/view.xhtml?req=\(title:41%20chapter:81%20edition:prelim\)%20](https://uscode.house.gov/view.xhtml?req=(title:41%20chapter:81%20edition:prelim)%20))

UC guidance on use and possession of marijuana on UC property (<https://www.ucop.edu/safety-and-loss-prevention/environmental/program-resources/uc-smoke-free/marijuana-and-drug-policy.html>)

University of California Contract and Grant Manual, Chapter 3-600 (Controlled Substances & Drugs and Narcotics (<https://www.ucop.edu/research-policy-analysis-coordination/resources-tools/contract-and-grant-manual/chapter3/chapter-3-600.html>))

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+-~~

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## **VII. FREQUENTLY ASKED QUESTIONS**

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Not applicable

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## **VIII. REVISION HISTORY**

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This Policy was revised to incorporate changes effective XX, 2023 to (1) specifically describe the scope of duties of the CSPO and the Campus Controlled Substances Program; (2) define the Campus Designation form of DEA Registration; (3) provide more specific procedures regarding Powers of Attorney; (4) specifically address requirements applicable to DEA Registrations other than Campus Designation DEA Registrations, such as individual schedule I DEA Registrations; (5) provide additional guidance as to import, export, interstate and intrastate use, transfer and transport of Controlled Substances, as well as Controlled Substances Analogues and DEA-exempt chemical preparations; and (6) establish responsible units and individuals for patient care and clinical Controlled Substances Programs.

This policy was reformatted into the standard University of California policy template effective June 1, 2012.

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## **IX. APPENDIX**

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Not applicable.

Appendix A-  
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## ~~II. PURPOSE~~

~~The purpose of this document is to provide examples of best practices to assist University locations in establishing and maintaining a Controlled Substances Program that is fully compliant with federal and state regulations. This non-mandatory appendix contains portions from several University programs which may be used while developing detailed procedures in accordance with the BUS 50 Policy.~~

## ~~● EXPECTATIONS~~

~~Each location must develop a Controlled Substances Policy and Program that meets the minimum requirements of BUS 50 and addresses the expectations of the local DEA office. Each location should collaborate with affected campus organizations (e.g. researchers, materiel management, EH&S, internal audit, and risk management) to work with and gain approval of their Policy and Procedures from their local DEA office. The preferred office of record for the Policy and home of the Program is the campus Environment, Health & Safety Department.~~

## ~~III. RESPONSIBILITIES~~

~~Each campus Chancellor or Laboratory Director is responsible for providing resources to effectively administer a Controlled Substance program and for delegating authority to a Responsible Official in order to establish and oversee the program.~~

~~The Responsible Official should be a direct report to the Chancellor or Laboratory Director and an individual who is authorized to legally commit on the behalf of the campus or National Laboratory that it will meet the federal and state requirements. The Responsible Official should designate the program's management team as follows:~~

~~A. Program Administrator – personnel from Environment, Health and Safety charged with implementing and managing the Controlled Substances Program on a day-to-day basis. The Program Administrator should provide an annual report to the Responsible Official describing the status of the program.~~

~~B. Materiel Manager – responsible for procuring controlled substances and listed and precursor chemicals for Authorized University Activities in compliance with DEA registrations, the location's Controlled Substances Program, and University/Laboratory policies.~~

## ~~IV. GENERAL PROGRAM REQUIREMENTS~~

### ~~A. DEA Registration~~

~~The Responsible Official must assign responsibility to either the Program Administrator or Materiel Manager for obtaining and maintaining the appropriate types of DEA Controlled Substance Registrations in order to~~

~~cover the Authorized University Activities at each principal place of business where Controlled Substances are manufactured, distributed, imported, exported, or dispensed by authorized University personnel.~~

## ~~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.~~

### ~~1. Authorization Process~~

~~Each location's Controlled Substances Program shall have an authorization process for initial request to store controlled substances in a facility/laboratory and for those individuals who require access to Controlled Substances for Authorized University Activities.~~

#### ~~a. Facility Evaluations~~

~~Each location must have written procedures for the evaluation of a proposed storage site for controlled substances with the Principal Investigator. This evaluation should include the control and security requirements, inventory and usage log requirements, and participation in the personnel screening program. The Principal Investigator must successfully complete the location's training and personnel screening programs prior to the approval of the storage site. Attachment A provides an example form for the initial storage site evaluation.~~

#### ~~b. Individual Authorization~~

~~Each location must establish standard operating procedures to authorize individuals for access and use of controlled substances. This must include successfully completing the location's training and personnel screening programs.~~

### ~~2. Training Program~~

~~Each location must provide training with respect to compliance with applicable laws and program requirements prior to authorizing an individual's ability to requisition or use controlled substances. At a minimum, the training program must include:~~

- ~~a. Storage site controls and security;~~
- ~~b. Ordering, delivery, and receipt;~~
- ~~c. Usage logs and biennial inventory requirements;~~
- ~~d. Transfers of Controlled Substances;~~
- ~~e. Import, export, and intra, interstate policies;~~
- ~~f. Disposal of Controlled Substances;~~
- ~~g. Diversion and loss reporting; and~~

~~h. Illicit activities and repercussions.~~

~~The actual format of the training can be any type of method deemed appropriate for the campus culture. These methods may include the traditional instructor-based classes, web-based tutorials, a reference guide approach with certification of understanding, or a combination of training methods. Each training program should include a method to measure effectiveness and understanding. This may include a short exam after the training session or an assessment during the routine audits.~~

~~Finally, each training program should have a re-training component for the authorized individuals at an established frequency that is no longer than four years. The re-training program should also be developed with the campus culture in mind and can take the form of an on-line tutorial, exam, or instructor-based class. The re-training material should cover the program requirements and any new policies and procedures that were instituted during the established re-training frequency.~~

~~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.~~

~~If a location deems it necessary to designate an alternate to sign order forms for Controlled Substances, the location must execute and have on file a fully executed Power of Attorney. The Responsible Official may grant this Power of Attorney based on specific University needs. The Power of Attorney remains in effect as long as the designated individuals remain in these roles. To revoke the Power of Attorney, the location must execute a Notice of Revocation and maintained with the original Power of Attorney. A Sample Power of Attorney and a Notice of Revocation Form is provided in DEA regulations (CFR Title 21, Food and Drug Act §1305.05) are provided in Attachments B and C.~~

~~Power of Attorney forms must be kept readily available for inspection upon request by the DEA or State Board of Pharmacy inspectors.~~

~~D. Import, Export, Interstate and Intrastate Use Requirements~~

~~The location's policy must comply with the requirements stated in the BUS 50 policy. Each location must establish procedures for individuals who conduct research outside the State of California that require transport or use of controlled substances. This may include having the Program Administrator act as the liaison between the Principal Investigator and the~~

~~DEA office in the State that the research is being performed in order to assist the researcher in obtaining a registration in that State. Similarly, procedures must be established for investigators to notify the Program Administrator prior to any intrastate transport and/or transfer of controlled substances.~~

~~E. Documentation of Local Controlled Substances Program Compliance~~

~~Each location must develop and publish written procedures that address the following federal or state requirements. Example procedures and forms are provided for each required program element:~~

- ~~1. Processes and controls with regard to ordering, procurement and distribution of Controlled Substances for Research Purposes. Minimally, these must address:~~
  - ~~a. Determine if a drug is a controlled substance through one of the following references:
    - ~~i. Refer to the [Drug Enforcement Administration](#) website for a searchable list of controlled substances.~~
    - ~~ii. Use the Physicians' Desk Reference, Red Book, or Veterinary Pharmaceuticals and Biologicals.~~
    - ~~iii. Contact the Program Administrator or a member of the Purchasing Department.~~~~
  - ~~b. Ordering controlled substances:
    - ~~i. All orders for controlled substances must be placed and/or approved by the Responsible Official or those individuals delegated by Power of Attorney, regardless of whether the controlled substance is purchased or obtained free of charge from the supplier. Departments must complete a Purchase Requisition (PR). No order for controlled substances may be placed by any other means.~~
    - ~~ii. Schedule I and II controlled substances may be included on one PR, but must not be included on a PR with substances from any other schedules or any other products. Controlled substances on Schedules III, IV, and V may be combined on a separate PR with no other products.~~
    - ~~iii. Information on the PR must include:
      - ~~1) A statement that the substance requested is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.~~
      - ~~2) A full description of the item requested, including vendor, catalog number, quantity, size of package, name of drug, and the number of the Federal Schedule of Controlled~~~~~~

~~Substances to which it is assigned.~~

- ~~3) A detailed statement of the purpose and/or manner of use that is planned and if it is to be used for teaching and research.~~
- ~~4) The name of the Principal Investigator.~~
- ~~5) The name of the authorized recipient, even if the same as the Principal Investigator (contact person at point of delivery).~~
- ~~6) The final delivery and storage location.~~
- ~~7) The appropriate study approvals from the location's Institutional Review Board (IRB), Animal Care and Use Committee, Radiation Safety Committee, and/or Chemical Safety Committee (i.e., Animal Care and Use Protocol Number). If the location does not have a committee to cover the specific research (specifically in cases where plants, non-regulated species are involved in research) the Program Administrator may review the research protocol.~~

~~Information on the PR must be very specific. Example language is provided as Attachment D.~~

- ~~iv. The PR must be ad hoc routed to the approving department head or one authorized designee for approval. The PRs will also be routed to the Program Administrator, Office of Environmental Health and Safety (EH&S) or designee for approval.~~
- ~~v. Purchasing will monitor for inappropriately procured substances that may have been procured under a departmental purchase delegation or through use of an incorrect commodity code. Purchasing and EH&S will follow approved escalation procedures if substances were purchased inappropriately. Attachment J provides an example escalation procedure. EH&S will also monitor for inappropriately acquired substances during the routine audits.~~

~~e. Receiving~~

- ~~i. Controlled substances may only be received at the addresses currently registered with the DEA.~~
  - ~~1) With the exception of pharmacies and a very few remote locations, all controlled substances are delivered to Central Receiving area who takes possession of the drug and initiates a Controlled Substance Delivery Record, which will follow the shipment to the authorized storage site.~~
  - ~~2) All controlled substances received require that a record of chain-of-custody be kept on a Controlled Substance~~



~~Delivery Record. Each shipment received shall be opened and the contents verified, under dual custody, every time it changes hands. Authorized recipients shall sign and note any discrepancy or damage on the Controlled Substance Delivery Record each time the drug changes hands.~~

- ~~ii. The ordering department will receive a photocopy of the purchase order from Purchasing. The authorized recipient designated on the Purchase Requisition must, as the ultimate receiver of the substance, sign the photocopy and be the last to sign the Controlled Substance Delivery Record.~~
- ~~iii. Both of the signed documents must be returned to Purchasing within 15 days of receipt of the controlled substance. If the required documentation is not returned to Purchasing within 15 days, a notice of negligence will be sent to the authorized individual with a copy to the department head and EH&S. If the information is not returned within 15 additional days, the Purchasing department will no longer place orders for the authorized individual in question and will send another letter to the authorized individual, department head, the appropriate Deans' office, and EH&S. The Purchasing Controlled Substance Database will be annotated, and all controlled substance buyers and managers will be notified.~~
- ~~iv. Purchasing will provide information to EH&S about the details of the delivery, including whether a partial delivery or complete delivery was made.~~
- ~~v. If the supplier delivers a controlled substance directly to a department (other than approved remote locations), the department must immediately contact Central Receiving to notify them that the delivery bypassed them and add a note to the photocopy of the purchase order stating that the delivery bypassed Central Receiving and was made directly to the department.~~
- ~~vi. Under no circumstances must a controlled substance be left unsecured and unattended, unless in a location approved by EH&S.~~
- ~~d. The approval process and requisition information for Investigational New Drugs:~~

~~See CFR Title 21, Food and Drug Act Chapter 1, Subchapter D, Part 312, Subpart B, Section 312 for federal approval process and requisition information relating to Investigational New Drugs.~~

- ~~e. Orders for Schedule I and II drugs using DEA Form 222:~~

~~The Purchasing Department must use the DEA 222 form for all orders of Schedules I and II controlled substances. Specific instructions (if needed) are available on the back of every 222 form.~~

~~Each research project using a Schedule I substance will need a separate DEA registration, approval by the State Research Advisory Panel of California (RAPC), and approval of the Office of Research (OR), and IRB.~~

~~Proposals requiring use of Schedule II substances (except stimulants) that will be used in human research must also be reviewed and approved by the RAPC prior to procurement.~~

~~f. Orders for Schedules III, IV, and V and other Dangerous Drugs:~~

~~Orders for Controlled Substances listed in Schedules III, IV and V, and other Dangerous Drugs may be secured by issuance of a standard University purchase order. No controlled substance may be purchased through a blanket order. Each request requires a new order.~~

~~g. Orders for Federal List I Chemicals/Precursor Chemicals::~~

~~A site-specific DEA registration must be used to purchase List I chemicals.~~

~~h. Orders for California Listed Chemicals/Precursor Chemicals:~~

~~California Listed Chemicals do not require a license or registration to purchase. The exemption for laboratory use of these materials is covered under California Business and Professions Code Chapter 9 Division 2 Article 2 §§ 4059 and 4059.5~~

~~i. Orders for Dangerous Drugs and Devices (Material requiring a Prescription):~~

~~University and National Laboratory Investigators engaged in Authorized University Activities are permitted to purchase and use dangerous drugs and devices without a prescription as exempted by California Business and Professions Code Chapter 9, Division 2, Article 2 §§4059 and 4059.5.~~

~~Purchase records which identify the date, name, and address of the supplier, drug or device, and quantity must be readily retrievable.~~

~~3. Controls, Storage, and Security safeguards to prevent unauthorized acquisition, access, use, theft, or diversion of Controlled Substances,~~

~~List I chemicals, California Precursor Chemicals, and other Dangerous Drugs and Devices. Attachment A provides an example of an evaluation of the storage site and Attachment E provides guidance on appropriate controls, storage, and security.~~

~~3. Each University location must establish a Personnel Screening Program 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. Attachment F provides an example screening form. The program can be implemented and managed at the Principal Investigator level and reviewed during the routine audits or centralized and managed by EH&S. See 21 CFR §1301.76 and 1301.90.~~

~~4. Record-Keeping and Inventory Requirements, including:~~

~~**f. Power of Attorney forms:**~~

~~See section IV.C. for policy description and attachments B and C for example forms.~~

~~**g. Purchasing and associated records:**~~

~~All purchase records must be maintained for at least three years.~~

~~**h. Distribution and chain-of-custody records:**~~

~~Documentation of the chain-of-custody must accompany each receipt of controlled substances. Attachment G provides example documentation for receipt and chain-of-custody.~~

~~**i. Proper retention schedules for acquisition, use, and disposition records;**~~

~~All records must be maintained for at least three years.~~

~~**j. Adequate recordkeeping by authorized individuals:**~~

~~**i. Usage log, inventory, and biennial inventories;**~~

~~Investigators must maintain a current inventory and usage log for all controlled substances. Attachment H provides an example usage log for controlled substances.~~

~~Every two years following the date of the registration's initial inventory the Program Administrator shall secure from each Department Chair or Principal Investigator an inventory of all stocks of Controlled Substances on hand. The biennial inventory shall be performed:~~

~~1. on the same day and month on which the initial inventory was taken; or~~

- ~~2. on a regular general physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply; the DEA shall be notified of the date; or~~
- ~~3. on any other fixed date which does not vary by more than six months from the biennial date that would otherwise apply; the local DEA Office may require notification of the date.~~

~~Attachment I provides an example inventory form for reporting the biennial inventory.~~

~~ii. **Separation of records by location;**~~

- ~~a. A separate inventory shall be made for each registration and stored at the location.~~

~~The inventory may be taken either as of opening of business or as of the close of business on the inventory date, and it must be indicated on the inventory.~~

~~iii. **Purchase records for Dangerous drugs and Devices.**~~

~~Purchase records of all pharmaceutical drugs and devices (California Business and Professions Code Chapter 9, Division 2, Article 2, § 4031) must be readily retrievable.~~

~~(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. However, all authorized individuals are expected to report missing controlled substances to their supervisor, Program Administrator, and the location's law enforcement unit (e.g., the University of California Police Department) as soon as the loss is discovered. The Program Administrator and local law enforcement will investigate the diversion, loss, or theft of Controlled Substances, Precursors, and List I chemicals. Reports will be kept confidential to the extent permitted by law and other University policies.~~

~~The Program Administrator must promptly (within 24 hours) submit DEA Form 106 to the local DEA office for each theft and any significant loss of Controlled Substances. According to DEA guidance:~~

~~*“Breakage of controlled substances does not constitute a “loss” of controlled substances. When there is breakage, damage, spillage*~~

~~or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process.~~

~~If the breakage or spillage is not recoverable, the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41, Registrants Inventory of Drugs Surrendered is not required for non-recoverable controlled substances."~~

- ~~6. Disposal or Destruction of any controlled substance must be in accordance with DEA policies, procedures, and regulations. See 21 CFR §1307.21.~~

~~Authorized Individuals must inform the Program Administrator or the authorized waste management team of the need to dispose of Controlled Substances or Dangerous Drugs that are expired or no longer needed for Authorized University activities. The Program Administrator or authorized waste management team member will coordinate disposal of any controlled substance with a reverse distributor or campus on site pharmacy.~~

~~The reverse distributor, or on site pharmacy, must provide documentation as to final disposition of disposed/destroyed/returned drugs to the Program Administrator or authorized waste management team. If applicable, the final disposition of such substances must be documented by receipt of one of the following:~~

- ~~a. A Certificate of Destruction and corresponding Form 222 for each Schedule I and II controlled substance covered by that certificate or a DEA Form 41;~~
- ~~b. A completed copy of the waste manifest from the Treatment Storage and Disposal Facility;~~
- ~~c. A certificate of return to manufacturer.~~

- ~~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 and provide documentation to the Program Administrator.~~

~~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 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. Questions regarding scope of practice should be referred to the Office of the General Counsel, Health Law Section.~~

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+-~~

**CONTROLLED SUBSTANCE PROGRAM-  
INITIAL STORAGE SITE EVALUATION FORM**

Date: \_\_\_\_\_

Principal Investigator \_\_\_\_\_ Location \_\_\_\_\_  
Department: \_\_\_\_\_ Phone: \_\_\_\_\_  
E-mail: \_\_\_\_\_

**A. Requirement Satisfactory Unsatisfactory**

**IX. STORAGE AREA**

Key Control (2 keys)		
Hinges inaccessible from outside		
Hasp inaccessible from outside when closed		
Tumbler/Padlock		

<b>Training Program Completion</b>		
<b>Personnel Screening Program Completion</b>		
<b>A. Review Usage Log</b>		
<b>Review Biennial Inventories</b>		
<b>Review Disposal Procedures</b>		

**B. Comments**

\_\_\_\_\_

Principal Investigator \_\_\_\_\_ Program Administrator

**Attachment B**

**POWER OF ATTORNEY FOR DEA ORDER FORMS**

*(Enables the signed individual to obtain and execute order forms on the Responsible Official's behalf)*

Name of registrant

Address of registrant

DEA registration number

I, \_\_\_\_\_ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint \_\_\_\_\_ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, solely for the purpose of executing applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S. C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

\_\_\_\_\_  
(Signature of person granting power)

I, \_\_\_\_\_, (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

\_\_\_\_\_  
(Signature of attorney-in-fact)

Witnesses:

1.

2.

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_ (month) \_\_\_\_\_ (year),  
at \_\_\_\_\_.



**Attachment G**

**NOTICE OF REVOCATION**

~~(Name of registrant)-~~

~~(Address of registrant)-~~

~~(DEA registration number)~~

~~The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney in fact \_\_\_\_\_ this same day.~~

\_\_\_\_\_  
\_\_\_\_\_  
(Signature of person revoking power)

Witnesses:

1. \_\_\_\_\_

2. \_\_\_\_\_

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_, 2007, at \_\_\_\_\_.

## **SAMPLE GUIDANCE DOCUMENT FOR INVESTIGATORS**

### **Ordering & Receiving Controlled Substances**

The United States Drug Enforcement Administration and the State of California [Board of Pharmacy](#) strictly regulate controlled substances. UC Davis has a specific procedure for ordering, delivery, and receipt of controlled substances on campus for clinical, research, and teaching needs.

#### **Determining if a Drug is a Controlled Substance**

The Drug Enforcement Administration provides searchable online [controlled substance schedules](#). You can also refer to medical reference manuals, such as:

- [The Physicians' Desk Reference](#)
- [Red Book](#)
- [Veterinary Pharmaceuticals and Biologicals](#)

If you are unable to use any of the above to determine if a substance is controlled, contact a member of the [Purchasing Agricultural & Scientific Team](#).

#### **Ordering Controlled Substances**

All orders for controlled substances must be processed on a [Requisition \(PR\)](#) and cite an appropriate [commodity code](#). Include the following information on the PR:

- A statement that the substance requested is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
- A full description of the item requested: quantity, size of package, name of drug, and the number of the Federal Schedule of Controlled Substances to which it is assigned.
- A detailed statement of the purpose and/or manner of planned use and if it is to be used for teaching, research or clinical applications.
- The name of the authorized custodian.
- The name of the end user, even if the same as the authorized custodian.
- The final delivery and storage location.
- The appropriate study approvals from the location's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Radiation Safety Committee, and/or Chemical Safety Committee. If the location does not have a committee to cover the specific research (specifically in cases where plants, non-regulated species are involved in research) the Program Administrator may approve the research protocol.

Note: Schedule III, IV, and V substances may be included on a single PR; Schedules I & II may be included on a single PR, but must be separate from the other schedules.

A sample statement satisfying the above conditions would resemble the following:

"This material is subject to the Comprehensive Drug Abuse Prevention & Control Act of 1970 (Controlled Substances Act) and is a Schedule II substance. The authorized

University of California – Policy  
BFB-BUS-50: Controlled Substances

~~custodian is Jonathan Doe. The substance will be used by Dr. Jane Deer to anesthetize dogs in research on heart disease. The approved storage site is Building Y, Room X."~~

~~Ad hoc route the PR to the approving department head or authorized designee for approval. If the department head/designee is not a DaFIS user, a hard copy signature must be sent to Purchasing. PRs citing controlled substance commodity codes will special conditions route to Environmental Health and Safety (EH&S) for approval.~~

### **Procedure for Receiving**

~~All controlled substances are to be delivered to Central Receiving area. They will take possession of the drugs and initiate a Controlled Substance Delivery Record, which will follow the shipment to the authorized storage site. Every time the shipment is transferred to another person it must be opened and the contents verified by both parties. In addition, an authorized recipient must sign and note any discrepancy or damage on the Controlled Substance Delivery Record each time the drug changes hands. An authorized recipient is the individual authorized to use or dispense the drug or someone who is listed on the Controlled Substances Receipt Authorization list (CSRA). Contact Purchasing to add or delete names from the CSRA list.~~

~~The ordering department will receive a photocopy of the purchase order from Purchasing and must complete the area stamped in red.~~

~~The end user designated in the description area of the Requisition must, as the ultimate receiver of the substance, sign the photocopy and will be the last to sign the Controlled Substance Delivery Record. Both of the signed documents must be returned to Purchasing within fifteen days of receipt of the controlled substance.~~

~~Please note that if the required documentation is not returned to Purchasing within fifteen (15) days of delivery of the controlled substance, a notice of negligence will be sent to the authorized end user with a copy to the department head and EH&S. If the information is not returned within fifteen additional days, the Purchasing department will no longer place orders for the authorized end user in question and will send another letter to the authorized end user, department head, the appropriate Deans' office, and EH&S. The Purchasing Controlled Substance Database will be annotated, and all authorized controlled substance buyers and managers will be notified.~~

~~If a controlled substance is delivered directly to your department by the supplier, contact Central Receiving to notify them that the delivery bypassed them. Also, add a note to your photocopy of the **Purchase Order** that the delivery bypassed Central Receiving and was made directly to your department.~~

### **Delivery Troubleshooting**

~~All controlled substance deliveries are opened and verified for accuracy at the Central Receiving department. If there is a discrepancy or damage, Central Receiving will contact Purchasing for product return arrangements. Purchasing will work with the department and the vendor to ensure that the most appropriate action is taken.~~

~~Questions regarding controlled substance purchasing procedures? You may contact any member of the \_\_\_\_\_.~~

### STORAGE REQUIREMENTS AND ACCESS RESTRICTIONS

**Summary:** Find out how to securely store controlled substances (CS) according to Environment, Health & Safety (EH&S) standards. **Before purchasing or installing a storage container** for your CS inventory, contact the Program Administrator (phone) to develop a storage plan.

<p><b>Storage requirements</b>  <del>Notify EH&amp;S immediately of missing controlled substances: (XXX) XXX-XXXX.</del></p>	<p><del>Principal investigators are responsible for providing and maintaining secure storage for their CS inventory that meets these criteria:</del></p> <p><b>Store CS according to schedule number:</b></p> <ul style="list-style-type: none"> <li><del>● Schedule I: Store in a safe or steel cabinet equivalent.</del></li> <li><del>● Schedule II-V: Store in a locked drawer or cabinet that is inaccessible from above or below.</del></li> </ul> <p><b>Install the following equipment according to these standards:</b></p> <ul style="list-style-type: none"> <li><del>○ Padlocks and hinges: Must have the mounting screws or bolts of the hasp inaccessible when the door is closed and the lock is fastened</del></li> <li><del>● Safes and steel cabinet equivalents:</del> <ul style="list-style-type: none"> <li><del>○ Must be cemented or bolted to the floor or wall, or weigh more than 750 pounds</del></li> <li><del>○ Storage units: Must be secure enough to show forced entry</del></li> <li><del>○ Drawers: Must be inaccessible from the upper or lower drawers in the stack. Assign the top drawer of the stack to use as the storage facility, if possible.</del></li> </ul> </li> <li><del>● Use CS storage units only for CS and their inventory logs.</del></li> <li><del>● Storage restrictions:</del> <ul style="list-style-type: none"> <li><del>○ Do not share CS storage facilities.</del></li> <li><del>○ Do not transfer CS from its original container for storage purposes.</del></li> <li><del>○ Do not store other chemicals or supplies in a CS storage unit.</del></li> <li><del>○ Do not store CS in a corridor.</del></li> </ul> </li> </ul>	
<p><b>Access restrictions</b></p>	<p><b>Restrict access only to authorized personnel</b> on your Controlled Substances Use Authorization (CSUA) and follow these precautions:</p> <ul style="list-style-type: none"> <li><del>● Keep storage key(s) in the physical custody of authorized personnel at all times.</del></li> <li><del>● You can make multiple key copies and assign them to authorized personnel.</del></li> <li><del>● Do not store keys in a drawer or on the wall.</del></li> <li><del>● When authorized personnel leave their position in the lab.</del></li> <li><del>● Change combinations or retrieve the individual's keys.</del></li> <li><del>● Document authorized personnel security changes in the inventory log.</del></li> <li><del>● Remove the authorized individuals from the CSUA.</del></li> </ul>	
<p><b>Moving or closing your lab</b></p>	<p><del>Relocation of CS during lab moves or closures is strictly regulated and must be approved by EH&amp;S.</del></p> <ul style="list-style-type: none"> <li><del>● Notify EH&amp;S with the online Lab Relocation or Closure Notification form 3 weeks before your intended move or lab closure.</del></li> <li><del>● <b>Moving within UCXX:</b> Contact the Program Administrator [phone] to have your new storage location approved <b>prior</b> to moving. Your CS inventory can be temporarily stored at a secure EH&amp;S facility during your move.</del> <ul style="list-style-type: none"> <li><del>○ Note: Moving Services must not transport CS.</del></li> </ul> </li> <li><del>● <b>Moving off campus or closing the lab:</b> Follow steps to terminate your CSUA.</del></li> </ul>	

**PERSONNEL SCREENING PROGRAM**

Principal investigators: Use this form to add an Authorized Personnel to your Controlled Substance Usage Authorization (CSUA). The following is to be filled out by all proposed handlers of controlled substances (CS) (21CFR1301.90). Return the completed form to the Program Administrator at Mail Code 0089 or fax ( ) or scanned & emailed to \_\_\_\_\_.

**APPLICANT INFORMATION:**

- Add to CSUA as an Authorized Personnel**
- Designate as CS Lab Contact**  
(Circle one: Primary / Secondary)
- Authorized Recipient (OK to Pick up Controlled Substance Shipments)**

Name: \_\_\_\_\_ Employee/Student/Passport #: \_\_\_\_\_

Lab/Office location: \_\_\_\_\_ Phone: \_\_\_\_\_ E-mail address: \_\_\_\_\_ Mail Code: \_\_\_\_\_ CSUA#: \_\_\_\_\_

Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date, and sentence on additional page.  Yes  No

In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details on additional page.  Yes  No

Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended, or denied?  Yes  No

By signing below, I authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions. I understand that any false information, omission of information, or misuse of controlled substances will jeopardize my position with the University. Information included herein will not preclude me from utilizing controlled substances in non-human research at \_\_\_\_\_, but will be considered as part of the overall evaluation of qualifications in the application.

The DEA requires that an employee who has knowledge of drug diversion from his/her employer by a fellow employee is obligated to report such information to a responsible security official of the employer. At \_\_\_\_\_, all such reports can be made confidentially to the Controlled Substances Program Manager who will inform the appropriate officials and initiate an investigation on the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries.

Applicant signature: \_\_\_\_\_ Date: \_\_\_\_\_

**PI authorization for the person (identified above) to handle controlled substances issued to the PI:**

Principal Investigator signature: \_\_\_\_\_ Date: \_\_\_\_\_

Principal Investigator name: \_\_\_\_\_

**CONTROLLED SUBSTANCE DELIVERY FORM**

PO#: 102000000  
 Vendor: MWI  
 PO Date: 04/30/2007  
 PI: John Smith

Received at:

Quantity	Concentration	Amt per Container	Substance Name	Schedule	Qty Rec'd
12 bottles	50.00 mg/mL	50.00 mL	Pentobarbital	II-N	10
2 bottles	4.00 percent	43.00 Patches	Nalorphine	III	2

Accepted at Mail Services by:	Distributed from Mail Services by:	Accepted from Mail Services by:
Sign: M. Green	Sign: M. Green	Sign: Jeffrey Smith
Print: M. Green	Print: M. Green	Print: Jeffery Smith
Date: 5/1/2007	Date: 5/3/2007	Date: 5/3/2007

Lab Contacts			Notified on:	
Primary:	Jeffrey Smith	@ucop.edu	5/1/07	
Secondary:	Jada Wang	@ucop.edu	5/1/07	

Mark receiving party	Authorized Recipients	
XXX	Jeffrey Smith	@ucop.edu
	Jada Wang	@ucop.edu
	Dominic Del-Re	@ucop.edu
	Chris Means	@ucop.edu
	Shigeki Miyamoto	@ucop.edu
	PI: John Smith	@ucop.edu

Comments:



**CONTROLLED SUBSTANCES BIENNIAL INVENTORY FORM**

The Biennial Inventory is a requirement of the Federal Drug Enforcement Administration (21 CFR 1304.11). Please return this form to the Program Administrator at EH&S by mail ( ) or fax ( ).

Principal Investigator Name: \_\_\_\_\_ Department: \_\_\_\_\_

Controlled Substances storage location:  La Jolla  Hillcrest  Elliot Field Station

**Instructions:** List all Controlled Substances in possession as of the close of business on February 8<sup>th</sup>. List open containers as separate line items. Unopened containers of same substance, manufacturer, volume, and concentration can be listed together on same line. Fill out separate forms for each storage location.

Line Item	Unopened Containers		Opened Containers			Controlled Substance Name	Drug Code & Schedule <sup>+</sup>	Finished Form <sup>‡</sup>
	Qty	Container size	Qty	Remaining amount*	Container size			
1								
2								
3								
4								
5								

Number of completed line items in table: \_\_\_\_\_ (write "Zero" if none)

**By signing below,** I agree the information listed here represents the actual amount of controlled substances existing in inventory as of the close of business on February 9<sup>th</sup>, 2007 (Biennial Inventory Date).

**Principal Investigator signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

For a list of Controlled Substances visit:

<http://www.deadiversion.usdoj.gov/schedules/alpha/alphabetical.htm>

\*— Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules). For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact count must be made.

<sup>+</sup> For DEA Drug Code and Schedule number, refer to DEA Controlled Substances website (above). DEA Drug Code is a 4-digit number. Controlled Substance Schedule number is expressed in Roman numerals, I through V; N denotes the item is non-narcotic and only applies to schedules II and III.

<sup>‡</sup> Finished Form refers to the strength and form of the item as commercially prepared.



## **CONTROLLED SUBSTANCE PROGRAM ESCALATION PROCEDURE**

### **I. Purpose:**

The purpose of this escalation procedure for the Controlled Substance Program is to ensure compliance with the U.S. Department of Justice, Drug Enforcement Administration regulations (21 CFR) in regards to purchasing and transfers of controlled substances.

### **II. Procedure:**

The following escalation procedure will be used for all inappropriate purchases and transfers between departments or authorized individuals of controlled substances:

An unauthorized purchase of controlled substance can occur in the following manners:

#### **1. DEPARTMENTAL PURCHASE ORDER (DPO);**

- a. Use of a procurement card;
- b. By telephone;
- c. By a vendor automated ordering system.

Once information has been obtained by the Purchasing Department that one of the above purchase types has occurred, the following escalation procedure will be implemented and tracked:

1. The Purchasing Department will immediately notify the authorized custodian and department office that inappropriate purchase has occurred. In all cases, the vendor will also be contacted regarding the appropriate purchasing procedures.

#### **2. Escalation Procedure:**

##### **a. First Occurrence**

A follow-up letter will be immediately faxed to the authorized custodian and department head stating the inappropriate purchase, actions to be taken, and consequences if this type of purchase of controlled substance continues. A copy of the existing policy will also be provided to the authorized custodian.

##### **b. Second Occurrence**

A follow-up letter will be immediately faxed to the authorized custodian, department head, and Dean or Vice Chancellor stating the inappropriate purchase, actions to be taken, and consequences if this type of purchase of controlled substance occurs again.

##### **c. Third Occurrence**

In the event that an authorized custodian attempts three (3) inappropriate purchases in any one calendar year, the purchasing privileges for controlled substances will be suspended for twelve (12) months by the Purchasing Department. A follow-up letter will be immediately faxed to the authorized custodian, department head, and Dean or Vice Chancellor stating that suspension has occurred.

Transfers of Controlled Substances must be in compliance with the approved procedures. This includes appropriate documentation by the transferee, recipient, and a copy of the transfer record to the Office of Environmental Health and Safety (EH&S).

When EH&S becomes aware of an inappropriate transfer, the escalation procedure as stated in section A.2.a-c in this document will be followed by EH&S staff.

## MODEL COMMUNICATION

The University of California, Office of the President invites comments on a proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching. The policy is proposed to be revised and includes the following key issues:

- Clarify in detail the scope of duties of the Campus Controlled Substances Programs and the Controlled Substances Program Officers;
- Define the Campus Designation form of Drug Enforcement Agency (DEA) Registration and address requirements applicable to DEA Registrations other than Campus Designation, such as individual schedule I DEA Registrations;
- Provide more specific procedures regarding Powers of Attorney;
- Provide additional guidance as to import, export, interstate and intrastate use, transfer and transport of Controlled Substances, as well as Controlled Substances Analogues and DEA-exempt chemical preparations; and
- Establish responsible units and individuals for patient care and clinical Controlled Substances Program.

If you have any questions or if you wish to comment, please contact \_\_\_\_\_ at \_\_\_\_\_, no later than \_\_\_\_\_, 2024.