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

Responsible Officer:	Chief Risk Officer
Responsible Office:	RK - Risk / EH&S
Issuance Date:	5/5/2009
Effective Date:	5/5/2009
Last Review Date:	
Scope:	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. 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.

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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 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)

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 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

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.
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> 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,

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.

III. POLICY TEXT

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:

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 perview 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).

IV. COMPLIANCE / RESPONSIBILITIES

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

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.

V. PROCEDURES

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.

VI. RELATED INFORMATION

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)

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.)

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=)

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)

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)

VII. FREQUENTLY ASKED QUESTIONS

Not applicable.

VIII. REVISION HISTORY

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.

IX. APPENDIX

Not applicable.