

UC SANTA BARBARA POLICY AND PROCEDURE

Controlled Substances

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Controlled Substances Policy

I. INTRODUCTION AND SCOPE

The University of California, Santa Barbara (UCSB) Controlled Substances Program describes the special requirements and procedures applicable to the procurement, storage, use, transfer, disposal, and inspection of Federal Drug Enforcement Agency (DEA) Controlled Substances, Listed Chemicals, Precursor Chemicals, and Dangerous Devices used for research and teaching activities at UCSB.

This policy was established to help ensure campus personnel are in compliance with federal (U.S. Department of Justice, DEA, CFR Title 21, Food and Drug Act §1300-1316) and state (California Health and Safety Code §11100-11700) regulations that relate to the acquisition, maintenance, storage, use, disposal and transfer of Controlled Substances.

In addition to Controlled Substances, the DEA and the State of California regulate chemicals that may be used in the production of these substances. The DEA maintains two lists of these chemical, List I and List II¹, while the State of California maintains a list of "Precursor Chemicals." The California Precursor Chemicals includes the DEA Listed chemicals, as well as additional chemicals. Requirements for the procurement and use of these chemicals are less restrictive than for controlled substances and are outlined in Appendix A.

These guidelines do not apply to Controlled Substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license, nor to the UCSB Student Health Services Pharmacy. Principal investigators, researchers, staff or any University employee obtaining or using Controlled Substances, Listed Chemicals, Precursor Chemicals and/or Dangerous Devices must remain in compliance with the Controlled Substance Program.

II. DEFINITIONS

Authorized Custodian - The Principal Investigator (PI) or DEA Registration Holder who is authorized by the Program Administrator to receive and store Controlled Substances and is responsible for the maintenance of usage logs and Biennial Inventory.

Authorized Personnel - Authorized Personnel are faculty, staff, students, or visiting scholars who have a need to handle or access Controlled Substances for use in department-approved projects at UCSB. The number of Authorized Personnel shall be kept to a minimum in order to maintain security. Authorized Personnel are responsible for understanding their responsibilities within the program and for complying with UCSB policy governing the use, storage, and disposition of Controlled Substances.

¹ The primary difference between List I and List II chemicals is the DEA reporting threshold for import, export, or sale (List II thresholds are higher).

In order to become an Authorized Personnel, the individual must sign the Controlled Substance Personnel Screening Data Sheet (PSDS), obtain the authorization signature of a Principal Investigator, file a copy with EH&S, and subsequently file for addition to the Controlled Substances Use Authorization (CSUA).

Applicants to become Authorized Personnel who have been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause shall be denied. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.²

Authorized University Activities - University approved research activities and animal care and use associated with research and teaching uses of Controlled Substances and Chemical Precursors.

Biennial Inventory – A detailed inventory of all Controlled Substances present in any authorized UCSB lab on a specified date and time to be conducted every two years at the direction of the Program Administrator. (See, [UCSB Controlled Substances Inventory Form](#))

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 Title 21 CFR §1308.11-1308.15.

Controlled Substances Use Authorization – (1) The specific authorization granted to an Authorized Person at UCSB. (2) The project documentation form required for Authorized University Activities. (See, [UCSB Controlled Substances Project Registration Form](#))

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:

- 1.) 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.
- 2.) 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.
- 3.) 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).

Principal 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.

DEA Registration Holder - An individual who holds a current DEA registration for an Authorized University Activity in their name.

² [21 CFR § 1301.76 \(a\)](#).

Department Chair - a faculty member (as defined in [APM - 110-4\(15\)](#)) who serves as the academic leader and administrative head of a department of instruction or research, or a clinical service³. The Department Chair is responsible for determining the need for and authorizing the Principal Investigator to approve purchase orders for Controlled Substances by Authorized Personnel and for assuring that the storage, use, inventories, transfers, and disposal of Controlled Substances by Authorized Personnel complies with applicable laws, regulations, and UCSB policy.

Listed Chemicals - Under federal law, any List I or List II chemical including a List I chemical specifically designated by the DEA Administrator in Title 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 Title 21 CFR §1310.02(b), that in addition to legitimate uses is used in manufacturing a Controlled Substance in violation of the Act. Information concerning the assignment of a particular substance to specific schedules may be obtained [here](#) or by contacting the Controlled Substances Program Administrator.

Materiel Manager - Designated by the DEA Registration Holder in each program or department engaging in Authorized University Activities, this position is responsible for procuring Controlled Substances and Listed or Precursor Chemicals for Authorized University Activities in compliance with DEA registrations, UCSB's Controlled Substances Program, and University/Laboratory policies.

Precursor Chemical - Under California 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, California Health and Safety Code §11100 et seq.). The California list of Precursor Chemicals, which can be found [here](#), includes DEA List I chemicals and other additional chemicals. California law requires campus vendors to uphold stringent regulations regarding the sale and distribution of these chemicals.

Principal Investigator – An individual who has primary responsibility for the design, execution, and management of a research project conducting an Authorized University Activity and who will be involved in the project in a significant manner.

Program Administrator – The Responsible Official's designee charged with implementing and managing the Controlled Substances Program on a day-to-day basis. The Program Administrator reviews departmental handling procedures for controlled substances, conducts site inspections, requests and reviews the biennial inventories and drug logs, and manages the disposal of unused, expired, or waste controlled substances. 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.

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

³ See also, [APM 245](#).

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

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

III. POLICY

1. UCSB and its employees shall comply with all applicable federal and state laws and regulations governing Controlled Substances, Listed Chemicals, Precursor Chemicals and Dangerous Devices. In addition to compliance with federal and state laws, university employees shall also comply with requirements set forth by [UCOP BUS 50](#).
2. All procurement and use of Controlled Substances must be under a registration granted by the Drug Enforcement Administration (DEA) and be made pursuant to the procedures set forth in Section V, herein.
3. Authority to possess or dispense Controlled Substances for research and teaching purposes shall be requested from the U.S. Department of Justice, Drug Enforcement Administration (DEA). Prospective DEA Registration Holders are required to notify the Program Administrator of their intention to obtain a DEA Registration prior to submitting an application to the DEA. Title 21 CFR §1301.13 lists the scope of activities authorized within each category; DEA registration categories, applications for registration, and instructions are available online [here](#).
4. DEA Registration for Controlled Substances listed in Schedules I-V is required for each Authorized University Activity at each geographic location such Authorized University Activity is undertaken. If an operation remote from the UCSB campus requires Controlled Substances, a separate registration is required for each remote Authorized University Activity.
5. Research projects conducted in California requiring the use of Schedule I or Schedule II Controlled Substance as their main study drug must be submitted to the [Research Advisory Panel of California](#) for review and approval prior to start-up if the project falls into one or more of the following categories:
 - i. [Non-Human research](#) of Schedule I Controlled Substance.
 - ii. Academic Human research of Schedule I or Schedule II Controlled Substance.
 - iii. Research for the Treatment of Controlled Substance Addiction or Abuse utilizing any drug, scheduled or not (SAT).
 - iv. Clinical Drug Trial protocols evaluating or comparing any Schedule II Controlled Substances
6. Controlled Substances shall only be used for Authorized University Activities by Authorized Personnel. To become authorized, all individuals must complete a [training module](#) and submit a completed [Personnel Screening Data Sheet](#) to the Program Administrator prior to having access to Controlled Substances. Principal Investigators must submit [this form](#).
7. The UCSB Student Health Pharmacy operates under the supervision of a licensed pharmacist and dispensing Controlled Substances for clinical use shall maintain internal policies and procedures governing procurement, use, storage, dispensing, and disposal of Controlled Substances consistent with licensing requirements and applicable laws and regulations. The UCSB Student Health Pharmacy shall not dispense Controlled Substances for use in research.
8. Violation of UCSB policy or DEA regulations may result in revocation of an individual's or department's privilege to obtain and use Controlled Substances, rescission of campus registrations, and imposition of fines and/or imprisonment of individual's responsible for the violations.

IV. AUTHORITIES AND RESPONSIBILITIES

1. Chancellor - Responsible for providing resources to effectively administer a Controlled Substances program and for designating, in writing, a Responsible Official who is ultimately responsible for the program.
2. Responsible Official - As designated by the Chancellor, the Responsible Official shall:
 - i. Establish and oversee UCSB's Controlled Substances Program in accordance with DEA regulations and best practices; and
 - ii. As appropriate, grant a Power of Attorney to managers to enable them to obtain and execute order forms for Controlled Substances.
3. Program Administrator - Authorizes the use of Controlled Substances for research on campus, reviews handling procedures, authorizes storage facilities, conducts regular site inspections, provides training on UCSB's Controlled Substance Program requirements, and requests and reviews the biennial inventories.
4. Department Chair - Responsible for authorizing faculty as Principal Investigators by signing the PI Personnel Screening Form, for authorizing the Principal Investigator to approve a purchase orders for Controlled Substances, and for assuring that the storage, use, inventories, transfers, and disposal of Controlled Substances by Authorized Personnel complies with applicable laws, regulations, and UCSB policy.
5. DEA Registration Holders and Authorized Personnel - Responsible for ensuring compliance with DEA regulations and UCSB guidelines for activities involving Controlled Substances.
6. DEA Registration Holders - Responsible for obtaining and maintaining current DEA Controlled Substance Registrations for the appropriate schedule(s) needed to conduct their research. DEA Registration Holders are also responsible for identifying Authorized Personnel, ensuring they submit a completed Controlled Substance Personnel Screening Form to the Program Administrator prior to being granted access to Controlled Substances, and assuring that no unauthorized individuals have access to Controlled Substances.
7. University Police Department - Investigates all suspected thefts and/or misuse of Controlled Substances.

V. PROCEDURES FOR HANDLING OF CONTROLLED SUBSTANCES

Authorized Personnel with a valid DEA Registration are permitted to procure Controlled Substances, in accordance with this policy and state and federal law, directly from vendors.

Authorized Personnel without a valid DEA Registration must procure Controlled Substances through the Program Administrator.

Procuring Controlled Substances

The DEA Registration Holder for the Authorized University Activity shall determine the need for, and approve, all purchase requisitions (PRs) for Controlled Substances, regardless of dollar value.

1. PRs shall be submitted through the campus purchasing department regardless of whether the Controlled Substance is purchased or obtained free of charge from the vendor.
2. All PRs for Controlled Substance and Listed or Precursor Chemical shall be reviewed and approved by the Program Administrator. Only approved PRs will be submitted to vendors by the campus Purchasing Department.
3. No orders for Controlled Substances may be placed directly with vendors by Authorized Personnel unless the Authorized Personnel holds a valid DEA Registration.

4. All orders for Controlled Substances shall be procured according to the following:
 - i. Principal Investigator/DEA Registration Holder determines if a drug/chemical is a Controlled Substance through one of the following references:
 - 1) Refer to the [DEA website](#) for a list of Controlled Substances.
 - 2) Use the Physicians' Desk Reference, Red Book, or Veterinary Pharmaceuticals and Biologicals.
 - 3) Contact the Controlled Substances Program Administrator.
 - ii. Principal Investigator/DEA Registration Holder approves PR for Controlled Substances. The Principal Investigator/DEA Registration Holder shall only approve PRs that are submitted in accordance with the following:
 - 1) 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.
 - 2) Controlled Substances from Schedules III, IV and V may be combined on a single PR with no other products. Orders may only be submitted for drug schedules covered by the individual's registration.
 - 3) DEA Registration Holders must keep the DEA Form 222 on file for all orders of Schedules I and II Controlled Substances.
 - 4) The following information must be included on the Purchase Requisition:
 - A full description of the item requested, including quantity, size of package, name of drug, vendor, catalog number, and the number of the Federal Schedule of Controlled Substances to which it is assigned.
 - DEA Registration Holder information.
 - iii. For Authorized Personnel without a valid DEA Registration, the completed PR must be submitted to the Program Administrator for approval in the Gateway system.
 - iv. A completed Purchase Order (PO) will then be submitted to the vendor by the campus Purchasing Department.
 - v. If necessary, a copy of the DEA Registration and/or DEA Form 222 shall be sent to the vendor directly by the DEA Registration Holder under separate cover.
 - vi. All purchasing records must be printed and retained by the DEA Registration Holder along with all other Controlled Substance documentation in accordance with the University of California Records Retention Schedule. All records shall be stored with the controlled substances.
5. The Program Administrator will monitor for inappropriately acquired controlled substances during site visits.

Receipt of Controlled Substances

1. Controlled Substances may only be received at addresses currently registered with the DEA by DEA Registration Holders.
2. Controlled Substances shall be received and signed for by Authorized Personnel whenever possible. For departments with central receiving, package contents must be confirmed by the DEA Registration Holder or Authorized Personnel before accepting delivery.
3. Documentation of chain-of-custody must accompany each receipt of controlled substances. This is accomplished by filling out a [UCSB Controlled Substances Delivery Record](#) for each item received. Campus personnel who receive Controlled Substances shall sign this record and note any discrepancy of package contents. Any discrepancies must be reported to the Program Administrator. The Delivery Record must be kept with the substance's [UCSB Controlled Substance Usage Log](#).

4. Under no circumstances may a Controlled Substance be left unattended unless in a locked, secure storage location approved by the DEA.

Transfer of Controlled Substances

1. Departments and Authorized Custodians may transfer a Controlled Substance to another UCSB Authorized Custodian by following the conditions and procedures below for each Controlled Substance transfer.
 - i. The transferor must ensure that the recipient of the Controlled Substance is a UCSB Authorized Custodian for that schedule and has an approved storage location. Contact the Controlled Substance Program Administrator to verify that the recipient is approved. Inter-registration transfers must be authorized by the Program Administrator.
 - ii. Each Authorized Custodian (transferor and recipient) must document the transfer in his or her [Controlled Substance Usage Log](#).
 - iii. Records for each transfer must be maintained in accordance with the University of California Records Retention Schedule.
 - iv. Drugs must be used only for the same purposes for which they were acquired (i.e., teaching, research or veterinary use).
2. Transfers of Controlled Substances that do not comply with the above procedure may result in revocation of Authorized Personnel or a department's privilege to obtain and use Controlled Substances, rescission of campus registrations, and imposition of fines and/or imprisonment of individuals responsible for the violations.

Import, Export and Interstate/Intrastate Use of Controlled Substances

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 Precursor 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.

Storage of Controlled Substances

1. Controlled Substances may be stored only in locations approved by the DEA. Minimum requirements for storage facilities include the following:
 - i. An acceptable storage cabinet must have inaccessible hinges when the door is closed and a locking device that allows no access to the mounting hardware when the door is closed and locked.
 - ii. The cabinet must have either a built-in tumbler-type lock or a padlock.
 - iii. If a keyed lock is used, the number of keys must be kept to an absolute minimum and each key must be kept in the physical custody of a person assigned responsibility for storage of Controlled Substances at all times.
 - iv. There cannot be any sign or other indication that the cabinet is used for storage of Controlled Substances.

- v. The storage container must be of the appropriate type for the schedule of the controlled substance to be stored.

Use and Inventory of Controlled Substances

Authorized Custodians must maintain a current inventory and usage log for all Controlled Substances. In addition, Authorized Custodians must conduct an inventory of all existing stocks of Controlled Substances in their possession, biennially, to maintain a registration with the DEA. All records must be maintained in accordance with the University of California Records Retention Schedule.

1. **Current Inventory** – A [UCSB Controlled Substance Inventory Form](#) shall be kept to document all Controlled Substance(s) in their lab's possession.
2. **Usage logs** – Authorized custodians must ensure that [UCSB Controlled Substance Usage Logs](#) are properly completed for each container of Controlled Substance.
 - i. Each container of Controlled Substances must have its own individual UCSB Controlled Substance Usage Log.
 - ii. Controlled Substance usage must be tracked on a per dose (use) basis and must be recorded to the nearest metric unit weight or the total number of units finished form during each withdrawal.
 - iii. All records of withdrawals of Controlled Substances from storage must be signed or initialed on the usage log by the person making the withdrawal.
 - iv. The Authorized Custodian must maintain all Controlled Substance usage logs for three years.
3. **Biennial Inventory** – The biennial inventory is a DEA requirement. This process shall be done in coordination with EH&S to ensure that the biennial inventory is done correctly and is accurate. Authorized Custodians are responsible for ensuring the following:
 - i. The biennial inventory must include the following information for each Controlled Substance in finished form:
 - 1) The name of the substance.
 - 2) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form. The number of units of each finished form of a Controlled Substance in a commercial container that has been opened will be determined as follows:
 - For Schedules I and II, an exact count or measure of the contents.
 - For Schedule III, IV, or V, an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact measure of the contents must be made.
 - ii. The Program Administrator will retain a copy of the completed inventory forms for two years. The Authorized Custodian or designee is responsible for retaining copies of both documents in conformance with the applicable record retention schedule.

Disposal of Controlled Substances

Disposal of any Controlled Substance must be done in accordance with DEA policies, procedures and regulations (21 CFR 1307.21). UCSB Animal Resource Center users have the option of on-site destruction as a means to disposal. The [campus veterinarian](#) shall be contacted for detailed information. All other Authorized Personnel shall dispose of Controlled Substances through a reverse distributor, [EXP Pharmaceutical Services Corporation](#). Disposal of controlled substances must be recorded in the usage log. In addition, Authorized Personnel shall retain documentation as to the final disposition of disposed drugs in accordance with the University of California Records Retention

Schedule. The final disposition of Controlled Substances must be documented by receipt of one of the following:

1. Certificate of Destruction or DEA Form 41. A corresponding DEA Form 222 is required for each Schedule I and II Controlled Substance covered by that certificate;
2. A completed copy of the waste manifest from the reverse distributor (users must request this documentation);
3. A certificate of return to manufacturer.

Training

The Program Administrator shall provide training on UCSB's Controlled Substance Program requirements. The online training module [TR36](#) addresses each of these requirements. Training shall be completed before individuals are granted access to or begin working with Controlled Substances. Online training shall also be completed by Authorized Personnel every three years thereafter. The DEA Registration Holder is responsible for providing their Authorized Personnel with lab specific training on procurement, storage, use, transfer and disposal of Controlled Substances.

Loss or Theft of Controlled Substances

Any loss, theft, or disappearance of Controlled Substances must be reported to the DEA, University Police Department, and Program Administrator immediately upon discovery. Upon notification the following actions must take place:

1. The DEA Registration Holder will complete and submit [DEA Form 106](#) to the DEA upon discovery.
2. The University Police will investigate and prepare a police report of the circumstances surrounding the loss or theft and submit to the Provost & Executive Vice Chancellor a separate memorandum explaining the circumstances.

VI. REFERENCES AND RELATED POLICIES

1. Public Law 91-513, Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to as Federal Controlled Substances Act.
2. University of California Business and Finance Bulletin, BUS-50: Controlled Substances Program
3. California Uniform Controlled Substances Act, Division 10 of the California Health and Safety Code.
4. UCSB Policy 1640 Use of Controlled Substances, September 1, 1975