Controlled Substances Used in Research and Teaching

Responsible Executive: Executive Vice Chancellor and Provost
Vice Chancellor-Administration and Finance

Responsible Office: Office of Environment, Health & Safety (EH&S)

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Policy Statement

Everyone who handles controlled substances in the course of research or instruction at the University of California, Berkeley must follow the procedures outlined in this policy to ensure compliance with the terms and conditions of the campus’s institutional Drug Enforcement Administration (DEA) registration. Procedures applying to federal list 1 and 2 chemicals, California precursor chemicals, and dangerous drugs or devices are also covered here.

This policy does not apply to controlled substances used in clinical settings. Please contact University Health Services for guidance in this area.

Who Is Affected by this Policy?

Everyone who handles controlled substances in the course of University research or teaching.

Who Administers this Policy?

Environment, Health & Safety (EH&S) is the principal administrator of this policy, with additional implementation responsibilities assigned to:

- Office of Laboratory Animal Care (OLAC)
- Procurement
- University Campus Police Department (UCPD)
- Criminal Background Check Review Committee
- Principal Investigators (PIs)
- Animal Care and Use Committee, Committee for Protection of Human Subjects, and/or Principal Investigator’s home department, school, or college
Why We Have This Policy

Controlled substances include many narcotics, stimulants, depressants, and hallucinogens. Their distribution and use are highly regulated to ensure they are not appropriated for personal use or otherwise abused. The federal Drug Enforcement Agency (DEA) issues licenses for the acquisition and use of controlled substances in research. To maintain its institutional DEA registration, the University of California, Berkeley must follow DEA regulations that require participating faculty, staff, and students to clearly understand that they must:

- Comply with federal and state laws and regulations and University policy pertaining to the possession and use of controlled substances.
- Maintain strict control over inventory and security of controlled substances.
- Ensure that written records are properly maintained.
- Ensure necessary authorization, including completion of a satisfactory criminal background check for all individuals registered in the Controlled Substances Program.
- Provide training to authorized researchers on laboratory-specific operations involving controlled substances and precursor chemicals.
- Ensure that periodic lab inspections are conducted, minimally on an annual basis.
- Complete a physical inventory biennially as required by regulations and directed by EH&S.
- Ensure application for authorization from the Research Advisory Panel of California (RAPC) if research involves Schedule I controlled substances, human research involving Schedule I or II controlled substances, or drug abuse treatment research.
- Ensure timely reporting of missing controlled substances to EH&S and other appropriate campus and government entities.

Responsibilities

Responsibilities for the campus Controlled Substances Program span several units, as outlined below. Overall program coordination and monitoring is the responsibility of EH&S.

Principal Investigators:

- Obtain approval to use controlled substances in research from their home department or campus oversight committee as appropriate.
- Register their research projects with EH&S prior to ordering controlled substances.
- Ensure that they and their staff and/or students handling controlled substances have passed a background check, successfully completed controlled substances training, and registered with EH&S.
- Ensure proper storage, use, record keeping, and disposal of all controlled substances purchased on their controlled substance project registration.
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- Maintain usage logs and inventory for controlled substances, ensuring that all paperwork is filled out completely and accurately including drug strength and finished form. Usage logs are obtained from the Controlled Substance Receiving Office (OLAC).
- Ensure that controlled substances are kept in a locked area except when being used. Schedule II substances must be kept separate from schedule III, IV, and V substances.
- Ensure that records for Schedule I and II controlled substances are kept separate from records for Schedule III, IV, and V controlled substances.
- Limit access to controlled substances and report changes in who is approved to work with controlled substances to EH&S.
- Report verbally and in writing any theft or loss to EH&S and UCPD immediately upon discovery.
- Contact EH&S for disposal of unwanted or expired controlled substances.
- Facilitate physical biennial inventory as directed by EH&S.
- Apply for and obtain additional state and federal approval prior to initiation of any use of Schedule I or Schedule II (human use only) controlled substances.
- Ensure that drugs and records acquired under other DEA registrations are kept separately from those acquired under the campus registration.
- Keep a copy of each receipt with the laboratory’s Controlled Substances Usage Logbook.

Academic Units or Committees Approving Use of Controlled Substances:

- Maintain a list of Principal Investigators (PIs) participating in the Controlled Substances Program.
- Approve research protocol requiring use of controlled substances.
- Initiate background checks of individuals working with controlled substances (academic units only).
- Notify EH&S to cancel project registration when a PI working with controlled substances terminates employment or ends project participation.
- Assist in the biennial inventory coordinated by EH&S.

EH&S:

- Reviews and records project applications;
- Maintains a database of authorized projects and personnel.
- Coordinates DEA audits.
- Communicates with federal and state agencies on all compliance issues.
- Coordinates periodic compliance monitoring in laboratories working with controlled substances.
- Coordinates drug diversion reports and issues DEA notification within 24 hours.
- Maintains files of project authorizations, employee background check verifications, trainings, inspections, and disposal records.
- Verifies facility closures, including document custody, after a principal investigator (PI) informs EH&S of the intent to close the research project.
- Maintains campus Controlled Substances Program web page and provides training on proper security and recordkeeping procedures.
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- Reviews and monitors security controls established in each laboratory.
- Promotes recognition of controlled substance hazards and develops effective and safe procedures through training and communication with PIs and laboratory contacts.
- Coordinates removal and disposal of controlled substances.
- Identifies, evaluates, and approves controlled substance disposal site(s) and vendors.Reviews permits, licenses, and other relevant records to ensure the disposal sites and vendors meet regulatory requirements.
- Receives radioactive controlled substances.
- Coordinates biennial inventory and collates data to determine the total amount of controlled substances on hand. This inventory must be conducted on a single day for all researchers covered under a blanket registration. Maintains a copy of biennial inventories for DEA inspection.

Office of Laboratory Animal Care (OLAC):

- Serves as controlled substances receiving office.
- Receives and maintains copies of all DEA 222 forms, purchase orders, and receipt records of ordered controlled substances.
- Securely stores controlled substance orders delivered by an outside vendor in a cabinet or safe until the orders are picked up by authorized user(s).
- Notifies individuals when orders are ready.
- Ensures that individuals picking up orders are authorized to receive the controlled substances by checking the employee ID card and database.
- Maintains records containing the following information for controlled substances received: PI name, controlled substance, strength, form, controlled substance authorization number, signature and date for receiving substance from vendor, signature and date for distributing substance to PI or OLAC pharmacy technician. At the time of pick up, the PI or the PI’s representative verifies the accuracy of the amount received by signing the appropriate paperwork which is kept in the logbook.
- Distributes new controlled substances usage logs.
- Provides copy of receipt to receiver of controlled substances.

Procurement:

- Applies for, maintains, and renews the campus DEA registration. Procurement is the liaison with DEA on registration issues only.
- Using the EH&S database, verifies that PIs who submit purchase requisitions are authorized to order controlled substances.
- Issues purchase orders for acquisition of controlled substances (Schedules II through V).
- Completes DEA 222 forms for purchase of Schedule II drugs. Maintains original..
- Maintains copies of all records, e.g., purchase requisition, purchase order, and DEA 222 forms.
- Communicates with OLAC and department purchasing contacts on issues of acquisition, substance back orders, and other supply concerns.
Campus Police (UCPD):

- Investigates reports of theft, loss, or diversion of controlled substances. Findings from said investigations are reported to the department head, EH&S, Procurement, OLAC, and ACUC.
- Performs background checks on all employees working with controlled substances.
- Conveys criminal background check clearances to EH&S.
- Once the initial background check is completed, monitors for criminal convictions involving controlled substances on an on-going basis.

Criminal Background Check Review Committee:

- Reviews criminal background checks that reveal convictions and determine whether such convictions disqualify individuals from working with controlled substances.

Procedures

(Note: an overview of this process may be found in graphic form at http://www.ehs.berkeley.edu/healthsafety/csflwcht.pdf.)

A. Eligibility to Obtain Controlled Substances

Only the following members of the campus community are eligible to obtain controlled substances:

- Voting members of the Academic Senate conducting research that requires use of controlled substances.
- Veterinarians in OLAC.
- Other affiliates in the campus community granted a special exception to use controlled substances in their research by the Vice Chancellor-Research.

B. Obtaining Authorization to Work with Controlled Substances

A flowchart showing the controlled substance registration process may be found at http://www.ehs.berkeley.edu/healthsafety/csregstrprocess.pdf.

Authorization to work with Schedule I controlled substances requires the Principal Investigator (PI) to obtain a separate DEA registration and apply for authorization from the Research Advisory Panel of California (RAPC). The procedures that follow are designed for Schedules 2 through 5 substances. PIs planning to work with Schedule I substances must inform EH&S.

In accordance with federal and state DEA regulations, PIs and all researchers requesting approval to work with controlled substances are subject to a criminal background check to determine whether any convictions disqualify them from working with controlled substances.
Background checks are conducted by the UCPD. The Criminal Background Check Review Committee reviews only those background checks that reveal convictions, and determines within seven calendar days whether such convictions disqualify individuals from working with controlled substances.

Detailed instructions on background checks may be found at http://www.ehs.berkeley.edu/healthsafety/csbkgrdckinst.pdf.

All PIs requesting approval to conduct research using controlled substances are required to complete the Controlled Substances Project Registration Form (http://www.ehs.berkeley.edu/healthsafety/csbkgrdckinst.pdf). EH&S maintains a controlled substances database containing information on all approved projects, the names of the approved controlled substances, where the controlled substances are located, and who is approved to work with the controlled substances. The DEA has access to this information.

PIs and others eligible to obtain controlled substances may delegate authority to work with controlled substances to individuals under their supervision (“authorized individuals”). All authorized individuals must pass a criminal background check before they are allowed to work with controlled substances.

In the course of conducting University business, staff in Procurement, EH&S, and OLAC may need to work with controlled substances. If they have not already passed a criminal background check, these staff members must pass one before they are allowed to work with controlled substances.

The PI, authorized individuals, and anyone else working with controlled substances must complete controlled substances training offered by EH&S prior to receipt of controlled substances.

1. Obtaining Authorization to Work with Controlled Substances in Research Using Human Subjects

The campus currently does not engage in research using controlled substances on human subjects. Approval of such research would be obtained from the Committee for the Protection of Human Subjects which would develop approval procedures as needed. Individual PIs must apply for authorization from the Research Advisory Panel of California (RAPC) if their research involves Schedule II controlled substances or drug abuse treatment research.

2. Obtaining Authorization to Work with Controlled Substances in Research Using Animal Subjects

The Animal Care and Use Committee (ACUC) must verify that the PI is eligible to obtain controlled substances under the provisions of Section A. ACUC verifies that the research project is approved to use controlled substances by signing the Project Registration Form completed by the PI and forwarding the form to EH&S. The PI is responsible for routing the registration form to ACUC for approval. ACUC then routes the form to EH&S.
Changes or modifications to the project protocol require review for conformity with the registration conditions. These changes must be submitted to ACUC prior to implementation.

3. Obtaining Authorization to Work with Controlled Substances for Research Not Involving Human or Animal Subjects

If the request for controlled substances is not related to human or animal research, the chair of the PI’s home department or dean of the PI’s school or college must verify that the PI is eligible to obtain controlled substances under the provisions of Section A above.

The dean or chair must approve the use of specific controlled substances in the specific research project by signing the Project Registration Form completed by the PI and forwarding the form to EH&S. The dean or chair may convene a review panel for this review process.

Changes or modifications to the project require review for conformity with registration conditions. These changes must be submitted to the PI’s dean or chair prior to implementation. Changes in personnel or laboratory storage location only require PI signature. For all changes, use the EH&S Controlled Substance Project Registration Update Form.

C. Ordering Controlled Substances

All orders for acquisition of controlled substances are made by the Procurement Office. Only the Director of Procurement has delegated authority to sign all forms and documents required by federal and state controlled substance acts.

The Director of Procurement may authorize one or more individuals within the Procurement Office to order controlled substances on his or her behalf by executing a power of attorney for each such individual. The power of attorney specifies the scope, effective date, and end date of the power of attorney appointment, and includes the text of pertinent federal and state regulations regarding DEA 222 forms, which can be ordered at https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp. Power of attorney may be revoked at the Director of Procurement’s discretion, or when the attorney-in-fact changes duties or leaves campus employment. Power of attorney documentation must be available for inspection by the DEA along with other records concerning the procurement of controlled substances.

Controlled substances must be requested on a separate requisition. The requisition is required even when the controlled substances are obtained at no charge. The Director of Procurement or designee must verify the following information from the PI prior to ordering the controlled substances:

- The PI’s campus address and phone number.
- The status of the project registration with EH&S.
- The chart string to be billed, if there is a charge for the controlled substances.
- Confirmation of the name, strength or concentration, dosage, schedule, quantity, and package or unit size of the controlled substances to be ordered.
The requisition for controlled substances must be in writing and must be signed by the PI. The Director of Procurement, or designate, must make sure the signature matches the one on the Controlled Substance Signature Card before filling the order.

Controlled substances listed under Schedule II must be ordered on DEA Form 222. Only the Director of Procurement or an attorney-in-fact may sign the form. The order form must not be used for substances other than controlled substances on Schedule II. This form is in triplicate. The brown copy is kept by the supplier. The green copy is forwarded by the supplier to the DEA. A copy of the original is forwarded to OLAC for its records.

Controlled substances listed under Schedules III, IV, and V may be secured by issuance of a separate purchase order. Only the Director of Procurement or an attorney-in-fact may sign the purchase order.

The Director of Procurement or the attorney-in-fact must keep all records required by federal, state, and University regulations concerning the ordering of controlled substances.

Orders must instruct the vendor to send the controlled substances to the Controlled Substances Receiving Office (OLAC).

D. Receiving Controlled Substances

All controlled substances are delivered to the Controlled Substances Receiving Office (OLAC).

Upon issuance of a DEA Form 222 or purchase order requesting the delivery of controlled substances, the Director of Procurement or designee sends a copy to the Controlled Substances Receiving Office so the appropriate OLAC officials know a shipment is coming.

The Director of OLAC maintains a file of OLAC employees authorized to receive controlled substances. Only those employees may receive deliveries of controlled substances. The file includes the date each employee was authorized to receive controlled substances. The employee must be given written notification of his or her authorization to receive controlled substances. Copies of the notification are retained by the Director of OLAC and the employee’s supervisor. A copy of the notification is placed in the employee’s personnel file.

The Controlled Substances Receiving Office maintains a log of receipts of Schedule II controlled substances and executes the blue (receiver) copy of DEA Form 222 indicating the amount and date received. The log includes the name and signature of the employee receiving the controlled substance.

The Controlled Substances Receiving Office maintains a separate log of receipts of Schedule III, IV, and V controlled substances. This log also indicates amount and date received and includes the name and signature of the employee receiving the controlled substance.

The Controlled Substances Receiving Office employee receiving controlled substances adds the controlled substances to an inventory maintained by the Controlled Substances Receiving Office. The inventory must be secure, with strictly controlled access. If the controlled substances go
through a chain of employees before being stored, the log must include the names of all employees in possession of the controlled substances and the time those employees had the controlled substances in their possession.

The Controlled Substances Receiving Office employee receiving a controlled substance order stamps “received”, the date, and his or her initials on the DEA Form 222 or purchase order requesting the controlled substances. The Controlled Substances Receiving Office employee then sends a copy of the form to Procurement so Procurement knows the shipment has arrived.

The Controlled Substances Receiving Office retains controlled substance receipt records until the controlled substances’ registrations have expired or otherwise closed.

E. Distributing Controlled Substances

All controlled substances are distributed by the Controlled Substances Receiving Office (OLAC).

Once an order is received, the Controlled Substances Receiving Office notifies the PI. Either the PI or an authorized individual must pick up the order. Controlled Substances Receiving Office employees authorized to transfer controlled substances must require the PI or authorized individual receiving the controlled substances to sign a log. Before releasing the controlled substance, the Controlled Substances Receiving Office employee must verify the identity of the person via photo ID or other means and check for proper authorization in the database. The Controlled Substances Receiving Office retains records indicating the date and time the controlled substances were transferred until registration of the controlled substances has expired or otherwise closed.

F. Record Keeping and Security

It is the PI’s responsibility to keep a perpetual inventory of controlled substance use and storage for each project. The inventory shall at minimum include:

- Substance name.
- The finished form (e.g., “10mg. per fluid ounce”) for each substance and the number of units or volume of finished form in each commercial container.
- The number of commercial containers of such finished form received from other persons and OLAC, including the date of and number of containers in each receipt.
- The amount of each unit or volume or portion thereof of finished form dispensed or used, the date of dispensing, and the signature of the individual who dispensed or administered the substance and the reason it was dispensed or used.
- The number of units or volume of the finished forms and/or commercial containers disposed of in any other manner, including the date and manner of disposal.
- For Schedule II items, the inventory records must be maintained separately from Schedule III through V items.
- Disposal must be recorded in the log book.
Records must be retained and made available to the DEA upon request for at least three years from the date of the record.

The PI must institute effective safeguards against theft or diversion, including the following:

- Keep records that include the signature of each individual through whose hands a controlled substance passed, up to and including the ultimate user.
- Keep controlled substances in a secure area with access limited to the absolute minimum number of individuals needed and authorized to handle daily transactions of such items.
- If transporting the controlled substances, move them in a manner that minimizes any chance of theft or diversion.
- Deny access to controlled substances to any individual who has had a personal application for registration with DEA denied or revoked, or who has not passed a criminal background check.

G. Compliance Monitoring

The Animal Care and Use Committee (ACUC) monitors controlled substance usage and records related to animal research. EH&S monitors controlled substance usage and records related to teaching and research not involving animals. EH&S periodically monitors employees working on individual projects for PI approval and completed background checks. The entire Controlled Substances Program may be reviewed and audited at any time by Audit and Advisory Services.

EH&S coordinates a campuswide inventory of controlled substances at least once every two years, and also checks individual workplaces with controlled substances at least annually. EH&S also checks its inventory results against the records of OLAC, Procurement, and the PI to make sure there are no inconsistencies.

If ACUC or EH&S detect an inconsistency in controlled substance inventory or records, or if OLAC detects an inconsistency in receiving, they immediately notify the department chair, UCPD, and the Director of Procurement. EH&S notifies the DEA if appropriate. The UCPD immediately conducts an investigation and reports its findings to the department chair and EH&S. If improper activity is uncovered, no new orders will be permitted for the PI until appropriate corrective actions are complete.

H. Disposal of Controlled Substances

Disposal of unwanted controlled substances is handled by EH&S. PIs must inform EH&S in writing that they wish to dispose of controlled substances. The request must include:

- Unwanted Controlled Substances Client Information form providing:
  - PI/authorized person (full name)
  - Location of the unwanted controlled substances
  - Contact information

- Schedule II or Schedule III–V Return Request form providing:
  - Name of the controlled substance, form, and strength
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- Amount or volume of the substance
- Name of authorized registrant

Completed forms must be delivered to EH&S. Upon receipt of the documents, EH&S schedules an appointment for the pick up of the controlled substance. The unwanted controlled substances are turned over to EH&S and chain of custody is documented by completing and signing the Return Request Form. Disposal of the material must be recorded in the logbook.

The controlled substances to be disposed of shall be classified by the authorized user as either “wasted drugs” or “expired drugs”.

- Wasted drugs include items such as unused tablets, injections, oral liquid, or preparations compounded in error which contain controlled substances.
- Expired drugs include controlled substances that have exceeded the expiration date, are classified as non-formulary, or have fallen into disuse.

EH&S arranges for disposal of controlled substances with an appropriate reverse distributor. Controlled substances must not be disposed of by disintegrating, crushing, or dissolving them in water.

EH&S retains a copy of the disposal form for three years.

I. Import, Export, Interstate and Intrastate Use Requirements

The import or export of dangerous drugs including controlled substances is not permitted without permission from the DEA Office of Diversion Control Import/Export Unit and the University of California, Berkeley’s Responsible Official. A DEA registration may be needed 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 and the DEA.

J. Dangerous Drugs and Devices (Material requiring a Prescription)

PIs engaged in authorized University Activities are permitted to purchase and use dangerous drugs and devices without a prescription as exempted by the California Business and Professions Code §§4059 and 4059.5. Purchase records must be kept readily available. A dangerous drug that is not a controlled substance may also be subject to FDA regulation and may require an Investigational New Drug permit issued by the FDA.

L. Purchasing List 1, II and Precursor Chemicals

Purchasing Listed and Precursor chemicals, from in-state vendors may be done by departments and/or Procurement. Whenever an out-of-state vendor is required, Procurement will place the order using the campus DEA registration number. These chemicals may not be exported.
End use storage for listed and precursor chemicals must follow campus chemical storage requirements for the hazard class of the chemical (e.g., flammable, toxic) and be recorded in the campus chemical inventory system.

**Web Site Address for This Policy**

http://campuspol.chance.berkeley.edu/policies/controlledsubstances.pdf

**Glossary**

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

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

*Dangerous Drug of Device* – The terms “Dangerous Drug” and “Dangerous Device” are defined in California Business and Professions Code §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 §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 §§4059 and 4059.5.

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

*Environment, Health and Safety (EH&S) Department* – The administrative unit that manages the location’s Environment, Health and Safety programs.
Listed Chemical- List I and II chemicals are specifically designated by the DEA Administrator in 21 CFR §1310.02(a) and (b). They have legitimate uses yet can be used in manufacturing a controlled substance in violation of the Federal Controlled Substances Act.

Locked Area – Most Schedule II substances and Schedule III through V substances must be stored in a substantially-constructed permanently-affixed locked cabinet or drawer. A lockbox or toolbox that can be easily carried out of the room is not adequate storage. Also, when using drawers, the locked drawer must not be accessible by opening or removing the drawer above it. Users will be advised of schedule II substances that require additional security. EH&S will inspect the laboratory for proper security before Procurement will place the first order for authorized controlled substances.

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).

Principal Investigator – The head of a research project is called a Principal Investigator. Academic appointees in the following title groups are eligible to submit proposals for research or training contracts or grants: Members of the Academic Senate, including emeriti; Appointees in the Agronomist series, including emeriti; Appointees at 50 percent or more of full time in the Adjunct Professor series; Appointees at 50 percent or more of full time in the Health Sciences Clinical Professor series; Appointees at 50 percent or more of full time in the Professional Research series; Appointees at 50 percent or more of full time in the Specialists in cooperative Extension series.

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

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

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

Related Documents