

Quick Guide to the Controlled Substances Program at UC Berkeley

The University of California Berkeley (UCBerkeley) Controlled Substances Program has been designed to comply with federal law and Drug Enforcement Administration (DEA) regulations governing the possession and use of controlled substances in research. This Guide summarizes the Program. Additional questions should be directed to the Office of Environment, Health and Safety (EH&S) at 642-3073.

Principal Investigator Responsibilities

To comply with federal law, principal investigators (PIs) with projects involving the use of controlled substances are responsible for:

- Obtaining authorization to utilize controlled substances in research from their department and any applicable campus oversight committees, e.g. Animal Care and Use Committee (ACUC).
- Registering research projects and the individuals who will have access to controlled substances with EH&S prior to ordering controlled substances.
- Ensuring that everyone who will have access to controlled substances successfully passes a background check through the UC Police Department (UCPD).
- Keeping accurate inventory and usage records for all controlled substances related to research projects.
- Ensuring that all controlled substances are kept in a properly secured location.
- Reporting immediately any changes in personnel approved to work with controlled substances to EH&S.
- Reporting verbally and in writing any theft or loss to EH&S immediately upon discovery (EH&S must notify DEA within 24 hours.)
- Contacting EH&S for disposal of unwanted or expired controlled substances.
- Facilitating a biennial physical inventory of all controlled substances related to research projects as directed by EH&S.
- Notifying EH&S prior to moving laboratories or storage locations on campus or shutting down a laboratory. (Please note: controlled substances may not be transported to other campuses or research facilities.)

Authorization to Use Controlled Substances

Because UC Berkeley must ensure that DEA regulations regarding controlled substances are followed, projects must receive authorization from a review panel knowledgeable enough about the research to understand why the research requires a controlled substance. If the research involves using animal subjects, that review panel will be ACUC. If the research does not involve animals, department chairs will need to convene a panel and authorize use by signing the Project Registration Form.

As part of the initial implementation of the new campus procedures, all PIs must complete the UC Berkeley Controlled Substances Program Project Registration Form, available from the

EH&S web site (www.ehs.berkeley.edu/healthsafety/controlsubs.html). It must be submitted to EH&S with approval signatures before a project will receive its Controlled Substances Use Authorization Number (CSUA #). Any orders for controlled substances must be processed through central Procurement, or if for animal use, through the Office of Laboratory Animal Care (OLAC). These departments will verify authorization prior to placing an order with a vendor.

Background Check Requirement

To comply with DEA regulations, everyone who needs to work with controlled substances, including the PI, is required to pass a criminal background check. This check does not need to be repeated for subsequent work with controlled substances. As part of the initial implementation of the new campus procedures, all individuals listed on the Project Registration Form will need to make an appointment with the UCPD to be fingerprinted. Instructions on how to obtain a background check can be found on EH&S's web site (www.ehs.berkeley.edu/healthsafety/controlsubs.html). Please coordinate the paperwork required to be fingerprinted with your department's human resources or personnel office.

On an ongoing basis, individuals who have not already gone through a criminal background check will need to do so at the time the PI wishes to authorize them to work with controlled substances.

A Background Check Q&A is available from EH&S's web site (www.ehs.berkeley.edu/healthsafety/controlsubs.html).

Security in the Laboratory

All controlled substances must be securely locked when not in use. Some Schedule II substances, such as carfentanyl, etorphine hydrochloride, and diprenorphine, require a safe. Other Schedule II substances and Schedule III through V substances must be stored in a substantially-constructed permanently-affixed locked cabinet or drawer, e.g. 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. EH&S will provide initial training and inspect the laboratory for proper security before Procurement will place the first order for authorized controlled substances.

How to Keep Records in Compliance with DEA Requirements

DEA regulations require that there is a chain of custody starting from the time the controlled substances are received to when they are either used or disposed. In addition, inventory and usage records must be kept and verified periodically. EH&S will provide laboratories with an initial inventory log book and train principal investigators and other researchers using controlled substances on how to use and store the log book properly. Additional inventory log books are available upon request from EH&S.

Monitoring by EH&S

Controlled substances will be purchased using the campus DEA registration number. To ensure that the DEA's regulations are being followed, EH&S will periodically monitor compliance with the UC Berkeley Controlled Substance Program. Principal Investigators are responsible for ensuring that controlled substances are maintained and used appropriately to prevent illegal diversion. If a research group is not adhering to the required procedures, it may lose authorization to order and work with controlled substances. EH&S procedures for out of compliance conditions will be to initially notify the PI. If resolution does not occur, the escalation process will be to notify the Department Chair, with a copy to ACUC if the research involves animals. Further escalation, if needed, will include notification of the Dean and the Vice Chancellor of Research Office.

Special Research Situations

Researchers with joint appointments, e.g LBNL or UCSF

Researchers with joint appointments must comply with and order controlled substances through UC Berkeley's controlled substance program for research conducted in UC Berkeley facilities, i.e. transfer of materials from LBNL, UCSF, or other organizations to UC Berkeley laboratories is not allowed.

Field Researchers

Field researchers must indicate on their Project Registration Form if controlled substances will be used in off-campus locations, e.g. during field trapping. At all times, a logbook must be kept in the researcher's on-campus approved storage location, indicating any withdrawals for field use. Additionally, a field logbook should be maintained indicating actual usage in the field. Upon return to campus, the inventory remaining and the logbook records should be synchronized.

Please note: Approval to take controlled substances out of the USA to conduct field work requires special authorization from the DEA. Notify EH&S and the Export Control Office in the Vice Chancellor of Research Office **at least 3 months** prior to your travel date to coordinate the appropriate DEA declaration forms.

Resources

Questions regarding the UC Berkeley Controlled Substances Program may be directed to Krystyna Kozakiewicz in EH&S at 643-1397 or krystyna.kozakiewicz@berkeley.edu.

Office of Environment, Health and Safety (EH&S):
www.ehs.berkeley.edu/healthsafety/controlsubs.html or 642-3073.

Drug Enforcement Administration (DEA) List of Scheduled Drugs:
<http://www.dea.gov/pubs/scheduling.html>