



Environmental Health & Safety

Controlled Substances Program

I. Policy

It is the policy of California State University, Fullerton to maintain, insofar as is reasonably possible, an environment that will not adversely affect the health, safety and well-being of students, employees, visitors and the surrounding community.

The purpose of the Controlled Substances Program is to provide researchers with information needed regarding the proper and safe use of controlled substances and precursor chemicals in their research. It will provide information on acquisition, storage, approved use, recordkeeping, and disposal.

II. Authority

The Drug Enforcement Administration (DEA) is the agency mandated to regulate the lawful use of controlled substances and List I chemicals under federal law Title 21 Chapter 13 Code of Federal Regulations (CFR) Part 1300 to end. The California Bureau of Narcotic Enforcement and the California State Board of Pharmacy are authorized to ensure compliance with California laws regulating controlled substances and prescription drugs, respectively.

III. Scope

The Controlled Substances program applies to all Cal State Fullerton faculty, staff, students, contract employees and other personnel working at the main campus and satellite locations where CSUF has management control of controlled substances.

IV. Definitions

Authorized User

Principle Investigators and staff authorized to use and/or pick up controlled substances including precursor chemicals for research. PIs must comply with all laws, regulations, and university policies and procedures regarding controlled substance use in research as described in this manual.

Controlled Substance

A controlled substance (CS) is a substance that has a stimulant, depressant, or hallucinogenic effect on the nervous system. Controlled substances are prescription drugs that are further classified as Schedule I-V and can only be obtained by registrants with the DEA (See 3b). The Controlled Substances Act (1970) listed substances that were controlled when the law was enacted. Since then, approximately 160 substances have been added, removed, or transferred from one schedule to another. A general reference list of controlled substances in alphabetical order can be found at: the [List of Controlled Substances](#). Federal regulations regarding schedules can be found in [Section 1308 of CFR Title 21 \(21 CFR §1308\)](#).

Drug Enforcement Agency Registration

The DEA registration number identifies and validates individuals and institutions that have been authorized by the DEA to purchase, possess, distribute or prescribe controlled substances. Controlled substances intended for research purposes acquired through drug companies or any other outside institutions must be obtained under the University's registration. An individual researcher

may not apply for an individual DEA registration at California State University Fullerton to acquire controlled substances intended for research, instruction, and chemical analysis purposes at CSUF. The CSUF Student Health and Counseling Center possesses a separate DEA registration number for distribution of controlled substances for medicinal purposes and has established their own policies and procedures.

Precursor Chemicals

DEA's strategy in curtailing illicit drug manufacturing is to control raw chemicals necessary to produce legal and illegal drugs called 'precursor chemicals' listed in CFR 21 §1310.02(a) [List I] and §1310.02(b) [List II]. These chemicals have the potential to be used in the manufacture of controlled substances. State and federal laws require that campus vendors follow stringent regulations regarding distribution of these chemicals. Agencies require purchasers of precursor chemicals to provide their DEA license registration and a brief description of the use/research involving the chemical.

DEA List I & List II Chemicals: http://www.deadiversion.usdoj.gov/chem_prog/34chems.htm.
The state of California maintains a list of [precursor chemicals](#).

Schedules of Controlled Substances

Schedule I

No currently accepted medical use. Has the highest potential for abuse. (e.g., GHB, heroin, marijuana).

Schedule II

Currently accepted medical use with restrictions. High potential for abuse with severe psychological or physical dependence. (e.g., amphetamine, methamphetamine, cocaine, codeine, morphine, meperidine, methylphenidate, pentobarbital (Nembutal)).

Schedule III

Currently accepted medical use. Abuse of drug may lead to moderate to low physical dependence or high psychological dependence. (e.g., Ketamine, Telazol, testosterone, pentothal. Euthasol is a Schedule III due to pentobarbital/phenytoin mix).

Schedule IV

Currently accepted medical use. Low potential for abuse relative to Schedule III. (e.g., barbital, butorphanol, chloral hydrate, diazepam).

Schedule V

Currently accepted medical use. Low potential for abuse relative to Schedule IV (e.g., buprenorphine and Zolpidem).

V. Accountability

A. Environmental Health and Safety

1. Oversee and maintain the Controlled Substance Program
2. Maintain DEA Campus registration. The Student Health Center maintains the Registration for prescription drugs.
3. Authorize and maintain list of Authorized Users
4. Provide consultation and approve purchases and transfers of controlled substances and List I chemicals
5. Conduct biennial inventory of controlled substances in research
6. Conduct random inspections of storage and recordkeeping
7. Dispose of expired controlled substances

B. Procurement/Ordering Departments

1. Obtain approval from EHS prior to processing orders
2. Process orders with vendors
3. Refer all calls for the DEA number to EHS

C. Principal Investigator (PI)

1. Obtain "Authorized User" status including all staff and students with access to controlled substances
2. Comply with all procedures to acquire and use controlled substances or List I Chemicals
3. Complete Application for Controlled Substance Use
4. Provide appropriate secured storage of drugs
5. Maintain Controlled Substance Usage Logs with purchase order invoice for 3 years
6. Submit inventory to EHS every 2 years as requested
7. Request disposal of any expired or no longer needed controlled substances
8. Notify EHS of suspected missing drugs. Comply with investigation by EHS, University Police, and the DEA

D. Research/Lab Personnel

1. Obtain "Authorized User" status
2. Maintain usage log according to proper procedures
3. Maintain security of drugs at all times

VI. Program

A. Obtaining a Use Authorization for Controlled Substances

Researchers must obtain authorization prior to the use, purchase, or transport of controlled substances. To become an Authorized User:

1. The Principal Investigator must complete an application: **Controlled Substances Use Authorization Form for Animals, Human Subject, and In-vitro and Screening Data Sheet for Principal Investigator.**
2. Complete **Screening Data Sheet for Authorized Personnel** for all additional personnel working with controlled substances. Ensure all staff and students using the controlled substances are listed
3. If you have questions call EHS at X7233 or email safety@fullerton.edu
4. Submit Use Authorization forms with original signatures to:

*Environmental Health & Safety
Environmental Compliance Manager
T1475*

5. Research involving the use of controlled substances with animals must have an approved IACUC protocol with the substances listed
6. Research involving human subjects and controlled substances must have an approved IRB protocol with the substances listed
7. Researchers may be required to obtain California Attorney General approval depending on the controlled substance used. [California law](#) requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances, to be reviewed and authorized by the Research

Advisory Panel of California in the Attorney General's Office. [*Guidelines are available along with an application form*](#)

B. Acquiring Controlled Substances and Precursor Chemicals

1. Acquisition via Vendors

- a. Campus, Auxiliary Services, Procurement or Academic Departments or the ordering department must submit the purchase requisition for Controlled Substances and precursor chemicals to EHS for approval. Order requisitions must be placed under the name of the approved Authorized User. A non-approved contact person can be listed on the "requested by" line of the requisition.
- b. Environmental Health & Safety will approve the requisition and contact the PI if necessary. EHS will send the requisition back to appropriate Procurement Office or ordering department for processing.

2. Acquisition via Any Other Company or Institution

A controlled substance provided by a private company or another university for research purposes must first go through the procurement process as described above.

3. Precursor Chemical Acquisition

Ordering of California designated precursor chemicals will require the manufacturer of the precursor chemical to send a form requesting the Campus' DEA registration. The Principle Investigator will need to contact CSUF EHS and provide the following:

- a. A description of the research to be performed
 - b. Use of the precursor chemical in the research
- CSUF EHS will fill out the form and contact the chemical manufacturer providing the appropriate DEA registration information to the company. Precursor chemicals may be delivered directly to the Chemical Stock room or to the Principle Investigator's office/laboratory

C. Delivery of Controlled Substances and Precursor Chemicals

1. Controlled Substances must be delivered directly to the address on the holder of the DEA registration (Environmental Health and Safety) unless special arrangements have been made through EHS. Precursor chemicals can go directly to the purchasing department.
2. EHS will accept delivery, verify accuracy, log in the delivery, and notify the vendor of any missing or incorrect orders by the next business day. EHS will notify the Authorized User and arrange for delivery. Orders will be delivered within 24 hours Monday – Friday. Late Friday deliveries will be on the next business day. Orders will be counted and verified by the Authorized User or their designee upon delivery. Authorized Users may designate research staff that has Authorized User status to pick up the order from EHS

D. Transfer of Controlled Substances

As of January 3, 2012, CSUF EHS and CNSM does not allow the transfers of controlled substances between CSUF Authorized Users or other institutions

E. Security of Controlled Substances and Usage Logs

Controlled substances and usage logs must be secured to provide for effective prevention of theft. Code of Federal Regulations 21 requires registrants to store controlled substances in a locked, securely constructed cabinet. Proper security of controlled substances and usage logs is the responsibility of the Authorized User. To prevent theft, controlled substances should never be left unattended, the inventory should be kept at minimum, and access provided to as few researchers as possible

Acceptable storage

1. Safes and steel cabinet cemented or bolted to the floor or wall
2. Locking storage drawers which are inaccessible from the upper or lower drawers in the stack

Unacceptable storage:

1. Portable, locked safety cabinets
2. Corridors

F. Recordkeeping

1. Usage Logs

The Authorized User is required by federal and state law to document the use of controlled substances by logging all details from delivery to disposal. Records must be secured in a locked location and include the order invoice sheet, all Usage Logs, and disposal records. Blank Usage Logs are provided on the EHS website or by calling EHS. **Other formats of the usage logs are not acceptable**

Usage Logs must include:

- Name of the drug
- Strength
- Amount received
- Name of principal investigator
- Date of delivery from EHS

Usage Logs must indicate:

- Amount of each use
- Date of use
- Name & signature of the Authorized User. Initials can be used after the first time a name and signature is entered
- Daily balance

When the Usage Log is completed, you must send a copy to EHS

2. Inventory Log

EH&S conducts an inventory every two years as required by federal law. Researchers will be notified by email two weeks before the completed and signed Inventory Log is due to be returned to EH&S. Researchers who fail to complete and return the Inventory Log by the date requested will have their Authorized User status suspended until submission of the Inventory Log

G. Inspections

EHS will conduct random inspections of research labs that use controlled substances including proper storage and recordkeeping procedures.

The DEA may conduct random audits and inspections of CSUF's Controlled Substance Program.

General laboratory safety inspections are conducted every two years and include security practices pertaining to controlled substances.

The Institutional Animal Care and use Committee (IACUC) conducts biannual inspections of all laboratories approved for animal research. This inspection includes a check of proper storage of controlled substances.

H. Theft

Theft or significant loss of controlled substances or alteration of records indicating drug loss must be immediately reported to EHS and the Authorized User. EHS will contact University Police and the DEA, as necessary.

I. Disposal of Controlled Substances

1. To schedule a pickup of expired controlled substances or precursor chemicals, submit the Request for Disposal found on the EHS web site.
2. EHS will schedule a time to pick-up the drugs from the Authorized User. University Police will witness the pickup and disposal of the material in accordance with DEA specifications.
3. Authorized Users must maintain a copy of the disposal records along with the usage log(s) and order invoice sheet for 3 years after disposal or terminal use.
4. Empty bottles from controlled substances must be triple-rinsed with tap water then disposed of in any appropriate waste container.
5. When an Authorized User leaves the University, all controlled substances must be disposed of in accordance with University policies and procedures. Controlled substances may not be transferred to another User or institution. All records of usage and disposal must be forwarded to Controlled Substance Coordinator in EHS.
5. The Department Chair is responsible if controlled substances are abandoned when an Authorized User leaves the University. Department Chairs must contact the EHS Controlled Substance Coordinator to arrange for the appropriate disposal and notification to the DEA. Failure to comply with the authorization, storage, security, inventory, and recordkeeping process may jeopardize the University's DEA registration and adversely impact other Authorized Users.

J. Prohibited Actions under the Controlled Substance Act

Any Authorized User that violates handling, security, and record-keeping requirements or abandons controlled substances may be subject to the civil penalties outlined in the [United States Code \(USC\): 21 USC Sec. 842](#). Please note that abandoning substances is equivalent to distributing a controlled substance to an unauthorized person. <http://www.dea.gov/diversion/21cfr/21usc/842.htm>

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