



CALIFORNIA STATE UNIVERSITY
FULLERTON

**CALIFORNIA STATE UNIVERSITY
FULLERTON**
Controlled Substances Program Procedure Manual

Environmental Health and Safety
800 N. State College Blvd. T-1475
Fullerton CA, 92831
Telephone: (657) 278-7233
Email: safety@fullerton.edu

Table of Contents

| | |
|---------------------------|---|
| Introduction | 3 |
| Procedures | 4 |
| Purchasing | 5 |
| Receiving..... | 5 |
| Distribution..... | 6 |
| Storage..... | 6 |
| Documentation..... | 6 |
| Security and Control..... | 7 |
| Inventory..... | 7 |
| Disposal | 8 |

| | |
|---------------------------------|------------------------|
| Issue Date: 10/2018 | Revision Date: 10/2018 |
| P.P. Number: CS-1 (Revision #2) | Page 3 of 9 |

Scope The purpose of this document is to establish procedures for the authorization, procurement, receipt, security, storage, control, annual inventory and disposal of Controlled Substances and Listed Chemicals for research and teaching purposes. A controlled substance is a drug or chemical whose manufacture, possession, and use are regulated by the government and require a Drug Enforcement Agency (DEA) registration. The Associate Director, Leonardo Lopez, of Environmental Health & Safety (EH&S) is the program administrator who oversees the day-to-day activities of the Controlled Substances Program.

Definitions **Controlled Substance** – 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. Possession and/or use is regulated under the Federal Controlled Substances Act and the California Uniform Controlled Substances Act.

Listed Chemical – Chemicals that are regulated by federal and/or state law that may be used to manufacture controlled substances and were established by Public Law 103-200, the *Domestic Chemical Diversion Control Act of 1993*.

Principal Investigator – A Principal Investigator (PI) includes Professors, Associate Professors, Assistant Professors, Instructors, and Veterinarians who are assigned space for research or teaching activities. A faculty member without assigned space may be considered a Principal Investigator with approval of their Department Chair.

Authorized Personnel – Authorized personnel are faculty, students, staff, or visiting scholars who have a need to handle or access controlled substances for department-approved projects at CSUF. The number of Authorized Personnel shall be kept at a minimum in order to maintain security. To become an Authorized Personnel, the individual must complete and sign the Personnel Screening Data Sheet, have no prior history with controlled substances abuse or diversion, and obtain signature authorization from the Principal Investigator on the project.

Responsibility The EH&S Controlled Substances Program Administrator (or the administrator’s delegated authority) is responsible for the following processes and procedures as they pertain to management of the CSUF Controlled Substances Program:

- 1) Maintenance of the Controlled Substances Program
- 2) Maintain DEA Campus registration. The Student Health Center maintains the registration for prescription drugs.
- 3) Review and approval of all controlled substances purchase requests
- 4) Annual (and as needed) audits of each PI’s controlled substances inventories (including required documentation) and controlled substances storage locations
- 5) Maintenance of the Controlled Substances Program webpage
- 6) Assist in the initial and annual renewal of Principal Investigator DEA registrations and any associated amendments

7) General administrative program management processes as defined in the manual

EH&S will maintain a controlled substances program file for each Principal Investigator (PI) who has been approved to order and research with controlled substances. Each file will contain the following:

- Controlled Substance Use Authorization (CSUA) for each research project.
- Letterhead addressing detailed usage of a substance
- Personnel Screening Data Sheets for each authorized lab personnel
- Biennial Inventory logs
- Copies of controlled substance use logs
- Copies of purchase requests for all controlled substances
- Delivery and distribution logs for each controlled substance order
- Audit/inspection records or reports from EH&S or the DEA
- Deactivation Form
- Other related correspondence

I. PROCEDURES

A. DEA Registrations

The Controlled Substances Program administrator (or delegated authority) shall assist the Principal Investigator in applying for an initial, renewal, and/or amendment(s) to their DEA registration. If the registration is no longer needed, the PI shall provide in writing to the DEA and the Controlled Substances Program Administrator a request to discontinue use of their registration.

The Principal Investigator must provide EH&S all applicable information that affects their DEA license. This includes, but is not limited to, changes in location, changes in research processes, changes in the type and/or amount of controlled substances and listed chemicals used, and changes in personnel allowed to have access to or use the material.

A copy of the PI's DEA registration shall be kept in EH&S office.

EH&S must provide the DEA all information that can affect the registration requirements once it is received from the registrant. Once the changes are made to the registration, EH&S will provide confirmation to the PI to proceed.

B. Controlled Substances Use Authorization

A Controlled Substance Use Authorization (CSUA) application must be completed for each new research project involving a controlled substance or listed chemical. The CSUA application is available online on the Controlled Substances Program webpage.

This application identifies:

- CSUA number
- Principal Investigator information (name, department, contact information)
- Controlled substance(s) or listed chemical(s) that will be utilized in the research project
- Storage location(s)
- All personnel authorized by the PI to receive controlled substances deliveries on their behalf

- All personnel authorized by the PI to conduct research utilizing the controlled substance

An updated CSUA form must be submitted if any changes occur in controlled substances storage location, research processes, personnel allowed to have access to or use the material, and any changes in the type and/or amount of controlled substances used after the initial CSUA has been submitted and approved by EH&S. If no changes occur, then the Controlled Substances Program administrator will work with the PI to update the CSUA annually. The CSUA will be terminated when the controlled substance is no longer necessary for the initial project for which it was approved.

II. PURCHASING

*** If you are ordering a controlled substance for a new research project, you must submit a new CSUA prior to making your purchase request.*

Steps for Ordering:

1. Prepare a Purchase/Transfer Request (see “Completing a Purchase Request” instructions below).
2. Complete the Controlled Substances Purchase/Transfer Request online form on the Controlled Substances webpage, or by hand.
3. Purchasers must write a letterhead using an official department letter template detailing specific usage of the item and quantity.
4. The Controlled Substances Program administrator will review the purchase request and notify the PI of approval/denial, or request for more information if necessary. EH&S will also send a copy of the approved purchase request to the PI.
5. EH&S shall place the order, and delivery information shall be sent to the Controlled Substance Program administrator and ordering PI.

If transferring from another owner, the new owner must fill out a Personnel Screening Data Sheet, and CSUA before filling out a new Purchase/Transfer Request form. A letterhead is not required if no new purchase is being made.

Completing a Purchase Request:

1. Purchase requests for Schedules I and II must be on a separate purchase request form than Schedules III through V. Controlled substance purchase requests can only include multiple line items if items are either all in Schedules I and II, or all in Schedules III through V.
2. Controlled substances and non-controlled substances shall be ordered separately.
3. All items on one purchase request must be under the same DEA registration.
4. [DEA Form 222](#) needs to be completed for Schedule I and II purchases only.
5. Controlled substances for non-patient purposes cannot be purchased with a medical doctor’s clinical DEA registration.

III. RECEIVING

- A. All shipments of controlled substances shall be delivered to the registered address (predetermined to be Shipping & Receiving) established with the DEA. **A note should be included in the address line to contact EH&S for pick-up from Shipping & Receiving.**

- B. Upon receipt, Shipping & Receiving must immediately contact EH&S for pickup. **Shipping & Receiving is advised to secure the package in their DEA approved locked cage without opening or disturbing the contents.** This process follows a specific Shipping & Receiving administrative procedure that manages the package from this point.
- C. EH&S staff will arrange a pick-up of the package with Shipping & Receiving, as well as a delivery time with the receiving PI (or their authorized delegate). EH&S will open the package to verify accuracy of the package contents with the purchase order. If there is a discrepancy or damage to the package or product contained therein, EH&S will notify the PI (or their authorized delegate), to arrange for order correction or product return.
- D. EH&S staff will sign for release of the package from Shipping & Receiving into the custody of EH&S staff. EH&S staff will receive and log the controlled substance in the Controlled Substances Shipment Logbook.

IV. DISTRIBUTION

- A. After the controlled substance package is received and logged by EH&S, distribution of the controlled substance package will be made to the requesting PI and/or authorized personnel listed on the CSUA.
- B. The PI or the authorized personnel will open the package in the presence of EH&S staff to determine its contents for accuracy, and sign the Controlled Substances Shipment Log acknowledging receipt of the package and its confirmed contents.
- C. The PI or authorized personnel must immediately place the controlled substance in their DEA approved locked cabinet, thus assuming responsibility for storage and use in accordance with applicable regulations.

V. STORAGE

- 1. Each Principal Investigator shall have appropriate locked storage and control measures as required by the DEA and pre-approved by EH&S. The methods for storing controlled substance shall be as follows:
 - A. Storage unit shall be secure enough to show forced entry.
 - B. Storage unit shall be bolted or cemented in place or in excess of 750 pounds.
 - C. Storage unit shall be equipped with a padlock, pin-tumbler, or combination lock.
 - D. If a padlock, pin-tumbler, or combination lock is used, a hasp shall be installed so that there is no access to the mounting screws or bolts when the door is closed and the lock is fastened.
 - E. Corridor storage of controlled substances is prohibited
 - F. Hinges shall be installed so as to prevent access to mounting screws or bolts when the door is closed.
 - G. The combination or key shall at all times remain in the physical custody of the individual(s) listed by the PI on the approved CSUA as "Authorized Personnel".
 - H. Storage unit shall contain only controlled substances and corresponding use logs. No other chemicals or supplies shall be stored in the controlled substances storage area.

VI. DOCUMENTATION

- A. Controlled Substances Use Logs for Schedules I and II must be filed separately than those for Schedules III – V.
- B. The Controlled Substances Use Log form shall be kept in accordance with EH&S standards. Controlled Substances Use Logs must be kept in a secure location either inside the approved controlled substances storage area or in close proximity and its location noted inside the storage area.
- C. All controlled substance dispensations from its original container shall be recorded on the Controlled Substance Usage Log provided by EH&S.
- D. The actual amount of controlled substances remaining in the drawer must equal the documented remaining amount in the logbook at all times.
- E. Any breakage of containers shall be noted on the corresponding Controlled Substance Use Log, initialed by the individual responsible for the breakage, and co-signed by the Principal Investigator. A copy of this Controlled Substance Use Log shall then be forwarded to EH&S for inventory management and review.
- F. Receipts of controlled substances shall be noted on the Controlled Substance Use Log. Purchase order number and supplier name shall be shown.
- G. Departmental copies of Controlled Substance Purchase/Transfer Request forms, Use Logs, and disposal documents shall be maintained by the Principal Investigator in the controlled substance binder and shall be available upon request.
- H. EH&S shall maintain a file of all new controlled substances purchased for each Principal Investigator and incorporate these controlled substances into the next inventory cycle.

VII. SECURITY AND CONTROL

- A. Controlled substances shall not be transferred from the original containers for storage and/or inventory purposes.
- B. Access to controlled substances shall be denied to any individual who has had a personal application for registration with the DEA denied or revoked. The Principal Investigator shall maintain a current list in the laboratory of those individuals handling controlled substances.
- C. It is the responsibility of each Authorized Personnel to notify the Controlled Substances Program Administrator immediately of any theft, loss, or disappearance of controlled substances. The Controlled Substances Program Administrator is responsible for notifying the DEA Regional Office and the California State University Fullerton Police Department.
- D. Department Chairs are responsible for notifying EH&S prior to Principal Investigator arrival on campus with controlled substances. The Controlled Substances Program Administrator shall then contact the DEA to determine the appropriate action. A CSUA application shall be submitted as necessary. Additionally, the Department Chair must notify EH&S when a Principal Investigator authorized to experiment with controlled substances dies or intends to terminate employment. Controlled substances in possession at that time will be returned to EH&S for disposal.
- E. Controlled substances shall not be transferred, shipped, or removed from the registration location except for in cases of disposal, return to supplier, or by prior agreement with the Controlled Substances Program and the DEA.

In the event of a 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 the University Police Department and the DEA as necessary.

VIII. INVENTORY

- A. Upon notification by and with directions from EH&S, it is the responsibility of each Department Chair and Principal Investigator to conduct an inventory of all controlled substances.
- B. Principal Investigators are responsible for conducting a Self-Assessment Audit every quarter.
- C. EH&S shall maintain a file of all new controlled substances purchased for each Principal Investigator and incorporate these controlled substances into the next inventory cycle.

Annual Inventory

The University and the DEA require an inventory be conducted and documented every 2 years. California State University, Fullerton shall conduct an audit and inventory inspection every year. PI's must declare their inventory status even if there is zero controlled substances in stock when biennial inventory is taken.

- a) An inventory inspection shall be conducted utilizing the Annual Inventory form. Once complete, this form shall be submitted to EH&S for review and shall be placed in the PI's file. The PI shall keep the original copy of the form in their controlled substances binder.
- b) Audits will be conducted every year using a Controlled Substances Audit Form. This form shall be submitted to EH&S for review and shall be placed in the PI's file. The PI shall keep the original copy of the form in their controlled substances binder.
- c) **EH&S will notify the PI by email with a specific date and instructions in advance when the annual inventory is due. NOTE: If the annual inventory is not received after 3 attempts, the CSUA will be suspended and any orders for controlled substances will be stopped.**

IX. DISPOSAL

To make arrangements for disposal of controlled substances in any manner other than the dispensation or use for which they were procured, contact EH&S. EH&S will receive the substances for disposal by completing a Chain of Custody Disposal form, indicate on the respective Controlled Substances Use Log that they have been received for disposal, and issue a copy of the Chain of Custody Disposal form to the laboratory as a receipt. EH&S will hold the substances, pending disposal by the DEA or DEA-approved vendor. Once the disposal has been completed, the respective Controlled Substances Use Logs must be retained for a minimum of three (3) years by the PI. Empty vials can be disposed of by Authorized Personnel in the same manner as any other chemical bottle of similar construction. A copy of the corresponding empty vials' Controlled Substances Use Logs shall be sent to the Controlled Substances Program administrator for inventory control.

Disposal must be arranged when:

- 1. A project has been closed or terminated and controlled substances are still in supply.
- 2. A Controlled Substance Use Authorization (CSUA) has expired and a renewal has not been submitted.
- 3. A Principal Investigator determines that the controlled substance is no longer required.

4. A Principal Investigator maintaining controlled substances separates from University employment.
5. A Principal Investigator maintaining controlled substances dies.

In the instances of terminating employment or death of a Principal Investigator, and in addition to the requirement to dispose of any remaining controlled substances, all inventory records, including Use Logs, must be maintained in the department or forwarded to EH&S for record retention and shall be destroyed three (3) years after date of controlled substance disposal.

X. DEACTIVATION

A user must fill out a Deactivation of Controlled Substances Use Authorization (CSUA) Form in the following cases:

- a) A user wishes to cancel authorization of controlled substances at California State University, Fullerton.
- b) A Principal Investigator maintaining controlled substances separates from University employment.
- c) A Principal Investigator maintaining controlled substances dies.

All controlled substances items must be relinquished through disposal prior to deactivation.

Failure to comply with the authorization, storage, security, inventory, and record keeping process may jeopardize the University's DEA registration and adversely impact other Authorized Users.