



**CALIFORNIA STATE UNIVERSITY
FULLERTON**

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

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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 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 or other appropriate administrator.

Authorized Personnel – Authorized personnel are faculty, staff, students, 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) General administrative program management processes as defined in this manual.

Principal Investigators (PIs)

Each principal investigator who is authorized to use controlled substances is responsible to understand and comply with all applicable rules and regulations by the Federal Drug Enforcement Agency (DEA) and California State University, Fullerton's Controlled Substances Program Manual for registration, purchase, use, and proper disposal of controlled substances in their research work. The PI retains all liabilities for loss, theft, or misuse of any controlled substance acquired through their registration.

- 1) Researchers must purchase the controlled substances using Federal DEA registration numbers and DEA/CSUF approved distributors.
- 2) The use of controlled substances is approved for individual researchers and only for the research location(s) described in their CSUA. Therefore, researchers must not distribute, transfer, or share the controlled substances to non-licensed researchers or other PIs. To do otherwise is considered a diversion of controlled substances and is against DEA and CSUF rules and regulations. Each PI who needs to use controlled substances in their research is required to register with CSUF EHS Office for a specific research location.
- 3) Researchers must maintain proper registration and documentation for the control of controlled substances by tracking the purchase, daily use, and disposal by maintaining specific records. (see Appendices A1-A6).
- 4) Authorized laboratory personnel (also known as authorized personnel) must perform research activities under the supervision of the registered PI or their authorized agent. The authorized personnel must complete the daily use forms accurately and return the unused chemicals and partially used vials to the PI or their authorized agent at the end of the day for proper secured storage.
- 5) Used, expired, unwanted, or partially consumed controlled substances container(s) must be disposed of through CSUF EHS Office only.
- 6) Controlled substances waste (used, expired, partially consumed, and generated from synthetic or analytical processes) is regulated by DEA. Researchers must treat the controlled substance waste separately and **must not treat** them as a hazardous waste, biological waste, or regulated medical waste. Researchers must be aware that the disposal of a mixed waste containing controlled substance(s) and other hazardous chemicals will be expensive and will take a longer lead time for DEA approval. The researchers wanting to dispose of controlled substances that are mixed with hazardous chemicals waste must consult with EHS to ensure compliance with RCRA regulations.

Researchers may contact EHS for specific questions related to registration, purchase, storage and security, and disposal.

I. PROCEDURES

A. DEA Registration

The Principal Investigator must provide EH&S all applicable information that affects the 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 DEA registration shall be kept in the 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 (see Appendix A1). The CSUA application is available online on the EH&S 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 (see Appendix A2).
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.

If transferring from another owner, the new owner must fill out a Personnel Screening Data Sheet (see Appendix A3) 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 usage logs. No other chemicals or supplies shall be stored in the controlled substances storage area.

VI. DOCUMENTATION

- A. Controlled Substances Usage Logs for Schedules I and II must be filed separately than those for Schedules III – V.
- B. The Controlled Substances Usage Log form shall be kept in accordance with EH&S standards. Controlled Substances Usage 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 (see Appendix A4).
- 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 Usage Log, initialed by the individual responsible for the breakage, and co-signed by the Principal Investigator. A copy of this Controlled Substance Usage 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 Usage Log. Purchase order number and supplier name shall be shown.
- G. Departmental copies of Controlled Substance Purchase/Transfer Request forms, Usage 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 Administrator 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 EH&S and the Authorized User. EH&S 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 biannually.
- 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 Usage 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 (see Appendix A5). 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 Usage 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 Usage 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 Usage 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 (see Appendix A6).

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

Appendix A2: Controlled Substance Purchase/Transfer Request (Example)

In addition to a Purchase Request, a submission of a *letterhead* stating the usage purpose is required by the manufacturer in order to purchase controlled substances.

**Submit to Controlled Substances Program Administrator at EH&S via email at Llopez@fullerton.edu or in person **

Applicant Information

Name: _____ Title: _____
 Department: _____
 Phone: _____ Email: _____

Controlled Substance Item Request

Please mark one of the following: New Purchase Transfer (from another owner)

Substance <i>If other than USP grade, specify</i>	Schedule (I-V, L1, L2)	Product Information (manufacturer, product #)	Quantity:	
			Unit size	# of units

Usage Purpose

Purpose: Please provide a brief description of exact controlled substance usage.

Certification

Please have approval from the Program Administrator and Department chair before signing.

Based on the nature of the research being conducted by the aforementioned Faculty/Senior Research Staff Member, I certify that his/her requested use of DEA Controlled Substances is necessary for their research efforts at California State University, Fullerton.

 Department Chair Signature Print Name Date

Principal Investigator

I certify that (1) the information provided above is accurate, and will abide by the usage requirements of the California State University, Fullerton Controlled Substances Program, and (2) all uses of these controlled substances will be in accordance with these requirements and in compliance with DEA regulations.

 Principal Investigator Signature Print Name Date

Appendix A3: Authorized Personnel Screening Data Sheet (Example)

Instructions: Use this form to add Authorized Personnel to each Controlled Substance Use Authorization (CSUA). The following is to be filled out by all proposed handlers of controlled substances (21 CFR 1301.90), including Principal Investigators.

****Do NOT print out this form****

Personal information

Name:

Faculty Student Volunteer

Location:

(Building & Room)

Email:

Campus Wide ID:

(Employee ID or Student ID)

Phone:

Principal Investigator:

Evaluation

1. Will you be authorized to sign for receipt of controlled substances? Yes No
2. Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court-martial). Yes* No
* If answer is "Yes" furnish details of the offense, conviction, location, date, and sentence on an additional page. Make sure to write your name and identification number on the top of the page
3. In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? Yes No
4. Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended, or denied? Yes No
5. Controlled Substances Training completion date? Date:

By signing below, I authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions. I understand that any false information, omission of information, or misuse of controlled substances may jeopardize my position with the University. Information included herein will not preclude me from utilizing controlled substances in non-human research at the California State University, Fullerton, but will be considered as part of the overall evaluation of qualifications in the application.

The Drug Enforcement Administration (DEA) requires that an employee who has knowledge of drug diversion from his/her employer by a fellow employee is obligated to report such information to a responsible security official of the employer. All such reports can be made confidentially to the Controlled Substances Program Administrator who will inform the appropriate officials and initiate an investigation on the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries.

Authorized Personnel Signature: _____

Date: _____

Authorization for the person (identified above) to handle controlled substances:

Principal Investigator Signature: _____

Date: _____

Department Chair or Dean Signature: _____

Date: _____

Department Chair or Dean Name (print): _____

Appendix A5: Chain of Custody Disposal Form (Example)

Instructions: Form to be completed by EH&S staff and signed by authorized individuals from the research lab. *Please fill out one disposal form for each container.* If the Principal Investigator leaves the university or chooses to stop using controlled substances, please fill out a Deactivation Form.

Principal Investigator: _____

Dept: _____

Product:	Amount Remaining:	Released to EH&S by (print):	Signature:	Date:
Schedule:	Container ID:	EHS Staff Recipient (print):	Signature:	Date:

Initial Amount: _____

Storage Location (Room No. & Specific Location): _____

- Breakage must be initiated by the individual responsible and co-signed by the PI.
- Report log discrepancies, suspected misuse, or theft to the EH&S Controlled Substance Program Administrator immediately.

**When this item is empty or no longer needed, verify log balance, reconcile inventory and submit a pick-up request.		
<input type="checkbox"/> Option 1: CS item has been used up and needs disposal. A. Request waste pick up at www.ehs.fullerton.edu , by email at safety@fullerton.edu , or by phone at (657)278-7233 (S-A-F-E) B. Disposed by EH&S (name): _____ Date: _____ C. Keep this original log sheet in the logbook	<input type="checkbox"/> Option 2: CS item is partially used or unused, and needs disposal. Request waste pick up at www.ehs.fullerton.edu, by email at safety@fullerton.edu, or by phone at (657)278-7233 (S-A-F-E) <hr/> For EH&S use only: CS transferred to EH&S for disposal. Name: _____ Date: _____ <input type="checkbox"/> Liquid <input type="checkbox"/> Solid Amount received: _____	<input type="checkbox"/> Option 3: CS Waste Request waste pick up at www.ehs.fullerton.edu , by email at safety@fullerton.edu , or by phone at (657)278-7233 (S-A-F-E) <hr/> For EH&S use only: CS transferred to EH&S for disposal. Name: _____ Date: _____ <input type="checkbox"/> Liquid <input type="checkbox"/> Solid Amount received: _____
**Retain log sheet until: _____ Retain for 3 years from the date of transfer to EH&S for disposal or the date of complete use.		

Appendix A6: Deactivation of Controlled Substances Use Authorization (Example)

Use this form to *cancel* an authorized personnel's Controlled Substance Use Authorization (CSUA).

To *dispose* of all remaining controlled substances or empty containers, choose one of three methods to schedule a pickup: Go to www.ehs.fullerton.edu, call (657) 278-7233, or email Safety@fullerton.edu.

The _____ Lab no longer needs authorization to use, purchase, or possess controlled substances for research purposes as of _____ (date).

Controlled substances cannot be transferred to another Principal Investigator without proper correspondence with the Controlled Substances Program Administrator. Under no circumstances can controlled substances be taken to another university due to U.S. DEA licensure requirements. All controlled substances remaining in inventory must be disposed of through Environmental Health & Safety by appointment.

A copy of all Controlled Substances Usage Log Sheets and documentation less than three years old must be retained on site*.

I have relinquished all controlled substances in my possession, and agree to deactivate my Controlled Substance Use Authorization.

Principal Investigator Signature: _____ Date: _____

Principal Investigator Name (print): _____

CSUA #: _____ Department: _____

Lab Room Number(s): _____

****Do NOT print out this form****

*If lab is leaving the University or closing down, these files can be given to EH&S for record retention.