

# Controlled Substances Program



**Environmental Health & Safety**



For Information Call EH&S (831) 459-2553  
[consub@ucsc.edu](mailto:consub@ucsc.edu)

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# UCSC Controlled Substance Program

## I. Introduction and Scope

The University of California, Santa Cruz (UCSC) Controlled Substance Program describes the special requirements and procedures applicable to the procurement, storage, use, transfer, disposal, and inspection of Federal Drug Enforcement Agency (DEA) Controlled Substances used for research and teaching activities at all UCSC locations.

Federal and state law regulates the manufacture, distribution, use, storage and disposition of controlled substances. Controlled substances generally include narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals (precursors) used in the illicit production of controlled substances. The Federal [Drug Enforcement Administration](#) (DEA) regulates the lawful use of controlled substances under federal law [Title 21 Chapter 13 Code of Federal Regulations \(CFR\) Part 1300](#) et. seq. 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.

This program does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license, nor to the UCSC Student Health Services Pharmacy. Medical and veterinary practitioners in University facilities are required to maintain appropriate state and federal licensure with respect to dispensing controlled substances.

In addition to controlled substances, the DEA and the State of California regulate chemicals that may be used in the production of these substances. The DEA maintains two lists of these chemicals, [List I and List II](#)<sup>1</sup>, while the State of California maintains a list of “Precursor Chemicals.” The California [Precursor Chemicals](#) include the DEA Listed chemicals, as well as additional chemicals. Requirements for the procurement and use of these chemicals are less restrictive than for controlled substances and are outlined in Appendix A.

## II. Definitions

Authorized Person –Principal Investigators and research staff who have successfully completed the authorization process for controlled substance use and/or pick up. (Attachment One)

Biennial Inventory – A detailed inventory of all controlled substances present at UCSC on a specified date and time. To be conducted every two years at the direction of the Program Administrator. (Attachment Two)

Controlled Substances (CS) – 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 (<http://www.deadiversion.usdoj.gov/schedules/schedules.htm> ).

Controlled Substance Use Authorization (CSUA) – The term refers to specific authorization granted to a *bona fide* user at UCSC. The project documentation form required for controlled substance use. (Attachment Three)

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<sup>1</sup> The primary difference between List I and List II chemicals is the DEA reporting threshold for import, export, or sale (List II thresholds are much higher).

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

Dangerous Drug or Device – The terms “dangerous drug” and “dangerous device” refer to drugs or related items that may only be obtained by prescription. These may or may not be controlled substances. See California Business and Professions Code Chapter 9, Division 2, Article 2 §4022, <http://law.justia.com/california/codes/bpc/4015-4043.html>.

Listed Chemicals – Chemicals that can be used to manufacture a controlled substance (per the Federal DEA). There are two lists, List I and List II, which differ by import/export/sales reporting thresholds. These lists can be found at [http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310\\_02.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm).

Precursor Chemical – Chemicals that can be used to manufacture a controlled substance (per the State of California). The California list of precursor chemicals includes the DEA List I Chemicals plus some additional chemicals. California laws require campus vendors to uphold stringent regulations regarding sale and distribution of these chemicals. This list can be found at <http://ag.ca.gov/bne/pdfs/laws03.pdf>.

Research Advisory Panel of California – A function of the California Attorney General’s office which, pursuant to California Health & Safety Code §11480 & 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 Individual (RI) – An individual (typically a Principal Investigator or Senior Staff with permanent appointment) directly responsible for the function of a particular laboratory, research center, or service center (Vivarium).

Schedules of Controlled Substances – Controlled substance schedules are classifications of narcotics and dangerous drugs, ranked according to their potential for abuse and other relevant factors, and are denoted by roman numerals I through V. Information concerning the assignment of particular substances to specific schedules may be obtained at <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>.

- Schedule I: No currently accepted medical use. Highest potential for abuse.
- Schedule II: Currently accepted medical use with restrictions. High potential for abuse with severe psychological or physical dependence.
- Schedule III: Currently accepted medical use. Abuse of drug may lead to moderate to low physical dependence or high psychological dependence. (Schedule III N = non-narcotic)
- Schedule IV: Currently accepted medical use. Low potential for abuse relative to Schedule III. (Schedule IV N = non-narcotic)
- Schedule V: Currently accepted medical use. Low potential for abuse relative to Schedule IV.

Usage Log – The form used by the Authorized Person to track controlled substance use. (Attachment Four).

### **III. Policy**

#### **Regulatory Compliance**

UCSC shall comply with all applicable Federal and State laws and regulations governing controlled substances.

## DEA Registration

Authority to possess or dispense controlled substances for research and teaching purposes shall be requested from the U.S. Department of Justice, Drug Enforcement Administration (DEA). All procurement and use of controlled substances must be under a registration granted to UCSC by the DEA. The UCSC Main campus research registration covers controlled substances in Schedules II through V. Additional UCSC registrations must be obtained for Schedule I substances or for substances that will be used long-term at a remote site (i.e., a location away from the main campus, such as a permanent field station).

Additional UCSC registrations are obtained for Schedule I substances.

Additional UCSC registrations are obtained for substances that will be received and used at satellite locations (i.e., a location not contiguous with the main campus, Long Marine Lab, 2300 Delaware, or a field station). Special considerations for satellite locations and field stations are described in supplemental procedures.

## Penalties for Non-Compliance

Violation of any aspect of this program or DEA regulations may result in revocation of the Principal Investigator's or a Department's privilege to obtain and use controlled substances, repossession of all controlled substances in inventory, suspension of purchase requisition authorization, and suspension or termination of Authorized Personnel privileges. In addition, the DEA may rescind the campus registration. Refer to Appendix B for the procurement-related *Controlled Substance Program Escalation Procedure* based on the University of California, Business and Finance Bulletin<sup>2</sup> BUS 50, and Controlled Substances Program Best Practices Guide<sup>3</sup>.

Personnel who intentionally divert controlled substances are subject to disciplinary action, up to and including termination of employment and referral to the appropriate law enforcement officials. Individuals responsible for the violations may be subject to fines and/or imprisonment.

## IV. Responsibilities

**Chancellor** In accordance with the BUS 50 (BFB-BUS-50: Controlled Substances), the Chancellor is responsible for providing resources to effectively administer the Controlled Substances program and for designating, in writing, a Responsible Official to establish and oversee the program.

### Responsible Official

As designated by the Chancellor the Responsible Official shall:

- Establish and oversee the Controlled Substances Program in accordance with DEA regulations and best practices;
- Sign all DEA registrations on behalf of the UC Regents; and
- As appropriate, grant a Power of Attorney to managers to enable them to obtain and execute order

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<sup>2</sup> initial release effective 5/5/09

<sup>3</sup> <http://www.ucop.edu/ucophome/policies/bfb/>

or

<http://policy.ucop.edu/manuals/business-and-finance-bulletins.html>

forms for controlled substances. The Responsible Official may designate one or more Program Administrators to implement and manage the program.

### **Materiel Manager**

The Materiel Manager or designee (in the Purchasing Department) is responsible for procuring controlled substances and listed precursor chemicals for Authorized University Activities in compliance with DEA registrations, the location's Controlled Substances Program, and University/Laboratory policies.

### **Program Administrator**

The Responsible Official's designee (typically in the Environmental Health and Safety Department) charged with implementing and managing the Controlled Substance Program on a day-to-day basis. The Program Administrator reviews departmental handling procedures for controlled substances, assures compliance with DEA regulations, authorizes storage facilities for controlled substances, conducts site inspections, requests and reviews the biennial inventories and drug logs, and manages the disposal of unused, expired, or waste controlled substances.

### **Department Head**

The department head<sup>4</sup> is responsible for determining the need for and authorizing the Responsible Individual (RI) to approve Purchase Requisitions for controlled substances by department members and for assuring that the storage, use, inventories, transfers, and disposal of controlled substances by department members comply with applicable laws, regulations, and campus policies.

### **Responsible Individual**

The RI is responsible for ensuring compliance with DEA regulations, program requirements, and University/Laboratory policy governing the acquisition, use, storage, and disposition of controlled substances.

### **Authorized Personnel**

A laboratory member (e.g., staff and/or students) who is authorized to use<sup>5</sup> Controlled Substances at UCSC. Authorized personnel are responsible for understanding their responsibilities within the program and for complying with UCSC policy governing the use, storage, and disposition of controlled substances.

## **V. Procedures**

### **Project Approval**

A "Controlled Substance Use Authorization" (CSUA) form must be completed and signed by the RI and approved by EH&S in order to work with controlled substances (Attachment Three). This form includes information on the controlled substance to be used, the project use and storage locations, and authorized personnel. In the event an IACUC approval is necessary, EH&S will process the request concurrent with the IACUC review process.

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<sup>4</sup> APM 245 and UCOP ISM Policy statements

<sup>5</sup> Use is defined as any possession, control, receiving, administration, or transfer.

The RI establishes *bona fide* need for controlled substance use. The following constitutes a *bona fide* need to handle, use or access controlled substances for research purposes:

- . Signature approval of need from the Department Chair. If the applicant is the Department Chair this approval must come from the Division Dean. In his/her absence, this may be delegated to the acting authority. In these instances, this individual would be delegated the authority to sign as a Department Chair / Dean Alternate. Department Chairs requiring a CSUA for their own projects must acquire authorization from their Dean.

AND

1. At least one of the following:
  - a. Animal Use: Principal Investigator must have an approved Institutional Animal Care and Use (IACUC) protocol listing the requested controlled substance. Prior approval by the State Attorney General's Office is required for use of a Schedule I controlled substance.
  - b. Human Use: Principal Investigator must have an approved Human Subjects protocol listing the requested controlled substance. Prior approval by the State Attorney General's Office is required for use of a Schedule I or II controlled substance on humans.
  - c. The use of precursor chemicals must be for legitimate UCSC-sponsored research applications.

Additional approval for any project which proposes to use a Schedule I controlled substance, any human research involving a Schedule I or II controlled substance, or research for treatment of drug abuse using any drug (scheduled or not) must be reviewed simultaneously by the State of California Research Advisory Panel prior to commencement of work.

## Field Research

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 usage log 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 usage log records should be synchronized.

## Export

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.

## Personnel Authorization

In order to request controlled substances, the RI and any supporting project personnel (users) must complete the Controlled Substance Authorization form (Attachment One) The Controlled Substance Authorization form must be signed by the RI, and a copy filed with EH&S. Background checks may be conducted through the California DOJ LiveScan Fingerprinting system or other resources.

## Controlled Substance Procurement

Controlled substances may be procured once the applicable Controlled Substance Use Authorization form has been approved by EH&S, and the RI and research staff have been Authorized. EH&S then provides to Procurement Services a list of authorized and approved requesters and PI's. EH&S maintains an up-to-date list of authorized CS purchasers on a restricted access file server.

The RI must determine the need for, and approve all requisitions for Controlled Substances, regardless of dollar value. Purchase requests must be submitted through the CruzBuy e-procurement system, using the DEA Controlled Substance form. The CruzBuy e-procurement workflow provides notification to EH&S on all controlled substance orders. Requesting units must identify the Schedule type of the CS within the requisition internal notes section.

No orders may be placed by departmental personnel directly with vendors and/or using a personal or UCSC credit card using UCSC DEA licenses. See Appendix C for a flow chart outlining the purchasing process.

Purchase Orders will be submitted to the controlled substance vendor by an authorized Procurement Services Buyer. Delivery to the main campus is to the UC Santa Cruz Student Health Services Pharmacy as stated on the main campus DEA permit.

Researchers with their own DEA registration or California Precursor Permit can place orders with vendors for controlled substance or precursor chemicals under their registration for delivery to their address and are not covered by this procedures manual.

### Schedule I

Controlled Substances listed in Schedule I must be ordered on DEA Form 222. In addition to this form, each research project will need a separate DEA registration, approval by the State Research Advisory Panel of California (RAPC), and approval of the UCSC Office of Research. Contact the Purchasing Department to order Schedule I materials.

### Schedule II

Controlled Substances listed in Schedule II must be ordered on DEA Form 222. Contact the Purchasing Department to order Schedule II materials.

### Schedules III – V

See Appendix C for a flow chart outlining the purchasing process.

Requisitions must be submitted to the controlled substance vendor by an "Authorized Departmental Purchasing Agent" (ADPA) for delivery to the UC Santa Cruz Student Health Services Pharmacy. Once the order is placed, the ADPA notifies the Pharmacy to expect arrival of the order.

### Incoming Transfer from Outside Entities

A no charge controlled substance provided by a private company for research purposes must first be requisitioned through the Purchasing Department for delivery to the UC Santa Cruz Student Health Services Pharmacy and must be pre-approved by EH&S. Drugs may not be delivered directly to researchers.

## **Controlled Substance Receipt (Main Campus)**

Controlled substances are delivered to the UC Santa Cruz Student Health Services Pharmacy (as listed on the Main Campus registration). The Pharmacist accepts delivery of orders, opens and verifies order accuracy, and notifies the vendor of any missing or incorrect orders by the next business day following delivery. The Pharmacist then notifies the RI and/or authorized laboratory contact via email. The RI or those authorized are responsible for picking up orders within 3 working days. Orders will again be counted and verified by the Pharmacy staff with the authorized individual when orders are picked up. Photo identification or signature verification may be required to pick up orders.

Once the products are received, a copy of the packing slip must be provided to Procurement Services, to the attention of the Buyer who processed the order.

## **Controlled Substance Receipt (Satellite Locations)**

Once the products are received, a copy of the packing slip must be provided to Procurement Services, to the attention of the Buyer who processed the order.

## **Import, Export, Interstate, and Intrastate Use Requirements**

### **1. Imports**

It is unlawful to import Dangerous Drugs, including Controlled Substances, into the United States unless: (i) the DEA grants an import permit to the University; or (ii) in the case of other Dangerous Drugs that are not Controlled Substances, the drug is subject to FDA regulation and may require an Investigational New Drug Permit (IND) issued by the FDA.

### **2. Exports**

The University does not permit the export of Dangerous Drugs including Controlled Substances, federal List I and II chemicals, or California-listed chemicals acquired under a University DEA registration or using University funds without first obtaining explicit permission from the DEA Office of Diversion Control Import/Export Unit and the institution's Responsible Official.

### **3. Interstate and Intrastate Use**

A DEA registration may need to be obtained 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.

## **Controlled Substance Transfer**

An authorized Responsible Individual may transfer controlled substances to another UCSC authorized Responsible Individual with prior approval from EH&S. Authorized personnel must follow the conditions and procedures below for each transfer.



## Same Registration

- Controlled substances used for an individual veterinarian license or other outside licenses cannot be transferred for use under the UCSC DEA registrations without approval from EH&S.
- The transferor must ensure that the recipient of the controlled substance has UCSC authorization and an approved storage location. Contact EH&S to verify the recipient is authorized.
- Notify EH&S (459-2553 or [consub@ucsc.edu](mailto:consub@ucsc.edu)) of the transfer within 24 hours.
- The transferor and recipient must document the transfer in their Controlled Substance Usage Logs.

Records for each transfer must be kept for at least 3 years.

Transfer of controlled substance outside of UCSC must have approval from the Program Administrator.

- Controlled substances must be used only for the same purpose for which they were acquired (e.g., teaching, research, or clinical use).

Transfer of controlled substance(s) between PIs within the same DEA registration will only allowed if:

- The substance is approved in the recipient's CUSA.
- The person receiving the substance(s) is an approved user in the CUSA.
- Documentation of the transfer is maintained by each lab and a copy sent to EH&S.

## Different Registration

Transfer to another DEA Registration (Long Marine Lab versus Main Campus) must be discussed with the Program Administrator.

Transfers of controlled substances that do not comply with the above procedure may result in revocation of a department's privilege to obtain and use controlled substances, rescission of campus registrations, and imposition of fines and/or imprisonment of individuals responsible for the violations.

## Storage and Use

Controlled substance storage and use locations must be approved by EH&S. Controlled substances must be stored securely in a manner adequate for safeguarding, and should be separated from other drugs, chemicals or items. This practice will help to prevent loss by limiting access to only those who are assigned to work with controlled substances. It is recommended access be limited to as few researchers as possible. When in use, controlled substances should never be left unattended.

Responsible Individual (RI) is responsible for providing and maintaining secure storage for their controlled substance (CS) inventory that meets these criteria:

- Store CS according to schedule number:
  - Schedule I: Store in a safe or steel cabinet equivalent.
  - Schedule II-V: Store in a locked drawer or cabinet that is inaccessible from above or below.
- Install the following equipment according to these standards:
  - Padlocks and hinges:
    - Must have the mounting screws or bolts of the hasp inaccessible when the door is closed and the lock is fastened

- Safes and steel cabinet equivalents:
  - Must be cemented or bolted to the floor or wall, or weigh more than 750 pounds
- Storage units:
  - Must be secure enough to show forced entry
- Drawers:
  - Must be inaccessible from the upper or lower drawers in the stack. Assign the top drawer of the stack to use as the storage facility, if possible.
- Use CS storage units only for CS and their use logs
- Acceptable field storage:
  - Lockbox in a locked vehicle.
  - Lockbox under direct control of researcher.
- Storage restrictions:
  - Do not share CS storage facilities.
  - Do not store other chemicals or supplies in a CS storage unit.
  - Do not store CS in a corridor.

The Authorized RI and research staff must maintain a usage log for each container of controlled substance (Attachment Four). Controlled substance usage must be tracked on a per dose (use) basis and must be recorded to the nearest gram weight or the total number of units finished form. All records of withdrawals of controlled substances from storage must be signed by the person making the withdrawal. The RI responsible for the controlled substance must maintain all controlled substance usage logs in a readily available location for at least two years after the date of final disposition.

Some teaching and research units may require controlled substances for the health maintenance of their animals. These substances may be kept in the approved storage site, but must be separated from the teaching and research substances. Documents must be available upon request to demonstrate that the substances were purchased or prescribed for health maintenance.

## **Inspections**

All users and locations are subject to unannounced DEA inspections. In addition, EH&S will schedule an assistance visit to each user's laboratory on a biennial basis.

EH&S will document inspection findings; the authorizing official will be copied on any reports with negative findings.

## **Biennial Inventory**

Each RI or authorized laboratory contact must conduct a biennial inventory of all existing stocks of controlled substances in their possession for UCSC to maintain registration with the DEA. EH&S will provide the biennial inventory form (Attachment Two) and an inventory due date at least one month in advance.

The inventory must include the following information for each controlled substance in finished form:

- The name of the substance or DEA identification code.
- The finished form (e.g., 10 mg tablet or 10 mg/ml).
- The number of commercial containers remaining on-hand

- The number of units or volume of each finished form in each commercial container (e.g., 100 tablet bottle or 3 ml vial).
- The number of units of each finished form of a controlled substance in a commercial container that has been opened will be determined as follows:
  - For Schedule II, an exact count or measure of the contents.
  - For Schedule III, IV, or V, an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact measure of the contents must be made.
- For expired or unused substances awaiting disposal: the purpose the substance is being maintained by the researcher.

## Disposal

Authorized personnel may dispose of empty controlled substance containers by defacing the label and discarding in the trash.

Authorized personnel must inform EH&S of the need to dispose of Controlled Substances that are expired or no longer needed. EH&S will coordinate disposal of any controlled substance with a reverse distributor or the Student Health Services Pharmacy. Other methods must be approved in writing by EH&S as advised by the DEA.

The reverse distributor, or Pharmacy, must provide documentation as to final disposition of disposed/destroyed/returned drugs to the Program Administrator. If applicable, the final disposition of such substances must be documented by receipt of one of the following:

- A Certificate of Destruction and corresponding Form 222 for each Schedule I and II controlled substance covered by that certificate or a DEA Form 41;
- A completed copy of the waste manifest from the Treatment Storage and Disposal Facility;
- A certificate of return to manufacturer.

## Theft, Loss or Breakage

Authorized personnel are expected to report missing controlled substances to their supervisor, the Program Administrator, and the UCSC Police Department as soon as the loss is discovered. The Program Administrator and law enforcement will investigate the diversion, loss, or theft of Controlled Substances. Reports will be kept confidential to the extent permitted by law and other University policies.

The Program Administrator must promptly (within 24 hours) submit DEA Form 106 to the local DEA office for each theft and any significant loss of Controlled Substances. According to DEA guidance:

*“Breakage of controlled substances does not constitute a “loss” of controlled substances. When there is breakage, damage, spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a “reverse distributor” or by a DEA approved process.*

*If the breakage or spillage is not recoverable, the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the*

*inventory records indicating what they witnessed. The submission of a DEA Form 41, Registrants Inventory of Drugs Surrendered is not required for non-recoverable controlled substances."*

## Non-significant Loss

The Controlled Substance Act does not define the term "significant loss".

Per DEA Diversion website guidelines, DEA has clarified what they term a significant loss.:

When determining whether a **loss** is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances;
3. Whether the **loss** of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the **loss** can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substances.

Non-significant loss secondary to miscounts or clerical errors must be documented in the inventory or usage record and recorded UCSC local form (Loss Log Attachment 5).

- When used to document non-significant loss, the DEA form is not used and DEA is not notified.

EH&S may perform a review of security and record keeping policies must be performed if multiple or chronic record discrepancies occur

## Training

Basic training is provided through the UCSC Learning Center or EH&S. EH&S may offer additional Controlled Substance Training as-needed. Basic training requirements include review of the listed material and a test:

- Storage site controls and security;
- Ordering, delivery, and receipt;
- Usage logs and biennial inventory requirements;
- Transfers of Controlled Substances;
- Import and export policies;
- Disposal of Controlled Substances;
- Diversion and loss reporting; and
- Illicit activities and repercussions.

## **Supplemental Procedures**

Long Marine Lab Satellite Procedure  
2300 Delaware Satellite Procedure  
Intra-Campus Transfer Procedure  
Remote (field use) Procedure  
Processing of DEA Form 222

## **VI. References**

University of California Business and Finance Bulletin BUS 50, *Controlled Substances Program*, effective May 5, 2009, and the associated *Controlled Substances Program Best Practices Guide (APPENDIX A)*

*FORMS UNMODIFIED*

# **Attachment One**

## **Authorized Personnel Form**

# Controlled Substance Authorization

This form must be submitted to EH&S prior to receiving or using Controlled Substances

Applicant's Name \_\_\_\_\_ Email: \_\_\_\_\_  
(last name) (first name) Phone: \_\_\_\_\_

Principal Investigator \_\_\_\_\_ Email: \_\_\_\_\_  
(last name) (first name) Phone: \_\_\_\_\_

Select One Role Only:

☐ Research Use & Pharmacy Pick-Up ☐ Pharmacy Pick-Up Only ☐ Research Use Only

## BACKGROUND SCREENING

Within the past five years, have you been convicted of a felony, or within the past two years of a 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). If the answer is yes, furnish details of conviction, offense, location, date, and sentence on a separate page and attach to this form.

☐ Yes ☐ No

In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details on a separate page and attach to this form.

☐ Yes ☐ No

Have you ever surrendered a controlled substance registration or had a controlled substance registration revoked, suspended, or denied?

☐ Yes ☐ No

## AUTHORIZED PERSONNEL RESPONSIBILITIES

- 1) Understand the health hazards of the controlled substance, including local and systemic toxicity, and the conditions and situations that could result in exposure.
- 2) Follow the appropriate work practices, which include:
  - Properly storing and securing controlled substances and usage logs in a securely locked safe or substantially constructed cabinet to prevent unauthorized access.
  - Accurately recording controlled substance usage, transfer, disposal, and other inventory fluctuations.
  - Reporting any lost or stolen controlled substance to EH&S.
- 3) Complete Controlled Substances Training.
- 4) Complete California Department of Justice Live Scan Fingerprinting, if requested.

## REPORTING DIVERSION OF CONTROLLED SUBSTANCES

The 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. At UCSC, all such reports can be made confidentially to EH&S, which will inform the appropriate officials and initiate an investigation of the allegations. UCSC will take reasonable steps to protect the confidentiality of the information provided, however absolute confidentiality cannot be guaranteed. The protection of an individual's right to privacy will be upheld in all confidential inquiries to the extent feasible.

## DISCIPLINARY ACTION FOR EMPLOYEES WHO ENGAGE IN ILLICIT ACTIVITIES

It is the position of the DEA that employees who possess, sell, use or divert Controlled Substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

I certify the accuracy of the above information and that I have read, understood, and agree with the above statements. **By signing below, I authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions.**

**Applicant's Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

# **Attachment Two**

## **Biennial Inventory Form**



# Controlled Substances Biennial Inventory Form

The Biennial Inventory is a requirement of the Federal Drug Enforcement Administration (21 CFR 1304.11). Please return this form to the Program Administrator at EH&S by mail ( ) or fax ( ).

Principal Investigator Name: \_\_\_\_\_ Department: \_\_\_\_\_  
Controlled Substances storage location: ☐ UCSC main campus ☐ LML

**Instructions:** List all Controlled Substances in possession as of the close of business on <<DATE>>. List open containers as separate line items. Unopened containers of same substance, manufacturer, volume, and concentration can be listed together on the same line. Fill out separate forms for each storage location.

Line Item	Unopened Containers		Opened Containers			Controlled Substance Name	Drug Code & Schedule <sup>2</sup>	Finished Form <sup>3</sup>
	Qty	Container size	Qty	Remaining amount <sup>4</sup>	Container size			
1								
2								
3								
4								
5								

Number of completed line items in table: \_\_\_\_\_ (write "Zero" if none)

**By signing below**, I agree the information listed here represents the actual amount of controlled substances existing in inventory as of the close of business on <<DATE>> (Biennial Inventory Date).

**Principal Investigator signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

For list of Controlled Substances visit:

<http://www.deadiversion.usdoj.gov/schedules/alpha/alphabetical.htm>

<sup>2</sup> For DEA Drug Code and Schedule number, refer to the DEA Controlled Substances website. DEA Drug Code is a 4-digit number. Controlled Substance Schedule number is expressed in Roman numerals, I through V; N denotes the item is non-narcotic.

<sup>3</sup> Finished Form refers to the strength and form of the item as commercially prepared.

<sup>4</sup> Measure in weight (powder or crystals) or volume (liquids) or number of units (tablets or capsules). For opened containers: If the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact count must be made.

# **Attachment Three**

## **Controlled Substance Use Authorization (CSUA) Form**

# UCSC Controlled Substance Use Authorization

To be completed by the Principal Investigator and submitted to the  
Environmental Health & Safety Department

## Principal Investigator

Name:

Phone:

E-mail:

Mail Code:

Department:

Office

Location:

## Controlled Substances Requested

List all controlled substances individually; list all items which may be needed this year or are currently in possession. See EH&S website for DEA Schedule and Number information.

Substance Name (Brand name in parenthesis)	DEA Schedule (ex., III)	DEA Number (Scheduled drugs only)	Estimated Need (1 year)		Purpose (ex., euthanasia, analgesia)
			Unit Size (ex., 100 mg/ml)	# Units (ex., 10 ml)	

## Project Information

Provide information on this project. Include a description of your research and describe security procedures to be used for controlled substances.

Project/Protocol Title

IACUC protocol #

Protocol expiration date

Duration of project (ex., ongoing, 6 months)

Project description:

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## Certification of *Bona Fide* Use

### 1) Will the controlled substance be used in animal research?

☐ Yes -- If yes, CARC Protocol Number:      Approval Date:

☐ No

### 2) Will the controlled substance be used in human subjects research?

☐ Yes -- If yes, IRB Protocol Number:      Approval Date:

☐ No

### 3) Other *bona fide* controlled substance use? (describe)

## 4) Departmental Chair Approval

Based upon the nature of the research being conducted by the aforementioned researcher, I certify that the requested use of DEA Controlled Substance(s) is legitimate and necessary for their research efforts at UCSC.

\_\_\_\_\_  
Department Chair Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

## Use/Storage Locations

Controlled substance storage locations are strictly regulated. Contact the Controlled Substance Program Administrator at (831) 459-2553 or [ehs@ucsc.edu](mailto:ehs@ucsc.edu) for more details *before* investing in storage devices. All facilities must be approved by the Controlled Substance Program Administrator prior to use.

Building	Room	Security Measures
		<input type="checkbox"/> Safe <input type="checkbox"/> Securely locked, substantial cabinet <input type="checkbox"/> Locked drawer <input type="checkbox"/> Other:
		<input type="checkbox"/> Safe <input type="checkbox"/> Securely locked, substantial cabinet <input type="checkbox"/> Locked drawer <input type="checkbox"/> Other:
Other Field Use: <input type="checkbox"/> Yes -- <input type="checkbox"/> No	Location:	Security Methods:

## EH&S Approval

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

## Controlled Substance Authorized Personnel

Provide information on all personnel working with controlled substances as part of this project.

### Primary Controlled Substance Lab Contact Information:

(This person will be contacted first when CS shipments arrive for pick up, audit scheduling, etc.)

Name:

Phone:

E-mail:

Mail Code:

### Secondary Lab Contact Information (if appropriate):

(This person will be contacted as a backup for Primary Controlled Substance Lab Contact.)

Name:

Phone:

E-mail:

Mail Code:

### Authorized Personnel:

List names of people authorized by the Principal Investigator to pick up CS shipments: (include lab contacts here as well, if applicable)

Name (print)	Authorized User Status form submitted to EH&S?

List names of all additional people authorized by the Principal Investigator to access, dispense, and/or handle CS: (those people authorized (in part A, above) to pick up shipments do not need to be listed here)

Name (print)	Authorized User Status form submitted to EH&S?

I authorize the personnel listed above to use Controlled Substances under my CSUA, signed:

Principal Investigator signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature

I understand that I must successfully pass a criminal background check before I am authorized to work with controlled substances.

I understand that all individuals in my lab that I authorize to work with these controlled substances must also successfully pass a criminal background check.

I understand that I must keep the list of authorized employees current by communicating with EH&S whenever an individual leaves or I intend to authorize a new individual.

I understand that I must provide proper security for the controlled substances at all times and keep accurate inventory and usage records.

I certify that (1) the information provided on this form is accurate; (2) that I am familiar with the requirements of the UCSC Controlled Substances Program; and (3) all uses of these controlled substances will be in accordance with these requirements and in compliance with DEA regulations.

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Print Name

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Signature

---

Date

# **Attachment Four**

## **Usage Log Form**

# Controlled Substance Usage Log

Environmental Health & Safety, UCSC

Principal Investigator:	Date Received:
CS Name:	PO #:
Amount/container (e.g., 100 mg):	Concentration: (e.g., 10 mg/ml):

# Containers: \_\_\_\_\_

Date	Cont. #	Used (ml)	Empty Y/N	User's Printed Name and Signature	Reason for Use/ Animal Protocol #/ Comments

CS transferred to EH&S for disposal? Y ☐ N ☐ If Yes: EH&S Initials

Date

Disposal #:

CS is completely used up? Y ☐ N ☐ If Yes, copy of log sheet sent to EH&S and empty bottle disposed by:

Date

- This log must be kept in the controlled substance storage drawer or safe. The log balance must match the physical balance of CS at all times.
- This log must be retained in the lab for 2 years from either the date of disposal or date of complete use: **Retain until:** \_\_\_\_\_
- Any log discrepancies, suspected misuse, or theft of controlled substance must be reported to EH&S immediately.
- When this controlled substance is no longer needed or has expired, call EH&S at 831-459-2553 for disposal instructions.
- When this controlled substance is completely used up, send a copy of the log sheet to EH&S; then deface label(s) and throw away in regular trash.
- Any breakage of containers must be initialed by the individual responsible for breakage and co-signed by a witness to the breakage.



## Controlled Substance Usage Log (Continuation Sheet)

[illegible]

## Appendix A

### Procurement, Use, and Disposal Procedures for Listed / Precursor Chemicals

The mission of the Federal DEA's Listed and the State of California's Precursor Chemicals Control Programs are to disrupt the illicit production of controlled substances by preventing diversion of chemicals used to make drugs. The illegal production of drugs such as methamphetamine, cocaine, heroin, and MDMA (ecstasy) requires enormous quantities of precursor and essential chemicals. These federal and state programs seek to minimize the regulatory burden on the legitimate chemical industry while instituting effective anti-diversion policies.

A DEA registration (or California Department of Justice registration) is required for purchasing precursor chemicals from vendors outside of California. If precursor chemicals are bought from a vendor within California, use of the registration is not required.

Once approved for purchase, Listed/Precursor chemicals may be acquired and managed in the same manner as all other hazardous materials used by the researcher. The specific procurement, use, recordkeeping, storage, and disposal requirements for controlled substances do not apply to Listed/Precursor chemicals. For example, these chemicals are not included in the controlled substance inventory; disposal of precursor chemicals shall be done through the EH&S *Online Tag* Program.

## Appendix B

### Controlled Substance Program Escalation Procedure

#### I. Purpose:

The purpose of this escalation procedure for the Controlled Substance Program is to ensure compliance with the U.S. Department of Justice, Drug Enforcement Administration regulations (21 CFR) with respect to procurement and transfers of controlled substances.

#### II. Procedure:

The following escalation procedure will be used for all inappropriate purchases and transfers between departments or authorized individuals of controlled substances.

An unauthorized purchase of controlled substance can occur in the following ways, for example:

1. Departmental Purchase Order (DPO);
  - a. Use of a procurement card;
  - b. By telephone;
  - c. By a vendor automated ordering system.

Once information has been obtained by the Purchasing Department that one of the above purchase types has occurred, the following escalation procedure will be implemented and tracked:

1. The Purchasing Department will immediately notify the authorized custodian and department office that inappropriate purchase has occurred. In all cases, the vendor will also be contacted regarding the appropriate purchasing procedures.
2. Escalation Procedure:
  - a. First Occurrence  
A follow-up letter will be immediately faxed to the authorized custodian and department head stating the inappropriate purchase, actions to be taken, and consequences if this type of purchase of controlled substance continues. A copy of the existing policy will also be provided to the authorized custodian.
  - b. Second Occurrence  
A follow-up letter will be immediately faxed to the authorized custodian, department head, and Dean or Vice Chancellor stating the inappropriate purchase, actions to be taken, and consequences if this type of purchase of controlled substance occurs again.
  - c. Third Occurrence  
In the event that an authorized custodian attempts three (3) inappropriate purchases in any one calendar year, the purchasing privileges for controlled substances will be suspended until the Dean or Vice Chancellor approves reinstatement. A follow-up letter will be immediately faxed to the authorized

custodian, department head, and Dean or Vice Chancellor stating that suspension has occurred.

Transfers of Controlled Substances must be in compliance with the approved procedures. This includes appropriate documentation by the transferee, recipient, and a copy of the transfer record to the Office of Environmental Health and Safety (EH&S).

# **Appendix C**

## **Controlled Substance Procurement Process**

