

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 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](#) to end. The [California Bureau of Narcotic Enforcement](#) and the [California State Board of Pharmacy](#) are authorized to ensure compliance with California laws regulating controlled substances and prescription drugs, respectively.

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](#)¹, 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 – Narcotic and non-narcotic drugs under the jurisdiction of the federal Controlled Substances Act and the California Uniform Controlled Substances

¹ 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).

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 project documentation form required for controlled substance use. (Attachment Three)

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.

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.

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 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 at a remote site (i.e., a location away from the main campus, such as a field station).

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 BUS 50, Controlled Substances Program Best Practices Guide.

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 or Laboratory Director

In accordance with the University of California's Business and Finance Bulletin BUS 50, Controlled Substances Program, (effective 5/5/09), the Chancellor or Laboratory Director 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 or Laboratory director, 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 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 (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 is responsible for determining the need for and authorizing 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.

Authorized Personnel

A Principal Investigator or laboratory member (e.g., staff and/or students) who is authorized to possess or use Controlled Substances at UCSC. Authorized personnel are responsible for understanding their responsibilities within the program and for complying with DEA regulations, program requirements, and University/Laboratory policy governing the acquisition, use, storage, and disposition of controlled substances.

V. Procedures

Project Approval

A "Controlled Substance Use Authorization" (CSUA) form must be completed 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.

Principal Investigators must establish that they have a *bona fide* need for controlled substance use. The following constitutes a *bona fide* need to handle, use or access controlled substances for research purposes:

1. 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 one individual of a comparable level of authority. In these instances, this individual would be delegated the authority to sign as a Department Chair Alternate. Department Chairs requiring a CSUA for their own projects must acquire authorization from their Dean or an individual of a comparable level.

AND

2. 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. 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 Principal Investigator and any supporting project personnel must complete the Controlled Substance Authorization form (Attachment One). This form must be signed by the Principal Investigator, and a copy filed with EH&S. Background checks may be conducted through the California Department of Justice LiveScan Fingerprinting system.

Controlled Substance Procurement

Controlled substances may be procured once the applicable Controlled Substance Use Authorization form has been approved by EH&S, and the Principal Investigator and research staff have been Authorized. 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 & II

Controlled Substances listed in Schedule I or II must be ordered on DEA Form 222. In addition to this form, each research project using a Schedule I substance 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 either Schedule I or II materials.

Schedules III – V

The Principal Investigator must determine the need for and sign all requisitions for Controlled Substances, regardless of dollar value. Purchase requests must be submitted through the CruzBuy system, using the DEA Controlled Substance form or the Hazardous Materials form, checking the “Controlled substance” box. The CruzBuy system requires EH&S approval on all controlled substance orders. No orders may be placed by departmental personnel directly with vendors and/or using a personal or UCSC credit card. 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.

A controlled substance provided by a private company for research purposes must first be requisitioned through the Purchasing Department at no charge 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

Controlled substances are delivered to the UC Santa Cruz Student Health Services Pharmacy. 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 Principal Investigator and/or authorized laboratory contact via email. The Principal Investigator is responsible for picking up orders within 3 working days. Orders will again be counted and verified by the Pharmacy staff with the Principal Investigator or designee when orders are picked up. Photo identification will be required to pick up all orders.

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

- 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 the recipient is authorized.
- Notify EH&S (459-2553 or ehs@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.
- Controlled substances must be used only for the same purpose for which they were acquired (e.g., teaching, research, or clinical use).

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.

Principal investigators (PI) are 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 Principal Investigator 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 metric unit 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 Authorized person 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.

Biennial Inventory

Each Principal Investigator 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.
- The finished form (e.g., 10 mg tablet or 10 mg/ml).
- The number of commercial containers.
- 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, or via another method 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.”

Training

EH&S provides Controlled Substance Training on an as-needed basis. Training includes:

- 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.

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* (<http://www.ucop.edu>).

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 ²	Finished Form ³
	Qty	Container size	Qty	Remaining amount ⁴	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>

² 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.

³ Finished Form refers to the strength and form of the item as commercially prepared.

⁴ 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 <i>(Brand name in parenthesis)</i>	DEA Schedule <i>(ex., III)</i>	DEA Number <i>(Scheduled drugs only)</i>	Estimated Need (1 year)		Purpose <i>(ex., euthanasia, analgesia)</i>
			Unit Size <i>(ex., 100 mg/ml)</i>	# Units <i>(ex., 10 ml)</i>	

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:

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 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.

Print Name

Signature

Date

Attachment Four

Usage Log Form

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:

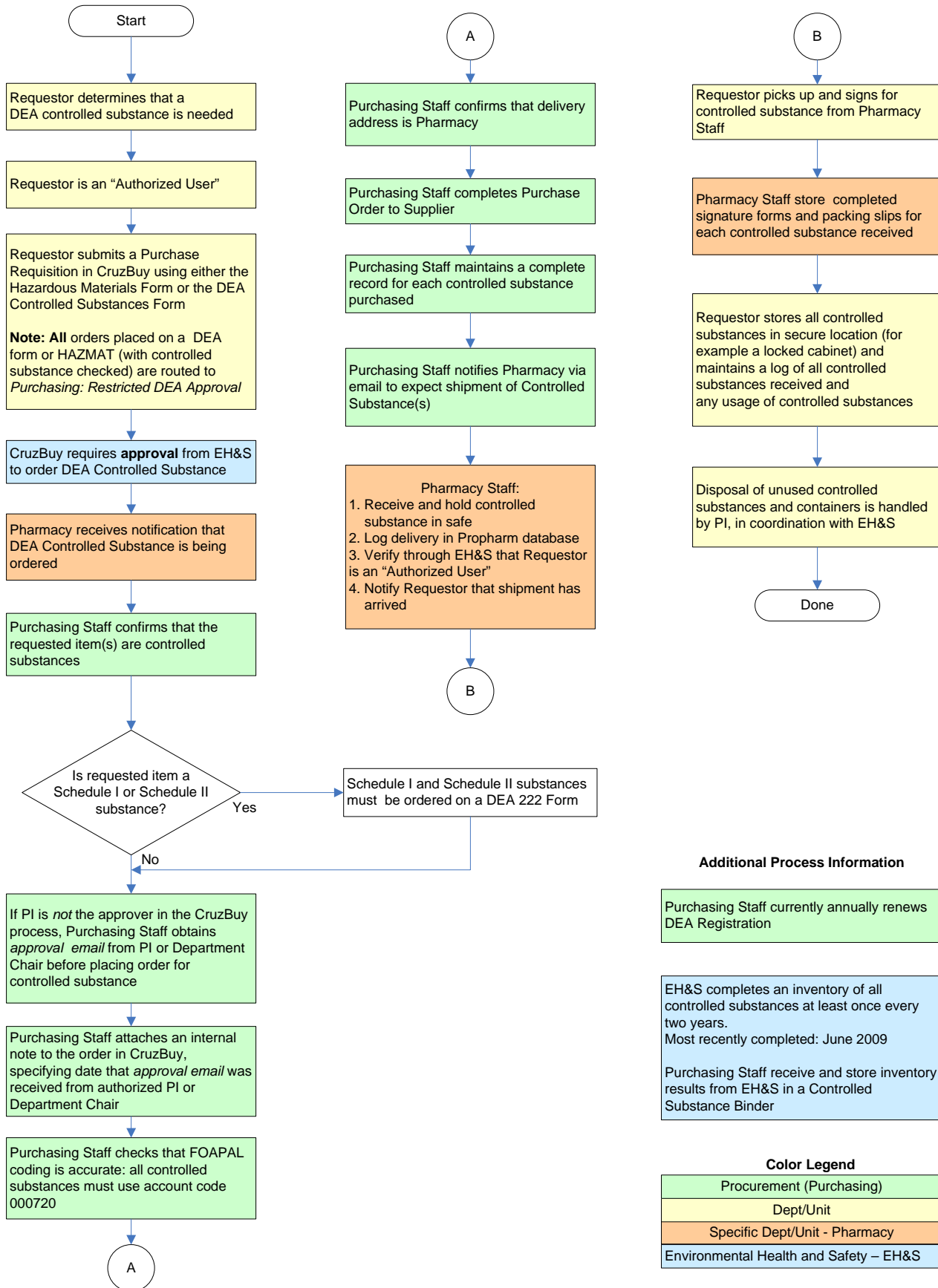
1. The Purchasing Department will immediately notify the authorized custodian and department office that inappropriate purchase has occurred. In all cases, the vendor will also be contacted regarding the appropriate purchasing procedures.
2. Escalation Procedure:
 - a. First Occurrence
A follow-up letter 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



Additional Process Information

Purchasing Staff currently annually renews DEA Registration

EH&S completes an inventory of all controlled substances at least once every two years.
Most recently completed: June 2009

Purchasing Staff receive and store inventory results from EH&S in a Controlled Substance Binder

Color Legend

Procurement (Purchasing)
Dept/Unit
Specific Dept/Unit - Pharmacy
Environmental Health and Safety – EH&S

