UCI Environmental Health & Safety

# Controlled Substances and Precursor Chemicals for Research Program

Responsible Administrator: Controlled Substances Program Officer
Revised: January 2024

**Summary:** Maintain and support all aspects of the UC Irvine Controlled Substances Use Authorization (CSUA) Program to comply with the Drug Enforcement Administration (DEA) registrations governing the use of controlled substances for research, veterinary and teaching purpose. This includes CSUA's for chemical precursors and the DEA List I/ Precursor chemicals and campus DEA liaison for Schedules II-V registrations.

## 1. Program Description

This procedure manual describes the University of California, Irvine's Controlled Substance and Precursor Chemicals Program and provides researchers with the knowledge needed to comply with applicable laws and regulations associated with the use of controlled substances and precursor chemicals in their research and instruction. Compliance with these procedures is required of all individuals authorized to conduct chemical analysis, instructional activities or research using controlled substances or precursor chemicals at the University of California, Irvine.

The Controlled Substance Program covers five main areas involved in the use of controlled substances in research: acquisition, storage, use requirements, recordkeeping and disposal. Procedures for the acquisition and disposal of precursor chemicals are covered.

Federal and state law regulates the manufacture, distribution, use, storage, and disposition of controlled substances and precursor chemicals. Controlled substances generally include narcotics, stimulants, depressants, hallucinogens, anabolic steroids and chemicals used in the illicit production of controlled substances. The Drug Enforcement Administration (DEA) is the agency mandated to regulate the lawful use of controlled substances and List I chemicals under federal law Title 21 Chapter 13 Code of Federal Regulation (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.

The University of California (UC) has established policies and procedures covering the acquisition and use of controlled substances for research purposes in compliance with both state and federal laws and are found in Business and Finance Bulletin BUS-50.

The University of California, Irvine has established Section 903-15: Guidelines On the Acquisition and Use of Controlled Substances and Precursor Chemicals for Research written in compliance with UC Bus 50 Policy.

This guideline can be found at: http://www.policies.uci.edu/

This procedure manual is not intended to provide guidance regarding the use of controlled substances by licensed healthcare personnel for non-research and/ or clinical purposes.

The Controlled Substance and Precursor Chemicals Program at UC Irvine is administered by Environmental Health and Safety.

## 2. Scope

1. Provide researchers with information needed regarding the proper use of controlled substances and precursor chemicals in their research.
2. Provide researchers with references to state and federal regulations and UC Irvine policies and procedures regarding controlled substances and precursor chemical use.
3. Describe requirements of five main areas of use of controlled substances in research at UC Irvine: acquisition, storage, approved use, recordkeeping and disposal. Requirements apply to researchers at the UC Irvine campus, UC Irvine Medical Center and affiliated sites. These requirements do not pertain to facilities, labs or buildings that are listed as inpatient or outpatient departments on the UC Irvine Medical Center's general acute care license.
4. Describe requirements for the acquisition and disposal of precursor chemicals used in research at UC Irvine.

## 3. Definitions

### 3a. Controlled Substance

A controlled substance (CS) is a substance that has a stimulant, depressant or hallucinogenic effect on the nervous system. Controlled substances are prescription drugs that are further classified as Schedule I-V and can only be obtained by registrants with the DEA (See 3b). The Controlled Substances Act (1970) lists substances that were controlled when the law was enacted. Since then, approximately 160 substances have been added, removed or transferred from one schedule to another.

A general reference list of controlled substances in alphabetical order can be found at: http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf. Federal regulations regarding schedules can be found in Section 1308 of CFR Title 21.

**Schedules of Controlled Substances**

**Schedule I:** No currently accepted medical use. Highest potential for abuse. (e.g., GHB, heroin, marijuana).

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

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

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

**Schedule V:** Currently accepted medical use. Low potential for abuse relative to Schedule IV (e.g., Zolpidem).

### 3b. DEA Registrations

The intent of DEA registration numbers is to identify and validate individuals and institutions that have been authorized by the DEA to purchase, possess, distribute or prescribe controlled substances.

Controlled substances and precursor chemicals intended for research and instructional purposes and acquired though drug companies or any other outside institutions must be obtained under an applicable university DEA registration. If an operation remote from the campus requires controlled substances, a separate registration is necessary for each type of activity involved. (See Section 6b)

An individual practitioner's DEA registration cannot be used to directly acquire controlled substances intended for research, instruction and chemical analysis purposes at UC Irvine for schedules II-V.

University hospital, clinic and pharmacy DEA registrations are valid only for use of controlled substances at these licensed premises and will not cover research facilities or medical office buildings that are not part of the licensed hospital, clinic or pharmacy.

Vendors and suppliers may only deliver controlled substances and precursor chemicals to the address listed on DEA registrations. Controlled substances and Precursor chemicals are delivered to EHS.

**3.a.i.** Institutional Research Registration (Schedules II-V)

EHS maintains the required departmental research registrations issued by the DEA covering use of Scheduled II-V controlled substances and precursor chemicals for research, instructional and chemical analysis purposes.

Researchers who wish to use a Schedule II controlled substance in a human subject's protocol must have their project reviewed by the State Attorney General's office. This review may take several weeks to months. A current letter of approval from the state Attorney General's office must be provided to EHS prior to obtaining the drugs. Contact EHS for more information regarding this process.

**3.a.ii.** Individual Research Registration (Schedule I)

EHS does not maintain an institutional research registration. Those individuals who wish to use a Schedule I controlled substance in their research must register independently with the DEA. The individual registration can be processed by submitting Form 225 to the DEA. For more information, please visit the DEA website https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp

In addition, Principal Investigators (PI's) who wish to use a Schedule I controlled substance must have their project reviewed by the state Attorney General's office. https://oag.ca.gov/research. Review may take several weeks to months.

For more information on Section 1301.18 Research protocols. (a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information.
https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR0f5a129834f0129/section-1301.18

| Business activity | Controlled substances | DEA Application forms | Application Fee ($) | Registration period (years) | Coincident activities allowed |
|---|---|---|---|---|---|
| (v) Research | Schedule I | New 225-Renewal-225a | 244 | 1 | A researcher may manufacture or im-port the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in § 1301.18 and to distribute such class to persons registered or authorized to conduct re-search with such class of substance or registered or authorized to con-duct chemical analysis with controlled substances |
| (vi) Research | Schedule II – V | New 225-Renewal – 225a | 244 | 1 | May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such sub-stances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to § 1301.24; and conduct instructional activities with controlled substances. |

### 3.c Precursor Chemicals

Precursor Chemicals, in addition to legitimate uses, have the potential to be used in the manufacture of controlled substances. State and federal laws require campus vendors to uphold stringent regulations regarding distribution of these chemical, therefore, researchers must order them through the Purchasing Department as a high value requisition and must have a Controlled Substance Use Authorization on file with EHS. (See Section 6a.)
The federal list (List I Chemicals) can be found at:
https://www.ecfr.gov/current/title-21/chapter-II/part-1310/section-1310.02

The state of California maintains a list of precursor chemicals which includes all federal List I Chemicals plus a few additional chemicals. The state of California precursor chemical list can be found at:
https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=10.&title=&part=&chapter=3.&article=1

The term “Precursor Chemical” will be used throughout this manual and refers to both lists: List 1 Chemicals (Federal list) and precursor chemicals (State of CA list).

A DEA registration or a California Department of Justice registration is required for purchasing precursor chemicals from vendors outside or in California. In addition, a minimum of 21 days processing period is required for such purchases to be completed. Plan to order quantities sufficient for a 3-6 month period to minimize expired waste and risk of theft. Allow time for delivery as this may be impacted depending on whether the hazard class of these chemicals requires shipment by ground transportation.

For more information on this issue, please view this selection from the regulation.

> 11100.1 Report of Controlled Substance Received from Outside State
> (a)Any manufacturer, wholesaler, retailer, or other person or entity in this state that obtains from a source outside of this state any substance specified in subdivision (a) of Section 11100 shall submit a report of that transaction to the Department of Justice 21 days in advance of obtaining the substance. However, the Department of Justice may authorize the submission of reports within 72 hours, or within a time frame and in a manner acceptable to the Department of Justice, after the actual physical obtaining of a specified substance with respect to repeated transactions between a furnisher and an obtainer involving the substances, if the Department of Justice determines that the obtainer has established a record of utilization of the substances for lawful purposes. This section does not apply to any person whose prescribing or dispensing activities are subject to the reporting requirements set forth in Section 11164, or to any manufacturer, wholesaler, retailer, or other person who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration of the United States Department of Justice, or to any analytical research facility that is registered with

the federal Drug Enforcement Administration of the United States Department of Justice.
(b) Any person specified in subdivision (a) who does not submit a report as required by that subdivision shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both that fine and imprisonment.
(2) Any person specified in subdivision (a) who has been previously convicted of a violation of subdivision (a) who subsequently does not submit a report as required by subdivision (a) shall be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both that fine and imprisonment.

To view the entire California Health and Safety code regulation, visit:
California Law/Code Search/ HSC

Recordkeeping found in this manual on the use of controlled substances does not apply to Precursor Chemicals at this time. These chemicals are not included in the controlled substance inventory. For more information, please see Section 10.c.

### 3.d. Authorized User Status

For the proposed project, the Principal Investigator must complete a Controlled Substance Use Authorization (CSUA) application and obtain authorization from EHS to purchase precursor chemicals under UC Irvine's institutional departmental research registration. To have authorization, researchers are required to:

1. Complete the "Controlled Substances" online training found in the UC Learning Center system.
2. Submit a Controlled Substance Use Authorization (CSUA) application for Controlled Substance Use in animals, humans and in-vitro research to EHS.
3. Complete Appendix 1A: Principal Investigator Personnel Screening Data Sheet for PI's. Signed by the Principal Investigator.
4. Complete Appendix 2A: Personnel Screening Data Sheet for all additional personnel working with controlled substances. (If an individual moves to a new laboratory or begins work under a new PI, the individual will need to complete a new Appendix 2A: Personnel Screening Data Sheet with new signatures and remove his/her name from the previous CSUA. Both PI's will need to amend his/her CSUA accordingly).

### 3.e. Principal Investigator Eligibility

**Principal/Co-Principal Investigator (PI) -** The UC Irvine employee/s who is/are responsible for the design, scientific/technical conduct, administrative conduct, and reporting of research, training, or public service projects supported by extramural funding. An essential qualification of the PI is that he or she will personally participate in the project to a significant degree. It is therefore contrary to University policy, to list as head of a project the name of an individual, however prestigious that person may be, who will contribute only a minimum or nominal portion of their own time and effort to the furtherance of the work.
**Lead PI -** The PI of a project as designated by a sponsor in accordance with its policy.
**Investigator -** A UC Irvine employee who is responsible for a portion of the design, scientific/technical conduct, administrative conduct or reporting of a research, training, or public service project supported by extramural funding, without undertaking or assuming the responsibilities of PI.

**Who is Eligible to Serve as Principal Investigator**
PI eligibility is determined in accordance with the University of California Systemwide Contract and Grant Manual (Subchapter 1-500). In addition, and with the approval of the appropriate campus official noted below, a person holding an appointment in one of the following title groups may serve as PI of a training or training-related research project:
1. Supervisor of Physical Education (APM-300) - Vice Chancellor for Research approval
2. Cooperative Extension Advisor (APM-335) - Vice Chancellor for Research approval
3. Continuing Educator (APM-340) - Dean, Division of Continuing Education approval

**Notification of PI Eligibility**
The approval by the Dean or ORU Director of a proposal in Kuali Research will serve as the

notification that the Principal Investigator(s) is eligible to submit the proposal, or an exception has been approved.

Additional guidance of Principal Investigator Eligibility

**Responsibilities**

**4. Controlled Substance Use Authorization for Research in University Facilities**

EHS will grant authorization to those researchers who have a bona fide need to handle, use, or access-controlled substances and precursor chemicals for research purposes. EHS has this authority over all researchers to help assure maintenance of the departmental researcher registrations for UC Irvine. For more information, please see Section 5.

The PI is responsible for ensuring that all staff and students using controlled substances in conjunction with their research and teaching are listed in the PI's CSUA application and will comply with all procedures as described in this manual.

Researchers must obtain authorization from EHS prior to the use, purchase or transport of controlled substances at the UC Irvine campus and UCIMC research laboratories. Controlled substances and Precursor chemicals acquired under UC Irvine's institutional departmental research registrations may not be removed, transported or used at another location unless prior written authorization is provided to EHS with approval from the local DEA office. If you need to transport controlled substances from the campus to the medical center, ensure you have a current CSUA summary from the controlled substance officer.

For further information on how to obtain Controlled Substance Use Authorization, see Section 3.d.

**5. Additional Authorizations or Registrations**

UC Irvine maintains the departmental research registration(s) with the DEA which allows researchers to use controlled substances and precursor chemicals; however, depending on your purpose and CS schedule number (II-IV), state and federal regulations may require you to simultaneously obtain other authorizations or registrations when you apply for a CSUA.

*Bona fide* needs to handle, use, or access controlled substances for research purposes are:

a) Animal Use: Principal Investigators must have an approved animal protocol listing the requested controlled substance. A list of current approved protocols is maintained by EHS through the IACUC. Prior approval by the State Attorney General's Office is required for the use of a Schedule I controlled substance. (See Section 3.b.ii.)

b) Human Use: Principal Investigators must have an approved Human Subjects protocol listing the requested controlled substance. Order requisitions intended for human use must specify an approved protocol number. Prior approval by the State Attorney General's Office is required for use of a Schedule I or II controlled substance. (See Sections 3.b.i., ii.)

In-vitro Use: Principal Investigators must complete the Controlled Substance Use Authorization (CSUA) Form and complete the appropriate sections of the form. For more information, please see Appendix A: Controlled Substances Use Authorization

**Program Components**

**6. Acquisition of Controlled Substances and List I /Precursor Chemicals**

**6.a. Acquisition via Vendors**

All acquisitions of controlled substances and List I / Precursor Chemicals for the purpose of research, instruction and chemical analysis must be requisitioned through the Procurement

Department as a high value requisition and pre-approved by EHS. Order requisitions must be placed under the name of the Principal Investigator who is an Authorized User. A secondary name for contact purposes can be listed on the "requested by" line of the requisition.

Requisitions must be submitted via the Kuali Financial System (KFS) accompanied by the assigned commodity code 51211900 to create a high value requisition by an authorized departmental purchasing agent. Depending on the DEA Registration, delivery of controlled substances will route to EHS. If you received a shipment directly to your laboratory, you must contact the Controlled Substance Program Coordinator immediately.

Procedures for using KFS to purchase controlled substances are located at the EHS Website "How To: Obtain Controlled Substances and Precursor Chemicals for Research". Once a PI has submitted a CSUA application and approval has been granted, EHS will assign a CSUA ID number. PI's and staff are advised to use this number when placing orders.

**6.b. Acquisition via Any Other Company or Institution**

A controlled substance (Schedule II-V) provided by a private company for research purposes must first be requisitioned through Procurement Services at no charge with delivery to EHS and must be pre-approved by EHS (See Section 6.a.) Drugs may not be delivered directly to researchers without EHS approval and/or a DEA 222 form.

**7. Pick Up of Controlled Substances and List I / Precursor Chemicals**

The delivery point of controlled substances is the EHS department on campus. The Controlled Substances Program Officer accepts delivery of orders, opens the orders and verifies order accuracy, and notifies the vendor of any missing or incorrect orders by the next business day following delivery. The Controlled Substances Program Coordinator then notifies the Principal Investigator or staff member who has Authorized User status of the delivery via email. The Principal Investigator is responsible for picking up orders within 3 working days for controlled substances only. Orders will again be counted and verified by the Controlled Substances Program Coordinator with the Principal Investigator or their designate when orders are picked up.

Principal Investigator may designate research staff who have Authorized User status to pick up deliveries from EHS. The option to add a secondary name on the purchase requisition alerts the Controlled Substances Program Coordinator to notify the designee as well as the Principal Investigator of delivery status. Photo identification will be required to pick up all orders. (See Section 6.a).

Approved Precursor chemical orders will be delivered to the Controlled Substances Program Coordinator at the EHS facility on campus. Within 3 business days, arrangements regarding delivery will be made with the primary contact person or authorized personnel in the laboratory.

**8. Transfer of Controlled Substances**

As of July 1, 2009, UC Irvine does not allow the transfers of controlled substances between UC Irvine Principal Investigators as this is no longer allowed under the DEA registration. Please note that it is a felony to provide/possess a controlled substance that is not registered with the DEA.

In addition, researchers may not transfer controlled substances to or from other institutions, either within state lines or across state lines.

Drugs no longer needed for research at UC Irvine must be disposed of in accordance with UC Irvine procedures. (See Section 13).

**9. Storage of Controlled Substances and Records**

Storage of controlled substances must provide for effective prevention of theft. Federal regulations require registrants to store controlled substances in a securely locked and

substantially constructed cabinet. As mandated by the Drug Enforcement Administration (DEA), all controlled substances listed in Schedules II-V must be stored in a securely locked box within a substantially constructed locked cabinet or double lock safe with limited access. Commonly used controlled substances include ketamine, buprenorphine and sodium pentobarbital. If controlled substances are stored in a locking toolbox or other portable storage device, the container must be securely affixed to an immovable object such as a wall. One example of a double-locking system in a l a b is when controlled substances are stored in a steel lock box contained within a locked desk drawer.

Note: The door to a room does not count as a lock in the double-locking system; there must be two locks that unlock solely to access controlled substances. Best practice required that each key to the locks must be kept in secure but different place away from the drug storage location. For labs with wall- mounted key lock boxes, one key should be locked in the lock box and the other key hidden in a distant location away from the lock box; but both keys are not to be stored together. The wall-mounted key lock box does not count as a lock in the double-locking system.

Proper storage of both drugs and usage logs is the responsibility of the Principal Investigator.

Minimum security standards for practitioners are set forth in the regulations (Title 21 CFR 1301.75) and are to be used in evaluating security. They may not necessarily be acceptable for providing effective controls and operating procedures to prevent diversion or theft of controlled substances. *Practitioners include physicians, dentists, veterinarians, researchers, hospitals, pharmacies or other persons registered to do research, dispense, or use in teaching or chemical analysis a controlled substance in the course of professional practice.*

- **Store Controlled Substances according to schedule number:**
  - Schedule I: Store in a safe or steel cabinet equivalent (substantially constructed cabinet).
  - 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 and weigh more than 750 pounds.
  - Storage units:
    - Must be secure enough to show forced entry. Secondary containment (security locked box) is required within a cabinet or drawer for the purpose of safeguarding and separation from other items.
  - 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.

Controlled substances must be stored securely in a manner adequate for safeguarding and must be separated from other drugs, chemicals or items. This practice will help prevent loss by limiting access to those assigned to work with the controlled substances. It is highly recommended that access be limited to one or two individuals. Be aware of DEA regulations that require cabinets to be firmly attached and secured to prevent possible removal.

- Use controlled substances storage units only for controlled substances and their inventory logs.
- Storage restrictions:
  - Do not share controlled substances storage facilities unless this was first approved by the Controlled Substances Program Officer.
  - Do not transfer a controlled substance from its original container for storage purposes.
  - Do not store other chemicals or supplies in a controlled substance storage unit.
  - Do not store a controlled substance in a corridor.

**Access Restriction:**

Restrict access only to authorized personnel on your CSUA and follow these precautions:

- Keep storage key(s) in the physical custody of authorized personnel or a designated secured location with limited access. You can make multiple key copies and assign them to authorized personnel.
- When authorized personnel leave their position in the lab:
  - Change combinations or retrieve the individual's keys.
  - Document authorized personnel security changes in your CSUA.
- Document the removal of authorized personnel from your CSUA by sending an e- mail to occhlth@uci.edu immediately.

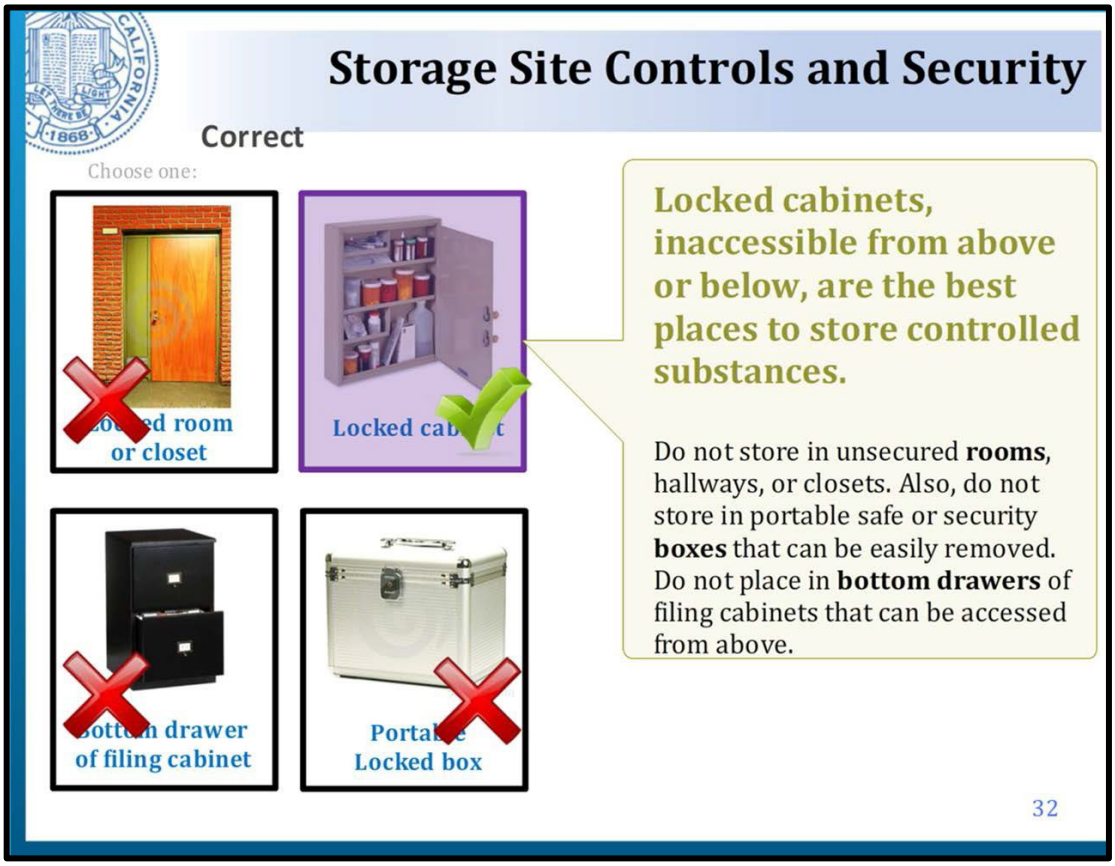
**Dilution and Mixtures of Controlled Substances:**

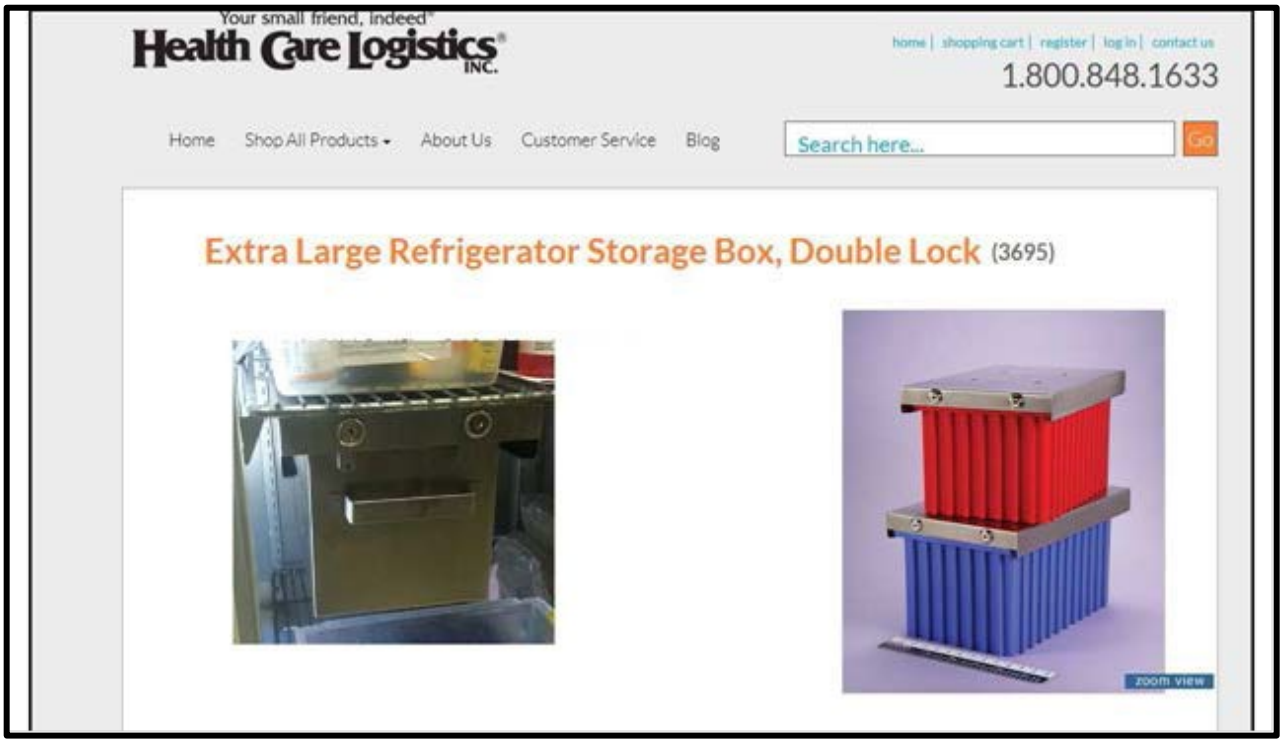
Controlled substances must not be left unattended on the countertops and/or lab benches. Dilutions and mixtures of the stock drug concentration must also be secured (same as pure concentration) and never left unattended and should be labeled properly. The diluted/mix or transferred product should be marked with the name of the drug, drug's lot number, expiration date and the date when the drugs are diluted or opened. Controlled substances must never be used after their expiration date in animal research.

**Acceptable Storage**

1. Safes and steel cabinet equivalents should be cemented or anchored to the floor or wall.
2. Locking storage drawers should be inaccessible from the upper or lower drawers in the stack. Assign the top drawer of the stack for use as drug and record storage.
3. Facilities Management (949 824-5444) can install padlock devices. Devices should be installed so that the mounting screws or bolts of the hasp are inaccessible when the door is closed, and the lock is fastened.
4. The following substance must be stored in a safe: Carfentanil atropine hydrochloride and diprennorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container. For more information visit the following website: https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm
5. Multiple companies and manufacturers sell safes and cabinets for this purpose.
   a. Grainger - www.grainger.com – Security Safe
   b. Health Care Logistics - www.healthcarelogistics.com/ - Narcotic Cabinets
   c. Controlled substances requiring refrigeration may be stored in a locked container securely fastened within a refrigeration unit. Health Care Logistics – Search under "Refrigerator Storage Box, Refrigerator storage lock boxes"

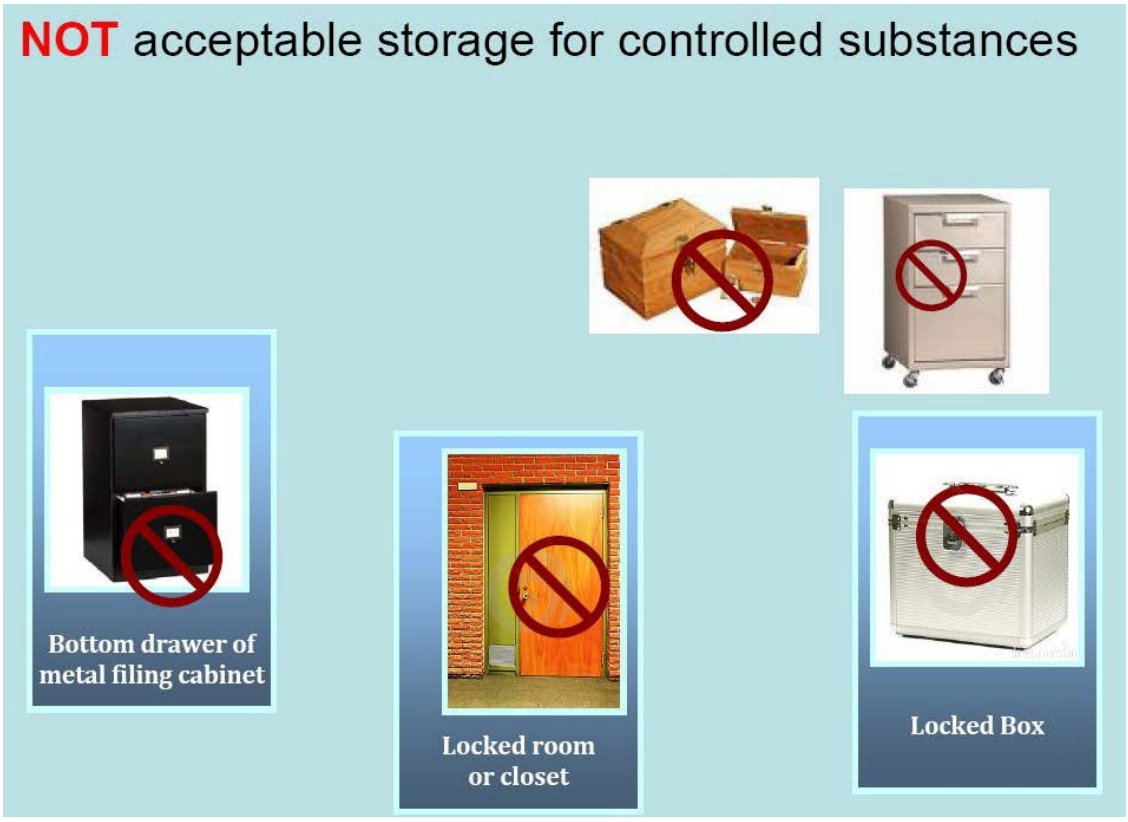
DEA inspectors will check to see if the cabinets are bolted to a permanent structure (i.e., wall or floor) and that the interior double locked compartment is bolted to the main cabinet. Keys allowing access to the controlled substances must be in the possession of authorized individuals.



Unacceptable storage:

1. Portable safety boxes are NOT adequate for storage of controlled substances.
2. Corridor storage of controlled substances is prohibited.




**Reporting Requirements**

**10.a.** **Recordkeeping of Controlled Substances –** ***Title 21 Code Federal Regulations (CFR) 1304.21 21*** ***and*** ***(CFR) 1304.04*** **21 USC§ 827(b)**

**10.b.** Usage Logs

For record keeping consistency, controlled substances usage logs (Appendix B: Controlled Substances Usage Logs for Research) are issued per assigned bottle by the Controlled Substances Program Officer and issued as part of the receipt when picking up controlled substances from EHS.

The PI and his/her staff are required by federal and state law to document the use of controlled substances. Records must include "details" from the date of order pick up from EHS throughout the controlled substance's life cycle, i.e., until containers are empty or disposed of in accordance with proper disposal procedures. (See Section 13.)

Records must be kept secure, preferably in the same secure storage with the drugs. Records must include the order invoice sheet, all usage logs for that order and any disposal records.

Usage logs must include the name and strength of the drug, amount received, name of the Principal Investigator and date of pick up from EHS. When controlled substances are delivered to EHS, completed usage logs will be provided as part of the authorized pick-up process. Usage logs must indicate the amount of each use, date of use, name and signature of the Authorized User using the drug and a balance remaining each day. Initials can be utilized after the first time a name and signature are entered on a usage log. Typically, the usage logs provide a legally defensible paper trail for the controlled drug while it was in

the responsible PI's possession. Without the usage logs, there would be no record of the controlled substances is proper vs. improper use.

**Usage Logs for Diluted/Mixed Controlled Substances**

All actions taken with a controlled substances, including diluting/combining/mixing must be recorded. Per the DEA, the following usage logs are available: Appendix H-1A – Aqueous Mixture Solution usage log and Appendix H-1B – Equithesin usage logs have been created to assist with the control of these items. For example, when diluting Ketamine and Xylazine (liquid to liquid), the aqueous mixture solution usage log is to be used to keep track of remaining solution in addition, the original vial of Ketamine that was used will be keeping track of the stock in the usage log given the lab by EHS during the pick-up.
Same process remains for an equithesin (powder to liquid) mixture solution.

When controlled substances are accidentally destroyed*, damaged or contaminated; there should be a line entry in the usage logs. In the case they are damaged or contaminated, you will need to request for disposal found on the EHS web site at: www.ehs.uci.edu.
**if a controlled substance is destroyed, you will need someone to witness this in the usage log and describe how it was destroyed with two signatures. The person that witnessed should be listed in the CSUA and be aware of all the program requirements.*

California law requires all controlled substance users retain all records relating to acquisition, usage and disposition of controlled substances for three years after disposal or terminal use.

## 10.c. Biennial Inventory and Annual Renewal

The DEA requires an inventory be conducted and documented every 2 years (biennial). The biennial Inventory is a snapshot of the department's on-hand controlled substance inventory at the "close of business" for that day. The annual CSUA renewal includes an annual inventory conducted by the Controlled Substances Program Officer, active CSUA's with no inventory are reported as zero inventory. (Precursor chemicals are not required to be included in the biennial or annual inventory)

**Conducting Inventory and Annual CSUA Renewal Inspection**

The annual inventory is required to be conducted on the same date for the applicable departmental DEA Researcher Registration and documented on Appendix C: UC Irvine Annual Controlled Substances Inventory Log by the Controlled Substances Program Officer. Principal Investigator's with active CSUA's will be notified by EHS when time to renew. Storage, recording keeping, training, personnel access and Office of Research approvals are also monitored for compliance during the CSUA renewal inspection.

## 10.d. Precursor Chemicals Storage and Recordkeeping

Precursor chemicals must be stored according to their hazard type described on the Chemical Hygiene Plan or based on the hazard class of the chemical (e.g., flammable, toxic). List I and California Precursor chemicals must be stored in a locked container within a room that is under human surveillance or locked when not staffed.

Please maintain the following documents for all precursor use:

1. Controlled Substance Use Authorization with a current list of Precursor chemical users.
2. Maintain chemical inventory through UC Chemicals.
3. Packing slips

## 11. Inspections

The Controlled Substances Program Officer conducts an annual scheduled inspection of labs with an active Controlled Substance Usage Authorization (CSUA) with EHS. The inspection includes but not limited to storage, recordkeeping, training records, expiration dates of controlled substances, and authorized personnel with access to controlled substances and/or List I/ precursor chemicals.
The local DEA conducts unannounced inspections of UC Irvine's Controlled Substances Program for Research. The DEA coordinates with EHS upon arrival of which storage locations will be subject to an unannounced audit.

The UC Irvine Institute of Animal Care and Use Committee (IACUC) conducts twice yearly inspections of all laboratories approved for animal research. This inspection includes a check of proper storage recordkeeping and expiration dates of controlled substances.

## 12. Theft

All employees who have knowledge of, or reasonably suspect, theft or significant loss of controlled substances and precursor chemicals, or alteration of records indicating drug loss must immediately report such information to the Controlled Substances Program Officer at EHS at 949-824-6200, the Principal Investigator and/or lab supervisor. If the Controlled Substances is stolen, lost or diversion is suspected EHS will forward information to the UC Irvine Police Department. EHS will submit the required Theft Notification Form to the DEA within the required 24 hours.

## 13. Disposal Procedures

### 13.a. Controlled Substances

When a bottle of a controlled substance is depleted, the empty bottle can be defaced (labels marked with sharpie) and placed in the regular trash by the lab. The log sheet must be marked empty and date of being defaced. Forward copy of the empty bottle usage log to the attention of the Controlled Substances Program Officer at occhlth@uci.edu .This is a requirement mandated by the Controlled Substances Act (CSA) which calls for “cradle to grave” control. The disposal of the empty vial must be recorded in the respective controlled substances accountability record.

To schedule a pick-up of expired or no longer needed, controlled substances, authorized personnel must submit an online request for disposal found on the EHS web site at: www.ehs.uci.edu.
Under hazardous waste pickup, select “Controlled Substances”.

The Controlled Substances Program Officer will coordinate an appropriate agreed pick-up time with the designated laboratory or drop off time at EHS.

Disposal records for controlled substances along with the usage log(s) and order invoice sheet for 3 years after disposal or terminal use. (See Section 10.a).

DEA inspectors require invoices and purchasing records for all controlled substances purchased through UC Irvine for a period of two years be readily available for review. The usage logs and the retrieval of empty bottles provide the ability to trace the use of the controlled substance from purchase to final disposal for the DEA.

### 13.b. List I and/or Precursor Chemicals

To schedule a pick-up of no longer needed Precursor chemicals, authorized personnel must submit an online request for disposal found on the EHS website at: www.ehs.uci.edu. Under hazardous waste pickup; select "Chemical."

Laboratories are required to update the appropriate chemical database when inventory has changed or been updated by UC Chemicals.

For empty List I and/or Precursor chemical bottles, contact the Controlled Substance Program Officer for proper disposal procedure.

### 13.c Diluted/Mixed Controlled Substances

When controlled substances are diluted or combined, each new container must be labeled and tracked.

1. The label must include the name of the controlled substances, lot number (or tracking number), date opened, final concentration, amount per container and expiration date if this is applicable.

2. When syringes are filled and stored in the controlled substance cabinet, a label with the above information must be attached to the syringe.

3. Partial Filled Bottles (e.g., expired, waste, contaminated): All bottles of expired, waste or contaminated controlled substances (except Schedule I substances), must be picked up by EHS.

The DEA strictly regulates the disposal of unwanted controlled substances. If controlled substances are mixed with radioactive waste, the drugs are not eligible for disposal under these guidelines. They should be disposed of as radioactive materials. The disposal of the CS vial must be recorded in the respective controlled substances accountability record.

Upon permanent closure of a researcher's lab or termination of employment, disposal of all controlled substances in accordance with University policies and procedures is required. Controlled substances may not be transferred to another institution. Records of disposal and all usage logs of closed labs must be forwarded to the Controlled Substance Program Officer.

Under no circumstances are controlled substances to be abandoned. However, occasionally faculty will leave without properly disposing of or transferring all controlled substances from their lab. Sometimes faculty acquired the controlled substances before registration was required. Under these circumstances, the school's department is responsible for the lab. Failure to comply with the authorization, storage, security, inventory, and recordkeeping process established within the University's program exposes the departmental DEA Researcher Registration of suspension or removal. Disruption of a departmental registration gravely impacts other researchers' ability to conduct research involving controlled substances and precursor chemicals. In these kinds of circumstance, Department Chairs must contact the Controlled Substance Program Officer to arrange for the appropriate disposal and notification to the DEA.

Employees who violate UC Irvine Policy and Procedures or applicable law related to controlled substances or Precursor chemicals will be subject to disciplinary action, up to and including termination of employment and/or referral to the appropriate law enforcement officials.

Any person who is registered with the DEA who violates recordkeeping requirements or abandons controlled substances will be subject to the civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Please note that abandoning substances is equivalent to distributing a controlled substance to an unauthorized person.

# RESPONSIBILITIES LIST

UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT (UCOP)

UCOP has responsibility for the establishment of the BUS 50 Policy - this policy applies to all authorized campus research and teaching activities which involve dangerous drugs, including controlled substances, listed and/or precursor chemicals, and dangerous devices. The Vice Chancellor for Research has been delegated authority by the Chancellor for the oversight of the program. The Chancellor is also required to assign Power of Attorney for acquisition and registration renewal to the EHS Executive Director. Daily operations and management is re-delegated to the Controlled Substances Program Officer – Environmental Health and Safety. (IDA 605)

ENVIRONMENTAL HEALTH AND SAFETY

Director of Environmental Health and Safety, in collaboration with the Controlled Substances Program Officer include:

1. Oversight of the Controlled Substance Program and precursor chemicals at the University of California, Irvine.
2. Maintain DEA registrations to conduct chemical analysis, instructional activities and research.
3. Maintain procedure manual: **Controlled Substances Use in Research and precursor chemicals** which provides training to researchers on acquisition, recordkeeping, and disposal of controlled substances.
4. Authority to sign applications for registration, DEA order form 222 and reports required under federal and state regulations and maintain CSUA's for the campus.
5. Approve and maintain CSUA's for the campus.
6. Approve purchases of controlled substances and precursor chemicals.
7. Conduct campus-wide inventory of controlled substances used in research.
8. Provide disposal service to researchers for expired or unwanted drugs.
9. Contract with reverse (disposal) vendor to dispose of controlled substances.
10. Consult with researchers on matters related to controlled substance use.
11. Coordinate with reverse distributor for disposal of drugs.
12. Maintain locked storage of drugs for disposal pending transfer to reverse distributor.
13. Collaborate with UCOP on controlled substance issues as needed.
14. Coordinate with state and federal agencies on all compliance related matters.
15. Conduct inspections of research laboratories for proper storage and recordkeeping of controlled substances.
16. Accept delivery of orders, open and verify accuracy of order, and notifies the vendor of any missing or incorrect orders by the next business day following delivery.
17. Store drugs in approved area by DEA.
18. Notify Principal Investigator when orders arrive.
19. Verify counts of controlled substances transferred to individuals with authorization to pick up orders who present photo identification.
20. Provide a usage log to authorized personnel with pick up access
21. Complete DEA 222 forms confirming delivery of Schedule II drugs.
22. Maintain copy of each DEA Form 222 with the corresponding purchase order for 3 years.
23. Store EHS supply of DEA 222 forms in a secure manner to prevent theft or loss.
24. Report on DEA 222 form all Schedule II orders to the DEA.
25. Delivery or pick up of Precursor Chemicals.

PROCUREMENT SERVICES

Director, Procurement Services responsibilities include:

1. Provide copy of DEA registration (renewals) to vendors.
2. Obtain approval from EHS prior to processing orders.
3. Process orders with vendors.
4. Notify EHS when orders are processed.
5. Contract with reverse (disposal) vendor to dispose of controlled substances.
6. Maintain copy of each DEA Form 222 with the corresponding purchase order for 3 years.
7. Maintain Schedule II controlled substance purchase records separate from III – V.

## PRINCIPAL INVESTIGATOR

To comply with federal law, principal investigators (PIs) with projects involving the use of controlled substances are responsible for:

1. Obtaining authorization to utilize controlled substances and precursor chemicals in research from their department and any applicable campus oversight committees, e.g., Animal Care and Use Committee (IACUC) or Institutional Review Board, (IRB).
2. Registering research projects and the individuals who will have access to controlled substances with EHS prior to ordering controlled substances.
3. Ensuring that everyone who will have access to controlled substances has successfully completed Form 2A and completes the training for CS/PS.
4. Keeping accurate inventory and usage records for all controlled substances related to research projects.
5. Ensuring that all controlled substances are kept in a properly secured location.
6. Reporting immediately any changes in personnel approved to work with controlled substances to EHS.
7. Reporting verbally and in writing any theft or loss to EHS immediately upon discovery (EHS must notify DEA within 24 hours.)
8. Contacting EHS for disposal of unwanted or expired controlled substances.
9. Notifying EHS prior to moving laboratories or storage locations on campus or shutting down a laboratory. (Please note: controlled substances may not be transported or transferred to other institutions or PI's).
10. Pick up orders EHS within 3 working days of notification of delivery. May delegate research personnel for pick up according to proper procedures.
11. Maintain Controlled Substance Usage Logs with purchase order invoice for 3 years. Submit inventory and renewals to EHS annually as required.

## RESEARCH PERSONNEL

Research personnel responsibilities include:

1. Obtain "Authorized User" status. Complete all training requirements and obtain authorization to use controlled substances and/or precursor chemicals.
2. Complete Appendix 2A: Personnel Screening Data Sheet for Controlled Substance Use.
3. Maintain usage log according to proper procedures.
4. Maintain security of drugs at all times.
5. Keeping accurate inventory and usage records for all controlled substances related to research projects.
6. Ensuring that all controlled substances are kept in a properly secured location.
7. Reporting verbally and in writing any theft or loss to EHS immediately upon discovery (EHS must notify DEA within 24 hours.)

## OFFICE OF RESEARCH ADMINISTRATION

Institutional Animal Care and Use Committee (IACUC) responsibilities include:

1. Provide EHS a report of IACUC-approved protocols utilizing controlled substances.
2. Perform twice yearly inspections of animal research laboratories for proper storage of controlled substances.

Institutional Review Board (IRB) responsibilities include:

1. Provide EHS a report of IRB-approved protocols utilizing controlled substances.
2. Ensure projects are reviewed by the State Attorney General's Office

**Appendices**

Appendix A:  Controlled Substances Use Authorization

Appendix 1A:  Principal Investigator Personnel Screening Data Sheet

Appendix 2A:  Personnel Screening Data Sheet

Appendix B:  Controlled Substances Usage Logs for Research

Appendix C:  UC Irvine Annual Controlled Substances Inventory Log

Appendix D:  Controlled Substances Purchase Process in Animals and Humans

Appendix E:  Controlled Substances Audit Sheet

Appendix F:  Termination of Controlled Substances Use Authorization

Appendix G:  Precursor Chemicals Audit Sheet Environmental Health and Safety

Appendix H-1A:  Record of Controlled Substances (CS II-V) Aqueous Mixture Solution Usage Log Administered

Appendix H-1B:  Record of Controlled Substances (CS II-V) Stock Solution (Equithesin) Usage Log Administered/Dispensed

Appendix I:  Chemical Precursor (CP) Purchase Process

Appendix J: UCI Controlled Substance Disposal Log

**Appendix A:**

# Controlled Substance and Precursor Chemical Use Authorization (CSUA) Form

This Authorization is required to obtain, possess and/or dispense controlled substances **(CS)**. Controlled substances are inclusive of scheduled drugs (I-V), List 1 Chemicals **(L1)** and/or California Precursor Chemicals **(PC)** for non-patient purposes at UC Irvine. The information described herein is used to obtain Federal licensure for the possession and/or use as described in this document.

**Return your completed and signed form to: Controlled Substances Coordinator/ EHS**

- **Zot code 2725 or occhlth@uci.edu**
- ***Fax a copy to 949-824-4535**

## 1. PI INFORMATION – MUST COMPLETE APPENDIX 1A

| | | |
|---|---|---|
| **Application Type: [ ]** New **[ ]** Annual Renewal **[ ]**Storage Location Change<br>**[ ]** Personnel Removal **[ ]** Personnel Addition **[ ]** Addition of Controlled Substance to existing CSUA #: | | |
| PI's Name(Last, First): | | UCI Employee #: |
| Home Department: | | UCI.EDU e-mail address: |
| Office Address: | | Zot Code: |
| Office Phone: | Fax Phone: | Emergency Phone (after hours)#: |
| Name of Department Chair/Director: | | |
| **Primary Controlled Substance Lab Contact Information: (This person will be contacted for controlled substance audits, recordkeeping, security and any shipment or ordering discrepancies). This person needs to complete Appendix 2A:** | | |
| Name : | Campus Phone: | UCI e-mail address: |

## 2. FACILITY INFORMATION:

Location of Controlled Substance Use: **[ ]** UCI Main Campus **[ ]** UCIMC **[ ]** Off site

location: For Off Site Location, please provide the full address, including if out of state:

| **Building:** ***e.g. Hewitt Hall Required for all (CS, L1, PC)*** | **Room #** ***e.g.103 Required for all (CS, L1,PC)*** | **Shared space** ***Required for all (CS, L1, PC))*** | **Describe in detail the storage cabinets or safe locking device for the controlled substance. (include specific security containers such as cabinet, safe, drawer, refrigerator or other)** ***Contact EHS if this information is not yet available*** ***Only CS users*** | **Describe in detail the type of proposed security for the controlled substance: (i.e. alarms, building access controls, days and hours of operations.) Only CS users** |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| | | [ ]No<br>[ ]Yes, PI's name: | | |
| | | [ ]No<br>[ ]Yes, PI's name: | | |

[ ] No [ ] Yes Is the use location different from the storage location ***(Controlled substances must be returned to approved storage location after procedure)***
List procedure location(s):
Building:
Room:
Building:
Room:
**CS STORAGE LOCATION: Controlled substance storage locations are strictly regulated. Contact the Controlled Substance Program Coordinator at (949) 824-1616 or occhlth@uci.edu for more details before investing in storage facilities. All facilities must be approved by the Controlled Substances Program Coordinator prior to use.**

## 3. AUTHORIZED PERSONNEL *required for all (CS, L1, PC)*

All Personnel listed must complete the Screening Data Sheet: **See Appendix 2A. Additional forms are available at** https://www.ehs.uci.edu/research-safety/occupational-health/controlled-substances/index.php**:**

| **Name:** Last, First | **UCI E-Mail** *e.g. anteater@uci.edu* | **Controlled Substance Screening Data Sheet submitted?** *Yes/No* | **Controlled Substance training completed?** Yes/No | **Authorized to Pickup Controlled Substances at EHS** Yes/No | ***Date Added:*** |
|---|---|---|---|---|---|
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If you need additional rows, hit the Tab button.

**4. Controlled Substance Information required from Title 21 PART 1301.18-Research Protocols**

Name(s) of controlled substance(s) to be used: (DEA drug codes can be found at: http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

**[ ] Animal Protocols: All CS used in animals:**

| Controlled Substance ***Ketamine (Example)*** | DEA Number/ ***7285*** | ***Annual CS estimate for this project 25*** | ***Title of Research Project: Studies Retinal Wound Evaluation with rats*** | Purpose: ***Analgesia, Euthanasia, - mice with spinal injury will be grafted with human spinal stem cells. The recovery of motor functions will be then followed for 6 months*** | Approved Animal Protocol # & Expiration date ***2015-1030 exp 6/2016*** | ***Duration of Project Ongoing, 6 months, 3 years etc.*** | ***Number and Species of Research Subjects 20 rats*** | ***Dosage to be Administered Ketamine: 75-100 mg/kg for*** | ***Route and Method of Administration via intraperitoneal (IP) injection*** |
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**[ ] Human Research:**

| Controlled Substance **(Concerta: methylphenidate)** | DEA # ***1724*** | Schedule **II** | Estimated Average Amount on Hand at any Given Time/ **56 pkg at 160ML** | estimated quantity to be used per year: **6 weeks** | Purpose: **This is a clinical trial to determine if an optimal dose of **** is effective for the treatment of ADHD in **** patients **** years** | IRB Protocol Number **2009-####** | Protocol Expiration Date **MM/DD/YY** | Duration of Project ***Ongoing, 6 months, etc***. |
|---|---|---|---|---|---|---|---|---|
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**[ ] In-Vitro protocol Information (Scheduled Drugs I-V only; not for animal use)**

| Controlled Substance **Diazepam** | DEA # **2765** | Schedule **IV** | Purpose: ***Chemical reagent, TC cell stimulant, chemical standard*** **Determine of melonin concentrating hormone effects*** ** | Duration of Project ***Ongoing, 6 months, etc.*** |
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**[ ] In-Vitro USE information: (L1 and CP only; not for animal use)**

| Precursor Chemical ***Piperidine*** | DEA # ***2704*** | Schedule **L1** | Purpose: *(Chemical reagent, TC cell stimulant, chemical standard* ) ***Agent will be used as reagent for the deprotection of *** in solid-phase organic synthesis to develop anti-tumor compound*** | Duration of Project ***Ongoing, 6 months, etc.*** | Will the CP or L1 chemicals used in this research be used to synthesize another controlled substance? |
|---|---|---|---|---|---|
| | | | | | [ ]No<br>[ ]Yes |
| | | | | | [ ]No<br>[ ]Yes |
| | | | | | [ ]No<br>[ ]Yes |
| | | | | | [ ]No<br>[ ]Yes |
| | | | | | [ ]No<br>[ ]Yes |
| | | | | | [ ]No<br>[ ]Yes |

If you need additional rows, hit the Tab button.

**Appendix 1A:**

# Principal Investigator Personnel Screening Data Sheet (Appendix 1A)

Controlled Substances Program - Environmental Health & Safety -UCI

All Principal Investigators (PI) filing for a Controlled Substance Use Authorization (CSUA) are required to submit a Personal Screening Data Sheet to EH&S, per UCI policies and procedures Sec. 903-15, Section 707-10 and 21CFR1301.90. CS training is required prior to personnel approval per UCOP BUS50.

**PI**: Complete CS Training and submit this form to EH&S by:

- Fax (949-824-4535) E-mail (occhlth@uci.edu) or Mail (Attn: EH&S CSUA, ZOT 2725)

CS Training required through UC Learning Center, keyword search "controlled substances". **Training completed on:** _____

PI Name (First Middle Last): _____ Date of Birth: _____

Driver's License/ID # or Passport#: _____ State/Country_____

UC/Affiliate ID#: _____ Lab/Office Location:_____ Zot Code _____

Home Address:_____

Phone Number:_____ E-Mail Address:_____

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.) If the answer is Yes, furnish details of conviction, offense, location, date, and sentence on additional page.

☐ 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 additional page.

☐ Yes ☐ No

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

☐ Yes ☐ No

By signing below, **I agree to comply with UCI's Controlled Substances Program Policies and Procedures** and 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 will jeopardize my position with the University. Information included herein will not preclude me from utilizing of controlled substances in non-human research at UCI, but will be considered as part of the overall evaluation of qualifications in the application.

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 UCI all such reports can be made confidentially to the Controlled Substances Program Coordinator who will inform the appropriate officials and initiate an investigation of the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries.

Principal Investigator Signature:_____Date:_____

09/2016

**Appendix 2A:**

# Personnel Screening Data Sheet (Appendix 2A)

Controlled Substances Program - Environmental Health & Safety - UCI

All proposed handlers of controlled substances (CS) must submit a Personal Screening Data Sheet to EH&S, per UCI policies and procedures Sec. 903-15, Section 707-10 and 21CFR1301.90. CS training is required prior to personnel approval per UCOP BUS50.

**Applicant:** Complete CS Training and submit this form to your PI for signature. Return form to EH&S by either:

- Fax (949-824-4535) E-mail (occhlth@uci.edu), or Mail (Attn: EH&S CSUA, ZOT 2725)

CS Training required through UC Learning Center, keyword search "Controlled Substances" **Training completed on:**_____

**ASSIGN APPLICANT PRIVILEGES:**

☐ **Designate as CS Lab Contact** (Circle one: Primary / Secondary
☐ **Authorized Recipient** (OK to Pickup Controlled Substance Shipments)

Applicant Name (First Middle Last): _____ Date of Birth: _____

Driver's License/ID # or Passport#: _____ State/Country_____

Employee or Student ID#: _____

Home Address: _____

Lab/Office Location: _____ Phone Number: _____ E-Mail Address:_____

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.) If the answer is Yes, furnish details of conviction, offense, location, date, and sentence on additional page.

☐ 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 additional page.

☐ Yes ☐ No

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

☐ Yes ☐ No

By signing below, **I agree to comply with UCI's Controlled Substances Program Policies and Procedures** and 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 will jeopardize my position with the University. Information included herein will not preclude me from utilizing controlled substances in non-human research at UCI, but will be considered as part of the overall evaluation of qualifications in the application.

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 UCI all such reports can be made confidentially to the Controlled Substance Program Coordinator who will inform the appropriate officials and initiate an investigation of the allegations. The protection of an individual's right to privacy will be upheld in all confidential inquiries.

Applicant signature: _____ Date: _____

PI authorization for the applicant (identified above) to handle and/or access controlled substances issued to PI:

Principal Investigator Signature:_____Date:_____

Principal Investigator name: _____

09/2016

**Appendix B:**

# Controlled Substances (II-V) Usage Log for Research

**One log sheet must be completed for each container of Controlled Substances**



| Top grey section generated by EH&S prior to pick-up by authorized personnel | PI's Name: | CSUA# : | Date Received: | Drug Name – Schedule # (II-V) |
|---|---|---|---|---|
| Unique Bottle ID #: | Container Amount i.e 100 mg, 100 mL: | | Lot or Serial #: | **Expiration Date:** |

| | Date | In Vitro/ /IACUC Protocol # | Authorized Personnel Name | Authorized Personnel Signature | Amount removed (units) from Original Vial i.e 100 mg, 100 mL | Balance (units) |
|---|---|---|---|---|---|---|
| 1 | | | | | | |
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| 3 | | | | | | |
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**If this controlled substance is no longer needed, submit pick-up request www.ehs.uci.edu/ controlled substance.**

- You must keep the original log sheet(s) in your files for 3 years either from the date of disposal or date of complete use: **Retain until: _____**
- When this controlled substance is completely used up, request disposal of empty bottles at https://app.smartsheet.com/b/form/ed47ead9df5646dda0430e5a2fa7b2a6 and have copies of the log sheet available.
- All controlled substances and usage log sheets must be kept adequately secured in approved area by EH&S
- Any log discrepancies, suspected misuse or theft of controlled substances must be reported immediately to EH&S 949-824-6200.
- Ensure Schedule II controlled substance inventory and records are maintained separately from Schedule III – V controlled substances.
- **Ensure record keeping is accurate and readily available to present for unannounced Drug Enforcement Administration (DEA) and EH&S audits**

PI:
CSUA Number:

# Appendix C
# UC Irvine Annual Controlled Substance Inventory Log

This inventory is a requirement of Part 1304.22 CFR*, Records and Reports of Registrants. You must keep a copy of this Inventory Log and the records related to the listed entries for at least 3 years from the date of the inventory for inspection by authorized UCI employees and DEA agents.

1. Your annual inventory must include all the Controlled Substances in your possession as of the date and time given below.
2. When issued a Control Substance Use Authorization (CSUA), an initial inventory must be taken with an actual physical count of all controlled substances in your possession. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory.
3. Prior to your inventory, if you have controlled substances in your possession that are expired or no longer needed i.e., from protocols that are no longer active, you should submit an online Disposal Request. You must include all controlled substances awaiting disposal in your inventory.
4. Schedule I and II drugs must be listed together and separate from Schedule III-V drugs.
5. List partial vials on separate lines.

Information regarding UCI's Controlled Substance Program is available at www.ehs.uci.edu > Occupational Health > Controlled Substances. Contact Monique Skahan, Controlled Substance Coordinator, at occhlth@uci.edu or mskahan@uci.edu if you have any concerns with this Inventory Log or the use of Controlled Substances for research or teaching purposes.

| Name of Drug | Strength per Unit | Volume of Container | # Full, unopened Containers | List Volume Remaining in Each Opened Container Separately |
|---|---|---|---|---|
| Example: Ketamine | 10mg/ml | 10ml vial | 3 | |
| Example: Ketamine | 10mg/ml | 10ml vial | 0 | 9ml |
| Example: Ketamine | 10mg/ml | 10ml vial | 0 | 5ml |
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Forms are available on our website

☐ I have **NO** inventory of Controlled Substances at this time.

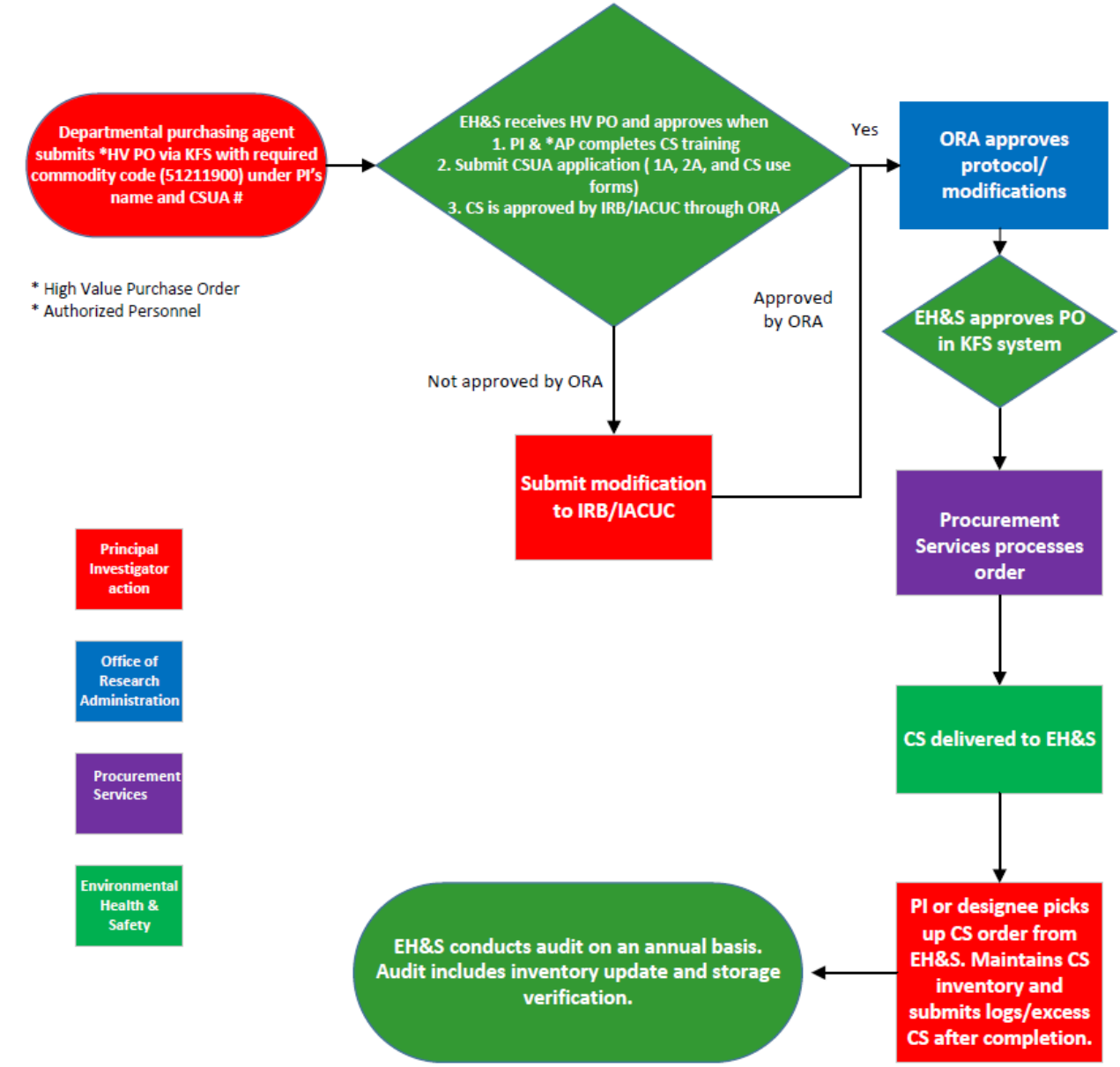
Location of inventory: _____ ☐ Campus ☐ UCIMC ☐ Other site
(Building & Room)

Inventory performed by: Date: _____*Time: am/pm
This inventory was taken ☐ At the start of the day ☐ At the end of the day
**The inventory may be taken either as of opening of business or as of the close of business on the inventory date and shall be indicated on the inventory.*
Code of Federal Regulations Section 1304.11 Inventory Requirements
http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm

Form effective 09/2016

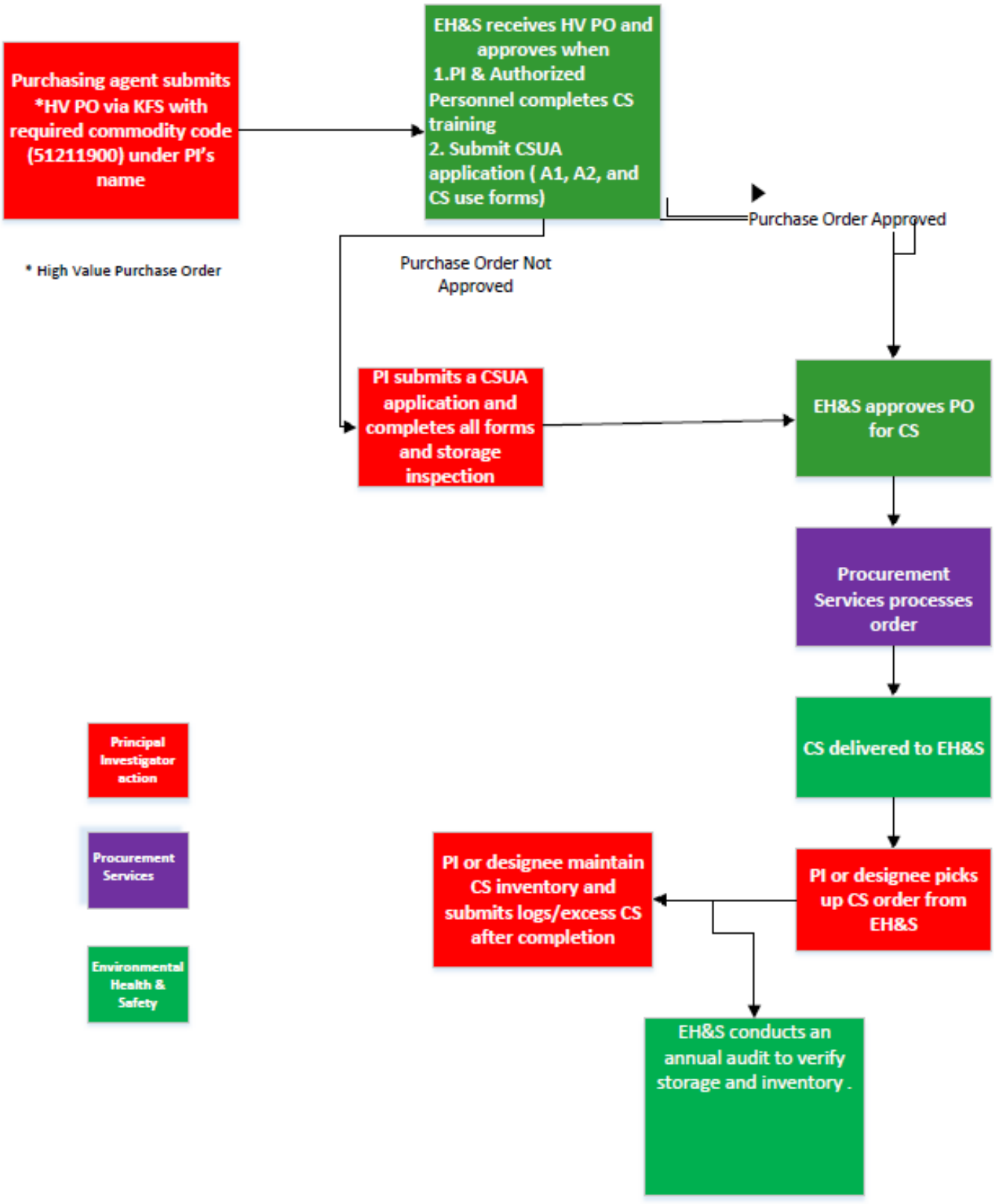
Appendix D: Figure 1

# Controlled Substance Purchase Process in Animals and Humans

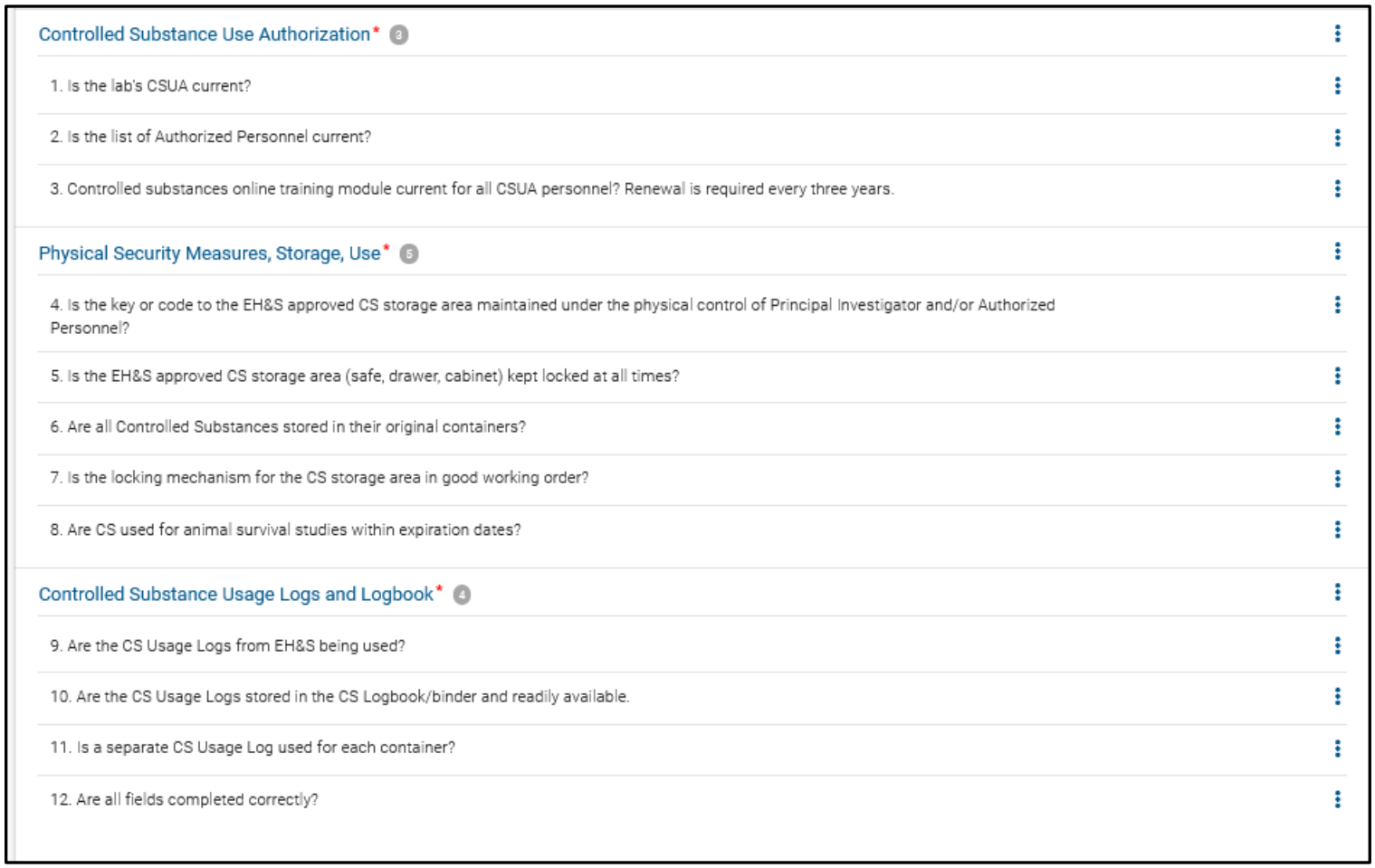


Appendix D: Figure 2

# Controlled Substance Purchase Process for In-vitro Use



# Appendix E: Controlled Substances Audit Sheet



Controlled Substance Use Authorization* 3

1. Is the lab's CSUA current?
2. Is the list of Authorized Personnel current?
3. Controlled substances online training module current for all CSUA personnel? Renewal is required every three years.

Physical Security Measures, Storage, Use* 5

4. Is the key or code to the EH&S approved CS storage area maintained under the physical control of Principal Investigator and/or Authorized Personnel?
5. Is the EH&S approved CS storage area (safe, drawer, cabinet) kept locked at all times?
6. Are all Controlled Substances stored in their original containers?
7. Is the locking mechanism for the CS storage area in good working order?
8. Are CS used for animal survival studies within expiration dates?

Controlled Substance Usage Logs and Logbook* 4

9. Are the CS Usage Logs from EH&S being used?
10. Are the CS Usage Logs stored in the CS Logbook/binder and readily available.
11. Is a separate CS Usage Log used for each container?
12. Are all fields completed correctly?

**Appendix F** **UC IRVINE CONTROLLED SUBSTANCE PROGRAM**

# Termination of Controlled Substances Use Authorization

Environmental Health and Safety

***Use this form to terminate a Principal Investigator's Controlled Substance Use Authorization (CSUA). To dispose of all remaining controlled substances,*** **researchers must submit the Request for Disposal found on the EHS web site at: www.ehs.uci.edu.**

CSUA #_____ Department: _____

PI's Name:_____ Department Chair's Name: _____

☐ I will no longer need authorization to use, purchase, or possess controlled substances for research purposes.

☐ I am aware that the Controlled Substances cannot be transferred to another Principal Investigator, nor can they be taken to another university due to U.S. DEA licensure requirements. All controlled substances remaining in inventory must be disposed of through EHS. *Under no circumstances are controlled substances to be abandoned. Any person who is registered with the DEA who violates recordkeeping requirements or abandons controlled substances will be subject to the civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Please note that abandoning substances is equivalent to distributing a controlled substance to an unauthorized person.*

☐ I have no Controlled Substances remaining in my possession and I have copies of all Controlled Substances Log Sheets.

Principal Investigator Signature:_____ Date: _____

I attest that this PI has relinquished all Controlled Substances under his/her possession.

EHS Witness (Print Name):_____Signature: _____

Title:_____Date: _____

**Return form to EHS Fax 949-824-4535 or Zot Code 2725**

**Question? Call 949-824-6200**

# Appendix G: Precursor Chemicals Audit Sheet Environmental Health and Safety

**Controlled Substance Use Authorization for Precursor Chemicals*** 3

1. Is the lab's CSUA current? Has the lab been informed to keep a copy of the CSUA summary in their lab safety binder?
2. Is the list of Authorized Personnel current?
3. Controlled substances online training module current for all CSUA personnel? Renewal is required every three years.

**Physical Security Measures, Storage and Use*** 2

4. Are the precursor chemical(s) stored based on the hazard class of the chemical (e.g., flammable, toxic)? For more information, please visit the Chemical Hygiene Plan.
5. Are the Precursor chemical(s) stored in a locked container within a room that is under human surveillance or locked when not staffed?

**Precursor(s) chemical listed in appropiate electronic inventory platform.*** 1

6. Are the Precursor chemical(s) listed in the UC Chemicals inventory or Ciber trac?

Appendix H -1A
approved
12/5/2023

# Record of Controlled Substances (CS II-V) Aqueous Mixture Solution Usage Log Administered

**One log sheet must be completed for each container of aqueous solution**

| PI's Name: | CSUA# : | Preparer's Name: | Date mixed: | Container type and volume (e.g. Plastic tube or screw cap vial, 50 ml): | Container ID # (assigned by lab): | Aqueous Solution Expiration date (assigned by lab): |
|---|---|---|---|---|---|---|
| Volume of solution used from Appendix B: (e.g. Ketamine or Buprenex): | | | Lot # from original: | | Concentration of original solution: | |
| Volume of solution used: (e.g. Xylazine) | | | | | | |
| Volume of solution used: (e.g. Other Chemical or Controlled substance): | | | Lot # from original: | | Concentration of original solution: | |
| Final Concentration of new aqueous solution: (e.g 10 mg/mL) | | | | | Final Dilution (e.g 100mL): | |

| | Date | Animal or In vitro | Authorized Personnel Name | Authorized Personnel Signature | Amount removed (units) from stock solution i.e 100 mg, 100 mL | Amount given to animal | Amount Wasted | Balance (units) |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 12 | | | | | | | | |
| 13 | | | | | | | | |
| 14 | | | | | | | | |
| 15 | | | | | | | | |
| 16 | | | | | | | | |
| 17 | | | | | | | | |
| 18 | | | | | | | | |
| 19 | | | | | | | | |
| 20 | | | | | | | | |

**If this controlled substance is no longer needed, submit pick-up request via www.ehs.uci.edu/ controlled substance (CS).**

- You must keep the original log sheet(s) in your files for 3 years either from the date of disposal or date of complete use: **Retain until: _____**
- When this controlled substance is completely used up, request disposal of empty bottles at https://app.smartsheet.com/b/form/ed47ead9df5646dda0430e5a2fa7b2a6 and have copies of the log sheet available.
- All controlled substances and usage log sheets must be kept adequately secured in a proper drawer or safe.
- Any log discrepancies, suspected misuse or theft of controlled substances must be reported immediately to EH&S at 949-824-6200.
- Ensure Schedule II controlled substance inventory and records are maintained separately from Schedule III – V controlled substances.

**Appendix H -1B** approved 12/5/2023

# Record of Controlled Substances (CS II-V) Stock Solution (Equithesin) Usage Log Administered/Dispensed

**One log sheet must be completed for each container of aqueous solution**

| PI's Name: | CSUA# : | Preparer's Name: | Date mixed: | Container type and volume (e.g. Plastic tube or screw cap vial, 50 ml): | Container ID # (assigned by lab): | Equithesin/Solution Expiration date (assigned by lab): |
|---|---|---|---|---|---|---|
| Volume of powder used: ( e.g. Pentobarbital) | | | Lot # from original: | | Expiration Date: | |
| Volume of powder used: (e.g. Chloral Hydrate) | | | Lot # of original: | | Expiration Date: | |
| Volume of powder/liquid used: (e.g. Other) | | | Lot # from original: | | Expiration Date: | |
| Final Concentration of new stock (e.g 10 mg/mL) | | | | | Final Solution (e.g 100mL): | |

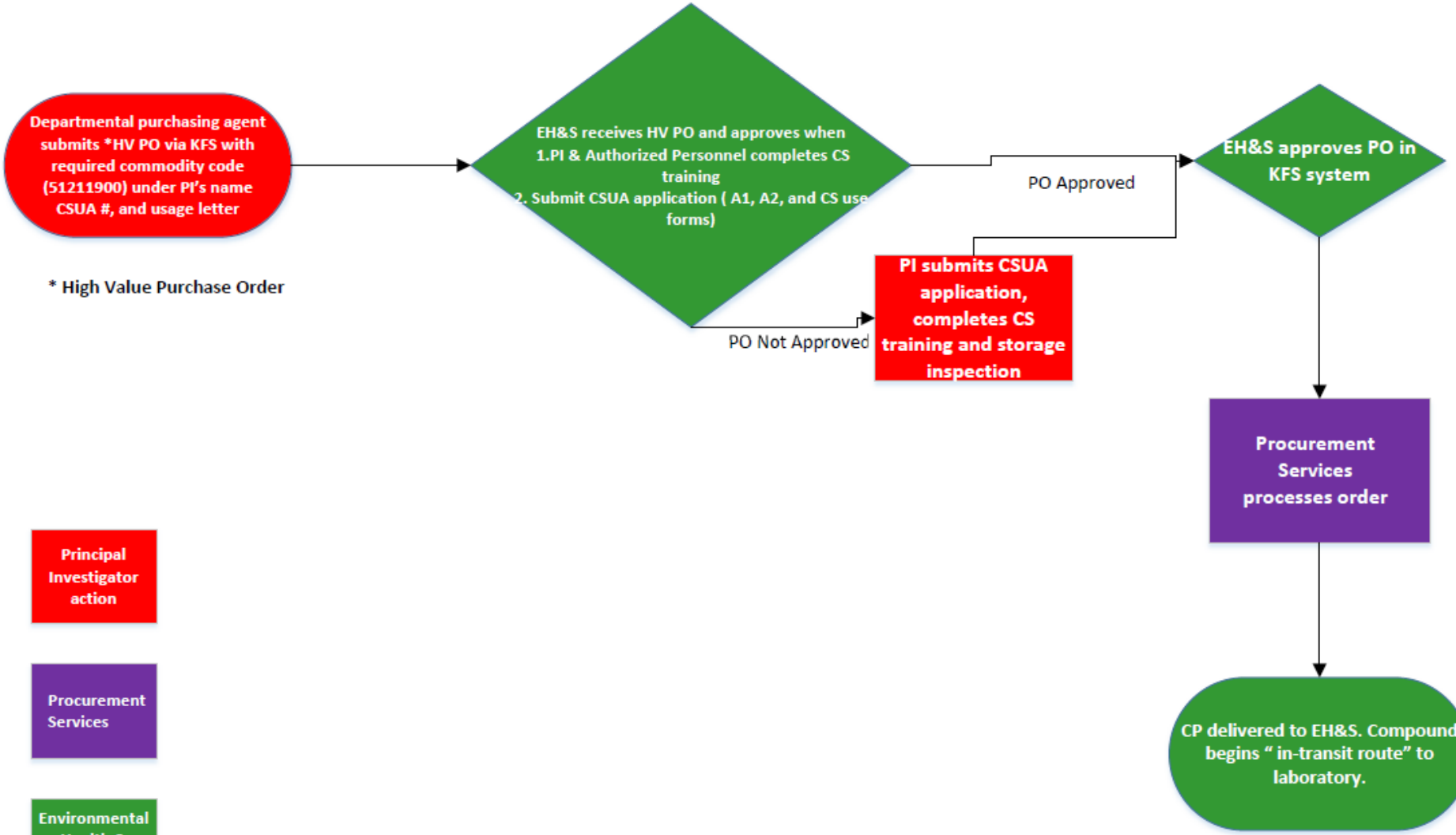
| | Date | Animal or In vitro | Authorized Personnel Name | Authorized Personnel Signature | Amount removed (units) from stock solution i.e 100 mg, 100 mL | Amount given to animal | Amount Wasted | Balance (units) |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 12 | | | | | | | | |
| 13 | | | | | | | | |
| 14 | | | | | | | | |
| 15 | | | | | | | | |
| 16 | | | | | | | | |
| 17 | | | | | | | | |
| 18 | | | | | | | | |
| 19 | | | | | | | | |
| 20 | | | | | | | | |

**If this controlled substance is no longer needed, submit pick-up request via www.ehs.uci.edu/ controlled substance (CS).**

- You must keep the original log sheet(s) in your files for 3 years either from the date of disposal or date of complete use: **Retain until:** _____
- When this controlled substance is completely used up, request disposal of empty bottles at https://app.smartsheet.com/b/form/ed47ead9df5646dda0430e5a2fa7b2a6 and have copies of the log sheet available.
- All controlled substances and usage log sheets must be kept adequately secured in a proper drawer or safe.
- Any log discrepancies, suspected misuse or theft of controlled substances must be reported immediately to EH&S at 949-824-6200.
- Ensure Schedule II controlled substance inventory and records are maintained separately from Schedule III – V controlled substances.

Appendix I:

# Chemical Precursor (CP) Purchase Process




* High Value Purchase Order

Appendix J

DEA Registration #

## UCI Controlled Substance Disposal Log

**Lead Researcher** _____ **Department** _____ **Location**_____

List all of same drug / same size packages being disposed of on one line. See examples below.

| Name of Drug | Strength | Volume of Container | Form | Quantity of Full Packs | List Partial Count per Open Container (list each) | Initials/ Copy of Log |
|---|---|---|---|---|---|---|
| Example 1: Buprenex | 0.3 mg/ml | 1ml per ampule | Liquid | 1 | 3, 3, 4 | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**IMPORTANT: USE LOGS ARE REQUIRED FOR DISPOSAL**

| I verify that the above information **is** correct. | | |
|---|---|---|
| | | |
| Lab Name (print) | Lab initials | Lab Signature / Date |
| | | |
| EHS Name (print) | EHS initials | EHS Signature / Date |

**WHITE—Reverse Distributor** **YELLOW – CS FILE (EH&S)** **PINK – CS LOG BOOK (LAB) KEEP FOR 3 YEARS** **F 12/14/2017**