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1. Introduction:

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 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.

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 policy BUS 50. 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 & Safety (EH&S).

2. Objectives:

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**

3.a **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](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 (21 CFR §1308).

**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., buprenorphine and Zolpidem).

3.b **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.

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 EH&S.
3.b.i. Institutional Research Registration (Schedules II-V)

EH&S maintains the required institutional 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 EH&S prior to obtaining the drugs. Contact EH&S for more information regarding this process.

3.b.ii. Individual Research Registration (Schedule I)

EH&S 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 http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_13.htm

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, http://caag.state.ca.us/research/. This 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. http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_18.htm

<table>
<thead>
<tr>
<th>Business activity</th>
<th>Controlled substances</th>
<th>DEA application forms</th>
<th>Application fee (dollars)</th>
<th>Registration period (years)</th>
<th>Coincident activities allowed</th>
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<tbody>
<tr>
<td>(v) Research</td>
<td>Schedule I</td>
<td>New--225</td>
<td>184</td>
<td>184</td>
<td>A researcher may manufacture or import 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 Sec. 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.</td>
</tr>
<tr>
<td></td>
<td>Renewal--225a</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(vi) Research</td>
<td>Schedules II-V</td>
<td>New--225</td>
<td>184</td>
<td>184</td>
<td>May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or re-registration 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 Sec. 1301.24; and conduct instructional activities with controlled substances.</td>
</tr>
<tr>
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<td></td>
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</table>

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 EH&S. (See Section 6a.)

The federal list (List I Chemicals) can be found at: http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm.
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: http://www.ag.ca.gov/bne/pdfs/laws03.pdf

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)
(1) 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: http://www.ag.ca.gov/bne/pdfs/laws03.pdf

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 EH&S to purchase precursor chemicals under UCI’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 EH&S. See Appendix A.
3. Complete Appendix 1A for PI’s. Signed by the Principal Investigator.
4. Complete Appendix 2A 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 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

All Academic Staff members in the following categories are eligible to participate in the Controlled Substances Program:

Eligibility Table

<table>
<thead>
<tr>
<th>Series and Titles</th>
<th>Principal Investigator Eligibility (1)</th>
<th>Lead Researcher Eligibility</th>
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<tr>
<td>Tenure/Tenure Track</td>
<td>Yes</td>
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<tr>
<td>Assistant, Associate, or Professor</td>
<td>(includes Emeriti)</td>
<td>(includes Emeriti)</td>
</tr>
<tr>
<td>In-Residence</td>
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<tr>
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<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>Clinical &quot;X&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assistant, Associate, or Professor of Clinical ______ (Dept. Name)</td>
<td>Yes, if salaried at 50% or more</td>
<td>Yes, if salaried at 50% or more. (2)</td>
</tr>
<tr>
<td>Clinical (With Salary)</td>
<td></td>
<td></td>
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<tr>
<td>Assistant, Associate, or Clinical Professor</td>
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</tr>
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<tr>
<td>Assistant, Associate, or Professor</td>
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<tr>
<td>Professional Researcher</td>
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<tr>
<td>Assistant, Associate, or Professor</td>
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<td></td>
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<tr>
<td>All other Series, Titles, Appointments</td>
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<td>No. (2)</td>
</tr>
</tbody>
</table>

(1)P For exceptions, see Principal Investigator Eligibility on Sponsored Projects webpage

(2) *Petition Process all other potential series, titles and appointments described above must have special approval from the Vice Chancellor for Research. To obtain such approval, the individual needs to secure a letter from the Department Chairperson, countersigned by the Dean, requesting approval for non-eligible employees. The approved petition should then be submitted to Environmental Health and Safety (EH&S) along with other appropriate application materials.
4. Controlled Substance Use Authorization for Research in University Facilities

EH&S 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. EH&S has this authority over all researchers to help assure maintenance of the institutional research registration(s) for UCI. 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 EH&S 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 UCI's institutional departmental research registrations may not be removed, transported or used at another location unless prior written authorization is provided to EH&S with approval from the local DEA office. If you need to transport controlled substances from the campus to the medical center, ensure you have an approval letter from the controlled substance coordinator.

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

5. Additional Authorizations or Registrations

UC Irvine maintains the institutional 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 EH&S 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.)

c) 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.

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 EH&S. 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 EH&S.
Precursor chemicals are delivered to the lab by EH&S. 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 on the Purchasing Department web site. Once a PI has submitted a CSUA application and approval has been granted, EH&S 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 provided by a private company for research purposes must first be requisitioned through Purchasing and Risk Services at no charge with delivery to EH&S and must be pre-approved by EH&S (See Section 6.a.) Drugs may not be delivered directly to researchers without EH&S approval and/or a DEA 222 form.

7. Pick Up of Controlled Substances and Precursor Chemicals

The delivery point of controlled substances is the EH&S department on campus. The Controlled Substances Program Coordinator 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 EH&S. 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 EH&S 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, UCI does not allow the transfers of controlled substances between UCI 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 UCI must be disposed of in accordance with UCI 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 (http://www.usdoj.gov/dea/pubs/scheduling.html) 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 lab 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 Coordinator.
  - 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 at all times.
  - 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 occhith@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 bolted 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 etorphine hydrochloride and diprenorphine 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: [http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm)
5. Multiple companies and manufacturers sell safes and cabinets for this purpose
   b. Health Care Logistics - [www.healthcarelogistics.com/ - Narcotic Cabinets](http://www.healthcarelogistics.com/)
   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.

**NOT acceptable storage for controlled substances**

10. **Recordkeeping of Controlled Substances** – *Title 21 Code Federal Regulations (CFR) 1304.21 21 United States Code (USC) § 827(a)(3) and (CFR) 1304.04 21 USC § 827(b)*

10.a. **Usage Logs**

For record keeping consistency, the Record of Controlled Substances usage logs (Appendix B) prepared by EH&S must be used. The usage logs are available via the EH&S website or the Controlled Substances Coordinator.

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 EH&S 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 EH&S. When controlled substances are delivered to EH&S, completed usage logs will be dispensed 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 is 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, if you are diluting Ketamine and Xylazine, you will need to keep track of the remaining excess and log it in if you have leftover material. In addition, you will need to keep track of the original vial of Ketamine that was used as part of the original preparation using Appendix B.

Blank Usage Logs are available on the EH&S web site at http://www.ehs.uci.edu/programs/occhlth/control.html. [Other formats of the usage logs are not acceptable per DEA.] (See Appendix B,H-1A and H-1B).

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 EH&S 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. 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.b. Biennial Inventory and Annual Renewal

The DEA requires an inventory be conducted and documented every 2 years. PI's must declare their inventory status even if there is zero CS in stock when biennial inventory is taken. The Biennial Inventory is a snapshot of the department’s on-hand controlled substance inventory at the “close of business” for that day.

Notification of Biennial Inventory

EH&S will notify the PI and CSUA Lab Contact(s) at least 30 days in advance via e-mail. The biennial inventory is to be conducted on a particular date chosen by the DEA agents and Controlled Substances Program Coordinator.

Annual Renewal

Each PI or authorized personnel will be required to sign an inventory log acknowledging the amount of controlled substances in their possession. The inventory takes place during their CSUA annual renewal which will include an inventory update. (See Appendix C).

EH&S requires submission of Annual Renewals which will include an inventory update. Researchers who fail to complete and return the annual update by the requested date will have their Controlled Substance Use Authorization suspended until submission of the Annual Renewal or declaration of controlled substances use termination is received. These recordkeeping requirements do not apply to List I and/or Precursor chemicals.

10.c. 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 CiBR-Trac - Chemical Inventory or ChemInnovation
   (for Chemistry Department)
3. Packing slips

11. Inspections

The Controlled Substance Coordinator will conduct random yearly or biennial inspections of research
labs which use controlled substances and Precursor chemicals. Included is an inspection of the proper
storage and recordkeeping of controlled substances.

The local DEA may conduct random audits and inspections of UCI’s Controlled Substance Program. An
inspection by the DEA would be conducted in coordination with EH&S.

The UCI 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 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 Coordinator at EH&S at 949-824-1616,
the Principal Investigator and/or lab supervisor. If the Controlled Substances is stolen or diversion is
suspected EH&S will forward information to the UC Irvine Police Department. EH&S will submit the
required Theft Notification Form to the DEA within the required 24 hours.

13. Disposal Procedures

13.a. Controlled Substances

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 EH&S web site at: www.ehs.uci.edu.
Under hazardous waste pickup; select "Controlled Substances".

The Controlled Substance Program Coordinator will coordinate an appropriate agreed pick up time with
the designated laboratory.

Principal investigators must maintain a copy of 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).

When a bottle of a controlled substance is depleted, the empty bottle along with the log sheet must be
returned to the Controlled Substances Program Coordinator. 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.

The DEA inspectors will ask to see invoices and purchasing records for all controlled substances
purchased through UCI for a period of two years. The use 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. 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 EH&S 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.

- Physical Sciences – ChemInnovation/CBIS
- All other Schools – CiBR-Trac Hazardous Materials Inventory

For empty List I and/or Precursor chemical bottles, contact the Controlled Substance Program Coordinator 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 EH&S.

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 Coordinator at EH&S Zot code 2725.

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 UCI’s Institutional License to loss of its registration and 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 Coordinator to arrange for the appropriate disposal and notification to the DEA.

Employees who violate UCI 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.


Contact Information:

Environmental Health & Safety

Monique Skahan, Controlled Substance Program Coordinator
949-824-1616
Fax 949-824-4535
Zot Code 2725

Karla Hill, Occupational Health Program Coordinator
949-824-3757
Zot Code 2725

Sheila Hedayati, Assistant Director, Research Safety and Compliance
949-824-9888
Zot Code 2725
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/ EH&S
- Zot code 2725 or occhlth@uci.edu
- *Fax a copy to 949-824-4535

1. PI INFORMATION – MUST COMPLETE APPENDIX 1A

<table>
<thead>
<tr>
<th>Application Type:</th>
<th>New</th>
<th>Annual Renewal</th>
<th>Storage Location Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel Removal</td>
<td></td>
<td>Personnel Addition</td>
<td></td>
</tr>
</tbody>
</table>

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:  

<table>
<thead>
<tr>
<th>Building: e.g. Hewitt Hall Required for all (CS, L1, PC)</th>
<th>Room #: e.g. 103 Required for all (CS, L1, PC)</th>
<th>Shared space Required for all (CS, L1, PC)</th>
<th>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 EH&amp;S if this information is not yet available Only CS users</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] No</td>
<td>[ ] Yes, PI's name:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>[ ] No</td>
<td>[ ] Yes, PI's name:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Version 1.2 09/2016
[ ] 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 [http://www.ehs.uci.edu/programs/occhlth/control.html](http://www.ehs.uci.edu/programs/occhlth/control.html): 

<table>
<thead>
<tr>
<th>Name: Last, First</th>
<th>UCI E-Mail e.g. <a href="mailto:antteater@uci.edu">antteater@uci.edu</a></th>
<th>Controlled Substance Screening Data Sheet submitted? Yes/No</th>
<th>Controlled Substance training completed? Yes/No</th>
<th>Authorized to Pickup Controlled Substances at EH&amp;S Yes/No</th>
<th>Date Added:</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Controlled Substance Ketamine (Example)</th>
<th>DEA Number/ 7285</th>
<th>Annual CS estimate for this project 25 bottles</th>
<th>Title of Research Project: Studies Retinal Wound Evaluation with rats</th>
<th>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</th>
<th>Approved Animal Protocol # &amp; Expiration date 2015-1030 exp 6/2016</th>
<th>Duration of Project Ongoing, 6 months, 3 years etc</th>
<th>Number and Species of Research Subjects 20 rats</th>
<th>Dosage to be Administered Ketamine: 75-100 mg/kg for 60 minutes</th>
<th>Route and Method of Administration via intraperitoneal (IP) injection</th>
</tr>
</thead>
</table>

If you need additional rows, hit the Tab button.
### Human Research:

<table>
<thead>
<tr>
<th>Controlled Substance (Concerta: methylphenidate)</th>
<th>DEA # 1724</th>
<th>Schedule II</th>
<th>Estimated Average Amount on Hand at any Given Time/56 pkg at 160ML</th>
<th>estimate quantity to be used per year: 6 weeks</th>
<th>Purpose: This is a clinical trial to determine if an optimal dose of **** is effective for the treatment of ADHD in **** patients **** years</th>
<th>IRB Protocol Number 2009-####</th>
<th>Protocol Expiration Date MM/DD/YY</th>
<th>Duration of Project Ongoing, 6 months, etc.</th>
</tr>
</thead>
</table>

If you need additional rows, hit the Tab button.
### In-Vitro protocol Information (Scheduled Drugs I-V only; not for animal use)

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>DEA #</th>
<th>Schedule</th>
<th>Purpose: <em>Chemical reagent, TC cell stimulant, chemical standard</em> Determine of melonin concentrating hormone effects***</th>
<th>Duration of Project <em>Ongoing, 6 months, etc.</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>2765</td>
<td>IV</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you need additional rows hit the tab button.

### In-Vitro USE information: (L1 and CP only; not for animal use)

<table>
<thead>
<tr>
<th>Precursor Chemical</th>
<th>DEA #</th>
<th>Schedule</th>
<th>Purpose: <em>(Chemical reagent, TC cell stimulant, chemical standard )</em> Agent will be used as reagent for the deprotection of *** in solid-phase organic synthesis to develop anti-tumor compound</th>
<th>Duration of Project <em>Ongoing, 6 months, etc.</em></th>
<th>Will the CP or L1 chemicals used in this research be used to synthesize another controlled substance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piperidine</td>
<td>2704</td>
<td>L1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 (orcifth@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 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: ________________

Controlled Substance Program, EH&S • Phone: 949-824-8200 • Fax: 949-824-4535 • ZOT CODE 2725
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 UCP 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 (occhth@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 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: __________________________

Controlled Substance Program, EH&S • Phone: 949-824-6200 • Fax: 949-824-4535 • ZOT CODE 2725
Appendix B:

Record of Controlled Substances (II-V) Administered/Dispensed
One log sheet must be completed for each container of Controlled Substances

<table>
<thead>
<tr>
<th>Unique Bottle ID #</th>
<th>PI's Name:</th>
<th>CSUA#:</th>
<th>Date Received:</th>
<th>Drug Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container Amount i.e 100 mg, 100 mL:</td>
<td>Lot or Serial #:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>In Vitro / IACUC Protocol #</th>
<th>Authorized Personnel Name</th>
<th>Authorized Personnel Signature</th>
<th>Amount removed (units) from Original Vial i.e 100 mg, 100 mL</th>
<th>Amount Wasted</th>
<th>Balance (units)</th>
</tr>
</thead>
</table>
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.ohs.uci.edu > Occupational Health > Controlled Substances. Contact Monica Skaham, Controlled Substance Coordinator, at occhih@uci.edu or mskaham@uci.edu, if you have any concerns with this Inventory Log or the use of Controlled Substances for research or teaching purposes.

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Strength per Unit</th>
<th>Volume of Container</th>
<th># Full, unopened Containers</th>
<th>List Volume Remaining in Each Opened Container Separately</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: Ketamine</td>
<td>10mg/ml</td>
<td>10ml vial</td>
<td>3</td>
<td>9ml</td>
</tr>
<tr>
<td>Example: Ketamine</td>
<td>10mg/ml</td>
<td>10ml vial</td>
<td>0</td>
<td>5ml</td>
</tr>
</tbody>
</table>

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

Form effective 09/2016

Version 1.2 09/2016
Appendix D: Figure 1

Controlled Substance Purchase Process in Animals and Humans

* High Value Purchase Order
* Authorized Personnel

Departmental purchasing agent submits *HV PO via KFS with required commodity code (51211900) under PI’s name and CSUA #

EH&S receives HV PO and approves when:
1. PI & *AP completes CS training
2. Submit CSUA application (1A, 2A, and CS use forms)
3. CS is approved by IRB/IACUC through ORA

ORA approves protocol/modifications

Approved by ORA

EH&S approves PO in KFS system

Central Purchasing processes order

CS delivered to EH&S

Submit modification to IRB/IACUC

PI or designee picks up CS order from EH&S. Maintains CS inventory and submits logs/excess CS after completion.

EH&S conducts two audits on an annual basis. Audits include inventory update and storage verification.

Principal Investigator action
Office of Research Administration
Central Purchasing
Environmental Health & Safety

Version 1.2 09/2016
Appendix D: Figure 2

**Controlled Substance Purchase Process for In-vitro Use**

PI submits CSUA application, completes CS training and storage inspection

EH&S receives HV PO and approves when
1. PI & Authorized Personnel completes CS training
2. Submit CSUA application (1A, 2A, and CS use forms)

Approval in place

Not approved

PI submits CSUA application, completes CS training and storage inspection

EH&S approves PO in KFS system

Central Purchasing processes order

CS delivered to EH&S

PI or designee picks up CS order from EH&S. Maintains CS inventory and submits logs/excess CS after completion.

EH&S conducts two audits on an annual basis. Audits include inventory update and storage verification.

* High Value Purchase Order

Departmental purchasing agent submits *HV PO via KFS with required commodity code (51211900) under PI’s name and CSUA #
Appendix E

RESPONSIBILITIES LIST

UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT (UCOP)

UCOP has responsibility for the establishment of policy HTUBUS-50 UT Acquisition and Use of Narcotics and Dangerous Drugs. The Associate Vice Chancellor of Administrative and Business Services has been delegated as the certifying officer to sign required documents in connection with the acquisition and use of controlled substances. The Director Purchasing and Risk Management has been further delegated such authority. TU(IDA267)UT

ENVIRONMENTAL HEALTH & SAFETY

Director of Environmental Health & Safety, in collaboration with the controlled substance coordinator 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 Substance 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 random 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 EH&S 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 of Precursor Chemicals to laboratories.

PURCHASING AND RISK SERVICES

Director, Purchasing and Risk Services responsibilities include:

1. Provide copy of DEA registration (renewals) to vendors.
2. Obtain approval from EH&S prior to processing orders.
4. Notify EH&S 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 EH&S 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 EH&S.
7. Reporting verbally and in writing any theft or loss to EH&S immediately upon discovery (EH&S must notify DEA within 24 hours.)
8. Contacting EH&S for disposal of unwanted or expired controlled substances.
9. Notifying EH&S 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 EH&S 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.
12. Submit inventory and renewals to EH&S 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 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 EH&S immediately upon discovery (EH&S must notify DEA within 24 hours.)

OFFICE OF RESEARCH ADMINISTRATION

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

1. Provide EH&S 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:

2. Ensure projects are reviewed by the State Attorney General's Office.
# Appendix F

## Controlled Substance Audit Sheet

**Environmental Health & Safety**

Labs that use Controlled Substances (CS) should store the Audit Sheet in the Controlled Substance Logbook.

## Controlled Substance Use Authorization

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<td>1.</td>
<td>Is the lab's CSUA current?²,³</td>
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<td>2.</td>
<td>Is the list of Authorized Personnel current (Section 3)?¹,²</td>
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## Physical Security Measures, Storage, Use

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<td>3.</td>
<td>Is the key or code to the EH&amp;S approved CS storage area maintained under the physical control of Principal Investigator and/or Authorized Personnel?²,³</td>
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<td>4.</td>
<td>Is the EH&amp;S approved CS storage area (safe, drawer, cabinet) kept locked at all times?²,³</td>
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<td>5.</td>
<td>Are all Controlled Substances stored in their original containers?²</td>
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<td>6.</td>
<td>Is the locking mechanism for the CS storage area in good working order?²</td>
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<td>7.</td>
<td>Are CS used for animal survival studies within expiration dates? To dispose of unwanted or expired CS, contact EH&amp;S.¹,²</td>
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## Controlled Substance Logbook

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<td>8.</td>
<td>Is a copy of the CSUA located in the CS Logbook/binder?²</td>
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<td>9.</td>
<td>Is a copy of the CS Inventory in the CS Logbook/binder?²</td>
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<td>10.</td>
<td>Is the CS Logbook/binder stored in a locked safe/cabinet/drawer?²</td>
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<td>11.</td>
<td>Is a copy of each CS Purchase Order in the CS Logbook/binder?²</td>
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## Controlled Substance Usage Logs

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<td>12.</td>
<td>Are the CS Usage Logs from EH&amp;S being used?¹,²</td>
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<td>13.</td>
<td>Are the CS Usage Logs stored in the CS Logbook/binder?²</td>
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<td>14.</td>
<td>Is a separate CS Usage Log used for each container?²</td>
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<td>15.</td>
<td>Are all fields completed correctly?²</td>
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<td>16.</td>
<td>Does the amount of material in each CS container match the amount listed on the CS Usage Log?²,³</td>
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</tr>
</tbody>
</table>

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¹ If "N", visit the Controlled Substance website at [http://www.ehs.uci.edu/](http://www.ehs.uci.edu/) for forms and further information.

² If "N", take corrective action as appropriate to fulfill requirement.

³ If "N", contact the Controlled Substance Program Coordinator immediately.

---

**Form 09/2016**

WHITE – CS FILE (EH&S)

YELLOW – CS LOG BOOK/BINDER (LAB)

PINK – PI COPY

Version 1.2 09/2016
Appendix G  UCI CONTROLLED SUBSTANCE PROGRAM

Termination of Controlled Substances Use Authorization

Environmental Health & 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 EH&S 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 EH&S. 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.

EH&S Witness (Print Name): ___________________________ Signature: ___________________________

Title: ___________________________ Date: ___________________________

Return form to EH&S Fax 949-824-4535 or Zot Code 2725

Question? Call 949-824-6200
## 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.

<table>
<thead>
<tr>
<th>PI's Name:</th>
<th>CSUA#:</th>
<th>Preparer's Name:</th>
<th>Date mixed:</th>
<th>Container type and volume (e.g. Plastic tube or screw cap vial, 50 ml):</th>
<th>Container ID # (assigned by lab):</th>
<th>Aqueous Solution Expiration date (assigned by lab):</th>
</tr>
</thead>
</table>

### 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):

<table>
<thead>
<tr>
<th>Date</th>
<th>Animal or In vitro</th>
<th>Authorized Personnel Name</th>
<th>Authorized Personnel Signature</th>
<th>Amount removed (units) from stock solution i.e 100 mg, 100 mL</th>
<th>Amount given to animal</th>
<th>Amount Wasted</th>
<th>Balance (units)</th>
</tr>
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If this controlled substance is no longer needed, submit pick-up request via [www.ehs.uci.edu/ controlled substance (CS)](http://www.ehs.uci.edu/). Retain until:

- 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.
- When this controlled substance is completely used up, request disposal of empty bottles at [https://www.ehs.uci.edu/apps/waste/controls/sub/cscollect.jsp](https://www.ehs.uci.edu/apps/waste/controls/sub/cscollect.jsp) 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.
# Record of Controlled Substances (CS II-V) Stock Solution (Equithesin) Usage Log Administered/Dispensed

One log sheet must be completed for each container of equithesin solution

<table>
<thead>
<tr>
<th>PI's Name:</th>
<th>CSUA# :</th>
<th>Preparer's Name:</th>
<th>Date mixed:</th>
<th>Container type and volume (e.g. Plastic tube or screw cap vial, 50 ml):</th>
<th>Container ID # (assigned by lab):</th>
<th>Equithesin/Solution Expiration date (assigned by lab):</th>
</tr>
</thead>
</table>

**Volume of powder used: (e.g. Pentobarbital)**
- Lot # from original: 
- Expiration Date:

**Volume of powder used: (e.g. Chlortal 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)**

<table>
<thead>
<tr>
<th>Date</th>
<th>Animal or In vitro</th>
<th>Authorized Personnel Name</th>
<th>Authorized Personnel Signature</th>
<th>Amount removed (units) from stock solution i.e 100 mg, 100 mL</th>
<th>Amount given to animal</th>
<th>Amount Wasted</th>
<th>Balance (units)</th>
</tr>
</thead>
</table>
Appendix I: Precursor Chemical (PC) Purchase Process

**Departmental purchasing agent** submits *HV PO via KFS with required commodity code (51211900) under PI’s name and CSUA #

* High Value Purchase Order

**EH&S receives HV PO and approves when**
1. PI & Authorized Personnel completes CS training
2. Submit CSUA application (A1, A2, and CS use forms)
3. Storage inspection in place

**PI submits CSUA application, completes CS training and storage inspection**

**PO Not Approved**

**PO Approved**

**Central Purchasing processes order**

**EH&S approves PO in KFS system**

**By appointment, PC delivered and transferred to PI’s lab. Stored in approved storage.**

**PC delivered to EH&S. Compound begins “in-transit route” to laboratory.**

*Principal Investigator action*

*Central Purchasing*

*Environmental Health & Safety*
# UCI Controlled Substance Disposal Log

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

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Strength</th>
<th>Volume of Container</th>
<th>Form</th>
<th>Quantity of Full Packs</th>
<th>List Partial Count per Open Container (list each)</th>
<th>Initials/ Copy of Log</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example 1: Buprenex</td>
<td>0.3 mg/ml</td>
<td>1ml per ampule</td>
<td>Liquid</td>
<td>1</td>
<td>3, 3, 4</td>
<td></td>
</tr>
</tbody>
</table>

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

I verify that the above information is correct. **3 signatures required**

<table>
<thead>
<tr>
<th>Lab Name (print)</th>
<th>Lab Initials</th>
<th>Lab Signature / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EHS Name (print)</th>
<th>EHS Initials</th>
<th>EH&amp;S Signature / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix K

### Precursor Chemicals Audit Sheet

Environmental Health & Safety

*Laboratories that use Precursor chemicals should store the audit sheet in the Precursor Chemical Binder or combined with your Controlled Substances Binder.*

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
<th>Controlled Substance Use Authorization for Precursor Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Is the lab’s CSUA current? ¹,³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Is the list of Authorized Personnel current (Section 3)? ¹,²</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
<th>Physical Security Measures, Storage and Use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. 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 [<a href="http://www.ehs.uci.edu/programs/lsg/TABLEofCONTENTS.pdf#page=069">http://www.ehs.uci.edu/programs/lsg/TABLEofCONTENTS.pdf#page=069</a>]? ²</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4. Are the Precursor chemical(s) stored in a locked container within a room that is under human surveillance or locked when not staffed? ²</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
<th>Precursor Chemical Binder</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5. Is a copy of the CSUA located in the Precursor chemical Binder? ²</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Y</td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td>N</td>
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<tr>
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<td>N/A</td>
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</tr>
<tr>
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<td>6. Is a copy of each CS Purchase Order and Invoice in the Precursor chemical Binder? ²</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
<th>For Questions 7 and 8, please answer only one of the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7. For Physical Sciences only - is the chemical listed in the Chemical Inventory (CHEMINNOVATION)?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
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<td>N</td>
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<tr>
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<td>N/A</td>
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</tr>
<tr>
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<td></td>
<td>8. For all other Schools - is the chemical listed in CiBR-Trac? ²</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
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<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

¹ If “N”, visit the Controlled Substance website at [http://www.ehs.uci.edu/](http://www.ehs.uci.edu/) for forms and further information.

² If “N”, take corrective action as appropriate to fulfill requirement.

³ If “N”, contact the Controlled Substance Program Coordinator immediately.

**Form 09/2016**