Introduction

This procedure manual describes the University of California, Merced’s Controlled Substance 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, Merced.

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 http://www.ucop.edu/ucophome/policies/bfb/bus50.html.

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

Definitions:

**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) listed 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/alpha/alphabetical.htm. 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).

**Precursor Chemicals**

Precursor chemicals and [List I Chemicals](http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm), 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 chemicals therefore researchers must order them through the Purchasing Department as a high value requisition.

The federal list (List I Chemicals) can be found at: [http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm).

The state of California maintains a list of precursor chemicals which includes all federal List I Chemicals plus a few more chemicals. The state of California precursor chemical list can be found at: [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=5761393734+5+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=5761393734+5+0+0&WAISaction=retrieve).

The term “precursor chemical” will be used throughout this manual and refer to both lists: List 1 Chemicals (federal list) and precursor chemicals (state of CA list).

**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 intended for research purposes acquired though drug companies or any other outside
institutions must be obtained under UC Merced’s institutional DEA research registration.

An individual practitioner’s DEA registration cannot be used to directly acquire controlled substances intended for research, instruction and chemical analysis purposes at UC Merced.

Vendors and suppliers may only deliver controlled substances and precursor chemicals to the address listed on DEA registration. At UC Merced, deliveries for purchases of controlled substances and precursor chemicals are made to:

    PI name and room
    University of California, Merced
    5200 North Lake Road
    Merced, CA 95343

Additional Registrations

The University’s registration with the DEA provide for use of controlled substances in Schedules II through V for non-human research at the UC Merced Campus. Additional registrations may be required.

The Controlled Substances Program Manager from EH&S shall assist the Principal Investigator in applying for any additional DEA registrations. These shall be renewed with the DEA on a yearly basis. If the registration is no longer necessary, it shall be discontinued by the Principal Investigator in writing to the DEA and Controlled Substances Program Manager. This shall be done after all controlled substances have been used or disposed.

Additional registrations are required for 1) use or possession of Schedule I controlled substances at any location for each project, human research requiring Schedule I or II 2) use or possession of controlled substances at locations other than the UC Merced Campus or 3) the manufacture of controlled substances, and 4) teaching/instructional purposes.

1. Projects requiring Schedule I controlled substances, human research requiring Schedule I or II controlled substances:

   At least 8 weeks before controlled substances are to be ordered, a complete written Research Application must be submitted simultaneously by the Principal Investigator to the Controlled Substances Program Manager and to the State of California Research Advisory Panel. Research Application forms are available at:  http://caag.state.ca.us/research/research.htm.

2. Use of controlled substances at locations other than the UC Merced Campus:

   Requests to use Schedule II through V controlled substances, for non-clinical research at locations other than the UC Merced Campus must be made by the Principal Investigator to the Controlled Substances Program Manager in EH&S.

3. Manufacturing of Controlled Substances:
A separate registration is required from the DEA to manufacture controlled substances. The requisite project protocol should define the items being manufactured and the reason(s) for and/or need to manufacture controlled substances. The Manufacturing Registration and corresponding project protocol will be filed with DEA by the Principal Investigator with consultation from the Controlled Substance Program Manager in EH&S.

4. Teaching/Instructional Purposes:

A separate registration is required for controlled substance use for instructional purposes. Any relevant animal, human, or in-vitro experimental protocols must also be provided.

**Campus Authorization Requirements**

A Controlled Substances Use Authorization (CSUA) must be completed prior to acquiring controlled substances. The CSUA form is used to update and keep current the above information for DEA licensing and EH&S Controlled Substances Program management purposes.

The form and instructions are available at [http://ehs.ucmerced.edu/](http://ehs.ucmerced.edu/). Authorizations will be issued annually by project to a specific Principal Investigator by the Controlled Substances Program Manager pending review of laboratory security and authorization information. Requests for renewal authorizations must be submitted for subsequent years of a project. Separate authorization is required for each location of use on the UC Merced Campus.

All applicants and authorizing parties must answer questions concerning 1) felony convictions in connection with controlled substances, 2) surrendering previous registrations or having a registration revoked, suspended, or denied, and 3) any use of narcotics, amphetamines, or barbiturates other than those prescribed to the applicant by a physician. A Departmental Dean cannot authorize his or her own CSUA application.

The CSUA shall be terminated when controlled substances are no longer necessary for corresponding project(s).

A CSUA may remain active during sabbatical leave of the PI as long as an acting PI is named in writing and approved by the Departments Dean and Controlled Substances Program Manager. The acting PI must file a Personnel Screening Data Sheet with EH&S if not already on file. Alternatively, the Department Dean may serve as the acting PI.

In case of sabbatical, a CSUA may be extended for up to 3 months beyond the one-year renewal if, due to extenuating circumstances the PI is not available, e.g., temporarily out of the country. The renewal shall be processed at the PI’s first opportunity upon returning to the project.
Purchasing Controlled Substances

1. All requests for controlled substances, including those provided at no charge to the University, shall be submitted to EH&S via a Purchase Requisition for review by the Controlled Substances Program Manager. CONTROLLED SUBSTANCES ARE NOT TO BE PURCHASED ON A LOW VALUE OR DEPARTMENTAL PURCHASE ORDER. (Purchase req.)

2. The Researcher submits a request through their appropriate administrative office with the following information indicated: name of researcher/PI, indicating the name of the custodian and end-user/researcher, a full item description (name, strength, size of package, etc.), quantity, Schedule number, requested delivery date, and a detailed statement of the purpose and the final delivery and storage location.

3. Purchase Requisitions may only include multiple line items if all items are either in Schedules I and II, or Schedules III through V. Additionally, all items on one Purchase Requisition must be obtained under the same DEA Registration. Controlled substances and non-controlled substances shall be ordered separately.

4. The Purchase Requisition must be signed by the Principal Investigator. Controlled substances for non-patient purposes cannot be purchased with a medical doctor’s clinical DEA Registration.

5. The Controlled Substances Program Manager will review each purchase requisition. Purchase requisitions which match the research needs as described in the CSUA in kind and quantity and are authorized by Principal Investigator signature shall be forwarded to the Purchasing department for order processing.

6. Registration information and DEA 222 forms (for Schedule I & II purchases only) will be forwarded to Purchasing for order placement and processing.

7. The Purchasing Division shall place the order, forward procurement and delivery information to the PI, and maintain a file identifying the name, address, and registration number of the person (vendor) from whom the controlled substance(s) were ordered and received.

The Purchasing Division of the Business and Financial Services Department will monitor for inappropriately procured substances that may have been procured under a departmental purchase order or through use of an incorrect commodity code. EH&S will also monitor for inappropriately acquired substances during site visits.

Receiving

All shipments of controlled substances shall be sent to the registered address, predetermined by the appropriate registration and established with the DEA. The PI is responsible for receiving all controlled substances obtained through the University’s registration. Only the PI may sign for and verify a controlled substance delivery. A Controlled Substance Delivery Record shall be completed and signed by the PI noting any discrepancy or damage on the Controlled Substance Delivery Record. If there is a discrepancy or damage contact the Purchasing office to arrange for return of product. Purchasing will work with the Controlled Substances Program Manager and the vendor to ensure that the most appropriate action is taken.

Once the PI receives and logs the shipment, the shipment must be carried directly to the Principal Investigator’s DEA approved storage location and stored immediately.
Storage, Control, Documentation, and Biennial Inventory

1. Each ordering department shall have adequate security for storage and control as inspected and approved by EH&S in accordance with the following standards:
   a. Storage unit shall only contain controlled substances and corresponding logbooks. No other chemicals or supplies shall be stored in the controlled substances storage area.
   b. Storage unit shall be secure enough to show forced entry.
   c. Storage unit shall be bolted or cemented in place or in excess of 750 pounds.
   d. Corridor Storage of controlled substances is prohibited.
   e. The cabinet shall be equipped with a padlock, pin-tumbler, or combination lock.
   f. If a padlock, pin-tumbler, or combination lock is used, a hasp shall be installed so that there is no access to the mounting screws or bolts when the door is closed and the lock is fastened.
   g. Hinges shall be installed in such a manner as to prevent access to mounting screws or bolts when the door is closed.
   h. The key shall at all times remain in the physical custody of the individual(s) listed by the Principal Investigator on the approved CSUA as Authorized Personnel.
   i. The combination (if any) shall be changed upon termination of Authorized Personnel status. This change shall be documented in the controlled substance logbook.
   j. Key(s) must be retrieved from Authorized Personnel upon termination of Authorized Status.
   k. Storage areas cannot be shared by multiple Principal Investigators.

2. Storage locations for Schedule I and II controlled substances will be inspected and approved by EH&S and the DEA.

3. It is the responsibility of each PI to ensure that a current inventory of all controlled substances under his/her control is maintained on the Controlled Substances Log Sheet, in a separate book for periodic audit by EH&S, the IUCAC and/or the DEA.

4. The controlled substances logbook shall be kept in accordance with EH&S standards. Controlled substance logbooks must be kept in a secure location either inside the approved controlled substances storage area or in close proximity and noted inside the storage area. Controlled Substance Log Sheets for Schedules I & II must be filed in separate logbooks than those for Schedules III-V.

5. All controlled substance dispensations from its original container shall be recorded on the Controlled Substance Log Sheet provided by EH&S. The amount of controlled substances remaining in the drawer must equal the amount documented as remaining in the logbook at all times.

6. Any breakage of containers shall be noted on the corresponding Controlled Substance Log Sheet, initialed by the individual responsible for the breakage and co-signed by the Principal Investigator. A copy of this Controlled Substance Log Sheet shall then be forwarded to EH&S for inventory management and review.

7. Receipts of controlled substances shall be noted on the Controlled Substance Log Sheet. Purchase order numbers and supplier names shall be shown. Departmental copy of purchase order, receipt, and disposal documents shall be maintained by the Principal Investigator in the controlled substance logbook and shall be available upon request.

8. Transfers of controlled substances in Schedules II-V to other Principal Investigators at the same
registration location are allowed only when a transfer of projects has occurred and when approved and coordinated by EH&S. Prior to transfer, a CSUA must be on file with EH&S for the individual requesting the transferred controlled substance(s). Contact the Controlled Substances Program Manager for details.

9. Controlled substances shall not be transferred from the original containers for storage and/or inventory purposes.

10. Access to controlled substances shall be denied to any individual who has had a personal application for registration with the DEA denied or revoked. The Principal Investigator shall maintain a list in the laboratory of those individuals handling controlled substances.

11. It is the responsibility of each authorized personnel to notify the Controlled Substances Program Manager immediately of any theft, loss, or disappearance of controlled substances. The Controlled Substances Program Manager is responsible for notifying the DEA Regional Office and the University of California Police Department.

12. Department Deans are responsible for notifying EH&S prior to Principal Investigator arrival on campus with controlled substances. The Controlled Substances Program Manager shall then contact the DEA to determine the appropriate action. A CSUA application shall be submitted as necessary. Additionally, the Department Dean must notify EH&S when a Principal Investigator authorized to experiment with controlled substances dies or intends to terminate employment. Controlled substances in possession at that time will be disposed of as specified in this manual.

13. EH&S shall maintain a file of all new controlled substances purchased for each Principal Investigator and incorporate these controlled substances into the next inventory cycle.

14. Upon notification by and with directions from EH&S, it is the responsibility of each Principal Investigator to conduct an inventory of all controlled substances.

15. Controlled Substances shall not be transferred, shipped, or removed from the registration location except for in cases of disposal, return to supplier, or by prior agreement with the DEA.

**Returns to Suppliers/Vendors**

To make arrangements to return controlled substances to the supplier/vendor, the Purchasing Division and EH&S must be contacted for instructions. The Purchasing Division will contact the supplier/vendor, identify the documentation needed, and advise the appropriate individuals of the procedure necessary to facilitate the return. Once the return is complete, EH&S will remove the items from its inventory records.

**Disposal**

To make arrangements for disposal of controlled substances in any manner other than the dispensation or use for which they were procured, contact EH&S. EH&S will receive the substances for disposal by completing a Chain of Custody form, indicate on the respective Controlled Substances Log Sheet that they have been received for disposal, and issue a copy of the Chain of Custody form to the laboratory as a receipt. EH&S will hold the substances, pending disposal by the DEA or DEA-approved vendor. Once the disposal has been completed, the respective Controlled Substances Log Sheets must be retained for a minimum of two (2) years by the Principal Investigator. Empty vials can be disposed by authorized personnel in the same manner as any other chemical bottle of similar construction. A copy of the corresponding empty vials’ Controlled Substances Log Sheets shall be sent to the Controlled Substances Program Manager for inventory control.
Disposal must be arranged when:

1. A project has been closed or terminated and controlled substances are still in supply.
2. A Controlled Substance Use Authorization has expired and a renewal has not been submitted.
3. A Principal Investigator determines that the controlled substance is no longer required.
4. A Principal Investigator maintaining controlled substances separates from University employment.
5. A Principal Investigator maintaining controlled substances dies.

In the instances of terminating employment or death of a Principal Investigator, and in addition to the requirement to dispose of any remaining controlled substances, all inventory records, including Log Sheets, must be maintained in the department or forwarded to EH&S for record retention and shall be destroyed 2 years after date of controlled substance disposal.

**Research Advisory Panel**

The Research Advisory Panel (established under Sec. 11480 of the State Health and Safety Code, website: [http://ag.ca.gov/research/index.php](http://ag.ca.gov/research/index.php)) meets to consider new research protocols in California. The following types of activities require approval of the Panel:

1. Research of any nature involving use of controlled substances listed in Schedule I (See Section VI.A.1.).
2. Human research using any Schedule I or Schedule II controlled substance
3. Research for the treatment of drug abuse using any drug, scheduled or not.

The Principal Investigator of each approved program must submit to the Research Advisory Panel an annual progress report each year, or if the program has been completed or discontinued, a final project report. A copy of each report shall also be sent to the Controlled Substances Program Manager at EH&S.

**Exemption of certain chemical preparations**

In rare cases, a chemical preparation or mixture containing one or more controlled substances may be declared exempt from all or any part of the Controlled Substance Act which preparation or mixture is intended for laboratory, educational, or special research purposes and not for general administration to a human being by the Drug Enforcement Administrator. Application for exemption shall be filed by the Principal Investigator. Application requirements can be obtained from the Controlled Substances Program Manager.