CONTROLLED SUBSTANCES PROGRAM MANUAL

The enclosed Controlled Substances Program Manual outlines the regulations and procedures governing the use of controlled substances at the University of California, San Francisco (UCSF) and its satellite locations. All UCSF Principal Investigators and laboratory personnel must adhere to the campus controlled substances policies and procedures in the conduct of their research and clinical activities, and as well as management of their laboratories.

This document supersedes all previous commitments, documents, and procedures.

This manual incorporates changes implemented resulting from recent United States Drug Enforcement Agency requirements. You will receive updated copies of this manual from the Office of Environment, Health and Safety as warranted.

Robert Eaton
Controlled Substance Responsible Official
Environment, Health & Safety Director
# GENERAL REQUIREMENTS

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SECTION 1 GENERAL REQUIREMENTS

A. PURPOSE

The acquisition, use and disposal of controlled substances at UCSF are subject to strict Federal and State Drug Enforcement Administration (DEA) regulations as well as University of California directives. These regulations and directives set specific requirements and restrictions on registration, acquisition, usage, record keeping, transfer, storage and disposal. The purpose of this document is to establish the University of California, San Francisco (UCSF) controlled substance procedures which meet Federal, State and University of California (UC) requirements. Specific references to regulations and University of California mandates are listed in Appendix A.

Individuals who manufacture, distribute, dispense, import, export, conduct research or perform chemical analysis with any controlled substances are subject to a DEA registration. The UCSF campus (locations in San Francisco City and County) is registered with DEA for all research activities involving schedule II through V controlled substances. Research involving schedule I drugs as well as the other activities referenced above require an independent registration directly with the DEA (EH&S must be immediately notified of all independent controlled substance registrations obtained by UCSF campus personnel).

B. DEFINITIONS:

Authorized User – A Principal Investigator or laboratory member who is authorized to possess or use controlled substances by the University or Laboratory.

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

Environment, Health and Safety (EH&S) – The administrative unit that manages the location’s Environment, Health and Safety programs.

Campus Procurement and Contracting (CPC): responsible for procuring controlled substances and listed and precursor chemicals for Authorized University Activities in compliance with DEA registrations, the location’s Controlled Substances Program, and University/Laboratory policies.

Program Administrator – person from Environment, Health and Safety charged with implementing and managing the Controlled Substances Program on a day-to-day basis. This person is also called Controlled Substance Officer.
Responsible Official – personnel with responsibility for oversight of the Controlled Substance Program. This is normally the EH&S Director.

Controlled Substances – Narcotic and non-narcotic drugs under the jurisdiction of the Federal Controlled Substances Act and the California Uniform Controlled Substances Act, including but not limited to those substances listed in 21 CFR §1308.11-1308.15

Listed Chemicals – Under federal law, any List I or List II chemical including a List I chemical specifically designated by the DEA Administrator in 21 CFR §1310.02(a), that in addition to legitimate uses, can be used in manufacturing a controlled substance in violation of the federal Controlled Substances Act, and any List II chemical specifically designated by the DEA Administrator in 21 CFR §1310.02(b), that in addition to legitimate uses is used in manufacturing a controlled substance in violation of the Act.

Precursor Chemical – Under California pharmacy law, a precursor chemical is any chemical that may be used to create controlled substances, including but not limited to catalysts, direct precursors or crucial ingredients used in the production of controlled substances (see also California Health and Safety Code §11100).

C. SCOPE
The procedures described below apply to all UCSF campus laboratory activities and non-medical support facilities, including those under contracts or grants.

D. WHO IS AUTHORIZED TO JOIN THE PROGRAM?
All Academic Staff members in the following categories are eligible to participate in the Controlled Substances Program and can approve purchase of DEA controlled substances upon registration in the program.

- Members of the Academic Senate
- “In Residence,” “Adjunct” and “Clinical” Professors, Associate Professors, Assistant Professors and Instructors
- Professional Research Series Professors serving 50% or more full time. Non-salaried individuals must have special approval; and
- “Emeritus” Professors and Associate Professors subject to decision of the Vice Chancellor of Academic Affairs

The requesting department is responsible for identifying personnel eligible to participate in the program.

1. Eligibility to Petition
   The following may petition for inclusion in the Program:
   - Members with “Emeritus” appointments (Professor or Associate Professor)
• Non-salaried members of the Professional Research Series
• Principal Investigators (PI) not covered by any of the above appointments.

2. Petition Process

All potential PIs falling in the categories described above must have special approval from the Vice Chancellor of Academic Affairs. To obtain such approval, the PI 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 the Office of Environment, Health and Safety (EH&S) along with other appropriate application materials.

3. Eligibility to Co-Authorize Purchase

Academic Staff members eligible to participate in the program may designate their Department Chairperson as co-authorized to approve purchase of DEA controlled substances.

4. Eligibility to receive DEA chemicals

Faculty member participants may designate persons authorized to receive DEA controlled substances. Persons authorized to receive DEA controlled substances must be employed by UCSF; authorized persons are usually laboratory supervisors. Students and postdoctoral fellows with PI authorization are also eligible to receive DEA chemicals. Visiting and collaborating faculty are not eligible.

E. PROGRAM ENROLLMENT

Eligible members may enroll in the program by:

1) Reading this Controlled Substance Program Manual
2) Completing online Controlled Substance Safety training
3) Submitting an online application in Research Information Online (RIO) including:
   a) The “Information on Authorized User of Controlled Substances” form must be filled out and signed by each authorized user including the PI.
   b) Controlled Substance Release Signature Card for the Authorized Recipient of materials
   c) An initial controlled substance inventory form

After enrollment, EH&S assigns a controlled substances number (CSA #) for each approved authorization. Authorized Users must use this internal number
instead of a DEA registration number on all correspondence and requisitions. Approved PIs are required to comply with all aspects of this program including maintenance of usage log, performance of biennial inventory, implementation of security measures, and proper disposal of controlled substances.

After enrollment, any modifications in authorized use locations, security location and method, authorized users and authorized controlled substances can be made by completing an online modification request.

Any changes or modifications to the protocol require review for conformity with the registration conditions. These changes must be approved by EH&S prior to their implementation.

F. RESEARCH ADVISORY PANEL OF CALIFORNIA

California law, pursuant to Health & Safety Code Sections 11480 & 11481, requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II controlled substances, to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General’s Office.

The Research Advisory Panel of California (RAPC) consists of representatives of the California State Department of Health, Board of Pharmacy, Attorney General, one member each from the University of California, a private University, statewide professional medical society and an appointee of the Governor.

The Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The Panel Members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

Who must apply?

Any investigator in the State of California must submit a Research Application to the Panel if planning to conduct:

- Non-Human research of Schedule I controlled substance
- Academic Human research of Schedule I or Schedule II controlled substance
- Research for the Treatment of Controlled Substance Addiction or Abuse utilizing any drug, scheduled or not
It is unlawful to engage in such research without prior Panel authorization.

Researchers using Schedule II (in non-human research) III, IV, or V controlled substances should not apply to the Research Advisory Panel.

Application requirements and guidelines have been developed for each of the above three categories. They are available from RAPC website and:

Research Advisory Panel of California  
455 Golden Gate Avenue, Suite 11000  
San Francisco California 94102-7004  
(415) 703-1373, FAX (415) 703-5889

For more information on the RAPC, see the Research Advisory Panel of California web site: http://caag.state.ca.us/research/

The Panel meets bimonthly (January, March, May, July, September, and November) to consider new and amended research applications. To be eligible for consideration, research protocols must be submitted prior to the submission deadline. Submission deadline information can be found in the RAPC website. Investigators are encouraged to submit protocols as early as possible to permit the Executive Secretary to review applications for completeness and, if necessary, clarify questions prior to meeting. Applicants are also encouraged to contact the Panel’s office for assistance in preparation of research applications.

G. RESPONSIBILITIES

In accordance with the University of California’s Business and Finance Bulletin BUS-50, Controlled Substances Program Best Practices Guide (dated 5/05/09), each campus Chancellor or Laboratory Director is responsible for providing resources to effectively administer a Controlled Substance program and for delegating authority to a Responsible Official in order to establish and oversee the program. The Responsible Official should be a direct report to the Chancellor or Laboratory Director and an individual who is authorized to legally commit on the behalf of the campus or National Laboratory that it will meet the federal and state requirements. The Responsible Official should designate the program’s management team as follows:

The following are the specific responsibilities delegated by the chancellor to individuals or Departments:

1. Participating Department
   - Maintains a list of faculty members participating in the program.
   - Ensures that faculty members are eligible to participate in the program.
• Notifies EH&S to cancel program registration when the PI terminates employment or stops program participation.
• Obtains and submits to EH&S a final inventory, showing that controlled substances remain with the department prior to program termination.
• Ensures that program members sign requisitions form.

2. **Faculty Member Participant (Principal Investigator)**

• Responsible for proper storage, utilization, record keeping and disposal of all controlled substances purchased on their internal Controlled Substance Authorization (CSA).
• Maintains usage logs and inventory for controlled substances for a period of three years.
• Provide EH&S a copy of independent DEA research registration involving Schedule I controlled substances.
• Add Schedule I controlled substances to the CSA after obtaining independent DEA registration.
• Ensures that Schedule I and II controlled substances are stored separately from Schedule III through V.
• Ensures that records for Schedule I and II drugs are kept separate from those for Schedule III through V controlled substances.
• Ensures that drugs acquired under separate DEA registrations are kept in separate locations.
• Ensures that records for controlled substances obtained under separate DEA registrations are kept separate.
• Ensures that controlled substances are kept in a locked area as stipulated in the CSA unless in usage.
• Reports verbally and in writing of theft or loss to EH&S and University of California Police Department (UCPD) immediately upon discovery.
• Applies for additional state and federal approval prior to initiation of any use of Schedule I or Schedule II (human use only) controlled substances.
• Ensures that all paperwork is filled out completely and accurately including drug strength and finished form.
• Contacts EH&S for disposal of controlled substances and used controlled substance containers.
• Completes physical biennial inventory as directed by EH&S.

3. **Program Administrator (EH&S)**

• Implement and manage the Controlled Substances Program on a day-to-day basis
• Reviews internal applications and issues approval numbers.
• Communicates with agencies on all compliance issues.
• Coordinates and performs annual compliance audits.
• Works with UCPD in investigation of drug theft, loss or diversion.
- Notifies diversion incidents (theft or loss) to DEA within 24 hours.
- Maintains files of internal authorizations, inspections and disposal.
- Performs facility closures, including document custody, after a PI informs EH&S of its intent to retire Controlled Substance Authorization.
- Maintains the Controlled Substance Program Manual and provides training.
- Reviews and monitors the security controls
- Coordinates removal and disposal of controlled substance waste.
- Identifies, evaluates and approves controlled substances disposal site(s).
- Reviews permits, licenses and other relevant records to ensure the disposal sites meet regulatory requirements.
- Coordinates biennial inventory and collates data to determine total amount of controlled substances on hand. This inventory must be conducted on a single day for all researchers covered under a blanket registration.
- Maintains copy of past biennial inventories for DEA inspection.
- Provide annual report to the Responsible Official describing status of the program.

**Controlled Substances Distribution Office (or off-site receiving office)**

- Receives copies of all purchase orders and 222 forms (Schedule I & II only) when controlled substances are ordered.
- Review CSA terms and conditions when drug order is delivered to Distribution Office from an outside vendor.
- Receives and stores controlled substances including radioactive controlled substances in a secure cabinet or safe.
- Ensures that Schedule I and II controlled substances are stored separately from Schedule III through V.
- Ensures that records for Schedule I and II drugs are kept separate from those for Schedule III through V controlled substances.
- Ensures that drugs acquired under separate DEA registrations are kept in separate locations.
- Ensures that records for controlled substances obtained under separate DEA registrations are kept separate.
- Maintains log book that contains the following information: PI, controlled substance, strength, form, date received from the carrier, initial and date for technician distributing substance to PI, and initial and name for PI representative picking up substance from distribution office. These records are entered into on-line data-base.
- Ensures that the date and quantity of drugs supplied to researchers is recorded on DEA 222 forms and other records.
- Maintains records of DEA 222 forms (blue copies) for drugs distributed to researchers.
- Maintains records of all controlled substance transactions.
- Notifies laboratory by phone when their orders are ready for pick up.
- Releases orders to researchers who are listed as Authorized Recipients in the CSA and have signature cards on file.
- At time of pick up, authorized recipient will verify accuracy of amount received by initialing log book.
- If controlled substances are not claimed within 30 days of initial lab notification they will be destroyed.

Robert Eaton, EH&S Director, is designated by the Chancellor as the Responsible Official and will be responsible for administering the UCSF Controlled Substances Program. Robert Eaton has delegated the routine operation of the program to various EH&S staff. If there are questions regarding the Program, please call (415) 476-1300 to talk to appropriate EH&S Specialist.

4. Campus Procurement and Contracting (CPC)
- Identifies need for new registrations, assesses current registration limitations, applies for, maintains and renews DEA registrations. Liaison with DEA on registration issues.
- Ensures that geographic locations distinct from the City and County of San Francisco have individual DEA registrations.
- Verifies CSA that PI’s or authorized requestors who submit special requests are authorized to order controlled substances. Reviews purchase requisitions to ensure that signature matches signature on file.
- Issues Purchase Orders (PO) for acquisition of controlled substances from outside vendors.
- Completes 222 forms for purchase of Schedule II drugs. This form is in triplicate. The brown copy is kept by the supplier. The green copy is forwarded by the supplier to the DEA and the blue copy is forwarded to the Controlled Substances Distribution Office for their records.
- Send copies of Purchase Order and 222 forms to EH&S when controlled substance is ordered.
- Aids in vendor selection; reviews vendor stability; initiates vendor security measures on UCSF accounts, identifies product substitutes and evaluates performance and pricing.
- Maintains a database of DEA orders for research and provides reports to EH&S. Liaison to program participants and DEA on issues of registration, acquisition, substance back orders, and other supply concerns.
- Maintains contractual and buying relationship with the vendors.
Jim Hine, Assistant Vice Chancellor/Chief Procurement Officer is responsible for ensuring that all CPC responsibilities are fulfilled. He has delegated his routine responsibilities to various CPC staff. If there are questions regarding the program please call (415) 476-5761 to talk to appropriate CPC staff.

5. UCSF Police

- Receives copies of EH&S reports on theft, loss or diversion of drugs.
- Meets with PI and conduct investigation.
- Provide copy of police report to EH&S and CPC. The report may need to be submitted to DEA.

H. ACQUISITION

The Department Chairman or the PI must determine the need for and sign all requisitions for controlled substances. PIs must follow current CPC purchasing procedures and all orders must have the information below:

- Correct category coding for controlled substances and precursor orders
- CPC order form signed by the PI or Department Chairman
- Account and Fund Numbers, including Fund Year (FY), if applicable
- Substance name, strength or concentration, dosage, schedule #, quantity, and package or unit size
- Contact phone number
- Address information on the requisition

1. Procedure for Executing Order Forms (CPC)

Controlled Substances listed under Schedules II can only be ordered on DEA Form #222. The form shall be prepared as follows:

- The form must be prepared by use of typewriter, computer, or pen.
- There are 10 lines on each form. Only one item can be entered on each numbered line. If one order form is insufficient to include all items in an order, additional forms must be used.
- Order forms for carfentanil, etorphine hydrochloride and diprenorphine must contain only these substances.
- A separate list of items should not be attached.
- The total number of items must be noted on the form in the space provided.
- The name and address of the supplier from whom the items are being ordered must be entered in the form. Only one supplier may be listed in one form.
- Only the Authorized Individual or the alternate, Attorney-In-Fact, may sign the form.
- DEA form #222 must not be used for substances other than controlled substances listed in Schedules I and II.

Controlled Substances listed under Schedules III, IV, and V can be secured by issuance of a standard UCSF purchase order by CPC. Only the Authorized Official or the alternate can sign the purchase order.

2. Controlled Substance Distribution Office

Controlled Substance Distribution Office (Parnassus L235 and Mission Bay N121), hours for researchers will be Monday - Friday 8:00 am to 12:00 pm. Distribution office will notify authorized recipients by phone when their orders are ready. Distribution Office will release controlled substances to authorized recipient only upon presentation of purchase order issued by the CPC.

I. POWER OF ATTORNEY

The Responsible Official may authorize one or more individuals, whether or not located at the registered location as the registrant, to obtain and execute order forms on his behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the Responsible Official and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the Responsible Official and CPC. The Power of Attorney shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records.

Any power of attorney may be revoked by the Responsible Official or his successor at any time by executing a notice of revocation. Notice must be filed with the power of attorney being revoked. The form for the power of attorney and notice of revocation are shown in Appendix D - Power of Attorney for DEA Order Forms.

1. UCSF Policy - Power of Attorney

Persons granted power of attorney must be a Campus Procurement and Contracting employee(s) of the University of California, San Francisco.
Persons granted power of attorney shall be informed in writing of the following:

- The scope of power of attorney
- Effective date of power of attorney
- Effective period of power of attorney
- Pertinent state and federal regulations regarding DEA 222 forms

A copy of this notification shall be sent to the employee’s supervisor, and a copy shall be filed in the employee’s personnel file.

2. Revocation of Power of Attorney

A revocation shall be issued when employees change duties, leave University employment, or otherwise requested by Responsible Official.

3. Record keeping for Power of Attorney

- A record shall be kept by the Responsible Official or delegate, identifying employees who have been issued power of attorney, indicating DEA registration the power was granted for, date of issuance, training on registration and notification letter.
- DEA Form #222 - This form shall be sent to registration address and forwarded to the Responsible Official or delegate. Each form number shall be logged by form number, showing receipt records, in a book for that DEA registration. Un-executed forms shall be kept separate from all other records.
- Any additional regulations printed on DEA Forms, including #222, #224, #225 and #363 forms, shall be followed.

J. RECEIPT OF CONTROLLED SUBSTANCES

1. Receipt at Registration Address

Controlled Substances can only be delivered to the exact address appearing on the DEA registration. This will be the Controlled Substance Distribution Offices as indicated in the UCSF blanket registrations.

2. Processing DEA Form #222 Record Receipt

The Controlled Substance Distribution Office (or equivalent) shall process receipt of Schedule II controlled substances and execute the blue (receiver) copy of DEA Form #222, indicating amount and date received. Persons processing receipt of Schedules III - V controlled substances shall also
indicate amount and date indicate received. Received controlled substance receipt shall be added to the substances inventory.

3. Record Keeping at Controlled Substances Distribution Office (or equivalent)

Personnel with responsibility for registration address shall maintain a log of individuals authorized to execute receipt including date of such authorization. Copies of the authorization shall be given to employee, supervisor, and placed in employee personnel file.

Executed receipt records shall be kept at Controlled Substances Distribution office or registered address until registration has expired or otherwise closed.

4. Transfer to Principal Investigator

Controlled Substance Distribution Office shall ascertain that person(s) receiving material on behalf of the PI is authorized to do so (with a signature card on file and listed as Authorized Recipient on the CSA). Signature verification shall be performed at all times.

5. Principal Investigator Record Keeping

The PI can obtain a Controlled Substance Usage Log via the EH&S website. An equivalent form may be used but must contain all the following information:

- The name of the substance
- The finished physical form (such as 10 mg tablet, or 10 mg concentration per fluid ounce) for each substance and the number of units or volume of finished physical form in each commercial container.
- The number of commercial containers of such finished physical form received from other persons, including the date and number of containers in each receipt.
- The amount of each unit, volume or portions of finished physical form dispensed or used, including:
  a. The date of dispensing
  b. The written or typewritten name or initials of the individual who dispensed or administered the substance.
  c. The reason it was dispensed or used.
d. The number of units or volume of the finished physical forms and/or commercial containers disposed of in any other manner, including the date and the manner of disposal.

- Records shall be maintained and available to EH&S and DEA for three (3) years. It is recommended that all records be maintained for five years.

**K. TRANSFER OF CONTROLLED SUBSTANCES**

Controlled substances used for an individual physician’s private license or other outside licenses cannot be transferred for use under the UCSF DEA registration without approval from EH&S.

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

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

- The substance is approved in the recipient’s CSA.
- The person receiving the substance(s) is an approved user in the CSA.
- Documentation of the transfer is maintained by each lab and a copy sent to EH&S.
- Appropriate security measures are in place

Transfer to another DEA Registration (Parnassus versus Mission Bay) must be discussed with the Program Administrator.

Refer to Appendix B for Transfer Of Controlled Substances Material form

**L. Inventory**

Participating members are required to submit a controlled substance inventory every two years (snap shot biennial inventory). The inventory will be submitted on a specific date and time announced by EH&S. Participating members must submit an on-hand physical inventory for controlled substances present in their labs. Failure to comply with this DEA requirement may result in EH&S terminating of Controlled Substance Authorization (CSA) and CPC suspending orders for controlled substances.

**M. Import and Export**

1. Import
It is unlawful to import Dangerous Drugs, including Controlled Substances into the United States unless the DEA grants an import permit to the University. For Dangerous Drugs that are not controlled substances; the drug is subject to FDA regulations and may require an Investigational New Drug Permit (IND).

2. Export

The University does not permit the export of Dangerous Drugs including Controlled Substances, Federal List I and II chemicals, or California-listed chemicals acquired under a University DEA registration without first obtaining explicit permission from the DEA Office of Diversion Control Import/Export Unit and UCSF’s Program Administrator.

N. TRAINING

All users must complete the controlled substance training provided by EH&S at UC Learning Management System. In addition, PI’s are responsible for providing lab-specific training in the following:

- The nature of controlled substance hazards including local and systemic toxicity.
- The specific research procedures that could result in exposure.
- Importance of properly securing controlled substances, completion of usage logs and reporting procedures for lost and/or missing drugs and Inventory.
- The purpose and application of emergency practices and procedures.
- The employee’s specific role in prescribed emergency procedures.
- Conditions and situations that could result in personal exposure.

O. SECURITY

Effective controls must be established by the participating member to guard against theft and diversion of controlled substances. For security reasons, it is recommended that large amounts of controlled substances be processed on several smaller orders.

The Federal Regulations set specific procedures for prosecution for any illicit activity involving sale, use or diversion of controlled substances. As a result the security of controlled substances needs to be guarded at all levels of usage. To comply with the requirements:
1) A receiving report must be made out which requires the signature of each individual through whose hands a controlled substance passes to and including the ultimate user.

2) Physical security controls must be appropriate for the schedules and quantity of controlled substances on hand. The controlled substances in this lab are stored in the following manner:
   - Schedule I & II: In a drug safe, vault or steel cabinet under lock and key and in a room that has limited access during work hours and is locked during non-working hours.
   - Schedule III to V: In a substantially constructed cabinet under lock and key (without wheels) and in a room that has limited access during work hours and is locked during non-working hours.
   - Others: as approved by the Program Administrator.

3) Access to controlled substances must be restricted to the absolute minimum number of individuals needed and authorized to handle daily transactions in such items.

4) Access to controlled substances may be denied to any individual who has had a personal application for registration with the DEA denied, revoked, or voluntarily surrendered at any time. To comply with this requirement, all personnel working with controlled substances need to complete the Information on Authorized User of Controlled Substance form.

5) Notification of any loss or theft of controlled substances must be made to UCPD and EH&S within 24 hours. EH&S will file the necessary reports including a police report (if needed) with the DEA Regional Office.

Note: Carfentanil, etorpine hydrochloride and diprenorphine must be stored in a safe.

**P. DISPOSAL OF CONTROLLED SUBSTANCES**

Controlled Substances are not allowed to be disintegrated, crushed into powder and dissolved in water for disposal. They must be picked up by EH&S who will arrange proper disposal. EH&S will coordinate and make arrangements with the designated disposal site. Only authorized users can handle and dispose controlled substance waste.

1. **Categories of Waste**

   Controlled Substances that can be surrendered for disposal are defined as follows:
• Wasted Drugs - These include items such as unused tables, injections, oral liquid or preparations compounded in error which contain controlled substances.

• Expired Drugs - These include controlled substances which have exceeded their shelf life, unwanted controlled substances classified as non-formulary, drug or drug that has fallen into disuse.

NOTE: Empty Containers - Insure no residual controlled substance is present, deface label, and dispose in regular trash or glass recycling.

2. Disposal Procedures
To submit controlled substances for disposal, please follow the procedures below:

EH&S disposal request form (Appendix B) must be completed to arrange for disposal. When completing disposal forms, include: Controlled Substance Authorization (CSA) number and expiration date, PI name, building and room number, phone number, if applicable, provide the original registration from where substances were obtained, list the name of the drug (full package drugs must be listed as a separate line item from partial package drugs), completed form must be signed and dated by authorized user.

To request a waste pick-up, fax (415-476-0581) or mail (Box 0942) the completed disposal form to EH&S.

File a copy of signed waste disposal forms in the lab for three years.

Q. CONTROLLED SUBSTANCES AUDIT

Routine audits of the Controlled Substances Program must be performed to:

• Evaluate the effectiveness of the program
• Verify adherence of participating members with federal and state regulations
• Evaluate the efficacy of safe operating procedures.

EH&S Safety Specialists conduct unannounced laboratory audits. The results of the audits are communicated to the PI and the Program Administrator (as needed). The audit includes administrative, security and operational aspects of the program, as well as specific requirements of the DEA registration. Appendix E contains a copy of a sample “Audit Form” and a definition of the terms.
R. DEFINITION OF DRUG CATEGORIES

Federal and State Regulations divide controlled substances into several groups. The schedules are defined below:

1. **Schedule I**
   - The drug or substance has a high potential for abuse.
   - The drug or substance has no currently accepted medical use in treatment in the United States.
   - There is a lack of accepted safety for use of the drug or substance under medical supervision.
   - This schedule has the most stringent requirements and controls.

2. **Schedule II**
   - The drug or other substance has a high potential for abuse.
   - The drug or substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
   - Abuse of the drug or other substance may lead to severe psychological or physical dependence.

3. **Schedule III**
   - The drug or other substance has a potential for abuse less than the drugs or other substances listed in Schedule I and II.
   - The drug or other substance has a currently accepted medical use in treatment in the United States.
   - Abuse of the drug or other substance may lead to moderate or low physical or high psychological dependence.

4. **Schedule IV**
   - The drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule III.
   - The drug or other substance has a currently accepted medical use in treatment in the United States.
   - Abuse of the drug or other substance may lead to limited physical or psychological dependence.
5. **Schedule V**
   - The drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule IV.
   - The drug or other substance has a currently accepted medical use in treatment in the United States.
   - Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs or other substances listed in Schedule IV.

6. **List 1 and 2 Chemicals**
   These substances should be handling in a manner that is equivalent to Schedule V controlled substances.

7. **DEA Controlled Substance List**

8. **CONTROLLED SUBSTANCE REGULATIONS**

9. **GENERAL REQUIREMENTS FOR HUMAN RESEARCH**
   - All controlled substances must be stored in accordance with clinical dispensation and quality assurance requirements.
   - All controlled substance studies involving human research must be approved by the UCSF Committee on Human Research (CHR).
   - DEA controlled Substances dispensed to humans in the course of clinical research shall be dispensed by licensed health professionals certified to do so, after consideration of patient history.
   - Controlled Substances must be FDA approved.
   - Compounding of drugs must be done by licensed individuals following federal guidelines and quality assurance specifications.
   - Use of controlled substance must be consistent with the State Business and Professional Code.

10. **DEA CONTROLLED SUBSTANCE EXEMPTIONS**
There are certain exemptions to the registration requirements which are detailed in the Federal Regulations. These are complex and are limited to products with specific manufacturer, trade name, NDC Code, form and active dosage. These include:

- Non-narcotic substance which may, under the Federal Food, Drug and Cosmetics Act (21 U.S.C. 301) be lawfully sold over the counter.

- The preparation is exempted by the DEA Administrator. These are preparations or mixtures intended for laboratory, industrial, educational or special research purposes and not for general administration to human beings or other animals. These preparations have to meet certain criteria depending whether they contain narcotic or non-narcotic ingredients. These are limited to named suppliers, product names and forms. A listing of the specifics can be found in 21 CFR, Part 1308.23 et. seq.

Contact the CPC or EH&S for specific questions on these items.
APPENDIX A
REFERENCES
The acquisition, use and storage of controlled substances are regulated by a number of Federal and State Regulations as well as policy directives from the University of California Office of the President. The Policies and procedures in this document are based on the following specific references:

- Code of Federal Regulations (CFR), 21 Food and Drugs, Part 1300 to end, revised April 1, 2010.
- California Uniform Controlled Substances Act, Division 10 of the California Health and Safety Code
- Annual Reports of the California Research Advisory Panel
- Letter of August 14, 1972, from Vice-President McCorkle to Chancellors and laboratory Directors: Delegation of Authority-registration and Acquisition of Narcotics and Dangerous Drugs.
- Letter of September 2, 1981 from President Saxon to Chancellors and others: University policy on the Protection of Human Subjects
- Letter of September 2, 1981, from President Saxon to Vice-President Frazer: Delegation of Authority, Protection of Human Subjects in Research.
- Letter of August 14, 1972, from Vice-President McCorkle to chancellors and laboratory directors: delegation of authority registration and acquisition of narcotics and dangerous drugs.
APPENDIX B
UCSF CONTROLLED SUBSTANCE PROGRAM FORMS

All UCSF Controlled Substance Program forms are available on the EH&S website.

- UCSF Controlled Substances Schedule II Disposal Request Form
- UCSF Controlled Substances Schedule III-V Disposal Request Form
- Information on Authorized Users of Controlled Substances Form
- Controlled Substance Release Signature Card Form
- Transfer of Controlled Substances Material Form
- Controlled Substances Inventory Form
- Controlled Substances Usage Log
UCSF CONTROLLED SUBSTANCES SCHEDULE II DISPOSAL REQUEST FORM
Mail: OEH&S, BOX 0942; FAX: (415) 476–0581 (Parnassus); 514-4297 (All other locations)

<table>
<thead>
<tr>
<th>CSA Number</th>
<th>CSA Expiration Date</th>
<th>Phone #</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Name:</td>
<td>Campus Location: Parn, Mission Bay, SFGH, MtZ, LHTS, Other:</td>
<td></td>
</tr>
<tr>
<td>School:</td>
<td>Department: Building: Room:</td>
<td></td>
</tr>
<tr>
<td>Type of DEA Registration: Research, Dispenser, Chemical Analysis, Other:</td>
<td></td>
<td></td>
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</tbody>
</table>

Instructions

1. a) List the controlled substance name and strength (e.g. 100 mg/ml) in column 1.  
   b) National Drug Code in column 2 (number is on the manufacturer's container or paperwork.  
   c) List the amount of controlled substance in column 3 (e.g. 3 packages of 100 tablets, 1 package with 33 tablets of 100). Note: The exact amount of the controlled substance must be specified.

2. Completed form must be signed and dated by principal investigator or authorized user.

3. Send original copy of form to OEH&S Box 0942 or Faxed at (415) 476–0581 (Parnassus) and 514-4297 (all other locations). The PI must also keep a copy.

4. Upon receipt of complete form, OEH&S will schedule the pickup of controlled substances.

<table>
<thead>
<tr>
<th>(1) Controlled Substance Name and Strength</th>
<th>(2) National Drug Code</th>
<th>(3) AMOUNT</th>
<th>(4) Controlled Substance Schedule II ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>QTY PACKAGE SIZE</td>
<td>QTY PARTIAL COUNT PACKAGE SIZE</td>
<td></td>
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<tr>
<td>FULL</td>
<td>PARTIAL</td>
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Schedule II

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Schedule II

Schedule II

PI or Authorized User Print Name, Sign and Date

OEH&S signature and pick-up Date
Instructions

1. a) List the controlled substance name and strength (e.g. 100 mg/ml) in column 1.
   b) National Drug Code in column 2 (number is on the manufacturer’s container or paperwork.
   c) List the amount of controlled substance in column 3 (e.g. 3 packages of 100 tablets, 1 package with 33 tablets of 100). **Note: The exact amount of the controlled substance must be specified.**

2. Completed form must be signed and dated by principal investigator or authorized user.

3. Send original copy of form to OEH&S Box 0942 or Faxed at (415) 476–0581 (Parnassus) and 514-4297 (all other locations). The PI must also keep a copy.

4. Upon receipt of complete form, OEH&S will schedule the pickup of controlled substances.

<table>
<thead>
<tr>
<th>(1) Controlled Substance Name and Strength</th>
<th>(2) National Drug Code</th>
<th>(3) Amount</th>
<th>(4) Controlled Substance Schedule III - V ONLY</th>
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</thead>
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<tr>
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<td>Full</td>
<td>Partial</td>
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<td>QTY PACKAGE SIZE</td>
<td>QTY PARTIAL COUNT PACKAGE SIZE</td>
</tr>
</tbody>
</table>

PI or Authorized User Print Name, Sign and Date     OEH&S signature and pick-up Date
Information on Authorized User of Controlled Substances

This is to be completed by each individual user seeking authorization

User: ___________________________ Title: ___________________________

Last First M.I.

Box: ______ Phone: (___) __________ Principal Investigator: ______________________

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.

Yes - Provide details as attachment  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.

Yes - Provide details as attachment  No

In addition, “I authorize UCSF to make inquiries of courts and law enforcement agencies for possible pending charges or convictions I may have”

Employee Responsibility to Report Drug Diversions (21 CFR, Part 1301.91)

The DEA requires that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area.

At UCSF all such reports can be made confidentially to Director of the Office of Environmental Health and Safety, (476-1794), who will inform the appropriate Campus Officials and initiate and investigation on the allegations.

Illicit Activities by Employees (21 CFR, Part 1301.91)

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

I certify the accuracy of the above information and that I have read, understood and agree with the above statements.

User Signature: ___________________________ Date: ___________________________
Controlled Substance Release Signature Card

INVESTIGATOR (Print/Type) DATE ID/Audit #

DEPARTMENT BOX PHONE

EMAIL ADDRESS

I (Signature)
I am a Principal Investigator at UCSF and expect to be ordering Controlled Substances for research purposes under the campus umbrella registration.

The Department Chairman who will be approving purchases of CONTROLLED SUBSTANCES in my absence is:

NAME (Print/Type) PHONE

SIGNATURE DATE

The person who will be picking up the CONTROLLED SUBSTANCES in my absence is:

NAME & TITLE (Print/Type) PHONE

SIGNATURE DATE

******
TRANSFER OF CONTROLLED SUBSTANCES MATERIAL

Location: (check appropriate campus DEA registration)
____ Parnassus DEA registration (Parnassus, Laurel Heights, Mount Zion)
____ Mission Bay DEA registration (Mission Bay, MCB, SFGH, Hunters Point, China Basin)
Other ________________________________

All transfer must meet the following conditions:

• The material transfer must be within the same DEA Registration
• If transfer is NOT within the same DEA Registration, call the Program Administrator at 415-476-3328.
• The substance is listed/approved in the receiving lab’s CSA.
• The receiving lab will not exceed its maximum possession limit.
• Material is only transferred to an Authorized Recipient.
• Appropriate security measures are in place.
• This transfer form is maintained by each lab.
• A copy of this transfer form is send to EH&S Attention: Program Administrator Box 0942 or emailed to kelly.nguyen@ucsf.edu

Note: The inventory of both labs will be adjusted to account for this transfer.

From: PI: ____________________________ CSA #: _______________________________
To: PI: __________________________________ CSA #: _______________________________

Transferred by: __________________________ Print Name __________________________
Received by Authorized Recipient: Print Name __________________________
Transferred by CSO: __________________________ Print Name __________________________

Date | Controlled Substance | Schedule | Total Quantity * | Form ** | Strength*** | Lot Number | Comments
-----|----------------------|----------|-----------------|--------|------------|------------|----------

*Total Quantity: ml for liquid form and mg/g for powder form
** Form: liquid, powder, tablet, capsule or patch
*** Strength/concentration: mg/ml, %
**CONTROLLED SUBSTANCE INVENTORY FORM**

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Substance Schedule Number</th>
<th>Total Inventory Quantity*</th>
<th>Reason for Substance Being Maintained</th>
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*Total quantity of the substance to the nearest metric unit weight or the total number of units (Schedule I or II: Perform an exact or measure of the contents).

**Authorized PI Signature**

**Print Name (PI)**

**PI Title**

**Department**

**Mail Box #**

**CSA #**

**Phone**

**Date**
One log sheet should be completed for each container of Controlled Substance. Controlled Substance usage must be tracked on a per dose (use) basis. Record total quantity of the substance to the nearest metric unit weight or the total number of units finished form. “Received” includes drugs imported, manufactured, purchased, delivered. “Use” includes exported, disposed, sold, transferred or otherwise utilized.

Principal Investigator: ___________________________ Building & Room Number: _______________

Drug Name: ___________________________ Lot or Serial #: _______________ Form and Strength _______________

<table>
<thead>
<tr>
<th>Date</th>
<th>Amount Received</th>
<th>Amount Used</th>
<th>Amount Transferred</th>
<th>Balance (unit)</th>
<th>Print Name</th>
<th>Initial</th>
<th>Comments</th>
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APENDIX C

TABLE LISTING DEA FORMS
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<thead>
<tr>
<th>Form Number</th>
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<tbody>
<tr>
<td>DEA #106</td>
<td>Report of theft or Loss of Controlled Substances</td>
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<tr>
<td>DEA #222</td>
<td>Ordering Schedules I and II</td>
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<tr>
<td>DEA #224</td>
<td>Registration of Schedule II-V for Instructional Use and Authority to Dispense under Hospital/clinical registration</td>
</tr>
<tr>
<td>DEA #225</td>
<td>Research Registration for Schedule I-V, chemical Analysis Registration and manufacturer Registration</td>
</tr>
<tr>
<td>DEA #363</td>
<td>Narcotic Treatment Program Registration</td>
</tr>
<tr>
<td>DEA #486</td>
<td>Import/Export Declaration for Precursor and Essential Chemicals</td>
</tr>
</tbody>
</table>
APPENDIX D

POWER OF ATTORNEY FORM
APPENDIX E

CONTROLLED SUBSTANCE AUDIT CHECKLIST
APPENDIX F

DEA CONTROLLED SUBSTANCE LIST