

# **CONTROLLED SUBSTANCES PROGRAM**

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
OFFICE OF ENVIRONMENTAL HEALTH AND  
SAFETY**

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## 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 Environmental Health and Safety as warranted.

  
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## **SECTION 1 GENERAL REQUIREMENTS**

### **A. PURPOSE**

The acquisition, use and disposal of Controlled Substances at UCSF is 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 (OEHS must be immediately notified of all independent Controlled Substance registrations obtained by UCSF campus personnel).

### **B. SCOPE**

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

### **C 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 Environmental Health and Safety (OEH&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**

Program 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.

## ***D. PROGRAM ENROLLMENT***

Eligible members may enroll in the program by completing the following and submitting to OEH&S:

- Two Controlled Substance Release Signature Cards (one to be filed with Materiel Management and the other with the Controlled Substances Distribution Office).
- A beginning inventory sheet showing “0” balance records for Controlled Substances filed with OEH&S.
- The “Information on Authorized User of Controlled Substances” form must be filled out and signed by each authorized user.
- Both pages of “Controlled Substances Use Application Form”

- The “Controlled Substances Security Form”
- On a separate sheet of paper the following information must be provided:
  - a. Title of project
  - b. Statement of purpose
  - c. Name of the Controlled Substances involved and the amount of each needed
  - d. Description of the research protocol including the number and species of research subjects
  - e. The dosage to be administered
  - f. The duration of the project
  - g. Location where research will be conducted, and
  - h. Indication of approval of Committee on Human Research (CHR) for human studies.

After enrollment, OEH&S assigns a controlled substances number to Program members. Members must use this internal number instead of a DEA registration number on all correspondence and requisitions. Approved enrollees 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, Authorized Users and authorized Controlled Substances can be made by completing OEH&S Form 3101 “Universal Use Modification Request Form.”

- Any changes or modifications to the protocol require review for conformity with the registration conditions. These changes must be submitted to OEH&S prior to their implementation.
- Refer to Appendix B for forms discussed in this section. The above forms must be completed and approved for all UCSF campus activities that use DEA controlled substances whether or not these activities fall under the UCSF blanket DEA registration.

## ***E. RESEARCH ADVISORY PANEL OF CALIFORNIA***

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. RAPC regulates research when the purpose of that research is to evaluate a schedule I or II Controlled Substance. In other words, their mandate is not to approve research where the controlled substance is a part of the research, only when the controlled substances is the focus of the research.

Who Must apply ?:

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

Research involving any Schedule I Controlled Substance or

- a) Human research utilizing any schedule I or schedule II Controlled Substance or
- b) Research for the treatment of drug 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 guideline have been developed for each of the above three categories. They are available from:

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 received by the 25<sup>th</sup> day of the month preceding an official meeting and must conform with the Panel's application requirements. One application copy is required. The Panel's staff will make 7 copies, which will be mailed out to the Panel members for review prior to the Panel meeting. 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.

## ***F. RESPONSIBILITIES***

In accordance with the University of California's Business and Finance Bulletin BUS-50, Acquisition and Use of Narcotics and Dangerous Drugs, (dated 8/31/81), The Chancellor has responsibility for meeting the requirements of Federal and State Requirements. The Chancellor shall designate an individual such as the Manager of the Office of Environmental Health and Safety to administer the UCSF controlled substances program. " 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 the Purchasing Department and OEH&S to cancel program registration when the member participant terminates employment or stops program participation.
- Obtains and submits to OEH&S, a final inventory, showing that controlled substances remain with the participant prior to program termination.
- Ensures that program members sign requisitions and pharmacy order forms.

## **2. Faculty Member Participant**

- Responsible for proper storage, utilization, record keeping and disposal of all Controlled Substances purchased on their internal audit number.
- Maintains usage logs and inventory for controlled substances for a period of three years. Usage log will be obtained from the controlled substance distribution Office at time drugs are picked up.
- Ensures that records for Schedule I and II drugs are kept separate from those for Schedule III through V controlled substances.
- Ensures that Controlled Substances are kept in a locked area unless in usage.
- Reports verbally and in writing of theft or loss to OEH&S and Materiel Management immediately upon discovery. OEH&S will notify DEA within 24 hours.
- 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.
- 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 OEH&S for disposal of Controlled Substances and used controlled substance containers.
- Completes physical biennial inventory as directed by OEH&S. Copies of usage logs used in the past calendar year will be required to be submitted at that time.

## **3. Office of Environmental Health & Safety (OEH&S)**

- Reviews internal applications and issues approval numbers.
- Communicates with agencies on all compliance issues.
- Coordinates and performs annual compliance audits.

- Investigates drug diversion reports and issues Agency Notification.
- Maintains files of internal authorizations, inspections and disposal.
- Performs facility closures, including document custody, after a participating member informs OEHS of its intent to close.
- Maintains the Controlled Substances Manual and provides training.
- Reviews and monitors the security controls established.
- Is responsible for promoting recognition of Controlled Substance hazards and developing safe procedures through peer review, newsletter, and communications with participating members.
- Coordinates removal and disposal of Controlled Substances.
- Identifies, evaluates and approves Controlled Substances disposal site(s). Reviews permits, licenses and other relevant records to ensure the disposal sites meet regulatory requirements.
- Receives radioactive Controlled Substances.
- Coordinates biennial inventory and collates data to determine total amount of individual controlled substances on hand. This inventory must be conducted on a single day for all researchers covered under a blanket registration.

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

- Receives copies of all Purchasing records, e.g., purchase requisition, purchase order, and 222 forms when controlled substances are ordered.
- When drug order is filled by Pharmacy or delivered to Distribution Office from an outside vendor, will (pick up from pharmacy daily) hold for distribution.
- Prepares controlled substance drug orders for distribution to researchers. This will include recording the drug name, quantity, strength and form into database and generation of drug log sheet to be used by PI.
- Notifies individuals by phone when their orders are ready.
- Releases orders to researchers who have copy of material management purchase order and signature card on file.
- Reviews signature cards to ensure that individuals are authorized to receive controlled substances.
- Maintains log book that contains the following information: PI, Controlled Substance, strength, form, controlled substance authorization number, initial and date for technician retrieving substance from pharmacy, initial and date for technician distributing substance to PI, and initial and date for PI representative picking up substance from distribution office.
- At time of pick up, PI's representative will verify accuracy of amount received by initialing log book.
- If controlled substances are not claimed within 30 days of initial PI notification they will be destroyed.
- Maintains records of Blue copies of DEA 222 forms for drugs that have been distributed to researchers.

- Maintains records for researcher registration separate from those for other UCSF DEA registrations.
- Maintains records for Schedule I and II drugs separate from schedules III through V.
- Ensures that the date and quantity of drugs supplied to researchers is recorded on DEA 222 forms and other records.
- Maintains copy of most all past biennial inventories on hand for DEA inspection.
- Maintains records of all controlled substance transactions.
- Stores all controlled substances in a secure cabinet or safe.

Ara Tahmassian, Ph.D. Assistant Vice Chancellor, is designated by the Chancellor as the Master Custodian and will be the responsible individual for administering the UCSF controlled substances program. He has delegated the routine operation of the program to various OEHS staff. If there are Questions regarding the Program, please call (415) 476-1300 to talk to appropriate OEHS staff.

#### **4. Materiel Management**

- 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 on OEHS on-line report that PI's who submit purchase requisitions are authorized to order Controlled Substances. Reviews purchase requisitions to ensure that signature matches signature on file.
- Issues Purchase Orders for acquisition of controlled substances. Controlled substances will be purchased from outside vendors as well as the UCSF pharmacy.
- 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.
- Copies of all records, e.g., purchase requisition, purchase order and 222 forms shall be delivered to OEHS 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 OEHS. Liaison to program participants and DEA on issues of

registration, acquisition, substance back orders, and other supply concerns.

Milan Gonzalez, Director of Material Management, is responsible for ensuring that all Material Management responsibilities are fulfilled. He has delegated his routine responsibilities to various Material Management staff. If there are questions regarding the program please call (415) 476-5544 to talk to appropriate Material Management staff.

## **5. UCSF Police**

- Receives copies of OEH&S reports on theft, loss or diversion of drugs.
- Meets with faculty member participant and investigates such reports.
- Reports findings to OEH&S and Material Management.

## **G. ACQUISITION**

The Department Chairman or the Participating Member must determine the need for and sign all requisitions for Controlled Substances. For an order to be processed the following general requirements must be met:

Requisitions must be submitted directly to Material Management. If there is no address information on the requisition, the requisition will not be processed. Researchers may use only a purchasing requisition to order controlled substances. The following information must be included on the requisition:

- Account and Fund Numbers.
- The PI's name and signature.
- Substance name, strength or concentration, dosage, Schedule, quantity, and package or unit size.
- Contact phone number

### **1. Procedure for Executing Order Forms (Material Management)**

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.
- The order form 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. Only the Authorized Official or the alternate can sign the purchase order. If the purchase order is issued as a blanket order with a specific vendor, records must be kept for each Controlled Substance delivered under the blanket order.

## **2. Controlled Substance Distribution Office**

Controlled Substance Distribution Office (L235), hours for researchers for all controlled substances orders will be Monday - Friday 10:00 am to 2:00 pm. Orders for controlled substances will be released by distribution Office only with a copy of the purchase order issued by the UCSF Material Management Department. Distribution office will notify individuals by phone when their orders are ready.

## ***H POWER OF ATTORNEY***

Any purchaser (Material Management) may authorize one or more individuals, whether or not located at the registered location of the purchaser, 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 same person who signed the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and 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 at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application

for registration or re-registration, and filing it 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 Materiel Management 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 Authorized Official.

## **3. Record keeping for Power of Attorney**

- A record shall be kept by the Authorized Individual 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 Authorized Individual 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.

# ***I. 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 Office in the case of the UCSF San Francisco blanket registration.

## 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 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

Personnel performing transfer shall ascertain that person(s) obtaining substances on behalf of the program participant is authorized to do so (with a signature card on file). If pickup person is unknown to personnel performing the transfer signature comparison (with the one on file) shall be performed.

## 5. Principal Investigator Record Keeping

- A usage record shall be maintained at each in-travel point through which the item passes from receipt at the campus until delivery to the ultimate user. ***At the time the PI picks up Controlled Substance from distribution office they will be given a computer generated log form that will help them to track 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, and the name, address and registration number of the person from whom the containers were received.

- 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 UCSF/OEH&S and DEA for three (3) years from the date of the record. It is recommended that all records be maintained for five years.

## **J. 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 blanket permit without approval from OEH&S.

Transfer of Controlled Substance(s) will only permitted by OEH&S if:

- The substances are all registered.
- The person receiving the substance(s) is approved under the appropriate registration.
- Documentation of the transfer is maintained by each registrant.
- Appropriate security measures are in place.

## **K. TRAINING**

PI's are responsible for training authorized users 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, usage log, and incident 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.

This training can be included in routine Hazard Communication training.

## **L. 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:

- 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.
- Physical security controls must be appropriate for the schedules and quantity of Controlled Substances on hand. Generally a securely locked and substantially constructed cabinet, or a safe, will provide adequate security for storage. Contact OEH&S for specific advice on security.
- Access to Controlled Substances must be restricted to the absolute minimum number of individuals needed and authorized to handle daily transactions in such items.
- 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 a statement attesting to the fact that they meet the above criteria.
- Notification of any loss or theft of Controlled Substances must be made to Materiel Manager and the OEH&S Director within 24 hours. Materiel Manager will file the necessary reports with the DEA Regional Office. The OEH&S Director will file the police report required by the DEA, if any.

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

## **M. 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 OEH&S who will arrange for proper disposal. OEH&S will coordinate and make arrangements with the designated disposal site. It is the responsibility of each person that orders and receives Controlled Substances to notify OEH&S about waste Controlled Substances.

## 1. Categories of Waste

Controlled Substances that can be surrendered for disposal are defined as follows:

- Wasted Drugs - These include items such as unused tablets, 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.

## 2. Disposal Procedures

To submit Controlled Substances for disposal, please follow the procedures below:

OEH&S disposal request form (Appendix B) must be completed to arrange for disposal. When Completing disposal forms, include, internal audit (IA) number, participating member name, mail box number, building and room number and 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 participating member. And a file copy must be filed and kept for three years, and the original should be sent to OEH&S, Box 0942. OEHS will then :

## ***N. 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.

OEH&S Department Safety Auditors (DSAs) conduct laboratory audits. The results of the audits are communicated to the participant and the Director of OEH&S. The audit includes administrative and operational aspects of the Program, as well as specific requirements identified during the Registration process. Appendix E contains a copy of a sample "Audit Form" and a definition of the terms.

## ***O. 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**

Schedule III Controlled Substances are defined as follows:

- 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**

Schedule IV Controlled Substances are defined as follows:

- 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**

Schedule V Controlled Substances are defined as:

- 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**

Refer to Appendix F for December 2000 list of DEA Schedule I-V and List 1 and 2 regulated chemicals.

## ***P. CONTROLLED SUBSTANCE REGULATIONS***

Please refer to <http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html> for DEA controlled substance regulations.

## ***Q. GENERAL REQUIREMENTS***

- 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 or approved by the FDA.
- 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.

## ***R. 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 Materiel Manager or OEHS 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:

- Public Law 91-513, Comprehensive Prevention and Control Act of 1970, referred to as Federal Controlled Substances Act.
- Code of Federal Regulations (CFR), 21 Food and Drugs, Part 1300 to end, revised April 1, 2000.
- California Uniform Controlled Substances Act, Division 10 of the California Health and Safety Code
- University of California, Office of the President, business and Finance Bulletin No. BUS-50, " Acquisition and Use of narcotics and Dangerous Drugs", dated April 15, 1988.
- Annual Reports of the California Research Advisory Panel
- Letter of August 14, 1972 , from Vice-President McCorcle 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**

- Instructions for Principal Investigators for completing controlled Substance Application Forms
- Controlled Substance Application forms (must be obtained from OEH&S)
- Information on Authorized Users Form (must be obtained from OEH&S)
- Signature Card (must be obtained from OEH&S)
- Controlled Substances Inventory Form
- Controlled Substances Security Form
- UCSF Controlled substances Disposal Request Form
- Universal Use Authorization Modification Request Form (must be obtained from OEH&S)
- Controlled Substances Usage log

**Instructions to Principal Investigators for completing  
Controlled Substance Application Forms**  
(August 2001)

1. **What is a CSA or Controlled Substances Application.** This document authorizes Principal Investigators to use controlled substances, as defined by the United States Drug Enforcement Administration (DEA), for research purposes.
2. **Who must apply for a CSA?** If your research requires the use of DEA regulated substances you must have an approved CSA issued by the Office of Environmental Health and Safety (OEHS). Please refer to the UCSF Controlled Substances Manual for further information. The controlled substances manual is available on the OEHS website at <http://www.ehs.ucsf.edu>. Controlled Substances Application forms can be obtained from your Departmental Safety Advisor (DSA).

Note: The CSA's described here are only required for UCSF campus PIs and do not apply to medical center personnel. Medical center controlled substance users must make other arrangements with the DEA.

- **The CSA application.** The basic CSA consists of the following: (1) Page one of the "Controlled Substances Use Application Form," (2) Page two of the "Controlled Substances Use Application Form" and (3) the "Information on Authorized User of Controlled Substances" form (4) Controlled substances security form - security measures to be taken to limit access to controlled substances, (5) Controlled Substances Inventory Form" showing "0" balance records, (6) Two Controlled Substance Release Signature Cards (one to be filed with Materiel Management and the other with the Controlled Substances Distribution Office), and (7), and on a separate sheet of paper the following information must be provided:
  - a. Title of project
  - b. Statement of purpose
  - c. Name of the Controlled Substances involved and the amount of each needed
  - d. Description of the research protocol including the number and species of research subjects
  - e. The dosage to be administered
  - f. The duration of the project
  - g. Location where research will be conducted, and
  - h. Indication of approval of Committee on Human Research (CHR) for human studies.

3.

4. **How to complete the application.** The forms are largely self explanatory: however, the following should be considered:

- a. Both pages of controlled substances application must be completed. PI representative must complete statement about security as noted on the first page of Controlled Substance Application.
- b. Only OEH&S triplicate forms can be used (because these forms must be signed in triplicate by Material Management, OEH&S and by the PI).
- c. As part of an individual background check "Authorized User Forms" must be filled out and signed by each authorized user (These are duplicate and not triplicate forms).
- d. Completed package must be turned over to your DSA, who will inspect the application for completeness. The DSA will also inspect the laboratory for ability to safely handle controlled substances.

## 5. Approval Process

- a. OEH&S CSA Coordinator will review submittal package for completeness. If any part of package is incomplete, entire package will be returned to the PI.
- b. After review by OEH&S CSA Coordinator, forms will be signed and approved by designated OEH&S official and Material Management official.
- c. OEH&S administrative staff will prepare a CSA summary sheet and assign an OEH&S approval number for each application.
- d. OEH&S CSA Coordinator will compile CSA permanent file.
- e. File copies will be delivered to the DSA. DSA will forward copies to PI to be kept in PI files. **This file must be kept up to date by PI.** In the event of an unannounced DEA inspection, all approved application paperwork must be available in PI file.
- f. Use of any Schedule I and any human uses of Schedule II drugs will require PIs to contact the Research Advisory Panel of California for authorization to perform research.

## 6. Modifications

1. If adding a user, an Authorized User form must also be completed and signed by the user. If not part of the original application package this form must also be initialed by the PI.
2. Changes in authorized use locations can be made with Form 3101 "Universal Use authorization Modification Request Form." Updated security measures must also be included.
3. Additional controlled substances can be added to CSA by submitting OEH&S Form 3101.

If there are any further questions, please contact your DSA.









**CONTROLLED SUBSTANCES SECURITY FORM**

The controlled substances in our lab are stored in the following manner:

Building(s) \_\_\_\_\_

Room Number(s) \_\_\_\_\_

\_\_\_\_\_ In a drug safe or steel cabinet under lock and key.\*

\_\_\_\_\_ In a vault constructed before September 1, 1971, which is substantially constructed with a steel door, combination or key lock, and alarm system or a vault constructed after September 1, 1971 with floor, walls and ceiling made of reinforced concrete at least 8 inch thickness.\*

\*One of these is required if controlled substance used is listed in Schedule I or II.

\_\_\_\_\_ In a room that has limited access during work hours and is locked during non-working hours.

\_\_\_\_\_ Other, explained as follows

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Principal Investigator (Print) \_\_\_\_\_

Principal Investigator(signature)\_\_\_\_\_

Date \_\_\_\_\_

**APENDIX C**  
**TABLE LISTING DEA FORMS**

<b>Form Number</b>	<b>Intended Use</b>
DEA # 41	Registrants Inventory of Drugs Surrendered (Disposal of Controlled Substances)
DEA #106	Report of theft or Loss of Controlled Substances
DEA #222	Ordering Schedules I and II
DEA # 224	Registration of Schedule II-V for Instructional Use and Authority to Dispense under Hospital/clinical registration
DEA #225	Research Registration for Schedule I-V, chemical Analysis Registration and manufacturer Registration
DEA #363	Narcotic Treatment Program Registration
DEA # 486	Import/Export Declaration for Precursor and Essential Chemicals

**APPENDIX D**  
**POWER OF ATTORNEY FORM**  
**(Obtained from Material Management)**

**APPENDIX E**

**CONTROLLED SUBSTANCE AUDIT PROCEDURE  
(Procedure kept at OEH&S)**

**APPENDIX F**

**DEA CONTROLLED SUBSTANCE LIST  
(Available from Department Safety Advisor)**