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Issuing Office: Environment, Health & Safety

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## **CONTROLLED SUBSTANCES FOR RESEARCH, TEACHING AND VETERINARY CARE**

### **I. REFERENCES**

- A.** Systemwide Business and Finance Bulletin (B&FB), BUS-50: Acquisition and Use of Narcotics and Dangerous Drugs.
- B.** Public Law 91-513, Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to as Federal Controlled Substances Act.
- C.** Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970. 21 CFR, Chapter II, Drug Enforcement Administration, Department of Justice.
- D.** California Uniform Controlled Substances Act, Division 10 of the California Health and Safety Code.
- E.** 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.
- F.** Letter of September 2, 1981, from President Saxon to Chancellors and Others: University Policy on the Protection of Human Subjects in Research.
- G.** Letter of September 2, 1981, from President Saxon to Vice President Frazer: Delegation of Authority --Protection of Human Subjects in Research.
- H.** Annual Reports of the California Research Advisory Panel.
- I.** Letter of December 15, 1986, from Chancellor Richard C. Atkinson to Vice Chancellor Steven W. Relyea, Business Affairs: Delegation of Authority—Registration & Acquisition of Narcotics & Dangerous Drugs.
- J.** Letter of April 3, 2006, from Senior Vice President Joseph P. Mullinix to Vice Chancellor Steven W. Relyea, Business Affairs: Approval of Policy Exception Request for the Management of Controlled Substances for Non-Clinical Research.
- K.** Letter of October 11, 2006, from Vice Chancellor Steven W. Relyea, Business Affairs: Delegation of Authority – Controlled Substances Program Manager.

### **II. SCOPE**

This policy sets forth requirements and procedures applicable to the authorization, procurement, receipt, security, storage, control, biennial inventory, and disposal of Controlled Substances, List I and Precursor Chemicals for research, teaching and veterinary care. This policy does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license, procurement or use for human care on ocean vessels, nor to licensed UCSD pharmacies.

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### III. DEFINITIONS

#### A. Controlled Substance

A controlled substance is a drug or chemical substance whose possession and use are regulated under the Federal Controlled Substances Act and California Uniform Controlled Substances Act. For purposes of this document, controlled substance policies and procedures shall also apply to control of List I and Precursor chemicals.

#### B. Schedules of Controlled Substances

Controlled substance schedules are classifications of narcotics and dangerous drugs, ranked according to their potential for abuse and other relevant factors, and are denoted by Roman numerals I through V. Schedules were established by Public Law 91-513, the Comprehensive Drug Abuse Prevention Act of 1970 (1980 Revision), in order to provide clear guidelines for the implementation of controls on the manufacture and procurement of controlled substances. Information concerning the assignment of particular substances to specific schedules may be obtained at <http://blink.ucsd.edu/go/cs> or by calling the [Controlled Substances Program Manager](#) in the Environment, Health and Safety Department (EH&S).

#### C. Listed Chemicals

Listed chemicals are chemicals of concern that can be used to make a controlled substance and were established by Public Law 103-200, the Domestic Chemical Diversion Control Act of 1993. There are two lists, List I and List II, though for the purposes of this document only List I chemicals are referenced. These lists can be obtained at <http://blink.ucsd.edu/go/cs>.

#### D. Precursor Chemicals

Precursor Chemicals, as used in this policy, are any substance listed under California Health and Safety Code sec. 11100 et seq. This list of chemicals can be obtained at <http://blink.ucsd.edu/go/cs>.

#### E. Purposes Covered by this Policy

Animal research, clinical research, teaching, veterinary care, and in-vitro (non-animal) research are covered by this policy. This policy does not cover research conducted with controlled substances acquired from a campus pharmacy.

#### F. Projects

Projects shall include an actual research project or a teaching or veterinary purpose.

#### G. Department Chair

A Department Chair shall include faculty appointed as Department Chair or Section Chair.

#### H. Principal Investigator

A Principal Investigator includes "In Residence," "Adjunct" and "Clinical" Professors, Associate Professors, Assistant Professors, Instructors, Professors, and Veterinarians

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**I. Principal Investigator**

A Principal Investigator includes "In Residence," "Adjunct" and "Clinical" Professors, Associate Professors, Assistant Professors, Instructors, Professors, and Veterinarians who are assigned space for research or teaching activities. A faculty member without assigned space may be considered Principal Investigator upon approval of their Department Chair.

**J. Authorized Personnel**

Authorized personnel are faculty, staff, students, or visiting scholars who have a need to handle or access controlled substances for Department-approved projects at UCSD. The number of Authorized Personnel shall be kept to a minimum in order to maintain security. In order to become an Authorized Personnel, the individual must sign the Controlled Substance Personnel Screening Data Sheet (PSDS), indicate no prior history with controlled substance abuse or diversion, obtain Principal Investigator signature authorization, file a copy with EH&S, and subsequently file for addition to the Controlled Substances Use Authorization (CSUA).

**IV. POLICY**

**A. Regulatory Compliance**

UCSD shall comply with all applicable Federal and State Laws and regulations governing controlled substances. All controlled substance policies and procedures shall apply to control of List I and Precursor chemicals as well.

**B. Registration**

Authority to possess or dispense controlled substances for research, teaching, and veterinary care purposes shall be requested from the U.S. Department of Justice, Drug Enforcement Administration (DEA). All projects involved in the possession or use of controlled substances II-V shall be covered under an applicable University registration.

Registration for Controlled Substances in Schedules II-V shall be held in the name of the academic department per geographical location and activity and coordinated by the Controlled Substances Program Manager. If an operation remote from the campus requires controlled substances, a separate registration is necessary for each type of activity involved.

Registration for Controlled Substances in Schedule I shall be obtained and managed by the Principal Investigator per geographical location and activity. This registration is not transferable.

**C. Approval of Projects**

Use of controlled substances under university registrations is restricted to projects where such use has been specifically authorized by the appropriate Department Chair as declared on the CSUA. In his/her absence, this may be delegated to one individual of a comparable level of authority. In these instances, this individual would be delegated the authority to sign as a Department Chair Alternate. Department Chairs requiring CSUA(s) for their own projects must acquire authorization from their Dean or an individual of a comparable level.

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Projects must be written to satisfy specific DEA requirements. An approved Institutional Animal Care and Use Program (IACUC) research protocol shall be sufficient project documentation for animal research projects. An approved Human Subjects Institutional Review Board protocol shall be sufficient documentation for human clinical research.

Additional approval for any project which proposes to use a Schedule I controlled substance, any human research involving a Schedule I or II controlled substance, or research for treatment of drug abuse using any drug (scheduled or not) must be reviewed simultaneously by the State of California Research Advisory Panel prior to commencement of work.

**D. Orders for Controlled Substances**

The Department Chair or Principal Investigator must determine the need for and sign all requisitions for Controlled Substances, regardless of dollar value. Purchase requests shall be submitted to the Controlled Substances Program Manager of EH&S for review. Approved requisitions will be forwarded by EH&S to the Purchasing Department in Business and Financial Services for order placement. All purchases of such materials using university-controlled funds shall be made only by Purchasing. No orders may be placed by departmental personnel directly with vendors.

**E. Penalties for Non-Compliance**

Possible penalties for violating DEA regulations include rescission of the university registrations authorizing the use of controlled substances, imposition of fines, and imprisonment of those responsible. Possible penalties for violations of this policy include CSUA revocation, repossession of all controlled substances in inventory, suspension of purchase requisition authorization, and suspension or termination of Authorized Personnel privileges.

**V. RESPONSIBILITY**

**A. Environment, Health and Safety**

The Controlled Substances Program Manager maintains delegated authority and responsibility for overall coordination of this policy and specific responsibility for the approval, receipt, and delivery of controlled substances to authorized personnel. EH&S is also responsible for disposal of controlled substances, biennial inventory notification to the Department Chair and/or designated Principal Investigator for inventory of controlled substances, authorizing the storage location approval process, and for approving all storage locations. The Controlled Substances Program Manager is responsible for obtaining and maintaining any powers of attorney required for program operation within EH&S. The above information shall be available to the DEA upon request. The Controlled Substances Program Manager shall perform announced and unannounced audits to measure compliance with these policies.

EH&S is responsible for maintaining a central storage and pick-up area for receiving incoming shipments at each of the main registered locations (Hillcrest, La Jolla, and Elliott Field), for obtaining appropriate signatures of persons authorized to receive controlled substances, and compliance monitoring by regular audits.

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**B. Department**

1. The Department Chair is assigned responsibility for approving projects involving the use of controlled substances by departmental personnel, for authorizing faculty as Principal Investigators, for notifying EH&S if a new Principal Investigator arrives on campus with controlled substances, for notifying EH&S when a Principal Investigator authorized to experiment with controlled substances dies or intends to terminate employment, and for preparation of such reports as may be required. Department approval is granted by Chair's signature on each Principal Investigator's CSUA application for one year and may be renewed.
2. The Department Chair is responsible for assuring that a current inventory of all controlled substances under his/her control is maintained by the Principal Investigator on the Controlled Substances Log Sheet in a separate, secure book for periodic audit by EH&S and/or the DEA.
3. The Department Chair and the Principal Investigator are assigned joint responsibility for determining the need for and signing (authorizing) all requisitions for controlled substances. The Principal Investigator is assigned primary responsibility for assuring that a current inventory of all controlled substances under his/her control is maintained, that inventory forms are submitted upon notification by and at the request of EH&S, that a current CSUA is on file with EH&S, ensuring that a list is maintained of those individuals handling controlled substances in the laboratory, and that all DEA security regulations are being followed.
4. The Department Chair and/or Principal Investigator is assigned responsibility for the preparation and submission of Research Protocol and all information required for Schedule I controlled substances.
5. The Principal Investigator is assigned responsibility for assigning and authorizing laboratory personnel to handle controlled substances. Each proposed laboratory personnel to handle controlled substances must fill out a Personnel Screening Data Sheet (PSDS). The PSDS shall be sent to the Controlled Substances Program Manager for review in order to become an Authorized Personnel. If an applicant has a criminal history of mishandling controlled substances, he or she shall not be granted access to the Principal Investigator's controlled substances.

**C. Materiel Management**

The Materiel Manager is assigned administrative responsibility for the purchase and return of controlled substances to the original vendor/supplier in coordination with EH&S. Authority to sign University Purchase Orders for controlled substances is restricted to authorized persons in the Purchasing Department in Business and Financial Services. This information shall be available to the DEA upon request.

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**D. Police Department**

The University Police Department investigates all suspected thefts or misuse of controlled substances.

**VI. REQUIREMENTS OF OTHER AGENCIES**

If approval of any other federal or state agency is required for the use of any controlled substance, application for such approval shall be filed by the Principal Investigator and evidence of approval submitted to the Controlled Substances Program Manager