

## **POLICY AND PROCEDURES RELATING TO THE USE OF CONTROLLED SUBSTANCES IN TEACHING AND RESEARCH 1**

### **I. PURPOSE**

To assure that California State University Fresno (Fresno State), its faculty, staff, and students are in compliance with all laws, federal and state, that apply to the procurement, use, storage, handling, and disposal of narcotics and dangerous drugs used in instruction and research.

### **II. AUTHORITY**

The Vice President for Administration is the responsible institutional official for the management of narcotics, dangerous drugs, and controlled substances. The Vice President for Administration is designated to appoint a University Committee on the Use of Controlled Substances in Teaching and Research (UCCS), which, with the Office of Environmental Health and Safety (EHS) has the responsibility to assure that departments, units, and employees comply with all applicable laws and internal requirements to safely manage and prevent diversion of controlled substances

- A. The University Committee on the Use of Controlled Substances in Teaching and Research shall be established for the purpose of general review of policies and procedures and shall be responsible for submitting recommendations to the Vice President for Administration in accordance with applicable provisions of the Code of Federal Regulations (CFR). This committee shall also be responsible for conducting annual audits of controlled substances.
- B. The UCCS shall be constituted as follows:
  - 1. Five members of the faculty, recommended by the Senate, appointed by the Vice President for Administration
  - 2. A member-at-large, recommended by the Director of Environmental Health and Safety, appointed by the Vice President for Administration
  - 3. A staff member of University Health and Psychological Services (UHPS), recommended by the Director of UHPS, appointed by the Vice President for Administration
  - 4. The Director of Environmental Health and Safety, ex officio.
- C. All appointed members shall serve a term of three years.

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<sup>1</sup> 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 licenser. Specifically, this policy does not apply to activities of the pharmacy at the University Health and Psychological Services or to campus physicians or veterinarians.

### III. REGISTRATION

All personnel engaged in research or instructional activities with controlled substances listed in Schedules I through V as defined in the CFR are required to register with the Drug Enforcement Administration through the UCCS and the Office of the Vice President for Administration. Registration requires the enrollment of the user and the specific application. Teaching or research with controlled substances by personnel who are not registered with the Drug Enforcement Administration, or by persons who are not being directly supervised by a current registrant is strictly prohibited. Teaching or research using controlled substances for applications which are not registered is strictly prohibited as well.

Who may register:

- Faculty members using controlled substances must register
- Graduate students and research assistants may optionally register, if they are employed by the state or the California State University, Fresno foundation and they have the sponsorship of a registered full-time faculty member
- Undergraduate students may not individually register, but may participate in the use of controlled substances in teaching and research under the direction of a registered user

Applicants for “Registered User” status shall apply to the UCCS through their Department or Division Chair and the Dean of their respective administrative unit.

**Use of materials off-campus:** Registered researchers using controlled substances for teaching or research off campus must carry a copy of their approved registration with them at all times. Non-registered persons who are using controlled substances for research while under the supervision of a registered user must carry, at all times while off-campus, a copy of the registered user’s approved registration and an authorization memo from the registered user.

### IV. PROCUREMENT

All shipments of controlled substances to the campus, except those to the pharmacy, must be received by the Office of Environmental Health and Safety, California State University, Fresno. The EHS shall distribute all controlled substances to registered users.

All shipments must clear the EHS regardless of funding source. No other offices or receiving points on campus are authorized to receive shipments of controlled substances.

## V. STORAGE, RESPONSIBILITY AND SECURITY

The responsibility for the use or abuse of controlled substances rests with the faculty or staff member registered to use the substance or under whose direction the substance is employed. The following security procedures shall be followed in order to ensure the protection of each registrant and to minimize the probability of theft or diversion:

- A. Each department in which controlled substances are used shall provide a secured storage area acceptable to the DEA. The Department Chairperson, as appropriate, shall issue separate or common secured storage to each registered faculty member. Responsibility for accurate inventory is equally shared among those faculty members who have access to common secured storage.
- B. All university personnel who require access to controlled substances shall file an application for registration with the UCCS which shall, upon review and approval, recommend access be provided by the responsible administrator.
- C. Registered personnel shall assume the following additional responsibilities upon receipt of access:
  1. Maintain an inventory log which shall remain in the designated storage area,
  2. Use the substance only as stipulated in the application, and
  3. Train subordinates and others who may be involved in the safe and proper handling, storage, and disposal of controlled substances.
- D. Applications for use of controlled substances shall be renewed annually. A current inventory, certified by the applicant, must be filed with the renewal.
- E. The Office of Environmental Health and Safety shall conduct semiannual unannounced inventory audits of each designated storage area. The inventories are filed with the Vice President for Administration.
- F. A report of each audit shall be submitted to the Vice President for Administration, the Provost and Vice President for Academic Affairs, the Deans, and Department Chairpersons, and members of the Committee on Narcotics and Dangerous Drugs.
- G. Custody and use of controlled substances by non-registered personnel is strictly prohibited except where authorized by and directly supervised by a registered user.

## **VI. DISPOSAL**

All controlled substances which are expired or otherwise unneeded must be disposed of by and through the Office of Environmental Health and Safety. All transfers to other individuals and organizations, including those with a legitimate license, are prohibited.

## **VII. PROTECTION OF HUMAN SUBJECTS**

Conducting research with controlled substances with human subjects is strictly prohibited without prior approval of the University Committee on the Protection of Human Subjects. All human subjects shall be deemed to be "at risk" in all research projects involving controlled substances. For more information, please refer to the University policy on Research with Human Subjects.

## **VIII. ADDITIONAL INFORMATION**

### **Responsible University Officer**

Vice President for Administration

### **Responsible Office**

Office of Environmental Health and Safety (EHS)

### **Applicable Laws & Regulations**

Public Law 91-513 (federal)

Title 21, Chapter II, Part 1301, Code of Federal Regulations (CFR)

### **Related Policy**

Institutional Animal Care & Use

Research with Human Subjects

## **WHO SHOULD BE FAMILIAR WITH THIS POLICY**

Vice President for Administration

Provost and Vice President for Academic Affairs

Associate Provosts

Associate Vice President for Academic Personnel

Associate Vice President for Grants and Research

Director of Human Resources

Director of Environmental Health & Safety

College / School Deans

Department Chairs

Instructional and research users of controlled substances

Revised Policy Recommended by the Senate

Approved by the President

April 2002

May 2002