

**POLICY AND PROCEDURES FOR
STORAGE, RESEARCH, AND CHEMICAL ANALYSES
WITH CONTROLLED SUBSTANCES
AT CALIFORNIA STATE UNIVERSITY, FRESNO**

Public law 91-513, as amended, provides authority with the Drug Enforcement Administration of the Department of Justice to set forth procedures for manufacturing, dispensing, conduction research and chemical analyses, and storage of controlled substances. The purpose of this policy is to ensure University compliance with this law under the general provisions of Title 21, Chapter II, of the Code of Federal Regulations.

Pursuant to the provisions of Part 1301, California State University, Fresno, has registered with the Drug Enforcement Administration to enable faculty to conduct research and chemical analyses with controlled substances. Section 1301.71 places responsibility on each registrant to provide effective controls and procedures to guard against theft and diversion of controlled substances. Additionally, subpart B of Part 1316 set forth procedures for the protection of researchers and research subjects. Review and adherence to the policies and procedures stipulated In this document should ensure adequate safeguard of privileges as well as protection of students, faculty, and the University.

SECTION I - AUTHORITY

The Vice President for Administration and University Relations is designated as the chief administrative officer of the University in whom authority is bested for enforcement of policy and procedures pertaining to storage, research, and chemical analyses with controlled substances. Requests for "Application for Access to Controlled Substances" and questions regarding compliance with the law should be directed to the office of the Vice President for Administration and University Relations.

A University Committee on Narcotics and Dangerous Drugs is herewith established for the purpose of general review of policies and procedures and shall be responsible for submitting recommendations to the Vice President for Administration and University Relations in accordance with applicable provisions of the Code of Federal Regulations. This committee shall also be responsible for conducting annual audits of controlled substances.

The Narcotics and Dangerous Drugs Subcommittee of the Administrative Assurance and Compliance Committee is herewith appointed as the interim University Committee on Narcotics and Dangerous Drugs. Appointments shall be made by the vice president for Administration and University Relations and members shall serve for a period of three years. The chairperson of the Administrative Assurance and Compliance Committee shall serve ex-officio.

SECTION II - REGISTRATION

Conducting research of chemical analyses with controlled substances by faculty of students who are not registered with the Drug Enforcement Administration is strictly prohibited. All faculty and students engaged in research, chemical analyses, or instructional activities with controlled substances listed in Schedules II through V and

Schedule I as defined in "Schedules of Controlled Substances", * Title 21, Chapter II, Code of Federal Regulations are required to register with the Drug Enforcement Administration. Additionally, separate registration is required for faculty and students who engage in 1) chemical analyses with controlled substances listed in any schedule, (2) research and instructional activities with controlled substances listed in Schedule I, and (3) instructional activities with controlled substances listed in Schedule II through V.

All Faculty and students required to register shall file notice of such registration and the type of activity with the Vice President for Administration and University Relations not later than September 30 of each academic year.

SECTION III - RESPONSIBILITY AND SECURITY

The Responsibility for the use of abuse of controlled substances rests with the faculty member or student who is 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:

1. Each department in which controlled substances are used shall provide a secured storage area or areas such as a drawer, safe, or cabinet capable of being locked. The department Chairperson, as appropriate, as appropriate, shall issue separate or common drawers to each registered faculty member. Responsibility for accurate inventory is equally shared among that faculty who have access to common drawers.
2. The Department Chairperson shall inform the School Dean and the Vice President for Administration and University Relation of Designated storage areas and the type of controlled substances contained in each area. The Vice President for Administration and University Relations shall, in cooperation with School Deans and Department Chairpersons, secure new locks and keys. The key shall be retained in the Office of the Vice President for Administration and University Relations who shall be responsible for their issuance to registrants.
3. All registered University personnel (including students) who desire access to controlled substances shall file an "Application for Access to controlled Substances" with the University Committee on Narcotics and Dangerous Drug which shall, upon review and approval, recommend issuance of a key by the Vice President for Administration and University Relations.

* Copies of "Schedules of Controlled Substances" are available for review in the office of the Vice President for Administration and University Relations.

4. Registered faculty and students shall assume the following additional responsibilities upon receipt of a key:
 - a. maintains an inventory log which shall remain in the designated drawer, safe or cabinet: and
 - b. use the substance only as stipulated in the application.
5. Applications for use of controlled substances shall be filed annually. The Vice President for Administration and University Relations, as appropriate, shall secure new locks and keys.
6. The University Committee on Narcotics and Dangerous Drugs shall conduct semi-annual unannounced inventory audits of each designated storage area as filled with the Vice President for Administration and University Relations. A report of each audit shall be submitted to the Vice President for Administration and University Relations, School Deans, and Department Chairpersons.

SECTION IV - - ORDERING CONTROLLED SUBSTANCES

Registrants who order controlled substances listed in any schedule shall report the date of receipt and amount of such substance to the University Committee on Narcotics and Dangerous Drugs.

SECTION V - PROTECTION OF RESEARCHERS AND RESEARCH SUBJECTS

Conducting research with controlled substances with human subjects is strictly prohibited without prior approval of the University Committee on the Participation of Human Subjects in Research Projects. Human subjects shall be deemed to be a risk in all research projects involving controlled substances,

1. In order to obtain approval, the researcher must follow the procedures as outlined in Section VI, b., of the Policy and Procedures on the Participation of Human Subjects in Research Projects.

Moreover, pursuant to research application requirements of the Research Advisory Panel, State of California, any investigator in California must submit a research application to the Research Advisory Panel of the State of California for any research involving Schedule I controlled substances, or human research involving any Schedule II narcotics,

Additionally, a "Notice of Claimed Investigational Exemption for a New Drug" (IND) must be obtained by anyone conducting human research with any Schedule I drug, or any drug which is used for a purpose other than that for which it is medically indicated.

2. The researcher who intends to maintain the confidentiality of those persons who are the subjects of such research shall upon registration or within a reasonable time thereafter, submit to the Administrator, Drug Enforcement Administration, Department of Justice, Washington D. C. 20537, a separate request for each research project involving controlled substances, which shall contain the following:
 - a. the researchers registration number for that project:
 - b. the location of the research project:
 - c. a general description of the research of a copy to the research protocol: and
 - d. a specific request to withhold the names and/of any other identifying characteristics of the research subjects and the reasons supporting the request.

In the event the request is approved by the Drug Enforcement Administration, the researcher shall notify the Administrator with 30 days after the date of completion of the research project.

3. The researcher must submit to the Vice President for Administration and University Relations and the Committee on the Participation of Human Subjects in Research Projects a copy of correspondence from the Drug Enforcement Administration approving the request prior to implementation of the research project.