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# Stanford University – Controlled Substances & Precursor Chemicals Program

## Answers:

### General

#### **1. What are controlled substances?**

Drugs and certain other chemicals both narcotic and non-narcotic, which come under the jurisdiction of federal and state laws regulating their manufacture, sale, distribution, use and disposal.

#### **2. What are precursor chemicals?**

Precursor chemicals are chemicals used in the course of legitimate research that can potentially be used in the illicit production controlled substances such as methamphetamine, cocaine, heroin, and MDMA (ecstasy). The mission of the DEA's and the CA-DOJ's Precursor Chemicals Control Programs are to disrupt the illicit production of controlled substances by preventing diversion of precursor chemicals.

#### **3. What is Stanford University's Controlled Substances & Precursor Chemicals Program?**

Research use of selected drugs and precursor chemicals are regulated by the **Federal Drug Enforcement Administration (DEA)** and California Department of Justice (CA-DOJ). To assist Stanford personnel in complying with these regulations and Stanford University policy, specific institutional requirements have been established for the management of controlled substances and precursor chemicals.

The University has an institutional registration with the DEA for research involving Schedule II-V Controlled Substances; precursor chemicals may be procured for the researcher using this institutional registration.

### Registrations/ Purchase Approvals

#### **4. If I already have my own registration with the Drug Enforcement Administration (DEA), do I need to participate in the University's program?**

No. You are expected to continue to administer and manage your own DEA registration. Keep in mind that compliance with federal and state laws and university procedures governing controlled substances and precursor chemicals is required of all individuals and groups associated with Stanford University. These regulations include the following:

- Code of Federal Regulations: Title 21, Chapter II (Parts 1300 to end) – These regulations implement the Controlled Substances Act of 1970, the Diversion Control Amendments of 1984, 1985, 1986 and subsequent amendments (<http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>).
- Health and Safety Code Division 10: California Uniform Controlled Substances Act. (<http://www.leginfo.ca.gov/cgi-bin/calawquery?codesection=hsc&codebody=&hits=20>).

#### **5. How do I enroll under the University's registration and get purchase approval?**

Any University faculty or senior research staff member needing to purchase controlled substances for research under SU's Institutional Registration must submit to EH&S:

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- *SU Controlled Substance Purchase Request Application (Form 1a)* - identifies the substances to be ordered. This form also provides proof of legitimate research use via approval from one of the following:
  - Administrative Panel for Laboratory Animal Care (APLAC) for animal research,
  - Institutional Review Board (IRB) for human subjects related research, or
  - the applicant's department chairperson.
- *SU Controlled Substance Authorized Researcher Application (Form 2)* - Only personnel whose submitted forms are cleared by EH&S will be institutionally authorized to access controlled substances. Authorization to access controlled substances will be denied to any personnel who have been convicted of a felony offense relating to controlled substances or who, at any time had an application for DEA registration denied or registration revoked—in accordance with Section 21 CFR 1301.90.

### 6. How long does it take to process a controlled substance or precursor chemical purchase request application?

Approximately 3-10 working days.

### 7. What type of research needs authorization from the Research Advisory Panel of California (RAPC)? How do I get authorization from RAPC?

Faculty and senior research staff must independently seek authorization from the RAPC if their research projects specifically involve:

- Any Schedule I controlled substance;
- Human research using any Schedule I or Schedule II controlled substance; or
- Research for the treatment of drug abuse using any drug, scheduled or not.

SU's Institutional Review Board (IRB) Office checks protocols to ensure that investigators have sought this authorization, when required. Researchers using Schedule II (in non-human research), III, IV, or V controlled substances need not apply to RAPC.

Applications are available at <http://caag.state.ca.us/research/research.htm> and additional guidance is provided in [SU Controlled Substances Authorized Researcher's Guide](#).

### 8. Why do I need my own registration with the DEA for work with Schedule I Controlled Substances? How do I get a registration for Schedule I Controlled Substances?

Per CFR 1301.18, faculty and senior research staff must independently obtain individual DEA registrations. Individual registration can be processed by submitting Form 225 to the DEA, which is available at [http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301\\_13.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_13.htm).

### 9. Why do I need to have my own registration with the DEA for work with any Controlled Substances off campus?

When performing research at a non-Stanford facility (such as the Veterans Administration Palo Alto Health Care System -VAPAHSC) or off the main campus (such as Hopkins Marine

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Station), SU faculty will be subject to the host institution's controlled substance program or if one does not exist, will need to register independently for an individual DEA registration.

### **10. What happens if I do not comply with the requirements of the University's Controlled Substances & Precursor Chemical Program?**

Failure to comply with the authorization, storage, security, inventory, and recordkeeping processes established within the University's program exposes Stanford to losing its registration and thereby gravely impacting your and other researchers' ability to conduct research involving controlled substances and precursor chemicals.

The consequences of engaging in illicit activities are reviewed in question 13 below.

### **Researcher Authorization & Security**

#### **11. Why do I have to provide background history information? Who reviews this information? Where is it filed?**

It is the position of DEA that obtaining certain information about employees is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. Thus, Stanford University has an employee-screening component of its Controlled Substances & Precursor Chemicals Program.

All faculty, staff and students intending to conduct research using Controlled Substances are required to complete Form 2, *SU Controlled Substances- Authorized Researcher Application*. This form is sent to EH&S's Controlled Substances Program Office and then forwarded to the Federal Drug Enforcement Agency's field office.

#### **12. How do I report a loss or theft?**

Any loss, stolen or suspected diversion of controlled substances shall be immediately reported via the Stanford University EH&S Emergency Line @5-9999. If the controlled substances are stolen or diverted, the information will be forwarded to Stanford University's Office of Public Safety. The University's Program then will submit the required loss/ theft reports directly to the DEA.

If any imminent safety threat exists, contact Public Safety directly at 9-911.

#### **13. What are the consequences of engaging in illicit activities?**

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. Stanford 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.

**14. If I think a co-worker is diverting controlled substances and/or precursor chemicals, why do I have to report him/her? How is this done confidentially?**

Per 21 CFR 1301.91, the DEA requires that an employee who has knowledge of drug diversion from the University by a fellow employee has an obligation to report such information to Stanford University's EH&S Emergency number @ 5-9999. Stanford 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.

**Storing, Transferring, Inventorying, & Disposing**

**15. How do I store controlled substances?**

Controlled substances shall be stored in a securely locked, substantially constructed cabinet, located where access is limited. EXCEPTION: The following substances must be stored in a safe: Carfentanil etorphine hydrochloride and diprenorphine.

**16. How do I store precursor chemicals?**

Precursor chemicals' storage must follow Stanford University's chemical storage requirements for the hazard class of the chemical (e.g., flammable, toxic).

**17. Can I transfer controlled substances to another faculty member on the Stanford campus?**

Yes. An intra-campus transfer of a controlled substance will be approved by EH&S if the following criteria are met:

- ✓ The original inventory must have been acquired under the Stanford DEA registration.
- ✓ The Faculty or Senior Research Staff Member receiving the substance(s) must submit a [\*SU Controlled Substance Purchase Request Application \(Form 1a\)\*](#) to EH&S and receive approval from EH&S for such transfer.
- ✓ Both parties maintain documentation of any approved transfer.

**18. Can I transfer controlled substances to another individual at another University or institution?**

No. Under no circumstances can controlled substances falling under SU's institutional registration be transferred off or onto the main campus.

**19. I have a dual appointment at Stanford University and the Veterans Administration Palo Alto Health Care System (VAPAHSC). Can I move controlled substances between Stanford University and VAPAHSC?**

No. Faculty with dual appointments at Stanford University and the VAPAHCS are prohibited from taking or transferring controlled substances in to or out of VAPAHCS laboratories. When performing research at VAPAHSC, SU faculty will be subject to VAPAHSC's Health Care System Memorandum No. 151-04-2, "Procedures for Obtaining, Storing, and Disposing Controlled Substances for Use on Animals in Research Studies".

## 20. Who checks our Controlled Substance Logbooks?

Each authorized Faculty or Senior Research Staff Member must maintain an up-to-date inventory of each controlled substance in possession using the *SU Controlled Substances Usage Log (Form 3)*. Records must be kept locally for a minimum of two years from the final disposition of the controlled substance. The usage log shall be readily available for periodic audit by SU EH&S and the DEA.

## 21. What is the biennial campus-wide inventory?

Per CFR 1304.11(b), the University must inventory each substance during a one-day institutional inventory in which participating faculty and senior research staff must complete the *SU Controlled Substances Biennial Inventory Form (Form 4)* every 2 years. From these records it must be possible to trace the flow of any drug from the vendor to the dispensing station (EH&S), to the end of use by the authorized research staff. Inventory records are to be maintained for at least two years.

## 22. How do I dispose of controlled substances and precursor chemicals?

Controlled substances to be disposed must be properly accounted for. Controlled substances are not allowed to be disintegrated, crushed into powder and dissolved in water for disposal. They must be requested for waste pick up by EH&S's Hazardous Waste Program. Participants of the University's Controlled Substances Program are to request waste pick-up from EH&S' Hazardous Waste Program by submitting the *SU Controlled Substances Disposal Request Form (Form 6)* via fax to x 5-3468. For disposal of precursor chemical waste, requests are to be made online at: <http://wastepickup.Stanford.edu>.

NOTE: EH&S only manages the disposal of DEA controlled substances (Schedule II-V) obtained under SU's institutional DEA registration; individual registrants are responsible for managing the disposal of their controlled substances per DEA requirements.