

## **Authorized Researcher's Guide**

### **SU Controlled Substances & Precursor Chemicals Program**

#### **RESPONSIBILITIES OF PARTICIPATING FACULTY AND SENIOR RESEARCH STAFF**

In order for Stanford University to ensure compliance and maintain its institutional DEA registration, it is critical that Participating Faculty/Senior Research Staff clearly understand their responsibilities, as follows:

1. Comply with university, federal and state regulations pertaining to the possession of controlled substances, via adherence to ***Stanford University's Controlled Substances & Precursor Chemicals Program***.
2. Maintain strict control over inventory and security for controlled substances.
3. Ensure that controlled substances are NOT intermingled in any manner (usage, storage, etc.) with those controlled substances owned by other individual(s).
4. Ensure Schedule II controlled substance inventory and records are maintained separately from Schedule III – V controlled substances.
5. Apply for authorization from the Research Advisory Panel of California (RAPC), if research involves Schedule I Controlled Substances, Human Research (involving Schedule I or II CS), or drug abuse treatment research.
6. Ensure necessary researcher authorization for individuals in the laboratory who are assigned to work with controlled substances (e.g., staff, graduate student, post-doc, visiting scholar or co-faculty) and maintain documentation to verify currently authorized researchers.
7. Provide training to Authorized Researchers on laboratory-specific operations involving controlled substances and precursor chemicals. Provide information on the health hazards of the substances, including local and systemic toxicity, and the conditions and situations that could result in exposure. Retain training records for at least one year.
8. Ensure Authorized Researchers receive, store, use, dispose of, and continually maintain usage log sheets and on-line chemical inventory management system for controlled substances per the University's Program. Maintain usage logs for 2 years after complete use or disposal of Controlled Substance.
9. Ensure that periodic self-inspections are conducted minimally on a quarterly basis, using ***SU Controlled Substance Periodic Inspection Checklist (Form 7)***. Retain inspection records for at least one year.
10. Biennially, complete and submit to EH&S the physical inventory, as required by regulations and directed by the institutional program.
11. Prior to moving, contact SU Controlled Substances Program Office to seek approval for moving storage location of Controlled Substances.
12. Immediately report missing controlled substances to Environmental Health & Safety by calling 5-9999. EH&S will forward cases of suspected theft or diversion to Stanford's Department of Public Safety. Any imminent safety threats are to be reported to Public Safety @9-911.
13. Ensure any delegated duties associated with this program are conducted in a timely manner.

#### **RESPONSIBILITIES OF AUTHORIZED RESEARCHERS**

An Authorized Researcher is responsible for:

1. Comply with university, federal and state regulations pertaining to the possession of controlled substances via adherence to ***Stanford University's Controlled Substances & Precursor***

**Chemicals Program** regarding:

- Authorization
  - Training
  - Security, receiving, storing, using, maintenance of usage log sheets, disposing of controlled substances
  - Separately maintain Schedule II controlled substance inventory and records from Schedule III – V controlled substances.
  - Reporting theft or loss of controlled substances.
2. If delegated by Participating Faculty/Senior Research Staff, participate in or conduct program activities such as maintaining on-line inventory, periodic inspections, biennial campus-wide inventory, etc.

## **1.0 Use Authorization/ Initial Purchase**

To gain use authorization and to purchase controlled substance under the University's DEA registration, perform Steps 1 – 4.

1. Complete and submit the *SU Controlled Substance Purchase Request Application (Form 1a\*)* to EH&S. The form includes:
- a. Basic purchase information
  - b. Proof of legitimate research use—(i.e., APLAC/IRB protocol approval or Department Chair approval)
  - c. Listing of designated researchers
  - d. Listing of designated storage locations (see Section 4.0 for requirements)

*\* For Schedule II requests, submit a separate Form 1a because records for Schedule II Controlled Substances must be maintained separately from Schedule III- V.*

2. Ensure all participating research personnel designated to handle controlled substances (including the faculty/ senior research staff members) complete and submit the *SU Controlled Substance Authorized Researcher Application (Form 2)* to EH&S. These forms are then made available to the Federal Drug Enforcement Agency's local field office.
3. As appropriate, apply for authorization from the Research Advisory Panel of California (RAPC) for the following activities:
- Use of 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.

**NOTE: Apply well in advance! — bi-monthly frequency of panel meeting may mean waits up to 60 days.** Applications are available at:

<http://caag.state.ca.us/research/research.htm>

4. After receipt and approval of Form 1a and Form 2, EH&S will coordinate with the authorized researchers to conduct a "Start-up Lab Inspection" of the laboratory to verify that security, storage, training, and recordkeeping requirements are met. [NOTE: All schedule II Controlled Substances must be stored distinctly from the Schedule III-V. Records must be maintained in a separate tagged section of the Controlled Substances Logbook.]

Item 5-6 to be completed by EH&S:

5. After use approval has been granted by EH&S, EH&S will provide approval notification, which includes assigning a SU Controlled Substances Authorization (CSA) number for tracking purposes. Ordering details will be verified.
6. EH&S will place the requested purchase using the University's DEA registration.

## **2.0 Receiving Controlled Substances & Department Charge Back**

1. Once the shipment arrives at EH&S (typically 3-10 working days after placing the order), EH&S's Controlled Substance & Precursor Chemicals Program Office immediately notifies the requesting faculty/ senior research staff member that item(s) are ready for pickup by Authorized Researchers carrying their University ID or other picture ID.
  2. EH&S will provide a *SU Controlled Substances Usage Log (form 3)* for the materials acquired.
  3. The Authorized Researcher is to deliver the controlled substance package directly to their laboratory's approved securely locked, substantially constructed storage cabinet.
  4. EH&S will initiate a journal transfer to charge back for the Controlled Substances ordered.
- For a graphical summary, see **Flow Chart 1: Purchase and Use Approval Process for Controlled Substances.**

## **3.0 Re-ordering Controlled Substances**

1. Each use approval is valid for a period of 2 years. If approved substances need to be re-ordered within this time period, the *SU Controlled Substance Re-Ordering Request (Form 1b)* is to be filled out and submitted to EH&S. After 2 years, any subsequent re-ordering will require re-submission of the *SU Controlled Substance Purchase Request Application (Form 1a)*

## **4.0 Maintaining Security in Lab**

1. **Storage:** Controlled substances shall be stored in a securely locked, substantially constructed cabinet, located where access is limited. EXCEPTION: The following must be stored in a safe: Carfentanil etorphine hydrochloride, and diprennorphine.
2. **Access:** Access must be limited to the smallest number of Authorized Researchers necessary to perform related research activities. Access is to be limited to assure complete accountability and reconciliation of any discrepancy that may result.
3. **Screening of Authorized Researchers:** All research users, including faculty and senior research staff, are required to undergo background screening via submission of the *SU Controlled Substance Authorized Researcher Application (Form 2)*, which EH&S forwards to the Federal Drug Enforcement Agency's field office. Access to controlled substances will be denied to any personnel who has 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.
4. **Work Practices:** Controlled substances must never be left unattended at any time. Discovery of an unattended controlled substance, or an unsecured storage area, may expose the institution to losing its registration.
5. **Containers/ Labeling:** Controlled substances must not be transferred from the original containers for inventory purposes. Identifying labels must not be removed from the original containers.
6. **Loss/ Theft:** Any loss/theft or diversion of controlled substances must be reported immediately to Environmental Health and Safety @5-9999. Any imminent safety threats should be reported directly to Stanford University Public Safety @ 9-911. Employee reports of known diversion of substances can be done so in a confidential manner.

## **5.0 Inventory and Recordkeeping**

1. **Ongoing inventory maintenance**—Participating Faculty/ Senior Research Staff members are required to keep track of usage of each controlled substance using the *SU Controlled Substance Usage Log (Form 3)*. Usage Log sheets must be maintained for a minimum of two years after the complete use or disposal of controlled substances, and be readily available for DEA inspection & SU EH&S compliance auditing purposes. Inventory must also be included in Stanford University's Chemtracker-Chemical Inventory Management System.
2. **Controlled Substances Periodic Inspection Checklist**— Participating Faculty/Senior Research Staff are to conduct self inspections minimally on a quarterly basis to ensure that their laboratory's Controlled Substance Usage Logs match the physical inventory and meet other compliance matters using *SU Controlled Substances Periodic Inspection Checklist (Form 7)*. Maintain inspection records for at least one year.
2. **Biennial Inventory participation**—On a biennial institutional cycle, each Faculty/ Senior Staff member participating in the University's DEA Controlled Substance Program will be directed to report their current inventory of controlled substances on a particular day in January using the *SU Controlled Substance Biennial Inventory Form (Form 4)*. Submit a separate Form 4 for Schedule II controlled substances inventory.

## **6.0 Disposal of Controlled Substances**

1. Controlled substances to be disposed must be properly accounted for, and are not allowed to be disintegrated, crushed into powder and dissolved in water for disposal.
2. 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.

## **7.0 Purchasing Precursor Chemicals**

1. For precursor chemicals to be purchased from outside of California, complete and submit the *SU Precursor Chemical Purchase Request Application (Form 5)* to EH&S. The form is to include:
  - a) Basic purchase information
  - b) Signature approval of responsible Faculty/ Senior Research Staff Member
  - c) Account number to charge department for purchase.
2. After EH&S verifies necessary information, EH&S notifies the requestor of the purchase approval and verifies purchase details as necessary.
3. EH&S places order with the vendor.
4. The vendor ships the precursor chemical order to EH&S.
5. EH&S notifies the researchers when the order is available for pick-up at EH&S.
6. EH&S initiates a journal transfer to charge the department.

➤ For a graphical summary, see **Flow Chart 2: Purchase and Use Approval Process for Precursor Chemicals**.