

Frequently Asked Questions for Faculty with Individual DEA Registrations

Purpose:

- Stanford University faculty holding individual registrations with the Federal Drug Administration (DEA) are subject to various regulatory requirements.
 - These FAQs are intended to provide basic guidance on the management of controlled substances for faculty with their own registrations.
-

General

1. **What are controlled substances?**
2. **How do I check the schedule of a controlled substance?**
3. **How do I contact the DEA?**

Registration & Approvals

4. **How do I renew my registration?**
5. **When must I seek authorization from the Research Advisory Panel of California?**

Researcher Authorization

6. **Why do I have to perform employee screening for my researchers that will work with the controlled substances under my registration? How do I do this?**

Storage/Security & Recordkeeping

7. **How do I store controlled substances?**
8. **How do I create and maintain usage logs for controlled substances?**
9. **What additional procurement and record keeping requirements apply to Schedule I & II controlled substances?**
10. **How do I conduct a biennial inventory?**

Disposal

11. **How do I dispose of controlled substances chemicals?**
12. **Why is it important to maintain custody when I move my lab or leave the University?**

Loss or Theft

13. **How do I report a loss or theft of controlled substances?**

Stanford University's Controlled Substance Program

14. **How do I enroll under Stanford University's registration?**

Stanford University
Controlled Substances & Chemical Precursor Program

Answers:

General

1. What are controlled substances?

They are 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. How do I check the schedule of a controlled substance?

DEA's Controlled Substances schedules are available at:
<http://www.deadiversion.usdoj.gov/schedules/schedules.htm>

3. How do I contact the DEA?

- Contact information for the DEA is available at:
http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/sanfran.htm

- The local DEA Office contact information is:

SAN JOSE RESIDENT OFFICE
One North First Street, Suite 405
San Jose, CA 95113

Diversion Number: (408) 291-2631
Diversion Fax: (408) 291-7720
Group Supervisor - Rikhart Rupnik
(408) 291-2631

- Stanford EH&S is also available for consultation on compliance requirements for individual registrants @723-0448.

Registration & Approvals

4. How do I renew my registration?

- To renew your registration, first go to the following website:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_13.htm
- Determine the type of business activity you conduct. (At Stanford, faculty typically holds an individual "practitioner" or "research" registration.)
 - ✓ Check the registration period (e.g., Practitioner registration is 3 years; Research registration is 1 year).
 - ✓ Check the fee (as of 2007, Practitioner registration is \$390.00; Research Registration is \$184.00)
 - ✓ Check the form needed for renewal (e.g., 224a for Practitioner, 225a for Researcher). [The DEA may send you an electronic renewal notice.]
- Registration renewal forms are available at:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Stanford University
Controlled Substances & Chemical Precursor Program

5. When must I seek authorization from the Research Advisory Panel of California?

- You must independently seek authorization from the RAPC if your 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.

Applications are available at: <http://caag.state.ca.us/research/research.htm>.

Researcher Authorization

6. Why do I have to perform employee screening for my researchers that will work with the controlled substances under my registration? How do I do this?

- 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.
- The DEA's employee screening procedures for anyone assigned to work with Controlled Substances are available at:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_90.htm
- The DEA does not provide specific background checks for employers to use. However, you can develop a background sheet using Stanford University's form, which is available at:
http://www.stanford.edu/dept/EHS/prod/researchlab/IH/cs_program/program/form2.pdf
[Note that it is critical that you do not actually use Stanford University's background form, as it may create confusion to a DEA inspector; he/she may think you are enrolled in SU's institutional program.]

Storage/Security & Recordkeeping

7. How do I store controlled substances?

Storage and security requirements of the controlled substances depend upon the schedule of controlled substances and the type of business registration. General storage/security information from the DEA is available at:

http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm

8. How do I create and maintain usage logs for controlled substances?

- Registrants must track each usage of controlled substance. Requirements are set forth in: http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_22.htm

Stanford University
Controlled Substances & Chemical Precursor Program

- The DEA does not provide specific recordkeeping forms. However, you can develop a log sheet using Stanford University's usage log, which is available at:
http://www.stanford.edu/dept/EHS/prod/researchlab/IH/cs_program/program/form3.pdf
[Note that it is critical that you do not actually use Stanford University's log sheet, as it may create confusion to a DEA inspector; he/she may think you are enrolled in SU's institutional program.]

9. What additional procurement and record keeping requirements apply to Schedule I & II controlled substances?

- To purchase a Schedule I or II Controlled Substance, you will need a "222" Form. This is a personalized form showing your DEA number. This form must be submitted to vendors during the ordering process. [The DEA uses these forms to closely track the purchase of these higher risk schedule drugs.]
- To order 222 forms, go to:
<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>
- Information about the additional storage, recordkeeping and inventory requirements for Schedule I and II Controlled Substances are available at:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm

10. How do I conduct a biennial inventory?

- Registrants must conduct an inventory of all stocks of controlled substances on hand no later than every two years from the previous biennial inventory date.
- You are required to maintain copies of your biennial inventory inspection for at least two years. A DEA inspector may ask to review the biennial inventory during a site inspection.
- The DEA's inventory procedures are available at:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm
- The DEA does not provide specific inventory forms. However, you can develop an inventory sheet using Stanford University's biennial inventory sheet, which is available at:
http://www.stanford.edu/dept/EHS/prod/researchlab/IH/cs_program/program/form4.pdf
[Note that it is critical that you do not actually use Stanford University's biennial form, as it may create confusion to a DEA inspector; he/she may think you are enrolled in SU's institutional program.]

Disposal

11. How do I dispose of controlled substances chemicals?

- The procedure for disposing of controlled substances is outlined at:
http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm#a
- The University's Hazardous Waste Program is not allowed to manage controlled substances acquired from individual registrants.

Stanford University
Controlled Substances & Chemical Precursor Program

- Individual registrants must arrange for the disposal of unwanted or expired controlled substances independently. The following vendor may be able to assist you in pick up your unwanted or expired controlled waste.

EXP Pharmaceutical Services Corp.
48021 Warm Springs Blvd.
Fremont, CA 94539
Tel: (800) 350-0397
Fax: (510) 933-1470
<http://www.expworld.com>

- To have a vendor dispose of your controlled substance waste, you will need DEA form 41. It is available at:
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html

12. Why is it important to maintain custody when I move my lab or leave the University?

- If you plan to move to another laboratory at Stanford, it is critical that you ensure that the controlled substances and their records are moved under your supervision to avoid them from being lost or stolen.
- If you plan to leave the University, you must make arrangements to move them with you or to arrange for their disposal. Abandoned controlled substances may result in criminal penalties.

Loss or Theft

13. How do I report a loss or theft of controlled substances?

- If any imminent safety threat exists, contact Public Safety directly at 9-911.
- The DEA provides direction on thefts for significant losses at
http://www.deadiversion.usdoj.gov/fed_regs/rules/2003/fr0708.htm
- To report losses or thefts, submit DEA Form 106 which is available at:
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

Stanford University's Controlled Substance Program

14. How do I enroll under Stanford University's registration?

- Stanford University's holds an institutional registration for its research use of Controlled Substances (for Schedules II – V). If you would like to consider enrolling in this program, please visit the following website for additional information:
http://www.stanford.edu/dept/EHS/prod/researchlab/IH/cs_program/index.html
- Questions regarding this program can be directed to SU's Controlled Substances Program: Julie Wang at 725-7521, <mailto:qlwang@stanford.edu> or Mary Dougherty at 725-1474, mdough@stanford.edu.

Stanford University
Controlled Substances & Chemical Precursor Program