

Frequently Asked Questions (FAQs) for Faculty Seeking or Holding Individual Federal Drug Enforcement Administration (DEA) Research Registrations

Purpose:

- Stanford University faculty seeking or holding individual research registrations with the Federal Drug Enforcement Agency (DEA) are subject to a number of specific regulatory requirements.
 - The Frequently Asked Questions (FAQs) below are intended to provide guidance on the application process with DEA investigators and to facilitate understanding of the responsibilities of holding an individual DEA research registration.
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2. **How do I check the schedule of a controlled substance?**
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What I Need to Know Before I Seek a Registration with the DEA

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17. **Why is it important to maintain custody of controlled substances when I move my lab or leave the University?**

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

Stanford University
Controlled Substances & Precursor Chemicals Program

Answers:

General

1. What are controlled substances?

Controlled substances are regulated 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/index.html>

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

Diversions Number: (408) 291-2631
Diversions Fax: (408) 291-2636
Group Supervisor - Rikhart Rupnik
(408) 291-2631

- Stanford University's Controlled Substances Program is also available for consultation on compliance requirements for individual registrants by calling EH&S at (650) 723-0448.

What I Need to Know Before I Seek a Registration with the DEA

4. Can I enroll under Stanford University's institutional research DEA registration?

- Stanford University holds an institutional registration for research use of Controlled Substances (for Schedules II – V). Faculty who are interested in considering enrollment in this program should visit the following website for additional information:
http://www.stanford.edu/dept/EHS/prod/researchlab/IH/cs_program/index.html
- **Exclusions:** Stanford University's institutional research DEA registration does not cover: (1) research off the main Stanford University Campus; (2) research involving Schedule I Controlled Substances; (3) use in patient care; (4) clinical trials in which participants take medication off-site. In these instances, the faculty member would need to seek his/her own registration (see #7 below).
- Coverage under the institutional registration may not be appropriate for every research program use. In such instances, a faculty member may need to apply for an individual research registration.

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- Questions regarding the institutional registration program or about individual registration can be directed to SU's Controlled Substances Program by calling EH&S at (650) 723-0448.

5. What are the benefits of enrolling under Stanford's institutional research DEA registration?

- Individual faculty do not have the management responsibility to apply for and to annually renew their registrations.
- Individual faculty do not bear the annual cost of holding a registration (in 2010, cost = \$184).
- EH&S administers the institutional DEA research registration which provides various services such as: support on security/recordkeeping issues, ordering of controlled substances (note - cost of controlled substances is borne by faculty), and administration of biennial inventories.

6. What would my responsibilities include if I hold an individual DEA registration?

Under Title 21 Code of Federal Regulations (CFR) 1300-1399, responsibilities of managing an individual DEA registration include, but are not limited to:

- a. Undergoing the application and review process by the DEA
- b. Ensuring personnel from your lab who would have access to controlled substances have undergone a screening process
- c. Ensuring security/recordkeeping requirements
- d. Renewing DEA registration annually
- e. Performing biennial inventory of controlled substances stocks
- f. Sending unused or expired controlled substances to a reverse distributor for disposal
- g. Reporting any discrepancy in inventory or losses of controlled substances to the DEA

Registration & Approvals

7. How far in advance should I submit the application to the DEA?

After you have determined that your research needs an individual registration (see #4-6 above), it is prudent to submit an application to the DEA approximately three months in advance of when your research would require the use of controlled substances. This timeframe should be adequate to go through the evaluation and vetting process by the DEA and then order the controlled substances from the vendor.

Caution: Do not submit your DEA application if your research plans are preliminary or if the faculty member will be traveling extensively. Once your application is in the DEA queue, the DEA office will want to review and expedite the application in a timely manner. The DEA will need to interact directly with the faculty applicant. Faculty are strongly advised to have the project well planned before initiating the application process in order to promptly answer questions posed by the DEA investigator. The DEA office processes hundreds of applications and any delay in responding to requests for follow up information may result in significant delays in processing your application.

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8. How do I apply for a DEA registration?

After you have determined that your research needs an individual registration (see #4-6 above), follow the directions below:

1. To apply for a registration, first go to the following website:
<http://www.dea diversion.usdoj.gov/drugreg/index.html>
2. Complete the online application for a “research” registration using “DEA Form 225.” Note: There are different forms for different DEA registrations (e.g., individual “practitioner” registration use “DEA Form 224”).
3. After you submit this application electronically, a DEA investigator will contact you for detailed information about the nature of your intended research (this DEA follow-up may occur days to weeks after the online submission). Be prepared to answer (verbally or in writing) the following questions including, but not limited to:
 - Specific Controlled Substances to be used (along with drug code)
 - Intended research use for each substance (describe the specific nature of the proposed research use)
 - Approximate yearly amount of each substance anticipated to be used in the research procedures
 - Name and address of vendor(s)
 - Location of storage/description of local security measures (e.g., securely locked, substantially constructed cabinet (or safe, if necessary) where access is limited)
 - General building security information (e.g., building alarm system, cardkeys, receptionist). DEA wants to know the relative security from theft and other access to these controlled substances.
 - List of personnel with access to controlled substances (e.g., name, title, birthdate)

Caution: *It is important that you respond to requests for information completely from the DEA investigator in a timely manner (e.g., within five working days).* Failure to respond in a timely manner and/or with incomplete information may result in rejection or a significant delay in the application.

9. When must I seek authorization from the Research Advisory Panel of California (RAPC)?

In addition to holding a DEA registration, you must independently seek authorization from the RAPC if your research project specifically involves:

- 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>.

Note: You must have DEA registration and approval from SU’s Institutional Review Board (IRB) Office before you seek RAPC approval.

10. How do I renew my registration?

- To renew your registration, first go to the following website:
<http://www.deadiversion.usdoj.gov/drugreg/index.html>
- Click on “Renewal Application.” Complete online application.

Researcher Authorization

11. Why do I have to perform employee screening for my researchers who 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 personnel assigned to work with Controlled Substances are available at 21 CFR1301.90-93:
<http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm>
- The screening process includes:
 - inquiring in writing if the employees have past felony convictions in the last five years or have used narcotics in the last three years other than those prescribed by a physician,
 - obtaining permission from the employees to make inquiries with local or federal law enforcement regarding felony convictions;
 - informing employees of potential disciplinary action for employees who engage in illicit activities;
 - informing employees of the regulatory responsibility to report suspect diversion.
- Questions regarding employee screening for controlled substances access can be directed to SU’s Controlled Substances Program by calling EH&S at (650) 723-0448.

Storage/Security & Recordkeeping

12. How do I store controlled substances?

- Storage and security requirements of the controlled substances depend upon the schedule of the 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
- Questions regarding security requirements can be directed to SU’s Controlled Substances Program by calling EH&S at (650) 723-0448.

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

- Registrants must track each usage of a controlled substance. Requirements are set forth in: http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_22.htm
- Questions regarding use logs can be directed to SU's Controlled Substances Program by calling EH&S at (650) 723-0448.

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

- To purchase a Schedule I or II Controlled Substance, the registrant will need a DEA Form 222. This is a personalized form showing the registrant's 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 I or II controlled substances.]
- To order DEA Form 222, 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

15. 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
- Questions regarding biennial inventories can be directed to SU's Controlled Substances Program by calling EH&S at (650) 723-0448.

Disposal

16. How do I dispose of controlled substances?

- The procedure for disposing of controlled substances is outlined at: http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm#a
- Individual registrants must arrange for the disposal of unwanted or expired controlled substances independently. The following vendor may be able to assist you in picking up your unwanted or expired controlled substance waste.

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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
- The University's Hazardous Waste Program is not allowed to manage controlled substances acquired from individual registrants. However, if there are any questions regarding management of controlled substances waste, EH&S is available for consultation at (650) 723-0448.

17. Why is it important to maintain custody of controlled substances when I move my lab or leave the University?

- If you plan to move to another location 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.
- Consult with the DEA office on these matters (see #3 above for contact information).

Loss or Theft

18. 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 or 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