

DEA Schedule 1

Research Applications, Process, and Requirements Checklist

This checklist is meant to include the basic items which need to be accomplished to apply for, retain, and closeout a Schedule 1 DEA registration. DEA registrations are not transferrable. Retain copies of all documents sent to regulatory agencies since any changes to your scope of work (including storage area) will need to be reviewed by the Research Advisory Panel of California (RAPC) and DEA prior to work. If your research involves Marijuana, also see [UC Guidance Memo 17-01](#).

- Schedule consultation with EH&S Controlled Substance Program Administrator. Process, timeline, and requirements will be reviewed with Principal Investigator (PI). As a courtesy, the Controlled Substances Program Administrator can assist the Schedule I applicant for approval, however **EH&S does not manage, monitor, or audit** Schedule I DEA Registrations. The responsibility and maintenance is solely the Schedule I applicant (PI).
- IACUC, IRB Approval or In Vitro protocol listing experiments using Schedule 1 Controlled Substance (Required prior to submitting applications)

Research

- [Research Advisory Panel of California \(RAPC\)](#):
 - [Non-Human Research Schedule I CS Application](#) – All sections of the application must be completed within the form field provided. Please type or print legibly. Incomplete fields or missing attachments will delay the application process.
 - PI's Curriculum Vitae
 - Approved IACUC/In vitro Protocol
 - Copy of DEA Registration Application form 225 (see below)
- Submission: All the application submission packets should be sent via e-mail in PDF format (Maximum e-mail capacity is 10 MB per e-mail) to jennifer.ahn@doj.ca.gov and also three sets of hard copies of the application packet should be mailed via U.S. Mail, FedEx, UPS, or any other commercial mail carriers to:
- Y. Jennifer Ahn, Pharm.D
Research Advisory Panel of California
Office of the Attorney General
455 Golden Gate Ave., Ste. 11000
San Francisco, CA 94102-7004
- o Note that the RAPC committee meets infrequently. Here is their posted schedule: <https://oag.ca.gov/research/meeting>.
 - o The response of the Panel review will be delivered via PDF format within 7 days after the meeting.

How to Register with the DEA

- [DEA Registration:](#)
 - Download and complete [DEA Registration Application form 225](#)
 - [DEA Research Protocol](#) List of Requirements (21 CFR 1301.18):
 1. Investigator:
 - i. Name and address
 - ii. Institutional or company affiliation
 - iii. Qualifications, including **CV** with a list of publications
 2. Research Project*:
 - i. Title of project
 - ii. Statement of the purpose
 - iii. Name of Controlled Substances (CS) involved, amount (**with justification**) of each needed and **source**.
 - iv. Description of the research to be conducted (**detailed description of procedures**), including number and species of research subjects, dosage to be administered, route and method of administration, and **duration of project**.
 - v. Location where research will be conducted.
 - vi. **Statement of security provisions** for storing and dispensing the CS(s) in order to prevent diversion (storage in accordance with [Sec. 1301.75](#)).
 - vii. If investigator plans to manufacture or import the CS(s), statement of quantity to be manufactured or imported and sources of chemicals to be used or substance to be imported.

* The necessary information is most likely contained in one of your existing documents, including a current existing IACUC protocol, project summary/protocol in grant submission, IRB protocol, or IND submission. If this is a clinical investigation, see [21 CFR 1301.18b](#).

 3. Authority (if applicable):
 - i. Institutional approval
 - ii. Approval of a Human Research Committee for human studies.
 - iii. Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number).
 - iv. Indication of an approved funded grant (number), if any.

Submission by mail (send three hard copies):

DEA Headquarters
ATTN: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

- Note: The DEA does not have a formal committee deadline. The DEA registration application must be approved by the FDA, the local DEA, and finally the DEA Headquarters has final authority to approve the DEA registration application. The DEA start reviewing applications whenever the application is received, and the process normally takes several months. To help your application get reviewed efficiently, ensure you submit all portions of the application and reply to any questions as soon as they're asked.

Preparation for Scheduled DEA Site Visit

- A dedicated storage location for Schedule 1 Controlled Substance (CS) and logbook must be identified and in place (separate from other CS) before the DEA site visit. Be sure to consider schedule 1 chemical's storage temperature requirements. Changes to Schedule 1 storage are only permissible by local DEA approval.
[DEA Diversion Schedule I Storage Requirements](#)

- DEA Headquarters will contact the local DEA investigator to schedule the site visit. The local investigator will contact the PI or lab contact to schedule and will ask for additional security, storage, and other information. *Recommended: inform the EH&S CS Program Administrator of the scheduled site visit date and time.*

Date and time of site visit: _____

Assigned DEA Investigator(s): _____

- o Examples of items that may be requested by DEA at or in advance of this site visit:
 - PI's Curriculum Vitae
 - List of personnel, including screening forms with CA driver's license number and last four digits of Social Security Number
 - Study Protocol (RAPC Approval, IACUC)
 - Power of Attorney template (Contact campus' EH&S CS Program Administrator for template)
 - List of controlled substances or chemical products that are expected to be handled under this registration
 - Controlled Substances Inventory log and logbook
 - Controlled Substance purchase policy
 - Supplier information (name of company, address, and DEA number of all expected controlled substances/listed chemical suppliers)
 - Floor plan or building diagram which shows controlled substances storage area
 - Security alarm description or contract (for building where controlled substances will be stored)
 - Disposal procedures
 - Standard Operating Procedures [SOP] and due diligence guidelines for handling controlled substances and monitoring suspicious activity
 - Specifications for controlled substances vault, safe, or storage cabinet

Post Approval of DEA Schedule I Registration

DEA Headquarters makes final determination of Schedule I Registration approval and DEA registration number is assigned and certificate is mailed.

- Forward copies of approval letters and certificates to EH&S CS Program Administrator
- Issue Power of Attorney (if any) as per [21 CFR 1305.05](#)
- Record Initial Inventory as per [21 CFR 1304.11b](#).
- Order 222 forms if none received:
<https://apps.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

Maintenance of DEA Schedule I Registration

Renew DEA Registration (Yearly)

Submit RAPC Annual Progress Report (<https://oag.ca.gov/research/progress>) (Yearly, due by end of February)

Renew/review Security Alarm and testing (if applicable) (Yearly)

Record Biennial Inventory (Every two years)

Screen new Authorized Personnel (As needed)

Closure of DEA Schedule I Registration

Relinquish any unused inventory to registrant (either reverse distributor or original supplier) per [21 CFR 1317](#).

Notify the RAPC in a letter form including a study completion date, and a final summary report of the study, and a drug usage log sheet if applicable in a PDF format only.

Notify DEA of desire to close-out DEA registration per [21 CFR 1301.52](#) including:

- Letter stating the desire to close the DEA registration

- Certificate of registration

- Any unexecuted order forms in his/her possession

Send to: Registration Unit, Drug Enforcement Administration

Maintain all files (including acknowledgement of Registration closure) at registered location for two years.

UC Resources

UCR Environmental Health & Safety

Controlled Substances Program

<http://ehs.ucr.edu/controlledsubstances>

UCOP Environmental, Health & Safety

[Controlled Substance Program Administrators](#)