Reed College DEA Controlled Substances

June 2024

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Purpose

Information below is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), U.S.C. 801-904; the Controlled Substances Import and Export Act (CSIEA), 21 U.S.C. 951-971; and Drug Enforcement Administration (DEA) regulations, CFR parts 1300 to end. This document is written for Faculty, as they are ultimately responsible for the use and storage of the substances registered to them.

Prior Approval

Faculty must obtain a Form DEA-225 "Researcher" Registration from the federal DEA. You must contact EHS prior to completing your registration application for a consultation (primer on the regulations, recordkeeping, etc.) and information to receive a fee exemption. Reed College will not pay any fines or damages resulting from noncompliance with federal, state, and local regulations, or resulting from noncompliance with Reed policies; such fines or damages are the sole responsibility of the registered individual.

Registration

Faculty members who order, store, use, and dispose of DEA Controlled Substance must register with the DEA (for Schedules I-V); to be a Registrant, the individual must be authorized to conduct research involving controlled substances at the Reed Institute, and be able to demonstrate the legitimacy of their research credentials (e.g. PhD or extensive research credentials).

Federal Registration

Contact EHS prior to completing your federal DEA application for a consultation (primer on the regulations, recordkeeping, etc.) to receive a fee exemption. Federal registration can be completed online at the DEA website, or via mail. Researchers must use the Form DEA-225 "Researcher" registration.

- DEA registrations must be renewed annually; the DEA will contact you the month prior to expiration for a renewal.
- For modifications*, transfers, or terminations of a registration, contact the DEA office and EHS.

  *Modifications include a change in the use and/or storage locations (e.g. laboratory or building moves, new use spaces, etc.). Separate research locations, such as labs housed within different buildings, require a separate registration; a single registration with multiple locations on campus for use and/or storage is not compliant with DEA regulation.

- Each Faculty must have an individual DEA Research registration. DEA Controlled Substances cannot be shared between Faculty unless both Faculty are co-researchers on the same grant and the second Faculty is listed as an authorized user under the Faculty with the registration.
    - A practitioner registration (DM, DVM) cannot be used.

Security and Access Control

- Only Authorized users shall have access to DEA Controlled Substances.
- All Controlled Substances must be stored behind at least two differently keyed locks at all times.
- Always keep all DEA Controlled Substances secured under lock and key and behind two differently keyed locks.
    - Only the registrant and authorized dispenser(s) should have access to the keys.
    - Only the registrant, authorized dispenser, and authorized users may use the DEA Controlled Substance.
    - A DEA approved safe must be used for Schedule I and II drugs, accessible only to authorized personnel. Store Schedule I and II DEA Controlled Substances separately from all other drugs and reagents.
- Return DEA controlled substances to their approved storage location(s) immediately after use, keeping them locked at all times except when removing, replacing, or actively working with them.
- Maintain only necessary stock as required for normal efficient operation.
- For Schedules I-II, the Controlled Substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled Controlled Substances, with the cabinet secured to a wall or otherwise not removable, as per federal regulations. EHS recommends the use of a wall-mounted safe (Schedule 1) or a wall mounted narcotics cabinet (Schedule II).
- For Schedules III-V, the Controlled Substance must be in a locked cabinet or safe. EHS recommends the use of a wall-mounted narcotics cabinet.
- Many drugs must remain refrigerated, and these same security requirements apply. EHS recommends purchasing a fridge narcotics box that can be mounted or somehow locked into the fridge such that the cabinet could not be picked up and taken to a secondary location.

Example
Schedules I&II

Example
Schedules III, IV&V

Lost or Stolen Controlled Substances

- Significant losses or theft must be reported immediately to the DEA. In addition, Reed College Risk Management and the Director of Community Safety.
- The registrant should provide initial notification in writing of the loss or theft to the DEA Portland field office.

  PORTLAND DISTRICT OFFICE

  100 SW MAIN STREET
  SUITE 500
  PORTLAND, OR 97204

  Phone 1: (888) 219 4261
  Fax 1: (503) 721 6602

- Use online DEA Form 106: Report of Loss or Theft to follow up with initial notification.
- All in transit losses and lost DEA Form 222s must be reported to the DEA.
- During initial inquiries into the incident, registrants must complete an online DEA Form 106: Report of Theft or Loss of Controlled Substances Form 106. A report must still be filed if lost or stolen material is recovered.
- Minor discrepancies in inventory **that are not attributed to theft or loss** can be reconciled on the inventory report with proper notation. A DEA Form 106 does not need to be submitted for this purpose. However, the DEA should be contacted for guidance on how to proceed with such matters. The DEA recommends a registrant should determine significant loss in relation to Controlled Substance activity, patterns or trends of loss, and loss of Controlled Substances with high risk of diversion. Refer to the DEA Office for Diversion Control for more information.

Record Keeping

A Controlled Substance Usage Log will be used to log the physical balance of the CSs at all times, and all discrepancies will be documented with explanation. This form will be kept for the duration of the project plus an additional 3 years. Logs shall be kept near the control substance work area.

A dilution log will be used to log a dilution, and each dilution will have its individual dilution log. These forms will be kept for the duration of the project plus an additional 3 years.

Forms that must be kept within your records include but are not limited to (keep separate from log):

- A copy of the invoice.
- A copy of the purchase order.
- A copy of the shipping document.
- A copy of the packing slip.
- The name, address, and DEA number of the company from which the Controlled Substance was purchased.
- The name of the Controlled Substance purchased.
- The size and strength of the Controlled Substance purchased.
- The amount purchased (which should match the amount received).
- Inventory forms (all inventory forms must be kept on file in the lab where the substance is used).
- Controlled Substance Use Log - Every container of Controlled Substance in your possession must have an associated use log that is kept in the same locked and secure place.
- Containers of concentrate or solids - A Controlled Substances must each have a log sheet to record the amount removed to make dilutions or solutions.
- Dilutions and solutions - if the staff has diluted a product for use, and uses it all during one application, there is no need to create an inventory for that dilution. If any diluted material remains for intended use at a later date, a new inventory page must be created, as it is considered a “new product” and dilution.
- Transfer Log - To track the transfer of Controlled Substances from one authorized person or location to another.
- Biennial Inventory Form - A full inventory of all DEA Controlled Substances must be completed every two years. Any product that is in the lab at that time must be inventoried, even if it has not been in the lab’s possession for the full two years.
    - Entries are made when the substance is dispensed and are hand-written in ink.
    - Waste bottles: If the lab makes a dilution of the product and does not use all of it in their work, the remaining portion is now considered waste. A new inventory form for the dilution must be initiated and kept for any amounts of that same dilution. Lab staff cannot add different dilutions to this waste bottle.

- Record of destruction of a lab's DEA materials will be recorded by the DEA program manager on the DEA Form 41. This form will be sent to the DEA regional manager and a copy sent to the individual Faculty.

Shipping, Transport, Exporting, and/or Transferring

- Federal law prohibits the export of DEA Controlled Substance unless certain requirements are met. Special licenses, as well as export and import permits, are required to export Controlled Substances.
- Controlled substances cannot be transported in personal vehicles; contact EHS for assistance in arranging for any necessary shipping/transport of DEA Controlled Substance.
- Transferring DEA Controlled Substance from one researcher to another is acceptable only if the following requirements are met:
  - Less than 5% of the Registrant's inventory is transferred: 5% or more constitutes the person transferring as a DEA Controlled Substance distributor and is outside of the Researcher registration's scope.
  - Researchers must document this on their inventory and use logs and
    - DEA Controlled Substance Schedule I and/or II must also have a Form DEA-222 associated with the transfer.

Disposal procedures

DEA Controlled Substances will be properly disposed of prior to DEA registration expiration and prior to the lab closing (if applicable).

Controlled substances will be disposed of one of two ways:

- Contact the Supplier:
  Some suppliers will take back pharmaceuticals for credit. If possible, this is the best means of Controlled Substance disposal.

- Reverse Distribution:
  - Contact a Reverse Distribution Vendor to register.
  - Complete the vendor's application for approval to ship material – either in paper form and sent by mail / fax or in electronic form (both require current DEA registration).
  - Additional Forms – Completing DEA D-222 form if necessary (for Schedule I & II Controlled Substances)
  - Payment – payment or payment information is required with application.
  - Always request documentation of return/disposal/destruction.

Appendix A: FAQ

1.) What are “controlled substances”?

Narcotic and non-narcotic drugs under the jurisdiction of the Federal Controlled Substances Act (CSA) and the State of Texas Controlled Substances Act, including, but not limited to, those substances listed in 21 CFR parts 1308.11-1308.15. These are known as scheduled controlled substances or scheduled drugs under the CSA.

2.) What does the controlled substance program include?

The major elements of the controlled substance program include project registration, procurement, storage and security, usage and disposal of unused, expired and waste containing controlled substances, and inventory procedures.

3.) What are the DEA schedules or code numbers for the controlled substances?

The DEA assigns each controlled substance a schedule number (I through V) according to its medicinal value, harmfulness, and potential for abuse or addiction. A higher schedule number indicates the substance has more medicinal value and less potential for abuse or addiction. The most common controlled substances used in research and respective schedule numbers and DEA codes are listed below. Controlled Substance Schedule DEA Code Buprenorphine III 9064 Diazepam IV N 2765 Ketamine III N 7285 Pentobarbital (e.g., Nembutal) II N 2270

4.) Who is considered a Licensed Researcher?

‘Licensed Researcher’ refers to the faculty member throughout this document and is someone who possesses a ‘Researcher’ category license through the DEA.

5.) Who are Authorized Laboratory Personnel?

Authorized Laboratory Personnel are research staff, including students and postdoctoral scholars that work under the direct supervision of a licensed researcher. In addition to the licensed researcher, the authorized laboratory personnel (also known as daily users) may participate in working with controlled substances as part of the approved experiments or treatments involving research animals. Authorized laboratory personnel can perform these functions without keys or combination access to the safe or cabinet where bulk quantities of controlled substances are stored. Licensed researchers must take responsibility for dispensing limited quantities of controlled substances to authorized laboratory personnel for daily use and maintaining unused substances in the safe or locked cabinet for proper storage. Licensed researchers are ultimately

responsible for the management of controlled substances acquired under their DEA registration or license.

6.) What should I use as the address for my DEA registration?

The DEA regulations require that licensed researchers have a separate DEA registration for each location where controlled substances are received, stored or used. If you are using DEA-controlled substances in different rooms within the same building, but only storing controlled substances at one location within a specified building, then your registration need only reflect the storage location. If you are planning to receive, store or use DEA-controlled substances in more than one building or you are storing DEA-controlled substances in more than one location within the same building, then you must have a separate DEA registration for each building and storage location. To minimize the need for transferring controlled substances between multiple registrations held by a single licensed researcher, they should order the controlled substances that they will need for each separate building/building location under the appropriate registration for such building/building location.

7.) I am a licensed healthcare professional and have a practitioner's registration with the DEA. Can I use this registration to cover my non-clinical research that involves the use of DEA controlled substances, or should I obtain a separate DEA registration for research use?

Clinical practitioners must maintain a separate 'Researcher' category license to conduct nonclinical research. While a DEA registration held by a practitioner may permit research use of the specified DEA controlled substance(s), the DEA registration is specific to a certain location where the controlled substances are received and stored. If you do not store controlled substances at your practice location, you may be able to maintain the single registration for the research location where the chemicals are received and stored. However, controlled substances acquired under the 'Researcher' category license must not be used in clinical practice. Please call the local DEA office 1-888-219-4261 if you need more guidance. Note: controlled substances used for clinical purposes must be prescribed and administered by Reed College's veterinarian.

8.) Do I have to apply for separate registrations for Schedule I controlled substances and Schedule II-V Substances?

Yes. Research investigators must apply for a separate registration if the research involves both schedule I and schedule II-V controlled substances. For registration with DEA, separate applications must be submitted for schedule I substances and schedule II–V substances. How often do I need to renew my registration? The DEA registration renewal is typically every year, based on the type of the activity (Title 21 Code of Federal Regulations (CFR) Part 1301.13).

9.) Can a registration be transferred to someone else once a licensed researcher leaves the campus?

No. Registration and authority to use controlled substances are not transferable. Individuals who want to use a controlled substance in their research are required to be registered with the DEA. DEA approval must be obtained prior to transferring any controlled substances to another research investigator. The transfer process is the same as one would use to purchase substances from an approved vendor or request a reverse distribution.

10.) Must each individual faculty member obtain their own registration(s) or can a designated departmental investigator obtain registration(s) on behalf of many other investigators within the same department?

Any research investigator that will be prescribing, administering, ordering, or dispensing controlled substances must individually register with the DEA. Please be aware that transfers of controlled substances between two licensed researchers are the same as the purchase of controlled substances from an approved vendor and therefore proper DEA procedures must be followed.

11.) Who must undergo a security screening, and how does the screening process work?

As part of the DEA registration, every 'Researcher' category registrant is required to undergo a DEA background check/screening. No additional screening is required by the College. Staff members working under a licensed researcher are not required to complete a DEA background/security screening.

12.) I am a licensed researcher with the DEA. Do my trainees or students need a DEA background check?

No. Any individual employed in research studies conducted in the licensed researcher's laboratory who has access to the controlled substance(s) must be approved by the licensed researcher. Licensed researchers are ultimately responsible for checking each staff's credentials for handling the controlled substances

13.) A controlled substance is backordered by Sigma-Aldrich and my current supply will not be sufficient for my ongoing studies. What should I do?

Proper attention to the inventory of controlled substances in a laboratory should typically prevent shortages from occurring. If a controlled substance is backordered at Sigma-Aldrich, for example, the licensed researcher or an Authorized Agent of the licensed researcher should contact the DEA to obtain permission to order the controlled substance from an alternate distributor. Be aware that borrowing a controlled substance from other licensed researchers is against DEA regulations.

14.) Can I transfer controlled substances to another authorized Faculty member at the College?

Yes, but only after receiving approval from the DEA and only if the following criteria are met: (1) the authorized Faculty who is to receive the substance(s) must first receive DEA approval for the transfer, and (2) both parties maintain proper documentation for any approved transfers. The transfer process is very similar to the purchase of controlled substances from an authorized distributor.

15.) Can I transfer controlled substances to another individual at another University or institution?

No. Such transfers are not allowed under any circumstances. Controlled substances procured under a specific research investigator's DEA registration cannot be transferred to another individual who is not registered with DEA. A better way for such transfers is via reverse distributors who ensure the proper paperwork and documentation for physical transfers.

16.) The DEA says that I need to double-lock my controlled substances. What does this mean?

This means that two locks must be in place to adequately secure the controlled substances. A laboratory door that is locked when authorized personnel (the licensed researcher, authorized agent(s) of the licensed researcher, or authorized lab personnel) are absent can serve as one of the "locks." Within the laboratory, controlled substances must be secured within a locked cabinet or safe that cannot be moved or transported. Schedule I and schedule II controlled substances must be secured within a specific type of safe or steel cabinet. The DEA regulations provide specifications regarding such enclosures. A narcotics cabinet (double lock, double door, which must be bolted to a wall) is recommended for drug storage. The safe or cabinet must remain locked at all times when controlled substances are not being dispensed from or returned to storage. Details regarding security requirements can be found in 21 CFR Section 1301.71.

17.) How do I store controlled substances during field work?

Controlled substances must be stored in a locked box either under direct control of an authorized agent or authorized lab personnel or in a locked building or vehicle when not in use during field work. An example of field work could be when the authorized work is performed in a fume hood located in a different room within the building or in an animal research area on a different floor of the same building.

18.) My colleague and I have separate DEA registrations in a shared laboratory. Can I share the drug locker of my colleague in the department?

No. Each licensed researcher should maintain their own secured lockbox or other secured cabinet for storage of DEA-controlled substances that are permitted by the individual license.

19.) I suspect that controlled substances have been stolen from the lab, but since I am not the licensed researcher or an authorized agent I can't be sure. What should I do?

The licensed researcher is ultimately responsible for the oversight of controlled substances that are maintained or used under their direction. Hence, any suspicion of possible diversion of a controlled substance should be initially brought to the attention of the licensed researcher, who must promptly report to the Environmental Health and Safety Department and Community Safety upon the discovery of the loss. Notification to the DEA should include the licensed researcher promptly completing a DEA form 106.

20.) What are the fines and penalties if I am non-compliant with the DEA controlled substance regulations?

Actions may include administrative, civil, or criminal prosecution. The DEA can fine a licensed researcher for each and every violation that it finds. Loss or suspension of a controlled substance license and DEA registration could be catastrophic for a research investigator.

21.) What is the definition of 'access to controlled substances'?

Anyone who has the ability to access or can gain access to controlled substances: a person who is responsible for (1) obtaining, assuring secure storage, managing the initial or annual inventory, (2) completing the aliquot logs and recordkeeping, (3) distributing controlled substances or a dilution thereof to other approved laboratory personnel, and (4) dispensing to an animal or disposing of controlled substances waste.

22.) How does a registrant report the breakage or spillage of controlled substances?

Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process. The DEA recommends that any registrant seeking to dispose of controlled substances first contact the nearest DEA Diversion Field Office for disposal instructions. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. If the breakage or spillage is not recoverable, the registrant must document the circumstances of the breakage in the inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41, Registrant Record of Controlled Substances Destroyed, is not required for non-recoverable controlled substances. The DEA procedures established for the destruction of controlled substances shall not be construed as altering in any way the state laws or regulations for the disposal of controlled substances. When this disposal occurs, it must be reported to the DEA on a DEA Form 41.

23.) How do I dispose of my controlled substance?

You may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a third party company who is authorized to receive such materials. These commercial operators are referred to as reverse distributors. Schedule I and schedule II controlled substances should be transferred via the DEA form 222, while schedule III–V substances may be transferred via invoice. The licensed researcher must maintain copies of the records documenting the transfer and disposal for a period of at least 2 years after disposal of a controlled substance. There is a charge for the use of a reverse distributor. The cost of waste disposal depends on the type and quantity of the substance. You may also try contacting the manufacturer to request authorization to return the controlled substances directly to them.

24.) Who are the 'reverse distributors'?

Reverse distributors (third party companies) are registered with DEA and are authorized to receive out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including unwanted bulk controlled substances samples from DEA licensed researchers and dispose of the waste(s) by appropriate DEA procedures.

25.) Is there any difference in the procedures for discarding empty vials (injectable drugs) of controlled substances vs. residual quantities of expired controlled substances?

Empty vials of controlled substances (injectable drugs) can be disposed of in red bag biohazardous waste containers, although the label should be removed or rendered unreadable. In addition, the disposal of the empty vial must be recorded in the respective controlled substances accountability record. Expired containers of controlled substances (with any contents remaining) must be separated from non-expired containers of controlled substances, and must be clearly labeled as being expired. The expired containers of controlled substances must remain in the locked controlled substances cabinet or safe. Final disposition of the expired quantity of the controlled substance must be documented in the respective controlled substance accountability record.

26.) I obtained a reagent that contains a controlled substance but it was sold to me without having to provide a DEA registration number? How can this be?

A manufacturer or distributor of certain reagents may apply to DEA for exemption from the requirements of DEA registration. These are typically research or analytical reagents that contain very small amounts of the controlled substance.

27.) Will EHS take custody and dispose of my DEA regulated material as a hazardous waste?

No. It is against the law for EHS to take possession of any DEA regulated substances from your research lab. The DEA strictly regulates all purchases, storage, dispensing and disposal of expired, unwanted or any other schedule I, II, III, IV and V controlled substances or drugs. Only individual licensed researchers who have submitted an application and are assigned a DEA registration number are allowed to purchase and possess DEA regulated controlled substances.

28.) How can I dispose of controlled substances left behind by a previously- licensed researcher or other investigator?

It is the responsibility of DEA- licensed researchers to dispose of all controlled substances before they leave the College. If the original licensed researcher is not available and DEA is not able to determine who in your department is registered, then you, the current owner, are responsible for contacting the EHS office.

29.) How do I dispose of an orphaned controlled substance?

Please refer to the responses to the previous questions. If your laboratory discovers a controlled substance and the registrant is not known to you or your department, please contact EHS for recommendations. Indicate you discovered an orphaned controlled substance in your laboratory that needs to be properly disposed of. Please be aware it is against the DEA regulations for EHS to pick up the controlled substances from your laboratory or provide you with a temporary storage; therefore, EHS cannot accept a controlled substance or controlled substance bearing waste. The pickup and disposal of orphan drugs must be properly handled through reverse distributors.

30.) Is it possible for EHS personnel to become a licensed researcher, which would then allow them to collect and segregate controlled substances from researchers around campus prior to disposal, either orphaned substances or the hazardous waste solvents containing controlled substances, and then ship the solvent waste off-site for thermal destruction?

No. The above described process is not an acceptable solution, as confirmed by the DEA. Therefore, EHS is not allowed to collect, store or ship off site any controlled substances. Please contact a reverse distributor.

31.) Is there a preferred disposal method available to dispose of orphan controlled substances?

No. The correct process for the licensed researcher is to legally dispose of any controlled substances under the ownership and control of the licensed researcher when these substances are no longer needed or prior to the licensed researcher leaving the facility. Proper disposal could be through a sale or transfer of the controlled substances to another licensed researcher authorized to possess the substances (only if authorized to do so by DEA) or, if the controlled

substances are to be destroyed, the licensed researcher must take arrangements for that destruction and dispose of them through a licensed reverse distributor. Reverse distributors are registered with DEA to accept the controlled substances from licensed researchers for appropriate destruction or other means of disposal.

32.) Could I be subject to an inspection?

Yes. The DEA has the authority to oversee and inspect facilities before and after registration approval.

33.) What specific records must be maintained after obtaining DEA registration for receiving, storing, and administering controlled substances?

It is imperative that each licensed researcher adheres to all DEA record keeping requirements to ensure proper security controls are in place and complied with.

34.) What are the elements of inventory requirements for controlled substances?

Each licensed researcher is responsible for their own annual inventory. Typical inventory checks include: 1) hands-on counting inventory and not a database check; 2) must be completed in a single business day, i.e., before the start of the work day or at the end of the work day; 3) at least two authorized personnel (licensed researcher or authorized lab personnel); and 4) use of an in-house developed initial inventory form, dispensation/disposal records, monthly inventory checks and annual inventory form. Once a controlled substance is used to make a dilution, it is important to track the usage, disposition and disposal of the new dilution which contains a controlled substance. An appropriate entry should be recorded on the original stock bottle's controlled substance aliquot log and dilution log.

35.) How long do I keep the copies of my controlled substance usage logs?

You must keep these at least two years after the final disposition of the controlled substance. The logs must be readily available for periodic review by the DEA.

Appendix B: Resources

DEA Researcher's Manual
Controlled Substances Act
DEA Forms and Applications