

DEA – Controlled Substances

Description

The [Federal Drug Enforcement Administration \(DEA\)](#) enforces regulations related to the importation, manufacture, distribution, possession, and use of controlled substances. To conduct research at UF involving any of these substances, Principal Investigators must obtain a DEA registration.

How To File a DEA Registration

You may file a DEA registration for controlled substances once a Florida [DBPR](#) exemption number is received. [Registrations can be completed online using the 225 application](#). UF researchers are exempt from the DEA registration fees. Please enter the PI's department chair or dean's name under the "Official's Name" on the application. Once document is received, a copy must be uploaded in the DEA/DBPR File Database. Please see our [how to use DBPR-DEA upload form guide](#) for assistance.

[Upload DEA/DBPR Records](#)

DEA Controlled Substances Requirements

As an active DEA registrant, you must:

- Properly screen and document, using the Authorized Personnel Log and Questionnaire, the laboratory staff who will use the controlled substances for research under your registration.
- Properly store controlled substances per DEA regulations.
- Maintain all records for a period of 3 years (minimum)
- Renew the DEA registration on an annual basis.
- Properly dispose of unwanted or expired controlled substances through a reverse distributor. The PI must maintain a valid DEA registration to dispose of any controlled substance.
- Report any theft or unaccounted significant losses to DEA (within 24 hours) using [Form DEA-106 and to UPD](#).

Required Documentation

Category	Form/Template	Notes/Requirements
Personnel	Authorized User Questionnaire	Certify each person (e.g., PI, lab personnel) who will handle controlled substances as part of a research protocol. Registrants may chose to conduct a background check.

Personnel	Authorized User Log	List each person (e.g., PI, lab personnel) allowed to handle controlled substances for research use as an authorized agent or authorized personnel.
		Include a date range for the authorization.
		For Schedule I & II only
	Form 222	
Purchasing	For Schedule I & II only – click here to order the form from the DEA.	Complete Part 1 & Part II of Form-222 and make a copy before ordering. Order your controlled substance and give the original Form-222 to the supplier. Retain the copy for your own records. Upon receipt of the substances, complete Part 5 with the date and amount received.
		Ensure invoice contains:
Purchasing	Invoices and Packing Slips	<ul style="list-style-type: none"> • Name, address, and DEA registration number of registrant. • Controlled substance name, concentration, dosage form, and quantity. • Include signature of authorized personnel receiving the substance and date received.
		Record controlled substances at a new storage location (including changes of address) immediately upon receipt of a DEA registration. Under inventory type, select “Initial.”
Inventory	Initial Inventory	
		If you have yet to store controlled substances at that location indicate, “Zero inventory – no controlled substances at present location.”
		List all of the controlled substances currently stored at the DEA registered location.
Inventory	Biennial Inventory	
		Perform every two (2) years after receiving the DEA registration. Keep the completed biennial inventory with the controlled substance records.

Usage Records	General Use Log	<p>Summarize the usage of a controlled substance from the time of acquisition to the end of use (e.g., administration and/or disposal), including recording expired or damaged controlled substances.</p> <p>Document the usage details for a controlled substance that has been withdrawn from its original container and mixed with a solution to dilute the concentration, including the:</p>
Usage Records	Diluted Solution Log	<ul style="list-style-type: none"> • Amount withdrawn • Waste amount (if applicable), and • Remaining balance through final disposal
Disposal/Destruction	Form 41	<p>To be completed and filed with controlled substances paperwork when substance is destroyed. Unwanted or expired controlled substances must be disposed of through a reverse distributor.</p>
Theft/Loss	Form 106	<p>Submit an online report within one (1) day of significant loss/theft. Must be completed by the DEA registrant.</p>

Disposal

All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant, must be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and must be rendered non-retrievable. A researcher may dispose of its controlled substances inventory in the following manner:

1. Promptly destroy that controlled substance in accordance with 21 CFR 1317.90 using an onsite method of destruction.
[See Controlled Substance Disposal RX Destroyer Guidance \(PDF\)](#)
2. Send those controlled substances to a DEA registered reverse distributor.
 - Clean Harbors Florida LLC: (863) 519-6331
 - Express RX Returns: (954) 589-2386
 - PharmaLink: (800) 257-3527
 - Rx Return Services: (727) 754-7848
 - Rx Reverse Distributors Inc.: (772) 388-1212
 - Woodfield Distribution LLC: (561) 998-3885
3. Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances.

Resources

- [DEA Researchers Manual](#)
- [How to use DBPR-DEA upload form guide](#)
- [Online Training: EHS900 – Managing Controlled Substances in Research Laboratories](#)