Responsibilities of Controlled Substance Registrants and Authorized Personnel

Controlled Substance Registrant:

Each researcher authorized to use controlled substances is responsible for understanding and complying with all regulations of the DEA regarding registration, purchase, use, and proper disposal of controlled substances used in their research. The PI retains all liabilities for loss, theft or misuse of any controlled substance acquired through their registration. For complete information see US DOJ DEA.

In brief, the registrant will:

- Ensure compliance with all federal and state laws
- Ensure safe, secure storage of controlled substances §1301.71
- Have employees with access to controlled substances fill out a questionnaire
- Maintain all required records for inventory, dispensing, and disposal of controlled substances
- Report any theft or losses of controlled substances
- Properly dispose of controlled substances
- Plan for the transfer or disposal of any remaining inventory before leaving the University or canceling a license/registration

Authorized Agent

- Complete an employee questionnaire
- Ensure controlled substances are stored in a way that will not lead to theft or misuse
- Maintain proper record keeping for controlled substances
- Report any theft or loss of controlled substances
- Properly dispose of controlled substances

Getting a DEA License:

1. **State of Florida Exemption**

The first step in the getting DEA research is to get a State of Florida exemption to use controlled drugs for research. The registration form can be found on-line with the Florida Department of Business and Professional Regulations (DBPR). It can be found in the lower right side of the webpage. There is no fee for this exemption. The time frame to obtain this exemption number is approximately 3-6 weeks.

The DBPR and DEA registration forms require very specific information, such as the address of the lab(s) where the products will be stored and used. This requires building *and room numbers* to be entered. So, using "1400 NW 10 Ave.", for example, is too generic for these forms. Please be as specific as possible when completing the form.

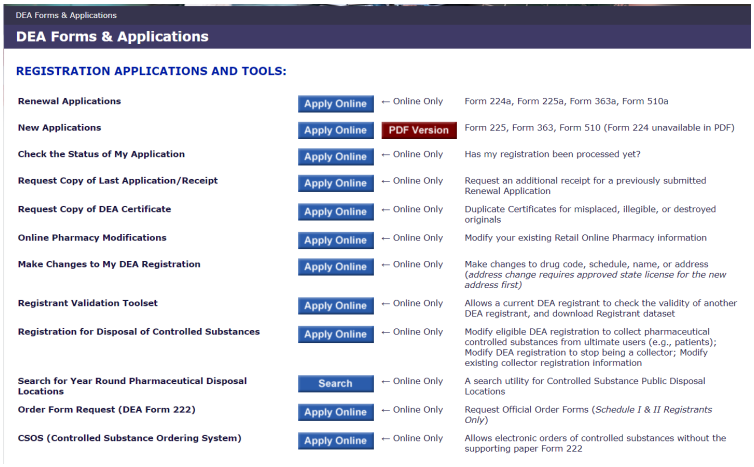
- Section V.3 will require a detailed explanation of the research being done with the drug products.
- Sections V.4 and V.5 will require a list of the controlled drugs that will be bought and the vendor information.

Once the exemption is granted, you will receive an exemption number. You will need to provide this number to vendors prior to their deliveries. Without this valid exemption, the vendors cannot deliver controlled drugs, etc., to the PI's labs. There are no special exceptions or allowances to these rules.

The DBPR exemption is valid for two years, and it is the PI's responsibility to keep a current exemption. The exemption must be maintained and renewed if the controlled drugs are in their lab, whether they are being used or not. If the exemption expires, you will need to reapply for the exemption. If anything changes with the lab's location, use, products, etc., the PI must amend the information accordingly. If the PI's exemption expires or is not modified as required, this will potentially be a violation of Florida statutes, as a PI cannot have the controlled drug in their possession without a valid exemption.

2. **DEA Controlled Substances Registration**

Once the DBPR exemption number is received, you can start the process of obtaining the DEA registration. The forms can be accessed online at DEA website application for registration https://www.deadiversion.usdoj.gov/online_forms_apps.html



DEA Forms & Applications

DEA Forms & Applications

REGISTRATION APPLICATIONS AND TOOLS:

Renewal Applications	Apply Online	← Online Only	Form 224a, Form 225a, Form 363a, Form 510a
New Applications	Apply Online	PDF Version	Form 225, Form 363, Form 510 (Form 224 unavailable in PDF)
Check the Status of My Application	Apply Online	← Online Only	Has my registration been processed yet?
Request Copy of Last Application/Receipt	Apply Online	← Online Only	Request an additional receipt for a previously submitted Renewal Application
Request Copy of DEA Certificate	Apply Online	← Online Only	Duplicate Certificates for misplaced, illegible, or destroyed originals
Online Pharmacy Modifications	Apply Online	← Online Only	Modify your existing Retail Online Pharmacy information
Make Changes to My DEA Registration	Apply Online	← Online Only	Make changes to drug code, schedule, name, or address (*address change requires approved state license for the new address first*)
Registrant Validation Toolset	Apply Online	← Online Only	Allows a current DEA registrant to check the validity of another DEA registrant, and download Registrant dataset
Registration for Disposal of Controlled Substances	Apply Online	← Online Only	Modify eligible DEA registration to collect pharmaceutical controlled substances from ultimate users (e.g., patients); Modify DEA registration to stop being a collector; Modify existing collector registration information
Search for Year Round Pharmaceutical Disposal Locations	Search	← Online Only	A search utility for Controlled Substance Public Disposal Locations
Order Form Request (DEA Form 222)	Apply Online	← Online Only	Request Official Order Forms (*Schedule I & II Registrants Only*)
CSOS (Controlled Substance Ordering System)	Apply Online	← Online Only	Allows electronic orders of controlled substances without the supporting paper Form 222

- Researchers will use the online 225 application for a new license application. The DEA application will ask for a "state license" number. There is no state license number in Florida, so enter the exemption number and expiration date where the state license number is requested.

- If you are amending your existing license for a new drug, schedule address or state, you will do this online at https://www.deadiversion.usdoj.gov/online_forms_apps.html

The time frame needed for the DEA registration process is typically two weeks but can extend up to 6 weeks, depending on the circumstances. The registration will involve the online submittal of the application and then telephone interviews with a DEA investigator to gather more specific information. The DEA investigator will also review the specific security and paperwork requirements with the PI. On rare occasions, DEA will do an announced site inspection prior to the registration being granted, but please note that the DEA will conduct a pre-registration inspection for ***all Schedule 1 applications***.

When the DEA inspectors arrive, please contact the Director of Compliance (ekapsali@med.miami.edu) so that she can act as the UM representative.

The DEA officials will need to see the following:

- Proposal of the research
- Who will be authorized to use the drug(s)?
- CVs for all staff involved with the research
- List of suppliers, as they need to ensure the suppliers have a DEA registration for those products
- How the ordering process will be done
- How the products will be received into the department or lab and who will sign for them
- A summary of the labs proposed scientific process
- Explanation of how the products will be secured
- The location where the products will be secured
- How other drugs have been handled (if the PI has had a registration for a different drug).

Once the exemption and DEA registration are both received, ensure that they are filed in a secure location where they can be easily accessed

If the laboratory changes locations (labs within the same building or a different building) where the controlled drug will be used, the PI must send an addendum to both the DBPR and DEA with the expected move date. The registration is specific to the labs in which the controlled substances will be used and stored. Without this amendment, the PI will be in violation of the regulations and could be subject to fines and possible imprisonment. If the PI or the lab is moving from UM to another university, the license will need to be changed for the new location. Contact the DEA directly at Office of Diversion Control website for this process.

The DEA regulations do allow PIs to have two valid registrations at one time. To have dual registrations, it is strongly suggested that the PI contact the DEA for their assistance with this. It is important to note that DEA Controlled Substances cannot be transported from one registration site to the other. The multiple sites are considered "coincidental activities" and both sites must be considered independent from each other. Each site must have complete sets of purchase, use, dilution and disposal recordkeeping.

The PI can modify the DEA license via their website. No letter to the DEA is required. Go to https://www.deadiversion.usdoj.gov/online_forms_apps.html Enter the changes as needed. A DEA investigator will contact the PI to verify the changes.

*The PI does not need to amend a registration if different staff are authorized (or withdrawn) to use the controlled drugs or if a different vendor is used for supplying the products.

FL DBPR exemption and DEA registration renewals

Both the FL DBPR exemption and DEA registration do expire. The FL DBPR is valid for two years and DBPR does not send out reminders about the need to renew. The DBPR will require an submission to be sent to them 60-90 days prior to the expiration of the exemption. It is strongly suggested that all PIs mark a calendar as to the expiration dates of these required documents.

The DEA registration is typically valid for one year only and must be renewed annually. The PI will be contacted by the DEA, usually three months prior to its expiration, to renew it. This is usually via email. The DEA will send only one reminder.

DO NOT let either of these expire! If either expires, the PI will need to start the process all over again. Unfortunately, this will also put the PI into a state of non-compliance with the Federal regulations. You will not be able to use, buy or dispose of any DEA controlled drugs without a valid registration. Additionally, you will potentially be in felony violation of the DEA regulations. Penalties for this could be severe and may include prison time and/or criminal fines.

If the PI allows the registration to expire and then renews or reapplies, the controlled drug purchased under the previous registration will not be covered under the new registration. The products purchased under the earlier registration cannot be used or disposed of under the new registration, but the PI is still responsible for securing them, even though they cannot legally have them. The PI will need special permission from the DEA to dispose of these products.

Authorized Staff

The Principal Investigator (PI) is responsible for obtaining and renewing all exemptions and registrations for controlled drugs regulated by the Florida Department of Business and Professional Regulation (DBPR) and US Drug Enforcement Administration (DEA). As the holder of the exemption, license, or registration, the PI is responsible for the safe and secure use, storage, and disposal of these regulated materials, as well as all associated recordkeeping and training of staff.

A PI may formally authorize specific staff members under his/her control, or a co-investigator on the research project, to have access to the regulated pharmaceutical substances, including controlled substances regulated by the DEA.