

CONTROLLED SUBSTANCES FREQUENTLY ASKED QUESTIONS

Are all drugs controlled substances?

No, most drugs are considered pharmaceuticals and are not controlled substances. Examples of drugs that are not controlled substances are Donepezil, Xylazine, and Atropine.

What are schedule numbers and DEA codes?

The U.S. Drug Enforcement Administration ([DEA](#)) assigns each controlled substance a schedule number (I through V) according to its medicinal value, harmfulness, and potential for abuse or addiction. The DEA code is a 4-digit number assigned to each controlled substance. Search the U.S. Drug Enforcement Administration (DEA) [List of Controlled Substances](#) to see if a drug is considered a controlled substance.

A higher schedule number indicates the substance has more medicinal value and less potential for abuse or addiction. The letter "N" can also accompany the schedule number, signifying the substance is a non-narcotic. If the DEA website has "N" in the NARC column, the item is a non-narcotic and if the DEA website has a "Y" in the NARC column, the item is a narcotic.

Some of the controlled substances used in research and their schedule numbers and DEA codes are:

Substance	Schedule	Narcotic?	DEA Code
Ketamine	III	N	7285
Pentobarbital (e.g., Nembutal)	II	N	2270
Buprenorphine	III	Y	9064
Fentanyl	II	Y	9801
Diazepam	IV	N	2765
Pentobarbital & non-controlled active ingredients (e.g., B-Euthanasia)	III	N	2271

I need to use a controlled substance in my research; what do I do?

Please refer to the flowchart given at http://www.luc.edu/media/lucedu/ors/pdfsanddocs/research/Flowchart_CS.pdf. Your first step would be to log in to the CAP system (<http://compliance.it.luc.edu/>), click on "Manage Hazardous Materials," and then "Controlled Substances Registration Request." After completing and submitting that form, you will be notified (assuming no issues or problems with the request) that it is OK to proceed with obtaining a license from the Illinois Department of Financial and Professional Responsibility (IDFPR),

<http://idfpr.com/>). On the page at <http://www.idfpr.com/profs/info/contsub.asp>, select “097 Other Cont Sub Licenses,” press “Go,” and then download the “[097 Other Controlled Substances Licensees](#)” packet. After obtaining IDFPR approval, you can then register with DEA (<http://www.justice.gov/dea/index.shtml>). On the page at http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm, select “Begin Application Process.” On the following page, select “Form 225” and “Researcher (II-V)” as the business activity. When you receive your DEA registration number, let ORS know. When you are ready to order controlled substances, log in to the CAP system.

I conduct research in several different locations on campus. Do I need a separate DEA registration for each location?

The activity associated with the controlled substance must be done at the registered storage location of the drug. There can only be one storage location for each registration, and ALL materials must be stored at the location on the license and registration.

Laboratories in separate locations that receive, store, or administer controlled substances at those locations must acquire a separate DEA registration for each location.

Materials may be checked out of the storage location for immediate use in a research protocol and then any remaining material returned to the storage location by the end of the day. Each step of this process must be documented and the materials must be secured at all times.

What fees are associated with getting and maintaining my IDFPR license and DEA Registration?

The initial application fee for the IDFPR license is \$50; the annual fee (paid every two years) is \$50. The DEA registration fee is currently \$244 per year.

How long does this process take?

The IDFPR licensure process takes approximately two months. The DEA registration process takes at least another month and a half, and longer if Schedule I drugs are involved.

How often do I need to renew my IDFPR license and DEA registration?

The IDFPR license must be renewed every two years. The DEA registration for researchers must be renewed annually. It is important to renew in a timely manner so as not to allow the license or registration to lapse; otherwise the whole process must be done over.

How long can I expect my renewal to take?

The IDFPR renewal can be done in the month preceding the expiration date by payment of the required fee. The DEA renewal takes approximately 4 weeks; DEA will send a reminder to the registrant 45 days prior to the expiration date.

How do I know when I have been approved and can begin using controlled substances?

The Illinois Department of Financial & Professional Regulation (IDFPR) will issue you a license number and the DEA will issue you a registration number once you have been approved. You will need the DEA registration number and the IDFPR license number to order controlled substances. You must also send a copy of your DEA registration to ORS.

What types of records do I have to keep?

The following records must be maintained and readily available:

- IDFPR controlled substances license
- DEA Certificate of Registration
- Signed and dated supplier packing slips
- Inventory records (initial and biennial)
 - in CAP (<http://compliance.it.luc.edu/>)
- Usage and administration records
 - in CAP (<http://compliance.it.luc.edu/>)

How do I purchase controlled substances?

Controlled substances must be ordered using the CAP system (<http://compliance.it.luc.edu/>). Refer to the [LUC Controlled Substances Policy and Procedures](#) for additional information and contact ORS for additional assistance.

Who can order controlled substances?

Only the DEA registrant may initiate an order for a controlled substance. The order request must be approved by the department chair or unit head and then is placed by Purchasing on behalf of the registrant. For Schedule I and II drugs, DEA Form 222 must be used; Schedule III, IV, and V drugs can be ordered directly from the manufacturer.

What are the requirements for storing and securing controlled substances?

At a minimum, controlled substances in Schedule II-V must be stored in a securely locked, substantially constructed cabinet. There are additional requirements for Schedule I controlled substances. Refer to the DEA publication: [Controlled Substances Security](#)

[Manual: A Security Outline of the Controlled Substances Act of 1970](#) for additional information.

Who can have access to the controlled substances in my laboratory?

Generally, only the DEA registrant can have access to controlled substances in your laboratory. However, the [LUC Controlled Substances Policy and Procedures](#) permits other employees who are supervised by that registrant and are at the same location to be authorized at the request of the registrant. Access includes, but is not limited to receiving packages, conducting inventories, having access to the keys for the storage unit, etc. The registrant should maintain a log book of who has access to controlled substances in their lab, and the substances and amounts used.

How do I get rid of controlled substances that are out of date or that I no longer need?

Contact ORS; ORS will then contact Environmental Services to dispose of controlled substances through a reverse distributor.

What penalties are associated with controlled substance violations?

The State of Illinois and DEA can impose administrative, civil, and criminal actions against a controlled substance licensee and DEA registrant for noncompliance and/or theft or loss associated with storage, administration, recordkeeping, etc., of controlled substances.

I no longer need a controlled substance license and registration. What do I need to do?

If you no longer need an IDFPR license and DEA registration you need to do the following:

- Cancel your DEA registration and IDFPR license.
- Notify ORS that you will no longer be using controlled substances.
- Contact ORS for disposal of your current inventory of materials. **It is the responsibility of the licensee/registrant to make arrangements for any remaining inventory before cancelling a license/registration.**

What federal and state requirements govern the use of controlled substances in research at Loyola?

These requirements include but are not limited to:

- [U.S. Controlled Substances Act \(21 U.S.C. 801 through 971\)](#)
- [U.S. Drug Enforcement Administration Regulations \(21 CFR 1300 through 1321\)](#)
- [Illinois Controlled Substances Act Rules \(77 Ill. Adm. Code 3100\)](#)

If I have questions about use of controlled substances, who at LUC should I contact?

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