DEA Registration and Licensing

Frequently Asked Questions

I do not presently hold a DEA research registration for controlled substances. How do I get one?

If you use controlled substances and do not presently hold a DEA registration, you must start the application process. See Obtaining a Controlled Substances License and Registration for additional information.

Who needs to have a DEA controlled substance research registration?

Each Principal Investigator must have a current DEA registration for the laboratory location where controlled substances are delivered, stored, and administered. Refer to the Obtaining a Controlled Substance License and Registration for more information.

21 CFR 1301.11

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to ***§§1301.22 through 1301.26****.*

I am a medical practitioner. Can I use the same license/registration for medical and research purposes?

If you are a medical practitioner, it is possible to use the same license for medical and research purposes for Schedule II-V controlled substances and with special approval, Schedule I. However, the location listed on the license and registration must be the same location where both activities take place. If this is not the case, you will need to obtain a separate research license and registration.

21 CFR 1301.13

(e)(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Online Pharmacy, Central fill pharmacy, Teaching Institution) … May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under State statute.

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.

21 CFR 1301.12

(a) As separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

What fees are associated with getting a DEA registration?

Employees of the University qualify for a fee exemption. The exemption requires an agency officer's signature to certify the exempt status. The Vice President for Research and Economic Development is the certifying official for UND.

21 CFR 1301.21

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration:

(1) Any hospital or other institution which is operated by an agency of the United States . . ., of any State or any political subdivision or agency thereof.

What types of records do I have to keep?

The following records must be maintained and readily available:

- DEA Certificate of Registration
- Authorized users questionnaire for access to controlled substances
- Controlled substance Authorized Users Log
- Acquisition and ordering invoices
    - Signed and dated supplier invoices or packing slips
- DEA Form 222s
    - Used, voided and unused Form 222s
- Inventory records
    - Initial inventory
    - Annual inventory
    - Biennial inventory – DEA
    - General inventory
- Usage and administration records
    - Multiple dose usage log
    - Diluted drug solution log
- Transfer records of controlled substances transferred between registrants
- Disposal records- DEA Form 41
- DEA Form 106- Report of Loss or Theft

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. Schedule I controlled substance must be stored in a securely locked, substantially constructed cabinet that is anchored to a wall or the floor. Controlled substances requiring refrigeration may be stored in a locked container securely fastened within a refrigeration unit. Refer to the DEA publication: Controlled Substances Security Manual: A Security Outline Of The Controlled Substances Act of 1970 for additional information.

21 CFR 1301.75

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.
(d) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.