

Controlled Substance Policy and Procedures

NORTHERN ILLINOIS UNIVERSITY

OFFICE OF RESEARCH COMPLIANCE AND INTEGRITY

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A. Controlled Substance Policy

1. Background, Purpose, and Scope

Many substances used for legitimate medical and scientific research purposes are otherwise illegal. The federal Controlled Substance Act ([21 USC Chapter 13](#)) regulates such use and requires users to be registered. Federal regulations for implementing this statute are promulgated in [21 CFR 1300-1399](#) and are enforced by the U.S. Drug Enforcement Administration (DEA). These regulations require legitimate users of controlled substances to register with the DEA and comply with requirements pertaining to secure storage, recordkeeping, inventorying, reporting loss, theft, or abuse, and safe disposal. These requirements are covered in this policy.

Illinois has its own [Controlled Substances Act](#) that follows and supplements the federal law. As such, users fall under the purview of “Controlled Substance Professional” and must be licensed by the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (IDFPR).

Controlled substances are categorized into five schedules by 21 USC §812. Schedules are based on whether the substances have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Occasionally, the schedule of a substance changes. The purpose of this document is to regulate and prevent the diversion of controlled substances used in the conduct of research activities at Northern Illinois University (NIU) and, by clarifying responsibilities, facilitate the process for the investigator. The scope of this document extends only to controlled substance licensees/registrants engaged in research activities at NIU.

2. Policy

All NIU faculty and staff conducting activities with DEA controlled substances must be registered with the DEA and IDFPR and comply with state and federal regulations regarding the acquisition, storage, use and disposal of those substances.

Registrants may authorize non-registered agents (see Appendix A for the definition of “agent”) to engage in controlled substance activities on their behalf. These are hereafter referred to as “authorized users”. Laboratory employees can be considered authorized agents of the registrant if they are acting in the usual course of their business or employment. The activities, including the administration of controlled substances, must be delegated by the licensee/registrant to the authorized user in writing.

3. Responsibilities

NIU faculty and staff engaged in research involving the use of DEA controlled substances will be responsible for registering with the DEA and IDFPR, updating the controlled substances database as described below, and for assuring compliance with applicable state and federal regulations. The registrant must not allow the permit to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

The Office of Research Compliance, Integrity, and Safety (ORCIS) will be responsible for assisting individuals engaged in research in complying with applicable rules and regulations in the form of educating researchers about requirements, maintaining the controlled substances website, and providing compliance oversight through inspections. However, it is ultimately the registrant's responsibility to ensure compliance with state and federal regulations.

4. Penalties for Controlled Substance Violations

The State of Illinois and the 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, and other aspects of controlled substances.

Failure to comply with NIU Controlled Substance Policy, state regulations, or federal regulations may result in ORCIS terminating your Controlled Substance Authorization and may also result in the suspension of controlled substance orders.

B. Controlled Substances Procedures

1. Registration

NIU faculty or staff wishing to obtain controlled substances must proceed in the following order:

1. Register with the [Illinois Department of Professional Regulation](#) (Appendix B). Submit Form IDPR 097 (other controlled substances licensees) for activities related to research, chemical analysis, instruction, and teaching.
2. Following approval of state registration, register with the Drug Enforcement Administration (Appendix B). Different activities have different registration requirements. [Forms and detailed instructions](#) are available on the DEA website. The required forms are as follows, according to activity:
 - a. For **research and chemical analysis**: Form 225. To renew an existing registration, use Form 225A.
 - b. For **instructional activities** and for **dispensing controlled substances as a practitioner** (dentists, physicians, veterinarians, nurse practitioners, hospitals, pharmacies), submit Form 224. These activities are authorized only for schedules II through V. To renew an existing registration, use Form 224A.
 - c. During the DEA application process, you may, as an employee of NIU, certify that you are a government employee in order to receive a fee exemption. The NIU Authorizing Official for this purpose is the PBDJ. Please consult ORCI's Controlled Substance website or call ORCI directly to obtain the official contact information for registration purposes.
 - d. You must have separate registrations for separate locations.
3. Notify the [Office of Research Compliance, Integrity, and Safety](#) (ORCIS) upon approval of the controlled substance registration.

2. Authorized Use

- The **registrant** is responsible for managing the controlled substances according to the regulatory requirements covering the following:
 - a. Inventory
 - b. Record keeping
 - c. Security provisions

- Registrants may authorize laboratory employees (termed, “authorized users”) to work with controlled substances on their behalf. Approved activities, including the administration of controlled substances, must be delegated in writing by the registrant to the authorized user.
- The registrant is required to screen employees before authorizing them to work with controlled substances. Screening is conducted as follows:
 - a. Employees must complete a questionnaire ([21 CFR, 1301.90](#)). The registrant retains this questionnaire as part of their records (see 5. Record-keeping Requirements” for information on filing the questionnaire).
 - b. Laboratory employees must undergo a criminal background check as part of the screening process.
 - i. ORCIS will support fees incurred for this service. After the employee completes the questionnaire (Section 3.a) the registrant submits to the Authorizing Official the name(s) of the employee(s) they wish to authorize. A criminal background check, consisting of local, regional, and federal inquiries, will be conducted by NIU Human Resource Services (HRS). Should the demand for authorized users increase substantially, ORCIS may require the contribution of the relevant department to supplement funding of background checks.
- Please note that IT IS A FELONY to provide a controlled substance to a person who is not registered with the DEA. Transfers of controlled substances can occur only between two DEA registrants. Transfers of schedule I or II controlled substances must be accompanied by a DEA form 222 completed by the registrant receiving the substance(s).

3. Employee Questionnaire

Employee Questionnaire must be included as part of the screening process before they are allowed to handle DEA-controlled substances.

- a. The Registrant must have the following questions answered in writing by any authorized agents:
 - i. Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.
 - ii. Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.
- b. Make copies of the form for each employee who will be working with these substances.

- c. Maintain these questionnaires on file at the registered location for a minimum of two years following the cessation of controlled substance activity.

4. Ordering Controlled Substances

To order controlled substances, you must first be registered with the DEA.

The Controlled Substance Ordering Form, DEA Form 222, is a paper-based form. It is requisitioned directly from the DEA and is required to be filled out in triplicate. The DEA Form 222 also allows the exchange of controlled substances from one DEA registrant to another DEA registrant (typically used when a controlled substance is sent to a reverse distributor for credit or disposal).

Schedule I or II registrants can [request the DEA Forms 222 online](#), upon which you will receive the maximum number of order form books allowed for your business activity. The link is:

- <https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>

Schedule III, IV, and V drug orders do not require a DEA Form 222. These substances can be ordered directly from the manufacturer. However, you may be asked to provide a copy of your DEA Registration before your order will be prepared and shipped.

You are responsible for accounting for each DEA Form 222 in your possession – this includes voided, used, and unused forms. “Record of DEA Form 222 Use” (Appendix C) can be used to maintain accountability (this form is optional for the registrant).

To fill in DEA Form 222 ([§1305.12 Procedure for executing DEA Forms 222](#)):

1. The form must be prepared by use of typewriter, pen, or indelible pencil.
2. There are 10 lines on each form. Only one item can be entered on each numbered line. If one order form is insufficient to include all items in an order, additional forms must be used. The number of lines completed must be noted on that form at the bottom of the form, in the space provided.
3. Order forms for carfentanil, etorphine hydrochloride and diprenorphine must contain only these substances.
4. The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.
5. Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration – either the registrant, or a person specifically granted power of attorney.
6. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

7. Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections or to enforce any Federal, State, or local law regarding controlled substances.

5. Record-keeping Requirements

Maintain the following records at the registrant's location as identified on the registration:

- Employee questionnaire and authorization records
- Executed order forms
- Inventory records (must be kept for a minimum of two years from the date of record)
- Drug dispensing records (must be kept for a minimum of two years from the date of record).

A registrant who wishes to maintain records at a location other than the registered location must notify the DEA. Refer to [21 CFR 1304.04](#) for guidance.

6. Controlled Substance Tracking

For each container of controlled substances, tracking records must be kept that note every time that these substances are used. Every mL or mg of a controlled substance must be accounted for in the dispensing records. A [Sample DEA222 Drug Control \(Dispensing\) Record](#) is available from ORCIS, for dispensing records. The drug control record should have an entry for each time material was removed from the container.

7. Inventory Procedures

Each person registered to handle controlled substances must maintain an inventory. The inventory should be:

1. Maintained at the registered location (unless a notification has been sent to DEA notifying that records will be maintained at a specific central location).
2. Available for two years after the using or disposing of the substance

3. Repeated every two years (**annual** inventory is recommended to ensure that expired substances are removed from inventory)
4. Updated on the effective date of a rule from the DEA that adds a substance to the Schedule (list of controlled substances) (occasionally the scheduling of a particular drug changes; the DEA announces such changes).
5. A [Sample Controlled Substance Inventory Sheet](#) (Appendix D) is available from ORCIS.

The information included in the inventory depends on whether the controlled substance is in finished form (i.e., commercially bought) or otherwise (for example, damaged, defective, or impure controlled substances).

1. For controlled substances in finished form (i.e. commercially bought), the inventory should include the following information:
 - a. Name, address, and DEA Registration Number
 - b. Date the inventory was taken, noting whether it was at the beginning or end of the day
 - c. Name of the substance
 - d. The form of the substance (e.g. 10 milligram tablet or 10 milligram concentration per fluid ounce or milliliter)
 - e. The number of units or volume of each commercial container (e.g. 100 tablet bottle or 3 milliliter vial)
 - f. The number of commercial containers of each substance form
 - g. Signature and date.
2. For each substance not listed above (i.e. for damaged, defective, or impure substances), an exact count of the dosage units must be made, or the container must be graduated to reflect its content, and inventory should include the following:
 - a. Name, address, and DEA registration number
 - b. Date the inventory was taken and whether it was at the beginning or end of the day
 - c. Name of substance
 - d. Total volume of substance or total number of units (e.g. 50 10mg tablets)
 - e. Reason the substance is being maintained by the researcher
 - f. Signature and date.

8. Security

Controlled substances must be kept in a securely locked, sturdy cabinet or safe that is secured to a wall or otherwise not removable. DEA inspectors will check to see if the cabinet is bolted to a permanent structure (e.g., a wall) and that the interior double lock compartment is bolted to the main cabinet.

DO NOT leave keys to the controlled substances cabinet in the lab. Keys allowing access to the controlled substances must remain in the possession of authorized users.

If there is a theft or loss of controlled substances notify ORCIS and NIU Police Department immediately, a [DEA Form 106](#) must be submitted to the DEA within 24 hours and the state administrator must be notified within 10 days of the discovery of the theft or loss.

9. Disposal

Empty Vials

Empty vials of controlled substances should be disposed of through ORCIS. Please [contact the office](#) for assistance. In addition, the disposal of the empty vial must be recorded in the respective inventory and dispensing records.

Expired Controlled Substances

Expired containers of controlled substances (with any contents remaining) must be separated from non-expired containers of controlled substances, and must be clearly labelled as being expired. The expired substances must remain in the locked controlled substance cabinet or safe.

A DEA Registrant in possession of controlled substances that are expired or unwanted must contact the ORCIS for the permitted disposal of the drugs. **All controlled substances designated for disposal must remain in a secured storage location until they are packaged and consigned for disposal.**

ORCIS will make the determination if on-sight disposal is available or a reverse distributor must be brought in. If on-sight disposal is recommended ORCIS will facilitate the disposal with the Registrant.

The Registrant 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.

10. Abandoned (Orphaned) Controlled Substances

Under no circumstances are controlled substances to be abandoned by a DEA registrant. However, researchers sometimes leave the university without appropriately disposing of or transferring all controlled substances from their lab. If the controlled substances were acquired before registration was required, the department responsible for the lab must contact the ORCIS to arrange for disposal. Depending on the situation, one of the two procedures will be followed:

- **If the researcher was a DEA registrant** and it can be determined that the controlled substances were acquired through a DEA registration, the department will need to complete a DEA Form 41 with a cover letter providing all the information required for disposal (see Section 9. Disposal) and explaining why the registrant did not complete Form 41. The department should contact the ORCIS to arrange for disposal.
- **If the researcher was not registered with the DEA and/or the controlled substances were acquired prior to registration requirements (pre-1970 for many substances),** the department must contact the ORCIS for disposal.

Any person who is registered with the DEA who violates record keeping requirements or abandons controlled substances will be subject to the civil penalties outlined in the United States Code (USC): [21 USC Sec . 842](#). Note that abandoning substances is equivalent to distributing controlled substances to an unauthorized person.

11. Cancelling Your Registration

It is the responsibility of the registrant to make arrangements for any remaining inventory before cancelling a registration.

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

1. Notify ORCIS that you will no longer be using controlled substances.
2. Contact ORCIS for disposal of your current inventory of materials.
3. Cancel your DEA registration and IDFPR license.
 - a. IDFPR (Appendix B: Contact Information):
 - i. To cancel your license, write a letter to the IDFPR and either mail it or send it by fax, listing the controlled substance license number and contact information.
 - ii. There is no penalty for allowing your current license to lapse.
 - iii. Should you wish to resume controlled substances activities, all future Illinois controlled substance license applications are treated as renewals, i.e. you do not apply as a new applicant. Be sure to update your information accordingly (e.g. location).
 - b. DEA (Appendix B: Contact Information)
 - i. To retire your registration, submit a letter by mail or fax, listing your registration number, location, and the Schedules for which you are approved. Describe why you are retiring your registration. You must hand-sign the letter.
 - ii. Send any remaining DEA Form 222s to the Regional DEA Office.
 - iii. There is no penalty for allowing your current license to expire.
 - i. To re-register within 30 days of expiration, submit a “renewal” of registration.
 - ii. If your registration has been expired for more than 30 days, you must submit a new request for registration.
 - iv. To request the withdrawal of an application for registration, submit a letter by mail or fax listing your name, location, and other contact information. Request that the application be withdrawn and refunded.

Appendix A: Glossary

Agent: An authorized person who acts on behalf of or at the direction of a registrant/licensee to perform controlled substance activities. The term, “agent” does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier’s or warehouseman’s business.

Authorized Official: The individual(s) formally authorized to be the “approver” of DEA registration applications on behalf of the institution. The Authorized Official for NIU is currently the Institutional Compliance and Attending Veterinarian.

Controlled Substance: Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end) and the Illinois Controlled Substance Act. Controlled substances are identified in the schedules contained within the “[List of Scheduling Actions, Controlled Substances, Regulated Chemicals](#)” published by the DEA.

Dispense: Prepare and distribute controlled substances to Authorized Users.

Registrant: A university faculty or staff member that holds a DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of controlled substances.

Researcher: Any NIU faculty or staff member that conducts research at NIU.

Reverse Distributor: A person or entity registered with the DEA and authorized to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction. Reverse distributors must destroy controlled substances received for the purpose of destruction within 30 calendar days of receipt. Day 1 is the day the substances are physically acquired through pick-up or delivery.

Schedule I: Drugs or other substances that have no currently accepted medical use and a high potential for abuse.

Schedule II: Drugs or other substances that have a high potential for abuse, currently have an accepted use in medical treatment in the United States, or have a currently accepted medical use with severe restrictions. Abuse may lead to severe psychological or physical dependence.

Schedule III: Drugs or other substances that have a lower potential for abuse than Schedule I or II drugs and have an accepted use in medical treatment in the United States. Abuse is associated with moderate or low potential for physical or psychological dependence.

Schedule IV: Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III and currently have an accepted medical use in the United States. Abuse may lead to limited physical or psychological dependence.

Schedule V: Drugs or other substances that have an accepted medical use in the United States and contain limited quantities of certain narcotics. Abuse may lead to limited physical or psychological dependence relative to those in Schedule IV.

Teaching Activity: Activities that include classroom demonstrations, laboratory exercises and research projects which are required for completion of a course at the undergraduate, graduate, or professional level.

Appendix B: Contact Information

Office of Research Compliance and Integrity

Office of Research Compliance and Integrity

Division of Research and Innovation Partnerships

Attention: ORCIS

Lowden Hall 301

Northern Illinois University

1425 West Lincoln Highway

DeKalb, Illinois 60115

(815) 753-1610

<http://niu.edu/divresearch/compliance/integrity/substances/index.shtml>

State of Illinois:

Illinois Department of Financial and Professional Regulation

Attention: Illinois Department of Professional Regulation

320 West Washington Street, 3rd Floor

Springfield, Illinois 62786

217-785-0800

<http://www.idfpr.com/profs/info/contsub.asp> (select "097 Other Cont Subs License")

Federal:

Drug Enforcement Administration

Kluczynski Federal Building

230 South Dearborn Street

Suite 1200

Chicago, Illinois 60605

(312) 353-1236 (new applications)

(800) 478-7630 (new applications in state only)

<http://www.deadiversion.usdoj.gov/index.html> (select "New Applications Online" in quick links section)

Appendix C: Record of DEA Form 222 Use

Appendix D: Sample Drug Inventory Form