



Approving University Official(s): Vice President for Research
Responsible Office: Center for Comparative Medicine
Effective date: September 1, 2022
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Policy on the Use of Controlled Substances in Research

Policy Statement

Some substances used in biomedical and other scientific research are controlled under federal and state laws and regulations. Northwestern University requires compliance with all applicable federal and state requirements regarding the use of controlled substances in performing research, including the federal Controlled Substances Act ([21 Chapter 13, Sec. 801 et seq.](#)), and its implementing regulations ([21 CFR 1300-1399](#)) and the State of Illinois Controlled Substances Act ([720 ILCS 570](#)), and its implementing regulations ([Ill. Admin. Code tit. 77, § 3100 et seq.](#)).

Purpose

The purpose of this policy is to ensure that all Northwestern University faculty, staff, students, and visitors conducting or assisting in the conduct of non-clinical research activities with controlled substances comply with all federal and state requirements pertaining to controlled substances.

Audience

Faculty, students, trainees, staff, visitors, and all other members of Northwestern University's research community.

Definitions

"Controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V as defined by [21 USC 812: Schedule of controlled substances](#).

"Authorized agent" means individuals authorized by the registrant to engage in registered activities, if such individual is acting in the usual course of his/her business or employment.

"Registrant" means any individual or entity registered or licensed with the federal Drug Enforcement Administration (DEA) and the State of Illinois to engage in specific activities with specific controlled substances.

"Registered" means an individual or entity who holds a valid federal and State of Illinois registration or license to engage in certain specific activities with specific controlled substances.

Policy Implementation

Northwestern's Office for Research (OR), through its Center for Comparative Medicine (CCM), assists the research community in complying with state and federal laws and regulations regarding the use of controlled substances in non-clinical research through implementation of the requirements below. All Northwestern University faculty, staff, students, and visitors conducting or assisting in the conduct of non-clinical research activities with controlled substances must comply with the requirements of this policy and the related [Procedures Regarding the Use of Controlled Substances in Non-Clinical Research](#) including the following specific requirements that apply depending on the context of the use of controlled substances:

Animal Research: The use of a controlled substance(s) for animal research may occur only after a research protocol has been reviewed and approved by the IACUC. All use of controlled substance(s) for animal research must comply with applicable CCM and IACUC policies. Please contact cs-compliance@northwestern.edu for additional guidance.

The Principal Investigator (PI) must also indicate the controlled substance(s) being utilized in the research, as well as the storage location of the controlled substance(s), in Lumen, the University's online safety data management tool. The Office for Research Safety can assist with [Lumen registration](#).

Human Research: This policy does not address the use of controlled substances in clinical research. If you intend to or are conducting clinical research using controlled substances, please contact FSMResearchCompliance@northwestern.edu for guidance.

Research that is neither Human Research nor Animal Research: For any such research utilizing controlled substances, the PI must indicate the controlled substance(s) being utilized in the research, as well as the storage location of the controlled substance(s), in Lumen, the University's online safety data management tool. The Office for Research Safety can assist with [Lumen registration](#).

Please note: It is recommended that an individual who has a controlled substance practitioner's license and registration should obtain a *separate* research license in order to conduct non-clinical research activity using controlled substances.

Requirements

Registration/Licensing

- Before a laboratory may begin any work with controlled substances, the PI must contact cs-compliance@northwestern.edu to notify the Controlled Substance Compliance Coordinator of the intent to obtain and use controlled substances.
- Only faculty PIs are authorized to obtain controlled substances registrations/licenses.
- Legal handling and administration of controlled substances requires appropriate registration with the federal Drug Enforcement Administration (DEA) and licensing through the Illinois Department of Financial and Professional Regulations (IDFPR). The Controlled Substance Compliance Coordinator can assist PIs with the state and federal registration processes in order to obtain the necessary registration and licenses (i.e., become a Registrant). See the [Procedures Regarding the Use of Controlled Substances in Non-Clinical Research](#).

Training

Before any work begins with controlled substances, the PI and all individuals in the laboratory involved in research using controlled substances are required to complete controlled substances training, which addresses licensing and registration requirements, record-keeping, storage, and disposal and waste.

PI Compliance Obligations

PIs with active controlled substances regulations/licenses must:

- Ensure all use of controlled substances in the PI's research, as well as any individual involved in such research, complies with all applicable state and federal laws and regulations, this policy, and the related [Procedures Regarding the Use of Controlled Substances in Non-Clinical Research](#).
- Properly store controlled substances per State of Illinois and DEA regulations.
- Properly screen and document as authorized agents all Northwestern investigators and laboratory staff who will use the controlled substances for research under the PI's license and registration.
- Maintain at all times accurate and complete records per compliance regulations.
- Provide license and registration information to cs-compliance@northwestern.edu.
- Meet annually with the Controlled Substance Compliance Coordinator to review controlled substance records and compliance to identify any areas where improvement is needed.
- Report to cs-compliance@northwestern.edu any instances of non-compliance with applicable requirements, this policy and related procedures (e.g., unresolved inventory discrepancies, container issues).
- Immediately report to the DEA, Controlled Substance Compliance Coordinator, and University Police any diversions, theft or significant loss of controlled substances, as outlined in the related procedures.

Consequences of Violating this Policy

Noncompliance with this policy (and related procedures) includes, but is not limited to: submission of incomplete, erroneous, or misleading information in order to obtain a controlled substances registration/license; failure to comply with training, record keeping, inventory, security, or disposal requirements; or failure to submit other required information. The Vice President for Research may impose corrective actions for noncompliance, up to and including barring an individual from performing research with controlled substances at Northwestern. Furthermore, noncompliance may be subject to the disciplinary policies and procedures as stipulated in Northwestern's Faculty Handbook, Staff Handbook, or Student Handbook, as applicable, and may result in disciplinary action, up to and including termination of employment or appointment, or expulsion, as applicable. In addition to disciplinary action, Northwestern may contact the appropriate governmental authority when violations of federal or state laws or regulations may have occurred.

Related Information

[Procedures Regarding the Use of Controlled Substances in Non-Clinical Research](#)

[DEA Manuals](#)

Contacts

Questions about this Policy should be addressed to the Controlled Substance Compliance Coordinator: cs-compliance@northwestern.edu

History

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Last Amended Date: N/A

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Policy URL: <https://controlledsubstances.northwestern.edu/docs/controlled-substance-policy-final-8-24-2022.pdf>