Applying for Use of DEA Scheduled Substances

Overview

A license to purchase and use controlled substances requires application to state and federal entities, including the New York State Department of Health Bureau of Narcotics Enforcement (NYS DOH) and the US Department of Justice Drug Enforcement Administration (DEA). Controlled substances are drugs and certain other chemicals, both narcotic and non-narcotic, which come under the jurisdiction of the NYS DOH and DEA. These controlled substances are listed on five separate DEA lists (Schedules). For a complete list, visit the following website: https://www.deadiversion.usdoj.gov/schedules/schedules.html

NOTE: This document addresses requirements for obtaining and renewing licensure from the NYS DOH and DEA. New and current Weill Cornell Medicine registrants should also consult the EHS document Security of DEA Controlled Substances, which discusses purchase, recordkeeping, storage requirements, safe handling, and disposal in greater detail.

Applicability

Researchers wishing to use controlled substances at Weill Cornell Medicine (WCM) must apply for Licenses with the state and federal agencies prior to purchasing and use in any protocols. Compliance can be accomplished by obtaining proper licensing from the NYS DOH Bureau of Narcotics Enforcement and the US DEA and adhering to the prescribed safeguarding, record-keeping, and handling provisions. Authorized users can also be added to the license by following the requirements specified in NYS DOH and DEA application instructions.

Responsibilities

DEA Registrants/NYS Licensees are legally responsible for managing the controlled substances in accordance with the regulations, including inventory, recordkeeping, and security provisions. Specifically, they are responsible for:

- Obtaining and maintaining appropriate licensure from the NYSDOH Bureau of Narcotics Enforcement- Form DOH 4330.
- Obtaining and maintaining appropriate registration from the US DEA (Based on Category; Research – Form 225/225a).
- Safeguarding controlled substances obtained through their license/registration from receipt until their destruction/disposal.
- Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.

Supervisor of Controlled Substance Activity (Supervisor) is an individual who undertakes responsibilities including ordering, receiving, inventory, recordkeeping, and dispensing on behalf of the registrant. The role is officially designated by the registrant on form DOH-4330. Supervisors will generally have access to the entire inventory of stored controlled substances. To take on supervisory responsibilities with schedules I & II controlled substances, a Power of Attorney must be officially completed, signed, and kept on file by the registrant.

Authorized Users are trusted lab members who receive controlled substances under authorized supervision of the primary DEA registrant or supervisor. Authorized users of controlled substances are responsible for managing the controlled substances in accordance with regulations, including inventory, record keeping, and security provisions. They are responsible for following established security measures for the storage, use, and ultimate disposal of the controlled substances used in their research. They must be listed on the animal use or research protocol detailed on the registrant's NYS DOH License. Authorized Users only have access to materials dispensed to them by the registrant or supervisor, generally dilutions.

Environmental Health and Safety (EHS) serves as a resource for researchers dealing with NYS and DEA regulations and inspections. Additionally, EHS can help with the paperwork process of obtaining licensure; however, all applications must come from the potential registrant. EHS also coordinates the disposal of controlled substances and can assist in filling out DEA Form 106 to report the theft or loss of controlled substances should such an event occur.

Weill Cornell Medicine

Environmental Health and Safety
TEL 646-962-7233 WEB weill.cornell.edu/ehs EMAIL ehs@med.cornell.edu
Weill Cornell Medicine | 402 East 67th Street, Room LA-0020 | New York, NY 10065

NEW APPLICANTS

All researchers who wish to purchase and use controlled substances must apply for individual licensing. You will be required to obtain a license from the NYS DOH and a registration from the DEA. Below is a summary of the order of events that must be followed by the lab prior to the commencement of work with scheduled materials. It is not an exhaustive list of individual steps to obtain a license that is required by each agency. Please refer to the linked instructional documents that will outline state and federal steps for obtaining licensure to work with scheduled materials in greater detail for each step.

1. The lab must review and prepare their storage areas as appropriate for the scheduled materials with which they intend to work. Storage requirements are more rigorous for Schedules I and II materials than Schedules III – V. These requirements also vary by main/reserve stocks vs. working stocks. Please review Instructions for Form DOH-4330 thoroughly for acceptable container types. Installation of safes, cabinets, and/or vaults will need to be coordinated with Weill Cornell Medicine Facilities Management & Campus Operations. EHS can assist with the selection of appropriate storage containers. See below for a summary of these requirements.

New York State Department of Health Controlled Substance Minimum Storage Requirements - Class 4 and 7		
	Schedule I & II Materials	**Schedule III - V Materials**
Reserve and Main Stock	A Safe with a TL rating of 30 or higher **or** a vault with a GSA class 5 rating. Safes weighing <750lbs. Must be bolted to the floor.	A cabinet that is stationary, securely locked, and of substantial construction (i.e., steel).
Working Solutions	A cabinet that is stationary, securely locked, and double-doored. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal.	A cabinet that is stationary, securely locked, and of substantial construction (i.e., steel)

Note: Prior to purchase, it is recommended to confirm with the vendor that model of the safe or lock box the lab plans to purchase meets all NYSDOH requirements for the appropriate schedule of drugs.

2. New Registrants must first obtain a license(s) with the NYSDOH by filling out Form DOH 4330. This occurs prior to submitting an application with the DEA to obtain a federal registration. Licenses are issued for using Schedule I materials and separately for Schedule II – V materials. Instructions for Form DOH-4330 for the state application can be found at NYSDOH- Bureau of Narcotic Enforcement. **Please send your completed application to Environmental Health & Safety so it can be reviewed and submitted to NYS Dept. of Health on your behalf.**
   - Researchers seeking to work with *Schedule I* materials should submit an application for a Class 7 Individual license.
   - Researchers seeking to work with *Schedule II - V* materials should submit an application for a Class 4 Individual license

- **Note: If you seek to use both *Schedule I* and *Schedule II – V,* you will need to submit separate applications for each license.**
- Checklist for NYS DOH License Application
  - Completed DOH-4330 application with appropriate signatures
  - Completed Appendix A1 (one appendix needed for each IACUC protocol)
  - Application fee $40: scan/photocopy of check/money order to NYS DOH Bureau of Narcotics Enforcement
  - Curriculum Vitae of proposed licensee
  - Copies of approved IACUC protocol
  - Policies and procedures for safe storage of C.S. and methods used to reduce potential for diversion
  - Copy of DEA registration (only applicable for clinicians with existing DEA registration
  - Digital photographs of all storage and security
    - Entrance and exits to the room where storage is installed
    - All areas of the room where storage is installed (to provide a 360-degree view)
    - All storage closed/locked and open to reveal all locking mechanisms and compartments
    - All security measures in place (key card access, alarm systems, locked doors, etc.)

3. Once the application has been submitted and appropriate storage is installed, the NYS Bureau of Narcotics Enforcement will schedule an onsite visit to review the storage and documentation of the potential registrant.

4. Upon approval and receipt of licensure from the NYS DOH, you must apply for a federal registration with the DEA. These forms are submitted online through the DEA's website. New applicants and renewals can be accessed through the DEA's Diversion Control Division Registration Page. Researchers should thoroughly review the DEA's resource Researcher's Manual: An Information Outline of the Controlled Substances Act.
   - Researchers must submit an application for a registration for either Schedule II-V or Schedule I.
   - **Note: Similar to NYS DOH, if you seek to use both Schedule I and Schedule II – V, you will need to submit separate applications for each registration.**

   - Checklist for DEA Registration Application
     - Completed DEA Form 225: Application for Registration under Controlled Substances Act
     - $296 application fee paid by credit card
     - Copy of state license from NYS Dept. of Health
     - Completed Power of Attorney (Schedule I & II only)

   - Supplementary Checklist for Schedule I Researchers
     - Must file and receive approval for a complete research protocol
     - Supplemental protocol that includes detailed information C.S. use locations and procedures for storage, dispensing, and security to prevent diversion
     - IACUC Approval Letter
     - Curriculum Vitae of proposed registrant

5. Once applications have been submitted, the DEA will schedule an on-site inspection to review storage, material logging requirements, and researcher protocols similar to the NYS DOH. This inspection is separate from the inspection by the NYS DOH

6. You may commence work with scheduled materials **only after** you have received both a license from the NYS DOH and a registration from the DEA.

RENEWAL APPLICATIONS

1. NYS DOH Licenses need to be renewed every two years. Registrants seeking renewal will submit Form DOH-4330 as they did when first applying with the NYS DOH. Each license type held by the registrant will require a separate application and fee. If there has been a change in relocation or ownership, the renewal is submitted as a "new" application and will require an inspection by the NYSDOH. Registrants who have had no changes to their working location will submit as a "renewal" under Application Type on Form DOH-4330.

2. DEA Registrations need to be renewed annually. Registrants who need to renew their federal license will complete this online by selecting *Renewal Applications* through the DEAs Registration Application and Tools using Form 225a.

NOTE: If there are any changes to your location up to and including the room/space where the materials are stored, you will need to update this by selecting *Make Changes to My DEA Registration* via DEAs Registration Application and Tools. You must complete this at any point that your location changes, regardless of the expiration date of your license.

- If either your NYS DOH license or DEA registration expires, all controlled substance activity must cease immediately. Renewals may be submitted during the grace period: within 60 days of expiration date for NYS DOH or within 30 days of expiration date for DEA. After that, a new application and inspections will be required.

References

Federal Regulations:
Controlled Substances Act – 21U.S.C. §801-971
Chapter II of the Code of Federal Regulation – 21C.F.R. §1300-1321

State Regulations:
New York State Controlled Substances Act – Public Health Law Article 33 §3300-3397
Rules and Regulations on Controlled Substances – Title10 NYCRR Part 80

Forms and Instructions

Environmental Health & Safety: Security of DEA Controlled Substances Guidance

DEA Researcher's Manual: An Informational Outline of the Controlled Substances Act

New York State Department of Health Bureau of Narcotic Enforcement: Instructions for License Application to Engage in a Controlled Substance Activity

DEA Diversion Control Division Registration Page:
NEW APPLICANTS: DEA Form 225: Application for Registration Under Controlled Substances Act of 1970:
RENEWALS: DEA Form 225a: Renewals of Registration Under Controlled Substances Act of 1970

Recommended Vendors

Gardall Premium Quality Safes: https://gardall.com/

Wilson Safes: https://www.wilsonsafe.com/

Empire Safes: https://empiresafe.com/

Controlled Substances Pre-Inspection Checklist

After NY State Department of Health receives your Controlled Substances license application, an inspection will be scheduled with a representative from the Bureau of Narcotics Enforcement (BNE). Please use the checklist below to ensure that all facilities, necessary paperwork, and other relevant items are ready for inspection.

Authorized Investigator:	Date:
Building:	Room Numbers of Storage/Use Areas:

Yes	No	N/A	Checklist
			Applicant and all authorized users acknowledge understanding of duties and responsibilities related to Controlled Substance use at WCM.
			Knowledge of Authorized User(s) and their trustworthiness.
			Knowledge of how Controlled Substances will be obtained, stored, and used in the animal/non-animal research program.
			Supervisor of Controlled Substance Activity has been designated on NYS Dept. of Health License Application (Form DOH-4330).
			List of Authorized Users is current. Authorized Users are limited to the minimum number of personnel required for research. All Authorized Users have completed Disclosure Questionnaire.
			An appropriately rated lock box and/or safe is properly secured and installed. It is in good working order and the keys are in a secure location.
			An appropriately rated floor safe is present if Schedule I or II CS will be used. It is bolted down if weighing less than 750lbs.
			Lock box and/or safe is currently empty.
			CS record keeping documents are organized and ready for inspection. Receipt Logs, Use Logs, and Initial and Biennial Inventory Logs.
			CS Usage Logs and Inventory Logs for Schedule I and II substances are maintained separately from those for Schedule III-V.
			All CS containers must be labeled with drug name, concentrations, vial # and expiration date.
			Users know that one log sheet or log entry should be completed for each container including each dilution.
			Users are aware that the physical amount in containers/vials must match information recorded in the inventory and use logs and that if there is a discrepancy, they must inform the PI immediately.

Signature: _____ Date: _____