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 (NYSDOH) and the US Department of Justice Drug Enforcement Agency (DEA). Controlled substances are drugs and certain other chemicals, both narcotic and non-narcotic, which come under the jurisdiction of the NYSDOH 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/.

NOTE: This document addresses requirements for obtaining and renewing licensure from the NYSDOH 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 NYSDOH Bureau of Narcotics Enforcement and the US DEA, and adhering to the prescribed safeguarding, record-keeping, and handling provisions. Secondary users can also be added to the license by following the requirements specified in NYSDOH and DEA application instructions.

Responsibilities
DEA Registrants (permit holders) 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).
- Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.

Secondary Users are Principal Investigators (PIs) and their designees who receive controlled substances under authorized supervision of the primary DEA registrant. Secondary users of controlled substances are responsible for managing the controlled substances in accordance with the regulations, including inventory, record keeping, and security provisions. They are responsible for establishing security measures for the storage, use, and ultimate disposal of the controlled substances used in their research.

Environmental Health and Safety (EHS) can help with the paperwork process of obtaining licensure; however, all submissions must come from the potential registrant. EHS also coordinates the disposal of DEA-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.

NEW APPLICANTS

All researchers who wish to purchase and use controlled substances must apply for individual licenses. You will be required to obtain licenses from the NYSDOH and 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. NewRegistrants 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 license. 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.
   - 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.

2. Once applications have been submitted to the NYSDOH, 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 Schedule I and II materials than Schedule 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

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<th>Schedule I &amp; II Materials</th>
<th>Schedule III - V Materials</th>
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<tr>
<td>Reserve and Main Stock</td>
<td>A Safe with a TL rating of 30 or higher or a vault with a GSA class 5 rating. Safes weighing &lt;750lbs. Must be bolted to the floor.</td>
<td>A cabinet that is stationary, securely locked, and of substantial construction (i.e., steel).</td>
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<tr>
<td>Working Solutions</td>
<td>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.</td>
<td>A cabinet that is stationary, securely locked, and of substantial construction (i.e., steel)</td>
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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.

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

4. Upon approval and receipt of licensure from the NYSDOH, you must apply for a federal license with the DEA. These forms are submitted online through the DEA’s website. New applicants and renewals can be accessed through Registration Applications and Tools. Researchers should thoroughly review the DEA’s resource Researcher’s Manual: An Information Outline of the Controlled Substances Act.

**NOTE:** Similar to the NYSDOH, applicants must apply for a license to conduct work with Schedule I materials. A Separate license is required for Schedule II – V materials.
5. Once applications have been submitted to the DEA may schedule an on-site inspection to review storage, material logging requirements, and researcher protocols similar to the NYSDOH. This inspection is separate from the inspection by the NYSDOH.

6. You may commence work with scheduled materials only after you have received all licensures from the NYSDOH and DEA.

RENEWAL APPLICATIONS

1. Registrants seeking renewal will submit Form DOH 4330 as they did when first applying with the NYSDOH. 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. Registrants who need to renew their license 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 your license(s) expire prior to submitting a renewal form, you will have to submit applications for a new license(s).

References

Federal: Title 21 CFR Part 1300-1308: https://www.ecfr.gov/current/title-21/chapter-II


Forms and Instructions


Registration, application, and reporting forms from DEA: New Applications, Renewal Applications, Make Changes to My DEA Registration https://www.deadiversion.usdoj.gov/online_forms_apps.html


Recommended Vendors

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