

Security of DEA Controlled 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/>.

Applicability

Controlled substances management practices apply to Individual registrants and their secondary users, who are Weill Cornell Medicine (WCM) faculty, staff, and students who utilize controlled substances when conducting research. Compliance can be accomplished by obtaining proper licensing from both the NYSDOH Bureau of Narcotics Enforcement and the US DEA. Registrants and their secondary users must adhere to the prescribed safeguarding, record-keeping, and handling provisions, or, for secondary users, by following the requirements specified in this document.

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:

- Reviewing, obtaining, and maintaining appropriate licensure from the NYSDOH Bureau of Narcotics Enforcement ([Form DOH 4330](#)).
- Reviewing, obtaining, and maintaining appropriate registration from the US DEA (Based on Category; Research – [Form 225/225a](#)). Researchers should thoroughly review the [DEA's Researchers Manual: An Informational Outline of the Controlled Substances Act](#).
- Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.

Registration and application forms may be obtained via the [DEA website](#).

Secondary Users are Principal Investigators (PIs) and their designees who receive controlled substances for use in research. 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) coordinates the disposal of DEA-controlled substances. EHS also assists the registrant in filling out DEA Form 106 to report the theft or loss of controlled substances.

Procedure

PURCHASE / REQUISITION OF CONTROLLED SUBSTANCES

1. **Before purchase**, it is recommended to call a supplier to confirm that their licenses are in good standing with the NYS DOH and the DEA.
2. **DEA Registrants (permit holders)** must obtain DEA [Form 222](#) prior to the purchase of schedule I and/or II materials. A copy of the DEA registration must accompany the requisition to the supplier. The controlled substances must be shipped to the registrant and address as indicated on the DEA registration. For Schedule I and II materials, Form 222 will be required for purchase and eventual disposal. A copy of the completed Form 222 must be [emailed](#) to the DEA at the close of the month in which the order was filled [21 CFR 1305.13(d)]. Schedule III – V materials **do not** require requisition of Form 222.
3. **Principal Investigators** may purchase controlled substances for use in research upon receiving licensure from the DOH and DEA. Their designees will be listed as “secondary users” on the licenses.



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RECORDKEEPING

1. The DEA registrant (An individual principal investigator who is a DEA permit holder) shall maintain an accurate log of each controlled substance **received, disposed, or otherwise used by him or her**. Records for schedule I and II substances are required to be maintained separately from all other records (i.e., a dedicated file). Records must include the following:
 - a. the name of the drug
 - b. date and amount received
 - c. the number of units or volume in each commercial container
 - d. the date and amount used
 - e. the use or purpose and the name or initials of the individual completing the written entry

A copy of the completed inventory must be retained for 5 years and be made available to WCM or regulatory authorities when requested.

2. Secondary users must maintain an accurate log of all controlled substances. Each dispensed bottle/vial/aliquot is accompanied by a Controlled Substance Usage Log Sheet for investigative staff to account for drugs received and administered. Additional bottles/vials of the same controlled substance are not dispensed until a properly completed log sheet and empty bottle(s) or vial(s) are returned to primary storage.
3. The DEA registrant must report any theft, loss, or discrepancy in the logs or inventory of controlled substances directly to the local DEA office immediately upon discovery. A secondary user must report any such event to the DEA registrant so that proper reports can be filed immediately. EHS is available to assist the registrant in filling out DEA [Form 106](#) to report the theft or loss to the local DEA office.

MINIMUM STORAGE REQUIREMENTS

Before purchase, it is recommended to call the supplier to confirm that the specific safe or cabinet model meets the requirements for the applicable schedule of drugs in NYS. Records of safe specifications must be maintained as these may be requested by investigators and for routine inspections and/or the event of lab moves.

1. All DEA registrants and secondary users of controlled substances must provide effective controls and procedures to guard against theft and diversion of controlled substances. Each DEA registrant and secondary user must have his/her own safety measures in place.
2. Access to any storage area for controlled drugs must be limited to authorized personnel only. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stocks of controlled substances to the smallest quantity needed.
3. **Reserve or main stocks** of controlled substances shall be kept securely as follows:
 - **Schedule I and II** controlled substances shall be kept in one of the following secure storage areas:
 - **Safe or Cabinet:** GSA Class 5 rated (or equivalent). Safes with a TL rating of 30 or higher are deemed to be equivalent to a GSA Class 5 rating. The door of the safe or cabinet must contain a multiple-position combination lock, a relocking device (or equivalent), and a steel plate having a thickness of at least one-half inch. Safes weighing less than 750 lbs must be bolted or cemented to the floor or wall.
 - **Vault:** Existing vaults must be of substantial masonry and have a multiple position combination lock, relocating device (or equivalent), and a door having a thickness of steel plate of at least one-half inch. Newly constructed vaults must have walls, floors, and ceilings constructed of at least eight inches of reinforced concrete. Less may be accepted where other safeguards are in place. *Class M modular panels with a GSA Class 5-rated door are deemed to be equivalent to the above. Vaults must be six-sided or have floors constructed as described above.*
 - **Schedule III, IV and V** controlled substances shall be stored in a cabinet that is stationary, securely locked and of substantial construction (i.e., metal).
4. **Working stocks** of controlled substances shall be securely kept as follows (applicable to WCM Principal Investigators who are DEA registrants/secondary users):
 - **Schedule I, II, III, and IV** controlled substances shall be kept in a stationary, locked, double cabinet. Both cabinets must have key-locked doors with separate keys. Cabinets shall be made of steel or other approved metal. Spring locks or combination dial locks are not acceptable.
 - **Schedule V** controlled substances shall be stored in a cabinet that is stationary, securely locked, and of substantial construction (i.e., metal).



5. General Provisions:

- There must be no signage or other indication that the locked safe, cabinet, box, or vault is used for storing controlled substances.
- The controlled drugs or the keys to the locked safe, cabinet or vault must never be left unattended.
- Regardless of schedule, all controlled substances must be kept locked in their storage location, except for the actual time required for authorized staff to remove, legitimately work with, and replace them.
- Only authorized personnel, as determined by the PI (DEA registrant/secondary user), must be allowed access to the keys or combinations to the locked safe, cabinet, box or vault.
- Employees must be prohibited from sharing keys or combinations with unauthorized personnel. If a common key is shared among lab personnel, it can be placed in a common area (e.g., office), but accessibility to the key should only be available as long as the common area is occupied. When unoccupied, the common area should be locked at all times, and there should be no access to the keys. There should be no signs posted outside the lab door showing the location of the keys. A swipe-card, combination key-pad lock, or key must be used to permit entry into this area.

SAFE HANDLING AND USE

1. Controlled substances are toxic chemicals and must be handled in a safe manner. For the safe handling and use of these chemicals follow the safety procedures for toxic chemicals given in the EHS program manual [4.1 - Laboratory Chemical Hygiene Plan](#) on the EHS website.
2. Expiration dates of all drugs should be checked on a monthly basis. Any controlled substance that has passed its expiration date should be returned to the vendor, if sealed, or disposed according to procedure given below.

DISPOSAL

For disposal of controlled substances at WCM, the following procedure must be followed:

1. Consult options for pharmacy take back programs and events.
2. Email Environmental Health and Safety at ehs@med.cornell.edu, providing EHS with an inventory of DEA-regulated materials to be disposed and the DEA Registrant's contact and license information.
3. Store DEA-regulated materials in accordance with the storage guidelines provided in this document while awaiting disposal. The material should be clearly identified "**Expired – Do Not Use**".
4. EHS assists with preparing required disposal documentation (e.g. DEA [Form 41](#) and [Form 222](#), if either is required) and submits to DEA registrant for review and signature.
5. EHS submits signed documents to the DEA for authorization for the destruction.
6. EHS coordinates witnessed disposal of DEA-regulated materials with the DEA registrant.
7. EHS notifies the DEA upon completion of disposal.
8. EHS and DEA registrant maintain documentation. Records, inventories and official paperwork must be kept and available upon request by appropriate authorities for **5 years**.

SPILL CLEAN-UP

All spills of controlled substances must be handled in accordance with the EHS program manual [4.3 – Chemical Spill Planning and Response](#) on the EHS website.

References

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

State: NYS Department of Health, Statutory Authority; Public Health Law, Sec 225, NYCRR Title 10, Part 80 – Rules and Regulations on Controlled Substances http://www.health.ny.gov/regulations/controlled_substance/part/80/docs/80.pdf

NYS Department of Health, Bureau of Narcotic Enforcement, License Application to Engage in a Controlled Substance Activity, February 2017. http://www.health.ny.gov/forms/instructions/doh-4330_instructions.pdf

Article 33 of the New York State Public Health Law <https://www.nysenate.gov/legislation/laws/PBH/A33>



Forms and Instructions

Registration, application, and reporting forms from DEA

https://www.dea diversion.usdoj.gov/online_forms_apps.html

Instructions for DEA Form 106: Report of Theft or Loss of Controlled Substances

<https://apps2.dea diversion.usdoj.gov/TLR/login.xhtml>

Request for DEA Form 222: US Official Order Forms – Schedule I & II

<https://apps.dea diversion.usdoj.gov/webforms/orderFormsRequest.jsp>

New York State Department of Health Bureau of Narcotic Enforcement: License Application to Engage in a Controlled Substance Activity <https://www.health.ny.gov/forms/doh-4330.pdf>

Appendices to the DOH-4330 Application https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/licensing.htm

DEA Form 41: Registrant Record of Controlled Substances Destroyed

https://www.dea diversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf

DEA Form 225: Application for Registration Under Controlled Substances Act of 1970 (New Applicants Only):

<https://apps.dea diversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>

DEA Researchers Manual: An Informational Outline of the Controlled Substances Act

[https://www.dea diversion.usdoj.gov/GDP/\(DEA-DC-057\)\(EO-DEA217\)_Researchers_Manual_Final_signed.pdf](https://www.dea diversion.usdoj.gov/GDP/(DEA-DC-057)(EO-DEA217)_Researchers_Manual_Final_signed.pdf)

Recommended Safe Vendors

Gardall Premium Quality Safes

<https://gardall.com/>