

# Security of DEA Controlled Substances



## Overview

Controlled substances are drugs and certain other chemicals, both narcotic and non-narcotic, which come under the jurisdiction of the NY State Department of Health (NYSDOH) Bureau of Narcotics Enforcement and the US Department of Justice Drug Enforcement Administration (DEA) laws. 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 Weill Cornell Medicine (WCM) faculty, staff and students who utilize controlled substances when conducting research. Compliance can be accomplished by either 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, 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:

- 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 for use in research animals from the Research Animal Resource Center (RARC). 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. **DEA Registrants (permit holders)** can purchase controlled substances directly from the DEA by submitting DEA [Form 222](#). A copy of the DEA registration must accompany the requisition. The controlled substances must be shipped to the registrant and address as indicated on the DEA registration.
2. **Principal Investigators** and their designees can receive controlled substances for use in research animals from RARC, in which case RARC will be the DEA registrant and the PI/designees will be the "secondary user".

### RECORDKEEPING

1. The DEA registrant (RARC and Principal Investigators who are DEA permit holders) 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 name of the drug, the date and amount received, the number of units or volume in each commercial container, the date and amount used, the use or purpose and the name or initials of the individual making 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.



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2. If the PI is the DEA registrant, any theft, loss or discrepancy in the logs or inventory of controlled substances must be reported directly to the local DEA office immediately upon discovery. EHS is available to assist the registrant in filling out DEA [Form 106](#) to report the theft or loss to the local DEA office.
3. Secondary users must maintain an accurate log of all controlled substances. Requests to purchase controlled substances by investigative staff are made to the RARC Veterinary Services department (VS) by completing a RARC Animal Health Service Drug and Supply Request Form. VS dispenses the drug after confirming that the agent is described in the animal use protocol and the individual picking up the drug(s) is authorized to do so. 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 RARC VS.
4. If the controlled substance is purchased from RARC, any theft, loss or discrepancy in the logs or inventory of controlled substances must be reported to RARC's Veterinary Services department immediately. The local DEA office will be notified by the registrant (RARC) upon discovery or after informed by the "secondary user".

### MINIMUM STORAGE REQUIREMENTS

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 of 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](mailto: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 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.

## 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  
<http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>

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](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, June 2013. [http://www.health.ny.gov/forms/instructions/doh-4330\\_instructions.pdf](http://www.health.ny.gov/forms/instructions/doh-4330_instructions.pdf)

Article 33 of the New York State Public Health Law <http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO>:

## Forms and Instructions

Instructions for DEA Form 106: Report of Theft or Loss of Controlled Substances  
<https://apps2.deadiversion.usdoj.gov/TLR/login.xhtml>

Request for DEA Form 222: US Official Order Forms – Schedule I & II  
<https://apps.deadiversion.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>

DEA Form 41: Registrant Record of Controlled Substances Destroyed  
[https://www.deadiversion.usdoj.gov/21cfr\\_reports/surrend/41\\_form.pdf](https://www.deadiversion.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>