Security of DEA Controlled Substances

Overview

Controlled substances are drugs, chemicals, or immediate precursors, 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). All controlled substances are classified into five distinct categories, known as schedules, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A complete list of Controlled Substances and their schedules can be found on the DEA website. Provisions outlined in this document must be followed to ensure the security of controlled substances.

Applicability

Controlled substance 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:

1. 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
2. For secondary users who receive C.S. from RARC, by following the requirements specified in this document.

Responsibilities

DEA Registrants are legally responsible for managing the controlled substances by 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).
- Ensuring that requirements for the receiving, storage, security, recordkeeping, and handling of all controlled substances within the lab are strictly met.

Supervisor of Controlled Substance Activity (Supervisors) 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 generally have access to the entire inventory of stored controlled substances.

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 by 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 in their research. **As of 2024, WCM PIs are required to apply as individual registrants. After September 15, 2024, RARC will not distribute to PIs that have not yet started the application process to obtain their licensing.**

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. Serves as a resource for researchers dealing with the NYS Department of Health and U.S. Department of Justice, Drug Enforcement Agency regulations, licensing/registration, and inspections. EHS will train researchers seeking to work with controlled substances and disseminate updates regarding applicable state/federal law changes. EHS will also coordinate with state and federal agencies on compliance-related matters, conduct inspections of research labs for proper storage and recordkeeping, and facilitate the disposal of controlled substances with reverse distributor vendors.

Procedure

MINIMUM STORAGE REQUIREMENTS

Before purchase, it is recommended to check with EHS to confirm that the specific safe or cabinet model meets the requirements for the applicable schedule of drugs in NYS.

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1. All DEA registrants and secondary users of controlled substances must provide adequate controls and procedures to guard against theft and diversion of controlled substances. Each DEA registrant and secondary user must have their 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 a minimum, essential for efficient operation, and the stocks of controlled substances must be kept to the smallest quantity needed.
3. Reserve or leading 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**: GSA Class 5 rated (or equivalent). Safes with a TL rating of 30 or higher are deemed to be comparable 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 with a steel plate thickness 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.*
4. ***Schedule III, IV, and V*** controlled substances shall be stored in a stationary, locked, double cabinet. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal. Working stocks of controlled substances shall be securely kept as follows (applicable to WCM Principal Investigators who are DEA registrants):
   - ***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 stationary, securely locked cabinet 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 the schedule, all controlled substances must be locked in their storage location, except for the 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 standard key is shared among lab personnel, it can be placed in a common area (e.g., office), but access to the key should only be available as long as the common area is occupied. The common area should always be locked when unoccupied, with no access to the keys. No signs should be 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.

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 before purchasing schedule I and II materials. A copy of the DEA registration must accompany the supplier's requisition. The controlled substances must be shipped to the registrant and address as indicated on the DEA registration. Upon completing Form 222, a copy must be emailed to the DEA at the close of the month the order was filled [21 CFR 1305.13(d)]. Schedule III – V materials do not require the requisition of Form 222.
3. **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.”
4. General Provisions:

- All purchases of controlled substances must follow a strict chain of custody from the vendor's approved courier directly to the DEA Registrant or Supervisor of Controlled Substance Activity.
- Packages must be unpacked, inspected, labeled, and logged immediately upon receipt.
- Controlled substances must be placed in the lockbox or safe after processing. Packages must never be left unattended or unsecured.

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. Records for schedule I and II substances must be kept separately from all other records (i.e., a dedicated file). Records must include:
    a. the name of the drug
    b. date and the 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 making the written entry

    A copy of the completed inventory must be retained for five years and be made available to WCM or regulatory authorities when requested.
2. If the PI is the DEA registrant, any theft, loss, or discrepancy in the logs or inventory of controlled substances must be reported to the local DEA office immediately upon discovery. EHS can 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 that 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 an adequately 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 being informed by the "secondary user."

SAFE HANDLING AND USE

1. Controlled substances are toxic chemicals and must be handled safely. 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 every month. Any controlled substance past its expiration date should be returned to the vendor if sealed or disposed of according to the procedure below.

DISPOSAL

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

1. Email Environmental Health and Safety at ehs@med.cornell.edu, providing EHS with an inventory of DEA-regulated materials to be disposed of and the DEA Registrant's contact and license information.
2. Store DEA-regulated materials by the storage guidelines provided in this document while awaiting disposal. The material should be identified as "**Expired – Do Not Use.**"
3. EHS assists with preparing required disposal documentation (e.g., DEA Form 41 and Form 222, if either is needed) and submits it to the DEA registrant for review and signature.
4. EHS submits signed documents to the DEA for authorization for the destruction.
5. EHS coordinates witnessed disposal of DEA-regulated materials with the DEA registrant.
6. EHS notifies the DEA upon completion of disposal.
7. EHS and DEA registrant maintain documentation.

THEFT OR LOSS

Registrants should immediately notify Environmental Health and Safety to report any potential loss/theft of controlled substances, regardless of the amount. Do not wait until the following business day. NYS BNE & the DEA require prompt reporting. If given immediate notification, EHS will have time to complete an internal investigation and assist registrants with the necessary reporting forms.

Reporting Theft or Loss to NYS BNE: NYS Article 33 of Public Health Law specifies a *Duty of Notification by Licensee*: Persons licensed and persons authorized to possess controlled substances must notify NYS DOH Bureau of Narcotics Enforcement of any incident or alleged incident of theft, loss, or possible diversion of controlled substances. Form DOH-2094 must be filled out and submitted within one business day. Do not submit any report to NYS BNE without contacting Environmental Health & Safety.

Reporting Theft or Loss to the DEA: Title 21 of the Code of Federal Regulations requires that registrants notify the local DEA Diversion Field Office in writing or by email within one business day of discovering theft or the significant loss of any controlled substance. The registrant must then complete a DEA Form 106 to document the circumstances of the left or loss within 45 days.

SPILL CLEAN-UP

The witnessed breakage or spillage of a controlled substance does not constitute a loss of controlled substances because the registrant can account for the controlled substances. Therefore, Form 106 must not be completed to report accidental spillage. While these types of incidents do not require notification to the DEA, Weill Cornell Environmental Health and Safety must be informed. If there is any accidental spillage or breakage, do not attempt to clean up the spill, and contact EHS immediately.

All spills of controlled substances must be handled according to the EHS program manual 4.3—Chemical Spill Planning and Response, available 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.deadiversion.usdoj.gov/online_forms_apps.html

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

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.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.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp