

Disposal:

If controlled substances expire or otherwise require disposal the Licensed Individual must contact an approved Reverse Distributor & arrange for the return of the controlled substances. A list of DOH approved Reverse Distributors can be accessed via the [Disposal Resources](#) section on the EH&S Controlled Substances website.

Report Loss, Theft & Unauthorized Use: What to do?

CONTACT THE **LICENSED INDIVIDUAL, COLUMBIA UNIVERSITY PUBLIC SAFETY & EH&S IMMEDIATELY!**

Training:

The University requires all Licensed & Authorized Individuals to complete an initial Controlled Substances Acquisition, Use and Disposal training program in Rascal. The training must be renewed triennially (every 3 years). Purchasing will require verification of training for Licensed Individuals before approving any controlled substance purchases. The training can be found online at: www.rascal.columbia.edu/ (Course Code TC0502).

Resources & References:

For a complete list of Controlled Substances please visit:

www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

&

www.health.state.ny.us/regulations/public_health_law/article/33/docs/33.pdf

CU Controlled Substance Policy

The acquisition, use & disposal of controlled substances in NYS are strictly regulated by the NYS Department of Health's Bureau of Narcotic Enforcement and the US Department of Justice Drug Enforcement Administration. These regulations are aimed at preventing diversion of controlled substances through a variety of administrative and physical controls. To assist researchers in understanding and meeting their individual obligations under these regulations, CU has established a [Policy for the Acquisition, Use and Disposal of Controlled Substances in Research](#) which is divided in 8 elements.

1. Researcher Licensing & Registration:
Researcher licensing (DOH)
Researcher registration (DEA)
2. Procurement of Controlled Substances
3. Storage & Security
4. Recordkeeping
5. Disposal
6. Reporting Loss, Theft or Unauthorized Use
7. Training
8. Resources & References



Use and Management of Controlled Substances Overview

Environmental Health & Safety



VISION STATEMENT

We provide expert guidance and timely service to the University Community through our commitment to health and safety.

Employing best practices and collaboration, and by building long term relationships, we promote a productive and safety conscious work environment.

www.ehs.columbia.edu

Campus Contact Numbers:

Columbia University Medical Center
212-305-6780

Morningside
212-854-8749



Introduction & Definitions

What is a DEA Controlled Substance?

A “controlled substance” is a drug or other substance, or immediate precursor, listed in any of Schedules I - V of the Federal Controlled Substances Act (21 U.S.C. §§ 801-971) or The NYS Controlled Substances Act (Article 33 of the NYS Public Health Law).

Who is a Licensed Individual?

A Licensed Individual is the Principal Investigator of a research protocol. The Licensed Individual is responsible for obtaining and renewing both DOH and DEA licenses / registrations and for assuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met.

Who is an Authorized Individual?

The Licensed Individual may authorize members of his or her staff to work with controlled substances under the Licensed Individual’s license/registration.

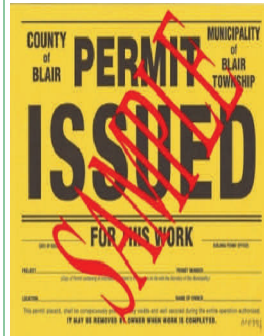
What Controlled Substances are commonly found at CU?

- Dehydrotestosterone
- Phenobarbitol
- Ketamine
- Buprenorphine

Researcher Licensing & Registration:

Initial DOH License Application:

- Those wishing to initiate the research use of controlled substances must obtain a DOH license prior to a DEA registration.
- DOH licenses must be renewed every 2 years.



New applicants will be subject to an on-site inspection by the DOH to review information concerning the operation of the laboratory & inspect for compliance with security/storage requirements.

Procurement of Controlled Substances:

There are four (4) essential steps in the process of purchasing controlled substances:

STEP 1: Submit purchase requisition via FFE.

STEP 2: Submit a valid DOH license and DEA registration certificate to Purchasing.

STEP 3: Purchasing department submits order to distributor.

STEP 4: DEA registrant receipt of controlled substances for inventory and storage.

<http://www.ehs.columbia.edu/ControlledSubstances.html>

Storage & Security:

It is the Licensed Individual’s responsibility to ensure that controlled substances are properly safeguarded & securely stored at all times at the address on file with the DOH and DEA.

Security requirements are dependent on a number of criteria, please visit the link below for assistance with determining the type of security measures needed for your lab.

<http://www.ehs.columbia.edu/StorageAndSecurityDecisionTreeAndSpecificationSheet.pdf>

Recordkeeping:

Significant recordkeeping is required at every point, including initial receipt, use, and disposal. Licensed individuals must maintain the following records:

- Receipt log
- Use log
- Biennial inventory
- Disposal, destruction/reverse distribution records
- If applicable, theft & loss records

Receipt, Use and Biennial Inventory Log records must be maintained for 5 years.



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