



UNIVERSITY AT ALBANY

State University of New York

The Use of Controlled Substances in Research

Policy Statement

Certain research activities conducted under the auspices of the University require the use of controlled substances. Controlled substances, which are substances with high potential for abuse, are identified in the schedules contained within the "Controlled Substances Inventory List," published by the U.S. Drug Enforcement Administration (DEA). In conducting research with controlled substances, University authorized employees must comply with federal and state laws and regulations regarding their use, including DEA registration and New York State Department of Health licensure; storage requirements; inventory maintenance; substance disposal; and reporting and record keeping, in accordance with Title 21, Part 1300-1308 of the Code of Federal Regulations (CFR) and Article 33 of the New York State Public Health Law.

Responsible Party

Authorized University or Research Foundation employees, including principal investigators or supervisors of research in which controlled substances are used, bear full responsibility for complying with federal and state laws and regulations, and with University policy regarding their use. Specifically, they are responsible for:

- Obtaining and maintaining appropriate licensure from the New York State Department of Health.
- Obtaining and maintaining appropriate registration from the DEA.
- Submitting copies of the license and registration to the representative Departments, each time they are issued or renewed.
- Establishing security measures for the purchase, acceptance, use, and ultimate disposal of the controlled substances used in their research.

Principal investigators or supervisors of research, in which controlled substances will be used, are responsible for obtaining approval for their use from all applicable University committees that oversee human subject and animal subjects research (e.g., the Institutional Review Board, the Institutional Animal Care and Use Committee) and must report their intention to use controlled substances to external funding sponsors upon submission of grant applications. Individuals who have obtained relevant approvals for the use of controlled substances will be authorized to purchase, accept, and appropriately dispose of these substances.

(If the controlled item is to be used within the context of the activities of an organized research unit, which are outside of the operation of a specific sponsored project, the director of this research unit will be responsible for complying with federal and state laws and regulations regarding the use of controlled substances, and must notify the representative Departments.

(Note: The Director of the College of Arts and Sciences Technical Services Group is the University employee responsible for the purchase, acceptance, storage, use, and disposal of syringes and needles.)

Purchasing Controlled Substances

Orders for controlled substances by DEA registrants (i.e., authorized University or Research Foundation employees) must be submitted to the Office of Purchasing and Contracts on a requisition signed by the registrant or authorized designee. The requisition must be accompanied by DEA Form 222 and a copy of the DEA registration. Prior to executing the order, the Office of Purchasing and Contracts will obtain a verification from the appropriate Departments and/or Principal Investigator(s) that research, in which the ordered controlled substance is to be used, has been approved for its use and is an active project or program.

Receiving Controlled Substances

The controlled substances must be shipped to the registrant and address as indicated on the DEA registration. Once received, the controlled substances should be opened to verify the contents and any discrepancies should be rectified with the supplier. If necessary, DEA should be contacted. From the time a controlled substance is accepted on campus until it is consumed or disposed of, a record (disposition record) of the chain of custody must be kept at each point where the substance changes hands or is used. The record is completed at each point by the person delivering the substance and includes the name of the substance, the quantity, and the signature of the person receiving it. The person making the withdrawal shall sign all records of withdrawals of controlled substances from storage.

Continuing Records and Inventory

The registrant shall maintain an accurate continuing record or log of each controlled substance received, disposed of or otherwise used by him or her, in accordance with 21 CFR 1304.21 and 1304.24. The registrant for each registered location and for each independent activity for which the registrant is registered shall maintain separate records. The registrant must maintain the continuing records for 5 years.

The records shall include the following information:

1. Name of each substance kept at the site.
2. Identification of each finished form and the number of units or total volume of each finished form in each commercial container.
3. The number of commercial containers of each finished form received; the date of and number of containers in each receipt; and the name, address, and registration number of the source from which the containers were received.
4. The amount of each finished form transferred or used, including the name and address of the person(s) to whom it was given, the date of transfer, the name of the individual who used the substance, and the reason it was used.
5. The number of units or volume of the finished forms and/or commercial containers disposed of in any other manner, as well as the date and manner of the disposal.

Inventory

An accurate inventory of controlled substances must be maintained by each DEA registrant. The registrant will conduct an annual inventory and reconciliation as part of a self-audit. Inventories for schedule I and II controlled substances shall be maintained separately from other laboratory records. A copy of the completed inventory must be retained for 5 years and be made available to University or regulatory authorities when requested.

The inventory will include the following information:

1. Name of substance.
2. Each finished form of the substance.
3. Number of units or total volume of each finished form in each commercial container.
4. Number of commercial containers of each such finished form.

(For guidance regarding damaged, defective, or impure substance awaiting disposal, see 21CFR 1304.15(d).)

Any discrepancy in the continuing record or inventory of controlled substances must be reported to the University Police and their Departments immediately upon discovery.

Storage

All DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. Controlled substances must be stored in a securely locked, substantially constructed cabinet. The following are considered in determining security requirements: the type of activity, the type and form of controlled substance, the quantity of controlled substance, the location of the premises, the type of building construction, the type of vault, safe, and secure enclosures, the adequacy of key control systems, the adequacy of electric detection and alarm systems, the extent of unsupervised public access, the adequacy of supervision over employees with access, procedures for handling visitors, the availability of local police and adequacy of the use and disposal tracking system (CFR 1301.71-1301.76).

Disposal

The registrant having custody of the controlled substance shall dispose of the controlled substance in accordance with NYS Department of Health, Bureau of Narcotic Enforcement (BNE) and the U.S. Department of Justice, Drug Enforcement Administration (DEA), Office of Diversion Control.

1st OPTION: Contact the purchasing vendor and determine if they can accept the controlled substances.

2nd OPTION: Visit the following link and dispose of your controlled substances through an approved reverse distributor.

http://www.health.state.ny.us/professionals/narcotic/pharmacies/surrender_to_independent_companies.htm

3rd OPTION: Visit the following link and request the assistance of the US Department of Justice's Drug Enforcement Administration for the disposal of your controlled substances.

http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm

Any questions or difficulties regarding the disposal of controlled substances should be directed to the Office of Environmental Health and Safety (EHS) at 442-3495 in Chemistry B73. They will advise the registrant on how to dispose of the controlled substance. The EHS Office is not responsible for the ultimate disposal of the controlled substances but rather the registrant.

A copy of all disposal forms should be sent to the EH&S Office in Chemistry B73 for our disposal records. The Principal Investigator should also retain copied of these disposal records for their files.

Relevant Federal and State Regulations concerning Controlled Substances

Federal: Title 21 CFR Part 1300

State: NYS Department of Health, Statutory Authority: Public Health Law, Sec. 225, NYCRR Title 10, Part 80 - Rules and Regulations on Controlled Substances