



Subject: **DEA CONTROLLED SUBSTANCES USE & DISPOSAL**

Policy No.

**APPLICATION**

All New York University academic and research facilities.

**PURPOSE**

It is the intention of New York University to comply with all federal, state and local laws which pertain to the use and disposal of substances identified by the U.S. Drug Enforcement Administration (DEA) as controlled substances for research and teaching purposes.

**POLICY AND GENERAL INFORMATION**

In order to use controlled substances for research purposes, a Unit Registrant must be registered with both the Department of Health of the State of New York, Bureau of Narcotic Enforcement and with the U.S. Department of Justice, Drug Enforcement Administration (DEA).

It is essential that all engaged in the use of DEA identified controlled substances adhere to the procedures in this policy. Violations may also lead to criminal penalties, sanctions, fines and/or suspension of research privileges.

**1.0 DEFINITIONS**

**1.1 Authorized Personnel**

An NYU employee authorized to use controlled substances by a Unit Registrant.

**1.2 Bureau of Narcotic Enforcement (NYS)**

The agency authorized by New York statute that requires any person who engages in research, teaching or educational projects involving the use, study or testing of controlled substances, to register (<http://www.health.state.ny.us/professionals/narcotic/>). Registration is renewed every two years.

**1.3 Controlled Substance**

Any substance listed in the Controlled Substances Act, in the Code of Federal Regulations (21 CFR, Part 1300)

**1.4 Disposal**

Disposal of a controlled substance that is outdated, excess or no longer intended for use. Disposal also refers to controlled substance that is residual (often referred to as waste) or has been contaminated through use or spills.

**1.5 Drug Enforcement Administration (DEA)**

| ISSUE DATE | REPLACES | ORIGINATOR                    | APPROVAL                             |
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The unit within the United States Department of Justice that establishes and enforces regulations for the handling and use of controlled substances under the Controlled Substances Act.

1.6 **Label**

The term “**label**” means a display of written, printed, or graphic matter upon the controlled substance container that list the contents of the container and other information related to use.

1.7 **Licensed Practitioner**

A physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice.

1.8 **Record**

An accurate, continuous and current record used to track the acquisition, receipt, use and disposal of controlled substances.

1.9 **Registration**

Formal grant of specific authority by the DEA and/or NYSDOH Bureau of Narcotic Enforcement.

1.10 **Research**

Any investigative activity engaged in by NYU personnel using university facilities or resources regardless of funding source.

1.11 **Teaching**

Teaching activities include classroom demonstrations, laboratory exercises and research projects that are required for completion of a course at the undergraduate, graduate or professional level.

1.12 **Unit**

School, department, or other group approved by the Senior Vice Provost for Research (Washington Square Campus).

1.13. **Unit Registrant**

An NYU employee delegated by his/her unit to hold DEA and Bureau of Narcotic Enforcement registrations in the name of the unit and responsible for ordering, storing, using and disposing of controlled substances.

**2.0 RESPONSIBILITIES**

2.1 **Senior Vice Provost for Research (NYU) responsibilities include:**

2.1.1 Providing policy direction to all departments;

- 2.1.2 Approving of controlled substance policy;
- 2.1.3 Requiring revisions to programs based on results of periodic evaluations by NYU Operational Risk Management, Department or changes in city, state or federal law.

2.2 **Department Chair or Head** responsibilities include:

- 2.2.1 Ensuring compliance with the policy in the departments;
- 2.2.2 Ensuring that all faculty, staff and students who work with controlled substances receive information about, and are trained according to, the policy;
- 2.2.3 Designating a Unit Registrant.

2.3 **Unit Registrant** responsibilities include, but are not limited to:

- 2.3.1 Maintaining DEA and Bureau of Narcotic Enforcement registrations;
- 2.3.2 Exercising signature authority to purchase and dispose of controlled substances used within that unit;
- 2.3.3 Authorizing NYU personnel to work with controlled substances;
- 2.3.4 Controlling access to controlled substances;
- 2.3.5 Ensuring proper use, storage and disposal of controlled substances and maintenance of records at each location;
- 2.3.6 Ensuring a comprehensive biennial inventory;
- 2.3.7 Reporting significant inventory discrepancies as required by DEA and Bureau of Narcotic Enforcement regulations.

2.4 **Authorized Personnel who work with controlled substances** are responsible for:

- 2.4.1 Familiarizing themselves with the hazards and effects of the controlled substances they use through attendance at training sessions conducted by the NYU Operational Risk Management Department;
- 2.4.2 Receiving, storing, and dispensing controlled substances within the facility in accordance with the Policy;
- 2.4.3 Maintaining a controlled substances inventory, as per this policy;
- 2.4.4 Notifying their supervisors of exposures, spills or any other pertinent problems.

2.5 **The Associate Vice President for Operational Risk Management** or designee is responsible for:

- 2.6.1 Developing the NYU Controlled Substances Use and Disposal Policy for review and approval of the Senior Vice Provost for Research;
- 2.6.2 Providing the units with information about the Policy;

- 2.6.3 Assisting the units in implementing the Policy;
- 2.6.4 Periodically evaluating the effectiveness of the Policy; and recommending revisions, if appropriate, to the Senior Vice Provost of Research;
- 2.6.5 Provide training as per this policy;
- 2.6.6 Ensuring compliance, as described in 11.0.

**2.6 Purchasing Services and Contract Administration is responsible for:**

- 2.6.1 Authorization of the purchase of controlled substances by ensuring the presence of the signature of the Unit Registrant.

**3.0 REGISTRATION**

In order to use controlled substances for research purposes, a researcher must work under the license of the Unit Registrant.

**3.1 New York State Department of Health (NYSDOH) Bureau of Narcotic Enforcement**

The NYSDOH Bureau of Narcotic Enforcement issues two classes of research licenses (Class 4 or Class 7). An application for license can be obtained at <http://www.health.state.ny.us/>

**Class 4 Researcher License:**

Each Unit Registrant responsible for the use of controlled substances in Schedule II -V (defined below), and must obtain a research license in Class 4.

**Class 7 Research and Instructional License:**

Each Unit Registrant responsible for the use of controlled substances in Schedule I (defined below) must obtain a research license in Class 7 and file with the Bureau three copies of a research protocol (standard operating procedure) describing the research project.

**3.2 Drug Enforcement Administration (DEA) -Federal**

A researcher registration is required by the DEA to conduct research with controlled substances in drug Schedules II through V. In addition, a special registration from the DEA is required to conduct research using Schedule I substances. This must be done after approval by the NYS Bureau of Narcotic Enforcement. An application for registration, as well as other pertinent information is available at <http://www.deadiversion.usdoj.gov>.

**4.0 SCHEDULES OF CONTROLLED SUBSTANCES (For a complete list, please reference Appendix A)**

**4.1 Schedule I Substances:**

The drugs in this schedule are those that have no accepted medical use in the United States and have a high abuse potential. Examples are heroin, marijuana and LSD.

#### 4.2 Schedule II Substances:

The drugs in this schedule have a high abuse potential with severe psychic or physical dependence liability. This Schedule consists of certain narcotic, stimulant and depressant drugs. Examples are morphine, codeine, methadone, amphetamine (Dexedrine), methylphenidate (Ritalin) and secobarbital.

#### 4.3 Schedule III Substances:

The drugs in this schedule have an abuse potential less than those in Schedules I and II and include compounds containing limited quantities of certain narcotic drugs and non-narcotic drugs. Examples are glutethimide (Doriden) and paregoric. Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital is in this schedule.

#### 4.4 Schedule IV Substances:

The drugs in this schedule have an abuse potential less than those listed in Schedule III. Examples are phenobarbital, chloral hydrate, diazepam, (Valium), dextropropoxyphene (Darvon) and pentazocine (Talwin).

#### 4.5 Schedule V Substances:

The drugs in this schedule have an abuse potential less than in Schedule IV and consist of preparations containing limited quantities of certain narcotic drugs generally for antitussive and antidiarrheal purposes.

### 5.0 **RECORDS**

5.1 Researchers, licensed and/or authorized to possess and use controlled substances, shall keep a record of all such substances received and used by them. Forms can be found in Appendix B to this policy.

5.1.1 A receipt record of all controlled substances received shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to meet this record requirement providing it contains all the information required. (See Form 2 in Appendix B)

5.1.2 A use record of all controlled substances used shall include: the name of the person authorized to control and use such drugs, the date, name, schedule, quantity of drug, and initials or signature of the user (See Form 3 in Appendix B).

5.1.3 In addition, such records shall contain the following information for each controlled substance:

- Name of substance;

- Each finished form (such as 10 mg. tablet or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container;
- The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received;
- The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance.

5.1.4 A record must be kept of any drug disposed of or returned to the vendor, by loss or waste or by destruction by the New York State Bureau of Narcotic Enforcement.

5.1.5 A Record of Utilization of Controlled Substances form can be used to monitor the use of these controlled substances. These forms could also be used to record the results of physical inventories required by New York State Bureau of Narcotic Enforcement.

5.1.6 The NYSDOH Bureau of Narcotic Enforcement requires records to be kept for 5 years. The Drug Enforcement Administration (DEA) requires records to be kept for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

## 6.0 **LABELS**

6.1 All controlled substances must be distributed in labeled containers. A different symbol is required for each schedule of controlled substances.

6.1.1 As new containers of controlled substances are received, each container must either maintain its original label, or have a new label with the appropriate information affixed to the container (see 6.4 for appropriate information needed).

6.1.2 For each container a receipt record must be created; it must be recorded as inventory and stored appropriately.

### 6.2 **Warning on label**

The label of a drug listed in schedule II, III, or IV must contain a clear, concise warning that it is a crime to transfer the drug to any person other than the intended recipient.

### 6.3 **Containers to be securely sealed**

In order to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, the bottle or other container, stopper, covering, or wrapper must be securely sealed as described in the DEA regulations for transportation for controlled substances.

### 6.4 **The controlled substance label must include the following information:**

6.4.1 the identity of the substance, identified with the chemical name that describes the contents. No abbreviations, structures or formulae should be used. If the container

has the original label, the information on the label will be sufficient to meet this requirement.

## **7.0 SAFEGUARDING CONTROLLED SUBSTANCES**

- 7.1 Controlled substances (including expired controlled substances) must be properly safeguarded and securely stored.
- 7.2 Access should be limited to a minimum number of personnel. Controlling access is the responsibility of the Unit Registrant.
- 7.3 At a minimum, a solid metal cabinet or safe compliant with the NYSDOH code with separate outer and inner, key-locked doors is required for drugs in Schedules III, IV and V. A safe is required for Schedules I and II drugs. If you need assistance in determining the requirements for storage, contact NYU Operation Risk Management Department.
- 7.4 A controlled drug access log must be utilized. It will list the identities of the Authorized Personnel who can access the keys to and open the locked drug storage cabinet. This log must be kept in the locked cabinet/safe and maintained by the Unit Registrant (See Form 1 in Appendix B).
- 7.5 A documented, physical inventory of controlled substances (See Form 4 in Appendix B) must be taken biennially ([www.health.state.ny.us/nysdoh/phforum/nycrr10.htm](http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm)). Expiration dates of all drugs should be checked on a regular basis.
- 7.6 In general, any controlled substance that has not been used within a six month period of time and/or has passed its expiration date should be returned to the vendor, if sealed, or disposed of as in Section 9 of this policy. Contact NYU Operational Risk Management Department for details.

## **8.0 ORDERING OF CONTROLLED SUBSTANCES**

- 8.1 All orders for controlled drugs must be on approved NYU requisition order forms (regardless of the dollar value of the purchase), be approved by the Unit Registrant and follow University procedure for ordering supplies
- 8.2 A DEA triplicate order form must be used for ordering Schedule I and II Controlled Substances, along with the NYU requisition order form and signature of the Unit Registrant.
- 8.3 Orders for Schedules III through V controlled drugs do not require a special government order form, but the licensee's signature as well as his/her typed DEA research number must be on the NYU purchase requisition form.
- 8.4 Quantities of controlled substances ordered should not exceed a six month supply, unless the smallest container to be provided by the manufacturer contains a larger quantity of the controlled substance than would be used within a six month period.
- 8.5 A copy of all purchase orders must be signed by the Unit Registrant and forwarded to NYU Operational Risk Management Department.

## 9.0 **DISPOSAL AND LOSS OF RECORDS**

There are three disposal options for expired or unwanted controlled substances recommended. Expired controlled substances can be accumulated for disposal, but must be secured.

### 9.1 **Contact the Supplier**

Some suppliers will take back pharmaceuticals for credit. If possible, this is the best means of controlled substance disposal.

### 9.2 **Sink Disposal**

Small quantities (less than 1 pound) that are miscible in water can be disposed in a sink under the supervision of and witnessed by the Unit Registrant using the following five-step controlled substance sink disposal procedure:

- 9.2.1 Contact the Unit Registrant with a controlled substance disposal request.
- 9.2.2 Complete the [Registrants' Inventory of Drugs Surrendered \(DEA Form 41\)](#) found in Appendix C prior to disposal. **NOTE:** The instructions provided on the DEA Form 41 are incorrect. Please disregard instruction number 5. That instruction directs the registrant to ship the drugs to the Special Agent in Charge of the DEA office that serves the registrant's area. Registrants should send the forms to DEA as detailed in instruction number 3, and await instructions on how to proceed.
- 9.2.3 Inform the Unit Registrant when the DEA Form 41 has been completed and is ready for review.
- 9.2.4 The Unit Registrant will forward two copies of the DEA Form 41 to the DEA's New York office at: New York Division DEA 99 10th Avenue, New York NY 10011, and provide one copy for the researcher's inventory records. The Unit Registrant will forward these forms to the NY office of the DEA with a projected two week disposal date.
- 9.2.5 Unit Registrant must also complete Section I of the New York State Department of Health Request for Approval of On-site Destruction of Controlled Substance form DOH-2340 from the Bureau of Narcotic Enforcement (Appendix D) and NY State Department of Health Controlled Substance Inventory Form DOH-166(Appendix E). The completed forms must be mailed 21 days prior to proposed date of destruction to New York State Department of Health, Bureau of Narcotic Enforcement, 90 Church Street, 14<sup>th</sup> Fl., NY, NY 10007.
- 9.2.6 DOH-2340 form will be returned to the registrant indicating if approval is granted. Destruction must be completed exactly as proposed.
- 9.2.7 At the end of the waiting period arrangements will be made for the Unit Registrant, another NY State Licensed practitioner, and an NYU Operational Risk Management Department representative to be present as witnesses to the disposal, verify the DEA Form 41, DOH 2340 and inventory records.
- 9.2.8 Once destruction has occurred, Section III of DOH-2340 must be completed and sent back to the DOH within 10 days of approved destruction.

### 9.3 **Reverse Distribution**

For large quantities (greater than 1 pound), contact a Reverse Distributor. This option transfers ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41. Contact information for two reverse distributors is listed below.

- National Notification Center: (800) 636-9826
- Guaranteed Returns, (800) 729-3279

#### 9.4 **Spills**

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss must be documented by the researcher and witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (tablets), must be placed in the disposal/destruction waste stream. If the spilled controlled substance is not recoverable (liquids); the researcher must document the circumstances in his or her inventory records and the witnesses must sign.

### 10.0 **LOSS OR THEFT**

Any loss or theft of controlled substances must be reported to NYU Operational Risk Management Department for investigation to determine if further action is required.

### 11.0 **COMPLIANCE SAFEGUARDS**

NYU Operational Risk Management Department will conduct periodic audits to ensure compliance with this policy. Such audits will include physical inventories and comparisons of these results with inventory records, examination or required licenses, etc.

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