

**POLICY FOR THE ACQUISITION, USE AND DISPOSAL  
OF CONTROLLED SUBSTANCES IN RESEARCH****A. Purpose**

The acquisition, use and disposal of controlled substances in New York State are strictly regulated by the New York State Department of Health (NYS DOH) Bureau of Narcotic Enforcement and the United States Department of Justice Drug Enforcement Administration (US DEA). These regulations are intended to prevent diversion of controlled substances. The purpose of this policy is to ensure that researchers planning work with controlled substances are aware of and understand their responsibility for complying with the relevant state and federal statutes and regulations governing the use of these substances.

**B. Applicability/scope**

This Policy applies to the use of controlled substances in research conducted under the auspices of Columbia University (the "University"), including all *in vivo* research under IACUC-approved protocols and *in vitro* research.

Any individual who uses or synthesizes controlled substances for research under the auspices of the University must be: (a) licensed with NYS DOH, and registered with the US DEA (a "Licensed Individual") to conduct such research; or (b) authorized under the license of a Licensed Individual with respect to such research.

The University does not hold an "institutional license" for use of controlled substances in research.

Even if an individual already has a practitioner's (clinical) license and DEA registration for treatment of patients with controlled substances, if he or she will also be conducting laboratory or non-therapeutic research involving controlled substances, a separate research license from NYS DOH is required. In addition, for research with Schedule I drugs, a separate registration with the DEA is required.

**C. Definitions**

**Controlled Substance** - 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:

<http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html>) or the New York State Controlled Substances Act (Article 33 of the NYS Public Health Law:

[http://www.health.ny.gov/regulations/public\\_health\\_law/article/33/docs/33.pdf](http://www.health.ny.gov/regulations/public_health_law/article/33/docs/33.pdf)). Controlled substances are divided into five categories, called Schedules, according to their potential for abuse, whether the substance has a currently accepted medical use in treatment in the United States, and their potential for physical and psychological dependence. Classification of a controlled substance in a particular Schedule affects the licensing, recordkeeping and security and storage requirements that are applicable, with drugs in Schedules I and II subject to the most stringent regulations.

**Licensed Individual** – the person ultimately responsible for controlled substance research compliance. Typically, the Licensed Individual is the Principal Investigator of a research protocol. See section **E. Responsibilities**.

**Other Authorized Individual** – a member of the Licensed Individual’s staff authorized to work with controlled substances under the Licensed Individual’s license/registration. See section **E. Responsibilities**.

## D. Procedures

### RESEARCHER LICENSING AND REGISTRATION

Authorization for acquisition of controlled substances for research is a two-step process: (a) licensing with the NYS DOH; and (b) registration with the US DEA.

#### 1. NYS DOH licensing

- a. Use of substances in Schedules II-V requires a Class 4 license. Use of substances in Schedule I requires a Class 7 license. Use of substances in both Schedule I and Schedule II-V requires both licenses.
- b. The license application must include:
  - i. The curriculum vitae of the individual responsible for overseeing the controlled substance activity (typically, the PI).
  - ii. A Controlled Substance Protocol, which includes the nature and objective of the project(s), a listing of controlled substances to be utilized, the quantity of the substances, the DEA registration number of both the researcher ordering and the distributor or manufacturer providing the substances, and the names and curriculum vitae of other Authorized Individuals who will be working with controlled substances on the project, if any. A Controlled Substance Protocol template is attached as Appendix A.
  - iii. If animals are used in the research, the species, number of animals, dose regimen and route of administration of controlled substances must be included. This information should be included in the Controlled Substance Protocol. An IACUC protocol should not be used as a substitute for a Controlled Substance Protocol.
- c. The license application is available at <http://www.health.state.ny.us/forms/doh-4330.pdf>. Instructions and additional information about licensing requirements are available at [http://www.health.state.ny.us/forms/instructions/doh-4330\\_instructions.pdf](http://www.health.state.ny.us/forms/instructions/doh-4330_instructions.pdf).
- d. Special requirements for new applicants:
  - i. New applicants should obtain the New York State license before submitting a registration to the Drug Enforcement Agency. On the New York State license

- application, new applicants should indicate that they are new applicants and do not yet have a DEA registration number.
- ii. New applicants will be subject to an on-site facility inspection by the Bureau of Narcotic Enforcement, which may review information concerning the operation of the laboratory and inspect for compliance with security and storage requirements for controlled substances. Applicants may prepare for this inspection by referring to the pre-inspection checklist at <http://www.ehs.columbia.edu/PreInspectionChecklist.pdf>.
  - e. NYS DOH licenses must be renewed every two years.
2. US DEA registration
- a. The US DEA registration requires inclusion of the licensee's state license number and identification of the controlled substances used. Note that for work with Schedule I substances, applicants must attach three copies of a more detailed Schedule I Controlled Substance Protocol. A Schedule I Controlled Substance Protocol template is attached as Appendix B.
  - b. The registration application, DEA Form 225, is available at [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm). Registration procedures, including detailed instructions on form submission, are available here : <http://www.deadiversion.usdoj.gov/drugreg/process.htm>. Persons who are already registered with DEA as a medical practitioner are not required to obtain an additional DEA registration for research involving any drug in Schedules II-V if this clinical registration is being actively used to prescribe drugs to patients.
  - c. For any research involving Schedule I drugs, a researcher's registration (DEA Form 225) is required for all researchers, including medical practitioners who are already registered with DEA.
  - d. Upon receipt of a registration application, the DEA may schedule a telephone interview or an on-site inspection.
  - e. New registrants must complete their initial inventory of controlled substances immediately upon receipt of their DEA registration, on the first day of business after registration. See Section H(4). In most cases, this initial inventory will show zero quantities.
  - f. DEA registration must be renewed annually, except for the practitioner's (clinical) registration described in paragraph (b) above, which must be renewed every three years.
3. Requirement to amend research license for new projects and/or additional substances

If a Licensed Individual wishes to use additional controlled substances not listed on the Controlled Substance Protocol submitted with his or her most recent license application or renewal, or begins a new research project involving controlled substances that is not within the scope of that Controlled Substance Protocol, then the Licensed Individual must submit an amendment to the license to NYSDOH that includes the additional controlled substances or a

Controlled Substance Protocol for the new project, as applicable. Amendments are submitted using the NYSDOH's initial license application form, which includes a place to indicate "amendment."

## **PROCUREMENT OF CONTROLLED SUBSTANCES**

Controlled substances are "restricted commodities" and may be ordered only through the Purchasing Department.

1. Individuals seeking to purchase controlled substances must first complete the Controlled Substance Acquisition, Use and Disposal training in Rascal (course TC0502).
2. All purchase requisitions for controlled substances that are submitted to the Purchasing Department for Purchase Order processing must:
  - a. use the correct commodity code (currently 51000000);
  - b. be accompanied by the appropriate documentation, including DEA Order Form 222 for schedule I and II substances, a copy of the Licensed Individual's DEA registration and NYSDOH license, as well as a copy of the Rascal certification of training completion;
  - c. the ship-to location on the requisition must match the address on the DEA registration;

The Purchasing Office will not issue any purchase orders for controlled substances unless the above requirements have been met.

3. Investigators may not procure controlled substances by use of an E-Z PO, P Card, or Travel and Expense Reimbursement (T&E).

## **STORAGE AND SECURITY**

Controlled substances shall at all times be properly safeguarded and securely kept at the address on file with the Drug Enforcement Administration and which corresponds with the information indicated in the ordering of the controlled substances. Adequate security and storage must be provided and access to such storage must be limited to Licensed and/or Other Authorized Individuals. Security requirements vary depending on: (1) whether the storage is for working stocks or reserve or main stocks; and (2) the schedule of controlled substance.

1. Working Stocks – appropriate for most individually licensed Principal Investigators.
  - a. Schedule I-IV controlled substances shall be kept in stationary (typically built in a wall), locked double cabinets. Both cabinets must have key-locked doors with separate keys; spring locks or combination locks are not acceptable.
  - b. Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.
2. Reserve or main stocks – generally restricted to activities carried out under institutional licenses or when more than one Principal Investigator will ultimately receive the material.

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- a. Schedule I and II controlled substances shall be stored in a GSA class 5 rated steel cabinet or equivalent safe approved by the Bureau of Narcotic Enforcement of the Department of Health. Any cabinet or safe weighing less than 750 pounds shall be bolted or cemented to the floor or wall in such a way that it cannot be removed. The door of the cabinet or safe shall contain a multiple position combination lock, a relocking device or the equivalent, and steel plate having a thickness of at least one-half inch.
- b. Schedule III, IV and V controlled substances shall be stored in a securely locked cabinet of substantial construction.

**REPORTING LOSS, THEFT OR UNAUTHORIZED USE**

Each incident or alleged incident of possible theft, loss or diversion of a controlled substance must be immediately reported to the Licensed Individual and Columbia University Public Safety. Thereafter, the Licensed Individual must promptly report the incident to the NYS DOH. Finally, the Licensed Individual must report to DEA the theft or significant loss of any controlled substances within one business day of discovery.

Each agency has its own form that must be used for this reporting. Links to the forms are available at [http://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html) and <http://www.health.state.ny.us/professionals/narcotic/forms.htm>.

**TRAINING**

The University requires all Licensed Individuals and Other Authorized Individuals to complete an initial Controlled Substances Acquisition, Use and Disposal training program in Rascal. The training must be renewed triennially.

Purchasing will require verification of training for Licensed Individuals before approving any controlled substance purchase. Training verification can be obtained by logging into the Rascal system, selecting “My Rascal” followed by “My Test History” and generating a transcript for the course.

**E. Responsibilities**

**Licensed Individual** - The responsibility for controlled substance research compliance rests with the Licensed Individual. Typically, the Licensed Individual is the Principal Investigator of a research protocol. The Licensed Individual is responsible for obtaining and renewing both the DEA registration and the New York State Department of Health license and for assuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met.

**Other 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 (“Other Authorized Individuals”). However, the Licensed Individual retains overall responsibility for meeting all regulatory requirements. Other Authorized Individuals must be listed on the Licensed Individual’s Controlled Substance Protocol submitted with the license application, as set forth in section D(1)(b)(ii) above. Licensed Individuals may not name as Other Authorized Individuals any person who: (i) has been

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convicted of a felony offense relating to controlled substances; or (ii) at any time, has had an application for registration with the DEA denied, a DEA registration revoked or has surrendered a DEA registration for cause.

Other Authorized Individuals must follow all of the rules and regulations outlined and referenced in this Policy, and are obligated to immediately report any suspected loss or diversion of controlled substances to their Licensed Individual and to the Columbia University Department of Public Safety (“Public Safety”).

**F. Emergency contacts****G. Medical Surveillance****H. Recordkeeping**

The controlled substances regulations require significant record keeping at every point, including initial receipt, use, and disposal. See N.Y. Pub. Health L. §§ 3300-3397 and 10 N.Y.C.R.R. §§ 80.37, 80.112, and 21 CFR § 1304.03 and 04. These regulations specify the information required in each type of record, summarized below.

The Licensed Individual is responsible for maintaining this documentation with respect to controlled substances used for his or her research. The records must be easily produced in the event of an inspection by NYSDOH or the DEA. Templates for recordkeeping are attached as Appendices C - E.

**1. Initial receipt documentation**

Initial receipt documentation must include the date of receipt, name, address and registration number of vendor, type, and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will suffice if all the aforementioned information is contained on it and quantities have been verified. Quantities should be verified and documented as soon as possible after receipt to assure that they are as expected.

Receipt Log templates for Schedule I-II and Schedule III-V are attached as Appendix C.

**2. Use documentation**

Use documentation must include the name of the Licensed Individual, the date, type and quantity of drug and signature of the Licensed Individual or Other Authorized Individual using the controlled substance.

- 3. In addition, such records shall include the following information for each controlled substance:**
- a. Name of substance.
  - b. 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.

- c. 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.
- d. 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.
- e. The number of units or volume of the finished form and/or commercial containers disposed of in any other manner by the researcher, including the date and manner of disposal.

A Use Log template is attached as Appendix D.

#### 4. Biennial Inventory Documentation

An inventory of the stock of controlled substances at all locations where controlled substances are present must be recorded on the day after the DEA registration is received, when research with/possession of controlled substances begins and then biennially thereafter. The inventory must specify whether it was taken at the open or close of business on that day.

- a. A separate entry must be made with respect to each kind of substance or preparation, and each kind or size of package.
- b. Each entry shall show the name, quantity and content of controlled substance and the size of the individual package, the number of packages and the total content of all packages covered by the entry on hand as of the date of the inventory.
- c. This biennial inventory must be retained on file with other controlled substances records.

#### 5. Record Retention

All controlled substance records shall be readily available and maintained at the premises where the licensed activity is conducted. Inventories and records of controlled substances listed in Schedules I and II, including DEA Form 222, shall be maintained separately from other controlled substance records of the Licensed Individual.

All records must be maintained by Licensed Individuals for a period of at least **five years** from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance.

### **DISPOSAL**

Licensed Individuals should make every effort to limit the amount of controlled substances requiring disposal by monitoring expiration dates and ensuring use of controlled substances within the appropriate timeframe, as well as limiting purchase/storage of controlled substances to appropriate quantities (e.g., sufficient to support the equivalent of 3-months of research). Disposal and/or surrender of controlled substances must be in accordance with applicable laws and regulations including, among others, 10 N.Y.C.R.R. § 80.51-52 and 21 C.F.R. § 1307.21.

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1. If controlled substances expire or otherwise require disposal, the Licensed Individual should contact a NYS DOH approved Reverse Distributor ([http://www.health.state.ny.us/professionals/narcotic/pharmacies/surrender\\_to\\_independent\\_companies.htm](http://www.health.state.ny.us/professionals/narcotic/pharmacies/surrender_to_independent_companies.htm)) and arrange for the documented return of the controlled substances through a reverse distribution process.
2. When controlled substances cannot be surrendered to a Reverse Distributor, the Licensed Individual must seek permission from the NYS DOH and the DEA to destroy on-site. The Licensed Individual must contact EH&S for assistance prior to initiating a Request for Approval of On-Site Destruction of Controlled Substances.
  - a. NYS DOH Instructions for On-site Destruction of Controlled Substances ([http://www.health.state.ny.us/forms/instructions/doh-2340\\_instructions.pdf](http://www.health.state.ny.us/forms/instructions/doh-2340_instructions.pdf)), along with Form DOH-2340, Request for Approval of On-site Destruction of Controlled Substances (<http://www.health.state.ny.us/forms/doh-2340.pdf>), and Form DOH-166, Controlled Substances Inventory Form, must be used to initiate and conduct on-site destruction.
  - b. In addition, in accordance with 21 C.F.R. § 1307.21, DEA Form 41 must be filed. DEA Form 41 is an on-line form that may be completed at [http://www.deadiversion.usdoj.gov/21cfr\\_reports/surrend/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html).
  - c. Controlled substances may be destroyed on-site or surrendered only with the permission of NYS DOH and DEA and in accordance with their respective regulations.
3. All controlled substances must remain securely stored in accordance with the “Storage” section of this Policy while awaiting NYS DOH and DEA approval for disposal.
4. If controlled substances are discovered for which registration cannot be ascertained, please contact EH&S for guidance.
5. Any person disposing of a controlled substance must maintain written records containing:
  - a. Date of return or destruction;
  - b. Name, form, quantity of the substance returned or destroyed;
  - c. Name, address, registry number of the person making the return;
  - d. Name, address, registry number of the supplier or manufacturer to whom the substances are returned or the name and license number of the persons performing and witnessing the destruction.

**I. Appendices**

- The federal list of Schedule I-V controlled substances can be found at <http://www.usdoj.gov/dea/pubs/scheduling.html>.
- The state list of controlled substances in Schedules I - V is contained in §3306 of the New York State Controlled Substances Act, which can be found at [http://www.health.state.ny.us/professionals/narcotic/laws\\_and\\_regulations.htm](http://www.health.state.ny.us/professionals/narcotic/laws_and_regulations.htm).



## J. Forms

- Appendix A: [Controlled Substance Protocol template](#)
- Appendix B: [Schedule I Controlled Substance Protocol template](#)
- Appendix C: Receipt Log templates ([Schedule I-II](#) and [Schedule III-V](#))
- Appendix D: [Use Log template](#)
- Appendix E: [Biennial Inventory template](#)

## K. References

The Office of Environmental Health and Safety (EH&S) provides support for researchers working with controlled substances with respect to secure storage, record keeping, disposal and other requirements. All forms and documents referenced in this Policy are available on the EH&S website (<http://www.ehs.columbia.edu/ControlledSubstances.html>). The University also has established a Controlled Substances Working Group, which helps develop resources to assist researchers in complying with federal and state regulations for use of controlled substances in research. Members include representatives from the Institute for Comparative Medicine, Research Compliance and Training, Environmental Health & Safety, the Institutional Animal Care and Use Committee, Research Pharmacy, Purchasing, the Office of the General Counsel, and faculty who use controlled substances in their research.

- <http://www.ehs.columbia.edu/ControlledSubstances.html>
- <http://www.health.state.ny.us/professionals/narcotic/>
- <http://www.deadiversion.usdoj.gov>

**New York Codes Rules and Regulations (NYCRR) New York State Department of Health  
Title 10, Part 80 Rules and Regulations on Controlled Substances**

- [http://www.health.state.ny.us/professionals/narcotic/laws\\_and\\_regulations.htm](http://www.health.state.ny.us/professionals/narcotic/laws_and_regulations.htm)