

## **Controlled Substances in Research Policy**

The Controlled Substances Act (CSA) requires that all users and purchasers of controlled substances obtain an annual registration unless exempted by law. State and local entities discourage University held licenses, therefore at Binghamton University each researcher utilizing controlled substances must apply for their own licenses and renewals individually. Institutional oversight of this program will be provided jointly by the Institutional Animal Care and Use Committee (IACUC) and Environmental Health and Safety (EHS). This document will regulate safe use of controlled substances and prevent loss and diversion.

### ***Penalties for Controlled Substances Violations***

The State of New York and the Federal Government can impose civil and criminal actions against any licensee engaged in noncompliance, misadministration, improper storage or recordkeeping, and other aspects of controlled substances.

Failure to comply with this policy may result in actions described above or termination of Controlled Substances Authorization and suspension of pending orders.

### ***Registration with New York State Department of Health (NYSDOH) Bureau of Narcotic Enforcement (BNE) and Federal Drug Enforcement Agency (DEA)***

Persons engaged in research of controlled substances in schedules II to V shall first obtain a Class 4 license from NYSDOH and thereafter a registration from the DEA.

- NYSDOH Form 4430- License to Engage in a Controlled Substance Activity
  - <https://www.health.ny.gov/forms/doh-4330.pdf>
- NYSDOH Form 4430 Appendix A1 Class 4 & 7 Individual Researcher Protocol
  - [https://www.health.ny.gov/forms/instructions/doh-4330\\_instructions\\_appendix\\_a1.pdf](https://www.health.ny.gov/forms/instructions/doh-4330_instructions_appendix_a1.pdf)
- DEA form 225 (New Application)
  - <https://apps.deadiversion.usdoj.gov/webforms2/spring/newLogin>

Registrations are non-transferable and materials purchased under registrations must be under control of the licensee at all times. The controlled substances license shall be permanently displayed at the address to which it applies.

### ***Renewal of Registrations***

The above licenses are only valid for a specified amount of time. Before expiration the licensee must renew their license using one of the following forms:

- NYSDOH Form 4430 (Required every two years)
  - <https://www.health.ny.gov/forms/doh-4330.pdf>
- DEA Form 225a (Required annually)
  - <https://apps.deadiversion.usdoj.gov/webforms2/spring/renewalLogin>

### ***Schedules of Controlled Substances***

Controlled substances are categorized by the DEA in five schedules based on potential for abuse and medical use. These schedules are commonly designated as C-I, C-II, C-III, C-IV, and C-V and are described below:

- **Schedule I** (C-I) controlled substances have no medical use and a high risk for abuse. *These materials are not authorized at Binghamton University.*
- **Schedule II** (C-II) controlled substances have a high abuse potential and a severe psychological or physical dependence liability, but do have a medical use in the U.S.
- **Schedule III** (C-III) controlled substances have less of an abuse potential than C-I and C-II and have accepted medical uses with a low to moderate risk for dependence.
- **Schedule IV** (C-IV) controlled substances have an accepted medical use and a lower potential for abuse and dependence liability than C-III.
- **Schedule V** (C-V) controlled substances have a low potential for abuse, low potential for dependence, and are currently accepted for use in medicine.

*The full list of controlled substances can be found on the list here:*

[https://www.deadiversion.usdoj.gov/schedules/orangebook/c\\_cs\\_alpha.pdf](https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf)

*Note: DEA Listed chemicals (precursors) are not covered under this policy*

#### **Procurement**

Controlled substances orders will be facilitated through [the RF Purchase Order workflow](#) for approval. Controlled substances **cannot** be purchased using a P-Card. Controlled substances can be ordered directly from the vendor once they have your NYSDOH and DEA licenses on file.

Prior to submitting the RF Purchase order form, confirmation from the IACUC administrator of an approved protocol by the IACUC for the use of the controlled substances is to be uploaded as supporting documentation in the RF Purchase Order workflow. A supplier quote is also required.

For ordering Schedule II controlled substances, the completion of DEA Form-222 with Part 1 and 2 completed is also required. This form can be requested on the [DEA website](#). Retain a copy of the DEA Form 222 for your records prior to submission to the vendor. Upon receipt of the controlled substances, complete DEA Form 222 Part 5 with the date and amount received.

#### **Security and Storage**

Controlled substances must at all times be kept under the control of the licensee or their authorized users at the address on file with the DEA. They must be available for inspection by properly authorized officers, agents and employees of the University, NYSDOH, and DEA.

Specific requirements for storage can be found on the NYSDOH 4330 form and *Individual Researcher Controlled Substance License Application Process*.

#### **Authorization and Security Screening**

Anyone wishing to work with controlled substances must either be a “Licensee” or an “Authorized User.” A licensee will be the person holding the license and has full authority and responsibility over the entire license. This will generally be the Principal Investigator.

An “Authorized User” is anyone else designated by the licensee as approved to work with controlled substances. Authorized users must be listed on the “Authorized User Log” which will verify their approval dates and that they have had appropriate training.

Any authorized users may be subject to a security screening.

#### **Inventory, Records and Usage Logs, and Records of Receipt**

**Record of Receipt:** A packing slip or DEA Form 222 for each controlled substance shipment received must be kept on file for a period of 5 years from the date container was used or sent back. The record must contain the date of receipt, name and address of vendor, type and quantity of drug received.

**Record of Authorized Users:** A record of all authorized controlled substances users shall include the name of the person authorized to control and use such drugs, the authorization beginning and ending dates, and signature of the user. No unauthorized user will be allowed to perform any work using controlled substances.

**Record of Use:** A record of each container received and quantities removed/remaining must be maintained. If using main stock and working stock containment, the quantity removed from the container must be moved to an appropriate 72 hour working stock container. The working stock container must be completely emptied within 72 hours either by use or by adding back to the original container and must be reconciled on the log sheet. Required records that must be maintained are indicated in the DEA Researcher's Manual:

[https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-057\)\(EO-DEA217\)\\_Researchers\\_Manual\\_Final\\_signed.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-057)(EO-DEA217)_Researchers_Manual_Final_signed.pdf).

The usage logs can be found on the EHS website:

<https://www.binghamton.edu/offices/environmental-health-safety/index.html>.

**Biennial Inventory:** The Licensee must prepare an inventory of all controlled substances every two years. The inventory must be kept at the registered location for five years and include:

- Each kind or size of package
- 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

#### ***Semi-Annual Inspections***

Semi-annual physical inventory inspections will be performed by EHS coinciding with the IACUC semi-annual program review with the Licensee or delegate. A copy of semi-annual inspections will be sent to the licensee and EHS. Any discrepancies discovered during semiannual inspections will be immediately reported to the IACUC.

#### ***Reporting Loss, Theft or Diversion***

In the event of loss, theft, or diversion, the licensee must immediately notify the DEA, NYSDOH, LAR Director, IACUC Administrator, Environmental Health and Safety, and University Police.

The following forms will be used for State and Federal reporting:

- NYSDOH Form 2094 ([DOH-2094](#))
- DEA Form 106 ([online](#))

Questions about this process may be directed to the DEA Call Center at 1-800-882-9539.

#### ***Disposal***

Controlled Substances remain controlled substances throughout their entire lifespan and therefore, should never be disposed of through the hazardous waste program. Each licensee must make arrangements with a reverse distributor before being authorized to purchase a controlled substance, and any time product needs to be sent back it must be arranged through the reverse distributor. Waste products must never be disposed of down the drain. Violating this rule may result in personal liability.

Empty controlled substance containers are considered empty when they have had all substances removed by normal means (pouring, siphoning, etc.) with less than 3% residue by weight and may be disposed of as regular trash once the container label is defaced. The normal triple rinse procedure does not apply to these containers.

***Non-renewal or Closure of License***

It is the responsibility of the registrant to make arrangements with a reverse distributor to remove any remaining inventory before canceling a registration. In the event of a licensee's license being revoked, not renewed, or closed, they must notify the NYSDOH Bureau of Narcotic Enforcement immediately. All licenses must be returned to the Bureau of Narcotic Enforcement.