

Use of Controlled Substances Guide

The purchase, use and disposal of controlled substances in New York are strictly regulated by the New York Department of Health (DOH) and the United States Department of Justice Drug Enforcement Administration (US DEA) and these regulations are intended to prevent diversion of controlled substances. Environmental Health and Safety (EHS) holds the responsibility to ensure that researchers and teaching faculty 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 whether for research veterinary care and laboratory teaching applications. This Guide contains language and adaptation from the US Department of Justice [DEA manual](#) for use of Controlled Substances including:

1. What is a Controlled Substance
2. Use Authorization
3. Purchasing Controlled Substances
4. Receipt of Controlled Substances
5. Storage and Control of Controlled Substances
6. Disposal of Controlled Substances

1. WHAT IS A CONTROLLED SUBSTANCE

Researchers and teaching faculty authorized to possess and administer Controlled Substances (CS) may do so under the College's valid DEA and NYSDOH license and only with prior approval of EHS; authorized personnel must comply with all applicable regulatory requirements relating to drug security, control, disposal and recordkeeping.

The DEA and New York State Health Department Bureau of Narcotic Enforcement (BNE) categorize CS materials into 'schedule' categories based on the likelihood of diversion, mostly due to abuse and addiction prevalence. Materials fall into one of five schedules, from highest control to least;

Schedule I No accepted medical use, high potential for abuse

(e.g., heroin, methamphetamine)

Schedule II High potential for abuse, severe psychological or physical dependence

(e.g., methadone, oxycodone)

Schedule III Potential for abuse less than Schedule I & II

(e.g., ketamine, and anabolic steroids)

Schedule IV Low potential for abuse relative to Schedule III

(e.g., midazolam, diazepam)

Schedule V Consist primarily of mixtures containing limited quantities of other scheduled material

(e.g., Codeine preparations - 200 mg/100 ml, atropine sulfate)

Skidmore College CS use in research, teaching and animal care is administered under a single, campus-wide license. EHS is responsible for maintaining the College's CS license. License renewal occurs every two years.

2. USE AUTHORIZATION FOR CONTROLLED SUBSTANCES

Proposed use of CS materials on laboratory animals is reviewed and approved separately by the College's Institutional Animal Care and Use Committee (IACUC) through the animal use protocol application process.

Once approved, researchers and authorized faculty may request authorization to use CS materials by submitting the completed, approved Institutional Animal Care and Use Committee (IACUC) protocol to EHS.

Faculty planning to work with CS on a *non-animal protocol* should consult with EHS to gain full understanding of regulations and expectations prior to planning research or teaching curriculum.

3. PURCHASING CONTROLLED SUBSTANCES

Approved faculty wanting to order CS must contact EHS with the below information. ONLY EHS staff whose names are on the NYS license are permitted to order CS.

- All requests must include approved IACUC protocol number, when appropriate
- CS name, quantity requested, preferred vendor

EHS will place the order using Dean of Faculty account number and reimbursements will be managed through Dean of Faculty office

CONTROLLED SUBSTANCE DELIVERY

Deliveries are made only to the address indicated on the College's DEA/NYSDOH licenses:

Skidmore College
Loretta Greenholtz
Director, EHS
815 N Broadway
Saratoga Springs, New York 12865

OR

Skidmore College
Kara Cetto Bales
Associate Director, EHS
815 N Broadway
Saratoga Springs, New York 12866

- Once ordered, controlled substances are tracked through delivery and EHS will notify requesting faculty and Campus Post Office of delivery status
- EHS is notified by Post Office when the item(s) arrive
- EHS personnel accepts material upon arrival
- CS is entered into the College's CS inventory
- Bar code ID No. is assigned to each vial
- Controlled Substance Use Log Book is amended to track use of CS from initial use to container completion
- EHS delivers CS to the vivarium safe and notifies faculty of arrival

INVENTORY AND ACCOUNTING OF CONTROLLED SUBSTANCES

EHS will conduct a biennial physical inventory reconciliation in June of even numbered years. DEA regulation states, "After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within [two years of the previous biennial inventory date.](#)"

4. Storage and Control of Controlled Substances

Controlled substances are stored in either the double-locking boxes mounted on a wall or the MESA safe bolted to the floor in the BTCIS vivarium.

ACCESS AND USE OF CONTROLLED SUBSTANCES

Once CS arrives on campus, and the appropriate bar code is affixed to the CS container, the CS will be stored in one of the two security safes. Faculty should contact EHS no less than 24 hours prior to needed use to retrieve CS. CS must be returned to storage safe within 24 hours. Any deviation from this practice must be first approved by EHS.

A separate Controlled Substance Use Log Book is maintained for each storage unit (C I-II and C III-V) and each container/vial of controlled substance. The Controlled Substance Use Log Book includes the following information:

- Principal Investigator
- Receipt date
- Unique identification number (bar code)
- CS type, strength/concentration, quantity used (ml, mg), and remaining stock quantity

Faculty must confirm starting volume/mass and each subsequent use, calculating balance to track the quantity remaining.

Each entry, or record of use, must be initialed by the individual intending the withdrawal **and** EHS.

Dilutions mixed from the original stock container must be tracked on a separate Usage Log Book, provided to EHS and documented in log book.

When a container is empty, the usage log must indicate 0.0 (or some volume less than a full dose) remaining.

MANAGING EXPIRED CONTROLLED SUBSTANCES

EHS will notify authorized faculty of expired/expiring CS. Expired CS, regardless of Schedule, will be placed in a zip-top plastic bag labeled “Expired – Do Not Use” and dated. Zip-lock bag will be stored in the vivarium floor safe in the basket labeled “expired CS”. EHS will remove the drug from the electronic inventory upon disposal. A determination will be made by faculty whether or not to reorder CS.

5. Destruction and Disposal - Controlled Substances

EHS schedules CS destructions periodically, as needed, throughout the year. EHS will coordinate and arrange the disposal and destruction of DEA material via outside vendor.

DISPOSAL OF NEEDLES/SYRINGES USED WITH CS MATERIALS

Used needles/syringes are disposed via regulated medical waste. Needles and syringes must be discarded in approved medical waste sharps containers. When full, sharps containers must be placed in regulated medical waste boxes for final disposal. A biohazardous waste disposal request must be submitted by faculty.

6. DEA List I and List II Chemicals

In 1988, Congress passed the Chemical Diversion and Trafficking Act (CDTA) and subsequent amendments placed 41 chemicals under control. These laws provide a system of regulatory controls and criminal sanctions to address both domestic and international diversion of important chemicals without interrupting access to chemicals destined for legitimate commerce. The CDTA created two categories for the controlled chemicals, List I and List II. If faculty or staff plan to purchase a List I or II chemical from a vendor **outside the U.S.**, the chemical must be registered with DEA Diversion Division. Please consult with EHS for details.

Click on [List I](#) and [List II](#) to view specific chemicals under DEA control.