

Controlled Substance Policy and Procedures for Laboratory Research

I. Introduction:

This policy - Hunter College's Controlled Substance Program, will provide in detail the requirements and procedures related to research involving the use of controlled substances. This will provide information on how to comply with applicable laws and regulations associated with the use of controlled substances. All researchers/individuals authorized to use controlled substances with their research are required to comply with these procedures.

Hunter College's Controlled Substance Program covers various areas involved in the use of controlled substances in research: purchasing, storage, use, storage, recordkeeping, and disposal. This program is administered by the Office of Environmental Health and Safety.

The use, distribution, storage, and disposal of controlled substances in the State of New York are regulated by law as mandated by the state (10 NYCRR Part 80, and Article 33: New York State Controlled Substances Act). The Drug Enforcement Administration (DEA) is the agency mandated to regulate the lawful use of controlled substances and List I chemicals under federal law (Title 21 Chapter 13 Code of Federal Regulations (CFR) Part 1300).

Controlled substances generally include narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and other chemicals used in the illicit production of controlled substances.

Hunter College has established this policy to cover all compliance requirements with both state and federal laws related to use of controlled substances.

II. Objective:

This program is aimed at providing information required regarding the proper use of controlled substances in research at Hunter College. Specifically, the objectives are as follows:

- To provide researchers/Principal Investigators a guideline in the proper use of controlled substances;
- To provide researchers/Principal Investigators references to state and federal regulations as well as Hunter College's institutional procedures regarding the use of controlled substances in research;

- To provide information regarding purchasing, storage, use, recordkeeping, and disposal of controlled substances in research.

III. Definitions:

III.a. Controlled Substance

A controlled substance (CS) is a substance that has a stimulant, depressant, or hallucinogenic effect on the nervous system. Controlled substances are prescription drugs that are further classified as Schedule I-V and can only be obtained by registrants with the DEA. The Controlled Substances Act (1970) listed substances that were controlled when the law was enacted. Since then, approximately 160 substances have been added, removed, or transferred from one schedule to another. A general reference list of controlled substances in alphabetical order can be found at:

https://www.deadiversion.usdoj.gov/schedules/orangebook/a_sched_alpha.pdf. Federal regulations regarding schedules can be found in section 1308 of CFR Title 21 ([21 CFR §1308](#)).

Schedules of Controlled Substances:

- Schedule I: No currently accepted medical use. Highest potential for abuse. (e.g., GHB, heroin)
- Schedule II: Currently accepted medical use with restrictions. High potential for abuse with severe psychological or physical dependence. (e.g., amphetamine, methamphetamine, cocaine, codeine, morphine, meperidine, methylphenidate, pentobarbital (Nembutal))
- Schedule III: Currently accepted medical use. Abuse of drug may lead to moderate to low physical dependence or high psychological dependence. (e.g., Ketamine, Telazol, testosterone, pentothal. Euthasol is a Schedule III due to pentobarbital/phenytoin mix)
- Schedule IV: Currently accepted medical use. Low potential for abuse relative to Schedule III. (e.g., barbitol, butorphanol, chloral hydrate, diazepam)
- Schedule V: Currently accepted medical use. Low potential for abuse relative to Schedule IV (e.g., buprenorphine and Zolpidem)

III.b. DEA Registrations

The intent of DEA controlled substance registration numbers is to identify and validate individuals and institutions that have been authorized by the DEA to purchase, possess, distribute or prescribe controlled substances. Hunter College's federal and state licenses to engage in research involving controlled substances will be managed by the Office of Environmental Health and Safety (EH&S.) Controlled substances intended for research purposes acquired through drug companies or any other outside institutions must be obtained under Hunter College's institutional NYSDOH and DEA research license/registration.

Vendors and suppliers may only deliver controlled substances to the address listed on DEA

registrations. At Hunter College, deliveries for purchases of controlled substances are made to Office of Environmental Health and Safety, E1211A 695 Park Ave., NY, NY 10065.

III.c. Institutional Research Registration (Schedules II-V)

EH&S maintains the required institutional research registrations issued by NYSDOH and DEA covering use of Scheduled II-V controlled substances for research.

Researchers who wish to use a Schedule II controlled substance in animals need to apply for IACUC approval prior to ordering a controlled substance. Contact EH&S for information.

III.d. Authorized User Status

To be an authorized user, the Researchers and research staff are required to apply for authorization to use and/or pick up controlled substances for research by:

1. Submitting an Application for Controlled Substance Use to the Hunter College Lab and Radiation Safety Committee (see required form);
2. Obtaining Laboratory and Radiation Safety Committee (LRSC) approval for use of a controlled substance in research
3. Acknowledging their intent to comply with all laws, regulations and college policies and procedures regarding controlled substance use in research.

Authorized users will be included on the list of researchers that are allowed to use and pick-up controlled substances from the EH&S office.

IV. Authorization to Use Controlled Substances for Research on College Laboratories

The EH&S office will grant "Authorized User" status to those researchers who have a legitimate need to handle, use or access controlled substances for research purposes.

The Principal Investigator is responsible to ensure that he or she and all affiliated research personnel using controlled substances in conjunction with their research have "Authorized User" status and comply with all procedures listed in the research protocol.

It is the responsibility of the researchers to obtain "Authorized User" status from LRSC prior to use, purchase, or transport of controlled substances at Hunter College. Controlled substances acquired under Hunter College's institutional research registration may not be removed, transported or used at another location, unless prior written authorization is provided to the

Principal Investigator by Hunter's LRSC.

*** Authorized User ***

As an authorized user, researchers must:

- Review procedures of the Controlled Substance Program every 3 years.
- Acknowledge their intent to comply with procedures by signing a form to include Employee ID or student ID number.

All Applications for Controlled Substance Use will be submitted with original signatures to:

Office of Environmental Health and Safety

Ricardo Franco

695 Park Ave. E1211A, NY, NY

10065

212-772-4462

rfran@hunter.cuny.edu

V. Use Requirements of Controlled Substances

Since Hunter College maintains the institutional research registrations with NYSDOH and DEA allowing researchers to use controlled substances and precursor chemicals. Therefore, approval by Hunter's LRSC for their use is required. All Principal Investigators must acquire and maintain a supply of controlled substances for their research.

Legitimate need to handle, use or access controlled substances for research purposes:

- a) Animal Use: Principal Investigator must have an approved animal protocol listing the requested controlled substance. A list of current approved protocols is maintained by EH&S and copies of it are forwarded to the NYSDOH no later than 10-working days after approval.

VI. Acquisition of Controlled Substances

VI.a. Acquisition via Vendors

Controlled substances and precursor chemicals for the purpose of research must be purchased under Hunter College's institutional NYSDOH and DEA research registration/license and delivered to Office of Environmental Health and Safety at 695 Park Avenue, Room E1211, New York, NY 10065.

VI.a.i. Pre-approval of Requisitions for Controlled Substances and Precursor Chemicals

All purchase requisitions for controlled substances must be first approved by EH&S. and prior to processing. All Principal Investigators must follow procurement procedures listed below in order to purchase of the controlled substance or precursor chemical. Orders are approved if:

- The order requisition is made under the name of a Principal Investigator or lead researcher with "Authorized User" status.
- If research involves animals, the Principal Investigator or lead researcher must have an approved animal protocol listing the requested controlled substance. A list of current approved protocols is maintained by EH&S.
- The delivery address listed in the purchase requisition/order is that of the Office of Environmental Health and Safety.

VI.b. Acquisition from Another Research Institution

All controlled substances and precursor chemicals provided by a research institution must first be approved by EH&S and, if needed, procured through the Purchasing Department (see sections 6.a and 6.a.i) All deliveries must be made directly to the Office of Environmental Health and

Safety. Drugs may not be delivered directly to Principal Investigators/researchers.

VII. Pick Up of Controlled Substances

ALL ordered controlled substances are delivered/shipped to:

Ricardo Franco
Office of Environmental Health and Safety
695 Park Ave. E1211A, New York, NY, 10065

The EHS office personnel accept delivery of orders, open and verify order accuracy, and notify the vendor of any missing or incorrect orders by the next business day following delivery. After checking the order, EHS office then notifies the Principal Investigator or Researcher of the delivery via email. The Principal Investigator is responsible for picking up orders within 3 working days. Orders will again be counted and verified by the EHS staff with Principal Investigator or designate when orders are picked up.

Principal Investigators/Researchers may designate research staff who have Authorized User status to pick up deliveries from the EHS office. Photo identification will be required to pick up all orders.

VIII. Transfer of Controlled Substances

Principal Investigators/Researchers may not be allowed to transfer controlled substances to or from other institutions without prior approval by EH&S.

A request to transfer controlled substances between laboratories needs to be submitted to EH&S prior to transfer. Transfer may only be conducted after approval from EH&S. Records of such transfers must be kept at least 3 years from the date of transfer.

Drugs no longer needed for research at Hunter College must be disposed of in accordance with Hunter College procedures.

IX. Storage of Controlled Substances and Records

There is a strict set of requirements set forth by regulatory agencies to prevent loss or diversion of controlled substances. Storage of controlled substances must provide for effective prevention of theft. Federal regulations require registrants to store controlled substances in a securely locked, substantially constructed cabinet. Proper storage of both drugs and usage logs is the responsibility of the Principal Investigator. Accurate drug inventory is the responsibility of all Authorized Users.

Both drugs and usage logs must be kept in a secure area while in use with access limited to as few individuals as possible, all of whom must be Authorized Users.

Controlled substances should never be left unattended to prevent theft. It should be kept at a minimum inventory, and access provided to as few researchers as possible.

It is mandated that Controlled substances must be stored securely in a manner adequate for safeguarding, and must be separated from other drugs, chemicals or items. This practice will help to prevent loss by limiting access to those assigned to work with controlled substances. It is recommended access be limited to one or two individuals.

Acceptable storage procedures include:

1. Safes and steel cabinet equivalents, which are cemented or bolted to the floor or wall
2. Locking storage drawers, which are inaccessible from the upper or lower drawers in the stack. Assign the top drawer of the stack for use as drug and record storage
3. Padlocked steel boxes. Devices should be installed so that the mounting screws or bolts of the hasp are inaccessible when the door is closed and the lock is fastened

Unacceptable storage:

1. Portable safety boxes are NOT adequate for storage of controlled substances.
2. Corridor storage of controlled substances is prohibited.

X. Recordkeeping of Controlled Substances

X.a. Usage Logs

Authorized Users are required by federal and state law to document their use of controlled substances. Records must include details from the date of order pick up from the Office of Environmental Health and Safety throughout the controlled substance's life cycle, i.e., until containers are empty or disposed of in accordance with proper disposal procedures.

All records must be kept secure in a locked area, preferably in the same secure storage with the drugs. Records must include the order invoice sheet, all Usage Logs for that order, and any disposal records.

All Usage Logs must include the name of the drug, date of delivery, amount received, strength, name of Principal Investigator and the date of pick up from EH&S. Usage Logs must indicate the date of use, amount of each use name and signature of the Authorized User using the drug, and a balance remaining each day. Initials can be utilized after the first time a name and signature is entered on a

Usage Log.

X.b. Inventory Log

EH&S conducts an inventory every two years as required by federal law. Each Principal Investigator will be required to sign an Inventory Log acknowledging the amount of controlled substances in their possession. Researchers will be notified by email two weeks before the completed and signed Inventory Log is due to be returned to EH&S.

Researchers who fail to complete and return the Inventory Log by the date requested will have their Authorized User status suspended until submission of the delinquent Inventory Log.

XI. Inspections

Inspections are routinely done by the EH&S. Some random inspections of research labs, which use controlled substances, may also be conducted including inspections related to the proper storage and recordkeeping of controlled substances.

The DEA may also conduct random audits and inspections of Hunter College's Controlled Substance Program. An inspection by the DEA would be conducted in coordination with EH&S. Principal Investigator's security practices pertaining to controlled substances are included during these inspections.

XII. Theft

In an event of a theft involving controlled substances, all employees who have knowledge of, or reasonably suspect, this said theft or significant loss of controlled substances, or alteration of records indicating drug loss must immediately report such information to the Principal Investigator, Department chairman, and EH&S. Public Safety will be notified by EH&S as appropriate. EH&S will submit the required Theft Notification form to the DEA.

XIII. Disposal of Controlled Substances

Any Authorized User who intends to schedule a pick up of expired or controlled substances can call EH&S to arrange for the pickup of the drug(s.) EH&S is responsible for determining proper off-site disposal for any controlled substances approved for disposal.

It is mandated that Principal Investigators maintain a copy of disposal records for controlled substances along with the usage log(s) and order invoice sheet for 3 years after disposal or terminal use.

Any empty bottles from controlled substances can be disposed of in any appropriate waste container as long as they are triple-rinsed.

If an event of a permanent closure of a researcher's lab or termination of employment, disposal of all controlled substances in accordance with college policies and procedures is required. Controlled substances may not be transferred to another institution without LRSC approval. Records of disposal and all usage logs of closed labs must be forwarded to EH&S.

Any employees who violate Hunter College Policy and Procedures or applicable law relating to controlled substances will be subject to disciplinary action, up to and including termination of employment and/or referral to the appropriate law enforcement officials.

Contact Information:

Ricardo Franco, Director of Environmental Health & Safety
Hunter College, Room E-1211A
695 Park Avenue
New York, New York 10065
212-772-4462