UCONN HEALTH

CONTROLLED SUBSTANCES POLICY

Environmental Health and Safety
UConn Health
263 Farmington Avenue
Farmington, CT 06030723
## Controlled Substances Policy

<table>
<thead>
<tr>
<th>Last Reviewed Date:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Last Revised Date:</td>
<td>2/1/2020</td>
</tr>
<tr>
<td>Effective Date:</td>
<td>2/1/2020</td>
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<tr>
<td>Applies To:</td>
<td>Registrants and authorized lab workers working in UConn Health laboratories with controlled substances</td>
</tr>
<tr>
<td>Contact:</td>
<td>Steven Jacobs    860-679-2723</td>
</tr>
</tbody>
</table>
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I. INTRODUCTION

Controlled substances are drugs, immediate precursors, or other substances regulated under the Controlled Substances Act (CSA) by both the federal Drug Enforcement Administration (DEA) and the State of Connecticut - Department of Consumer Protection, Drug Control Division (CT-DCP). The DEA classifies controlled substances into five schedules based on their medicinal value, harmfulness, risk to public health, and potential for abuse and/or addiction. Schedule I controlled substances are the most restrictive. A comprehensive list of controlled substances, DEA drug code numbers, and CSA schedules is available on the DEA website. A summary of the DEA schedules, descriptions, and examples of controlled substances is listed below:

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse.</td>
<td>Heroin, Marijuana, Lysergic Acid Diethylamide (LSD), Methaqualone</td>
</tr>
<tr>
<td>II.</td>
<td>Drugs, substances, or chemicals with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.</td>
<td>Adderall, Cocaine, Fentanyl, Hydromorphone, Methadone, Methamphetamine, Meperidine, Oxycodone, Ritalin</td>
</tr>
<tr>
<td>III.</td>
<td>Drugs, substances, or chemicals with a moderate to low potential for physical and psychological dependence.</td>
<td>Anabolic steroids, Tylenol with codeine, ketamine, testosterone, buprenorphine</td>
</tr>
<tr>
<td>IV.</td>
<td>Drugs, substances, or chemicals with a low potential for abuse and low risk of dependence.</td>
<td>Xanax, Soma, Valium, Ativan, Talwin, Ambien, Tramadol</td>
</tr>
<tr>
<td>V.</td>
<td>Drugs, substances, or chemicals with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.</td>
<td>Lomotil, Motofen, Lyrica, Parepectolin</td>
</tr>
</tbody>
</table>

In addition to controlled substances, the DEA also regulates List I and List II precursor chemicals.
Precursor chemicals are chemicals that can potentially be used in the illicit production of controlled substances. List I chemicals typically represent precursor reagents while List II chemicals mainly represent solvents that can be used in the synthesis and purification of controlled substances. Regulated List I and II chemicals are indicated below:

### Table 2. Precursor Chemicals

<table>
<thead>
<tr>
<th>List I Chemicals</th>
<th>List II Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alpha-phenylacetoacetonitrile</strong></td>
<td><strong>Acetic anhydride</strong></td>
</tr>
<tr>
<td>Pseudoephedrine</td>
<td>Toluene</td>
</tr>
<tr>
<td>Benzaldehyde</td>
<td><strong>Acetone</strong></td>
</tr>
<tr>
<td>Anthranilic acid</td>
<td>Hydrochloric acid</td>
</tr>
<tr>
<td>3,4-Methylenedioxyphenyl-2-propanone</td>
<td><strong>Benzylic chloride</strong></td>
</tr>
<tr>
<td>Nitroethane</td>
<td>Sulfuric acid</td>
</tr>
<tr>
<td>Benzyl cyanide</td>
<td>Ethanol</td>
</tr>
<tr>
<td>Methylamine</td>
<td><strong>Ethyl ether</strong></td>
</tr>
<tr>
<td>Gamma-Butyrolactone</td>
<td>Methyl Isobutyl Ketone (MIBK)</td>
</tr>
<tr>
<td>Ephedrine</td>
<td><strong>Potassium permanganate</strong></td>
</tr>
<tr>
<td>Ethylamine</td>
<td>Sodium Permanganate</td>
</tr>
<tr>
<td>Red Phosphorus</td>
<td></td>
</tr>
<tr>
<td>Ergotamine</td>
<td><strong>Phenylacetic acid</strong></td>
</tr>
<tr>
<td>Propionic anhydride</td>
<td>N-Methylephedrine</td>
</tr>
<tr>
<td>White phosphorus</td>
<td>Ergocristine</td>
</tr>
<tr>
<td>Ergonovine</td>
<td><strong>Phenylpropanolamine</strong></td>
</tr>
<tr>
<td>Isosafrole</td>
<td>N-Methylpseudoephedrine</td>
</tr>
<tr>
<td>Hypophosphorous acid</td>
<td>Piperidine</td>
</tr>
<tr>
<td>N-Acetylanthranilic acid</td>
<td>Hydriodic Acid</td>
</tr>
<tr>
<td>Norpseudoephedrine</td>
<td><strong>Piperidine</strong></td>
</tr>
<tr>
<td>N-Methylephedrine</td>
<td><strong>Toluene</strong></td>
</tr>
<tr>
<td>Safrole</td>
<td></td>
</tr>
<tr>
<td>N-phenethyl-4-piperidone</td>
<td></td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td></td>
</tr>
<tr>
<td>Piperidine</td>
<td></td>
</tr>
<tr>
<td>N-Methylpseudoephedrine</td>
<td></td>
</tr>
<tr>
<td>2-Butanone (i.e., Methyl Ethyl Ketone)</td>
<td></td>
</tr>
</tbody>
</table>

The DEA requires manufacturers, distributors, importers, and exporters to maintain records of the manufacture and distribution of precursor chemicals. Manufacturers and distributors commonly require purchasers of List I chemicals to provide additional information (e.g., an authorized purchaser form, letter of intended use, etc.) prior to completion of the order.

Additional information may also be required for List II chemicals that exceed certain order frequencies or threshold quantities.

Lab personnel are not required to have a controlled substance registration to purchase precursor chemicals. Precursor chemicals do not require additional storage or recordkeeping requirements. List I and List II chemicals must be stored with other compatible chemicals by hazard class as indicated in the [UConn Health Chemical Hygiene Plan](#).

II. **SCOPE AND APPLICABILITY**
The Controlled Substance Policy was designed to ensure that controlled substance registrants and authorized lab workers comply with Code of Federal Regulations (CFR) Title 21, Food and Drug Act §1300-END enforced by the Department of Justice- Drug Enforcement Administration (DEA) and state regulations enforced by the Connecticut Department of Consumer Protection, Drug Control Division (CT-DCP). The policy applies to all individuals involved in the procurement, registration, recordkeeping, security, storage, usage, and disposal of unused, expired, and waste containing controlled substances at UConn Health.

III. **ENFORCEMENT**

UConn Health is committed to providing a healthful and safe environment for all activities under its jurisdiction and complying with all applicable federal, state, and local safety regulations and standards. Registrants and authorized lab workers share the responsibility for properly managing controlled substances and maintaining compliance with guidelines in the Controlled Substances Policy. While Environmental Health and Safety serves as a resource to registrants and authorized lab workers for proper management of controlled substances, it is ultimately the registrant’s responsibility to maintain and comply with all federal and state requirements. Failure to comply with all applicable DEA and CT-DCP regulations may result in criminal prosecution and civil penalties as well as disciplinary measures in accordance with UConn Health Laws and By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, and the University of Connecticut Student Code.

IV. **DEFINITIONS**

- **Annual Inventory [Formerly the Biennial Inventory]** – an annual inventory of all controlled substances present in the lab that shall be conducted within four days of the first day of May of the calendar year.

- **Authorized Lab Worker**- an individual acting on behalf of or at the direction of a registrant regarding the ordering, dispensing, and management of controlled substances.

- **Controlled Substance**- a narcotic or non-narcotic drug, other substance, or immediate precursor, included in Schedules I, II, III, IV, or V.

- **Controlled Substance Units**- a single controlled substance unit shall be the equivalent of 100 tablets or capsules, one pint of a liquid, one multiple dose vial, ten suppositories, ten single dose ampules or other single dose package forms for injection whether powder or in solution.

- **Department of Consumer Protection- Drug Control Division (CT-DCP)** - a state agency that
works to protect the health and safety of Connecticut residents by regulating all persons and firms involved in the distribution of legal drugs, medical devices and cosmetics in Connecticut.

- **Drug Enforcement Administration (DEA)** - a federal agency tasked with enforcing the controlled substances laws and regulations of the United States.

- **Laboratory** - a room approved by the Department of Consumer Protection entrusted with the custody and use of controlled substances for the purposes of instruction, research, or analysis.

- **Precursor Chemical** - a substance whose principal compound can be used or produced, primarily as a chemical intermediary, in the manufacture of a controlled substance.

- **Registrant** - a practitioner, principal investigator, laboratory/facility manager, or other person authorized to order, dispense, and manage controlled substances under their DEA and CT-DCP registrations.

### V. ROLES AND RESPONSIBILITIES

Individuals overseeing or working in laboratories with controlled substances are responsible for following the guidelines listed in the *Controlled Substances Policy*. The responsibilities of each position are outlined below:

#### A. UConn Health Chemical Hygiene Officer (CHO) [EH&S Chemical Safety Manager]

- Reviews and updates the *Controlled Substances Policy* annually.
- Verifies registrant’s federal and state controlled substance registrations are up-to-date prior to approving orders.
- Provides information to registrants and authorized lab workers to ensure work involving controlled substances is carried out in compliance with federal and state regulations and the *UConn Health Controlled Substances Policy*.

#### B. Registrant

- Complies with the requirements of the *Controlled Substances Policy*.
- Ensures *Lab Safety and Chemical Waste Management Training* or *Lab Safety and Chemical Waste Management Retraining* and *Controlled Substances Training* are completed by all authorized lab workers, including the registrant (e.g., principal investigators, laboratory/facility managers, etc.) prior to working with or overseeing work with controlled substances.
substances.

- Ensures *Hazard Communication, Personal Protective Equipment, and Controlled Substances* trainings are completed by all authorized lab workers, including the registrant (e.g., practitioners, veterinarians, etc.), prior to working with or overseeing animal care using controlled substances.
- Provides a copy of their federal DEA registration to EH&S upon initial approval and renewal.
- Informs EH&S, DEA, and CT-DCP prior to relocating controlled substances to a new location.
- Maintains an accurate, up-to-date inventory of controlled substances.
- Stores controlled substances in accordance with all DEA and CT-DCP regulations and standards.
- Notifies CT-DCP when authorized lab workers are added or removed from having access to controlled substances.
- Ensures that records for Schedule I and II drugs are kept separate and secure from those for Schedules III, IV and V.
- Ensures that drugs and records acquired under separate DEA registrations are kept in separate locations.
- Keeps an accurate log of controlled substances that have been used. Provides training to authorized lab workers that addresses the hazards, controls, work practices, personal protective equipment (PPE), and emergency procedures specific to work with controlled substances.
- Provides appropriate personal protective equipment identified in the *Workplace Hazard Assessment* to authorized lab workers for work with controlled substances.
- Ensures authorized lab workers properly collect, label, and manage controlled substances and wastes.
- Contacts EH&S for disposal of controlled substances.
- Completes an *annual inventory* as directed by EH&S.
- Reports all thefts, burglaries or other losses of controlled substances to the Drug Enforcement Administration, Drug Control Division (DCP.DrugLoss@ct.gov), the UConn Police Department, and EH&S upon discovery.
- Lab-related accidents, injuries, and/or emergencies involving controlled substances must be reported to EH&S and to your supervisor and together it must be reported to Gallagher Bassett (3rd party Worker’s Compensation Agency) at 1-800-828-2717.

C. Authorized Lab Worker

- Reviews and follows policies, procedures, and work practices outlined in the *Controlled Substances Policy* and lab-specific procedures.
- Completes *Lab Safety and Chemical Waste Management Training* or *Lab Safety and Chemical Waste Management Retraining* and *Controlled Substances Training* prior to
working with or overseeing work with controlled substances (e.g., postdoctoral researchers, graduate students, etc.).

- Completes *Hazard Communication, Personal Protective Equipment, and Controlled Substances* trainings prior to working with or overseeing animal care using controlled substances (e.g., Animal Care Services).
- Uses engineering, administrative, and work practice controls to minimize exposure to controlled substances.
- Wears appropriate personal protective equipment as specified in the *Workplace Hazard Assessment Form*, safety data sheets (SDSs), or other applicable documentation.
- Receives approval from the registrant prior to conducting work involving controlled substances.
- Notifies and consults with the registrant prior to making changes to previously approved procedures involving controlled substances.
- Properly collects, handles, labels, stores, and manages controlled substances and wastes.
- Reports unsafe conditions and near misses to the registrant and EH&S.
- Adheres to all UConn Health, Departmental, and laboratory-specific safety policies, procedures, and directives.

D. **Environmental Health and Safety**

- Maintains and updates the *Controlled Substances Policy*.
- Provides guidance for controlled substance registration.
- Provides training regarding controlled substances.
- Communicates with DEA and CT-DCP on compliance issues.
- Assists registrants and authorized lab workers with compliance.
- Maintains records of controlled substance registrations.
- Coordinates removal and disposal of controlled substances with CT-DCP.
- Notifies registrants to complete their annual inventory prior to May 1st each year.

VI. **TRAINING**

The Occupational Safety and Health Administration (OSHA) requires that training be provided to all employees at the time of initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. Individuals performing protocols or experiments in laboratories with controlled substances are required to complete either in-person *Initial Laboratory Safety and Chemical Waste Management Training* or online *Laboratory Safety & Chemical Waste Management Retraining* each year. Individuals using controlled substances to provide veterinary care for vertebrate animals (e.g., veterinarians, Animal Care Services) are required to complete, at a minimum, *Hazard Communication* and *Personal Protective Equipment* training.
In addition, all registrants and authorized lab workers must complete online *Controlled Substances Training* through EH&S. The training covers the following topics:

- The location and details of the Controlled Substances Policy;
- Roles and Responsibilities;
- Registration and Renewals;
- Purchasing Controlled Substances;
- Recordkeeping;
- Thefts, Burglaries and Other Losses; and
- Disposal

The one-time training must be completed through EH&S *prior to work with controlled substances*.

**VII. REGISTRATION AND RENEWALS**

Prior to ordering controlled substances, practitioners, principal investigators and laboratory/facility managers must register and be approved by both the State of Connecticut - Department of Consumer Protection, Drug Control Division (CT-DCP) and the federal Drug Enforcement Administration (DEA). The state registration must be completed and approved first in order to register with the DEA.

State and federal regulations require separate CT-DCP and DEA registrations for each location where controlled substances are stored. If controlled substances are being used in different rooms within the same building, but only storing controlled substances at one location, registrations must only reflect the storage location. If controlled substances will be stored in more than one building or be stored in more than one location within the same building, CT-DCP and DEA registrations are required for each building and/or storage location. The following procedures must be carried out when applying for controlled substance registrations with the CT-DCP and DEA:

**A. State Registration**

1. Complete the applicable Department of Consumer Protection (CT-DCP) Application.
   a. Registrants working in laboratories that use controlled substances for research purposes must complete the *Controlled Substance Laboratory Registration*.
   b. Registrants administering, distributing, or procuring controlled substances in the course of their professional practice (e.g., medical doctors, veterinarians, etc.) must complete the *Controlled Substance Practitioner Registration*. 
2. Pay the initial application CT-DCP fee.
3. Retain a copy of the application.
4. Verify or track the registration.
5. CT-DCP will arrange to inspect the laboratory or work area. Inspection criteria can be reviewed on the CT-DCP website.
6. Applicants approved by CT-DCP will receive either a State of Connecticut Controlled Substance Laboratory Registration or a State of Connecticut Controlled Substance Practitioner Registration.
7. Controlled substance registration certificates must be maintained at the registered location and be kept available for official inspection.

B. Federal Registration

1. Complete the applicable Drug Enforcement Administration (DEA) Application
   a. Registrants working in laboratories that use controlled substances for research purposes must complete DEA Form 225.
   b. Registrants administering, distributing, or procuring controlled substances in the course of their professional practice (e.g., medical doctors, veterinarians, etc.) must complete DEA Form 224.
2. Pay the initial DEA registration fee.
   Note: UConn Health registrants are exempt from paying the federal fee. Registrants must complete Section 6 on the form to claim the exemption. The Director of EH&S must be used as the certifying official.
3. Retain a copy of the registration certificate.
4. Verify or track the registration by calling 1-800-882-9539 or the DEA Field Office.
5. Upon approval, a Certificate of Registration will be provided by DEA and must be maintained at the registered location in a readily retrievable manner and kept available for official inspection.
6. Provide EH&S MC1514 a copy of the “Certificate of Registration”.

C. Modifications, Transfers, or Terminations of Existing Registrations

1. Contact EH&S at x2723 with the proposed changes.
2. EH&S will contact the CT-DCP and/or DEA and provide the proper forms to the registrant to modify, transfer, or terminate an existing registration.

Note: Transfers of controlled substances are allowed on a case by case basis among registrants as long as proper registration, storage and security measures are verified and approved by CT-DCP and/or DEA. Transfer of controlled substances from UConn Health registrants to other individuals outside of UConn Health is not allowed.
D. Registration Renewal

1. State of Connecticut Controlled Substance Registration Renewal
   a. Controlled Substance Laboratory Registrations will expire annually on January 31st and require renewal through CT-DCP. CT-DCP will contact the registrant approximately 30-45 days prior to the expiration. State registrations can be renewed on the Department of Consumer Protection website.
   b. Controlled Substance Practitioner Registrations expire every two years on February 28th of odd numbered years. CT-DCP will contact the registered practitioner approximately 30-45 days prior to the expiration. Practitioner registrations can be renewed on the Department of Consumer Protection website.

2. Drug Enforcement Administration (DEA) Controlled Substance Registration Renewal
   a. DEA federal controlled substances registrations will expire each year for registrants using controlled substances for research purposes. DEA will contact the registrant approximately 65 days in advance of renewal. Registrants are required to complete DEA Form 225a to renew their registration.
   b. DEA federal controlled substances registrations will expire every 3 years for registered practitioners. DEA will contact the registered practitioner approximately 65 days in advance of renewal. Registrants are required to complete DEA Form 224a to renew their registration.

   Note: DEA fees for laboratories are exempt.

VIII. PURCHASING CONTROLLED SUBSTANCES

Controlled substances are a restricted item through the Purchasing Department. Purchase orders for Schedule I and II control substances must be submitted via online request using DEA form 222. Purchase orders for Schedules III, IV, and V controlled substances are placed by providing a copy of the registrant’s DEA registration to the chemical supplier, vendor, or manufacturer that distributes the drugs. Orders may only be submitted for drug schedules covered by the registrant’s registration.

Manufacturers and distributors of controlled substances are required to verify that registrants are registered and authorized to use the specific controlled substances being ordered. Registrants must use the proper codes when placing orders for controlled substances.

A. HuskyBuy

Controlled substances are a restricted item and must be purchased though HuskyBuy.
using the Account 75515 (Restricted Chemicals & Reagents). EH&S will approve orders of controlled substances upon notification by Purchasing. EH&S will confirm that CT-DCP and DEA registrations are current prior to approval and verify that controlled substances being ordered are approved through their registrations. Registrants must provide current copies of registration certificate(s) to EH&S, if EH&S does not have updated records on file.

B. Procurement Cards (Pro-Cards)

Controlled substances are a restricted commodity through the Purchasing Department and may not be purchased with procurement cards. All requisitions must be placed and approved by EH&S through HuskyBuy.

IX. SECURITY AND STORAGE

Controlled substances must be stored in compliance with federal and state regulations. Registrants shall maintain all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel. Such specific authorization should be given by registrants only to the minimum number of lab workers absolutely essential for efficient operation. If a lab is shared between two or more registrants, separate approved storage devices and records must be maintained. The following guidelines for security and storage of controlled substances must be followed:

A. Security

- Controlled substances must be maintained in a secure area such as a locked safe, steel cabinet, or other suitable storage location approved by CT-DCP and/or DEA.
- Approved storage devices must remain locked at all times, unless actively adding or removing controlled substances.
- All controlled substances must be double-locked to prevent theft. A laboratory door that is locked when registrants and authorized lab workers are absent can serve as one of the locks and the lock on the approved safe or steel cabinet that cannot be moved or transported can serve as the second lock.
- Keys must never remain in an approved safe or other storage device.
- Keys to approved safes or other storage devices must be stored in a location that is only accessible to registrants and authorized lab workers.
- Controlled substances being used must be immediately returned to the approved storage location upon completion of each process, if excess remains.
- Authorized lab workers must monitor maintenance personnel or other visitors occupying areas where controlled substances are stored.
B. Storage

- Schedule I and II controlled substances, with the exception of barbiturates used solely for sedative or anesthetic effects on animals and in a quantity not more than 10 controlled substance units, require greater storage requirements than Schedules III, IV, and V.
- Safes for Schedule I and II controlled substances approved after January 1, 1975 must meet the following requirements:
  - Minimum of a B Burglary Rate;
  - Equipped with a relocking device;
  - Weight of 750 pounds or more or rendered immobile by being securely anchored to a permanent structure of the building;
  - Adequate interior space to store all controlled substances required to be kept within the safe; and
  - Approved by CT-DCP.

- Schedules III, IV, and V controlled substances must be stored in a safe, a lock box that is bolted down, a top drawer to a cabinet that is bolted down, or another suitable storage device and be approved by CT-DCP.
- The minimum quantity of controlled substance(s) to maintain efficient operation must be stored.
- No additional chemicals can be stored with controlled substances.
- Expired controlled substances must be separated from non-expired control substances within the approved storage device and be clearly labeled as expired.
- If theft, burglary, or other loss of controlled substances has occurred, the Commissioner of Consumer Protection may require additional safeguards for storage.

Failure to comply with federal and state storage requirements may result in seizure of controlled substances by the Commissioner of Consumer Protection.

X. RECORDKEEPING

Registrants are required to generate and maintain inventories and records of all transactions regarding the receipt, distribution, and disposal of controlled substances. Copies of records must be kept in a secure location, separate from non-DEA records, and be written in English. Records and inventories must be made available for inspection by federal and state officials for a period of three years following disposition of the drugs. Retaining records for five years is recommended.

The Department of Consumer Protection, Drug Control Division recommends storing the required controlled substance records in two separate binders. The following table lists the recommended...
recordkeeping requirements for controlled substances:

Table 3. Recordkeeping Storage Requirements

<table>
<thead>
<tr>
<th>BINDER 1</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Receipt Records to document each controlled substance</td>
</tr>
<tr>
<td>2.</td>
<td>Disposition Records for each controlled substance used</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BINDER 2</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>State of Connecticut (CT-DCP) Controlled Substance Registration Certificate</td>
</tr>
<tr>
<td></td>
<td>Federal (DEA) Controlled Substance Registration Certificate</td>
</tr>
<tr>
<td>2.</td>
<td>Annual inventory conducted within four days of the first day of May of the calendar year</td>
</tr>
<tr>
<td>3.</td>
<td>Invoices for controlled substances received in separate sections within Section 4</td>
</tr>
<tr>
<td></td>
<td>a. Schedule I receipt invoice(s), if applicable, with executed DEA 222 form attached</td>
</tr>
<tr>
<td></td>
<td>b. Schedule II receipt invoice(s) with executed DEA 222 form attached</td>
</tr>
<tr>
<td></td>
<td>c. Schedule III-V receipt invoice(s)</td>
</tr>
<tr>
<td>4.</td>
<td>Controlled Substance Lab Worker Authorization</td>
</tr>
<tr>
<td>5.</td>
<td>Controlled substances destroyed jointly with the CT-DCP or the DEA</td>
</tr>
<tr>
<td>6.</td>
<td>Inspection report(s) (lost and/or theft reports)</td>
</tr>
<tr>
<td>7.</td>
<td>Study protocol(s)</td>
</tr>
<tr>
<td>8.</td>
<td>Completed records from Binder 1</td>
</tr>
<tr>
<td>9.</td>
<td>State Policy</td>
</tr>
<tr>
<td>10.</td>
<td>UConn Health’s Controlled Substance Policy</td>
</tr>
</tbody>
</table>

A. Purchasing Records

Registrants must maintain records for each controlled substance purchased. Each purchasing record must be annotated with a handwritten date and time of receipt. Registrants and authorized lab workers must verify controlled substance shipments for accuracy upon delivery and relocate them to approved storage locations immediately after verification. Purchase records for Schedule I and II controlled substances must be stored separately in Section 3a and 3b of Binder 2 and include:

1. Copy of the invoice (if applicable); and
2. DEA Form 222.
Purchase records for **Schedule III, IV, and V** controlled substances may include:

1. Copy of the invoice;
2. Copy of the shipping document; or
3. Copy of the packing slip.

Schedule III, IV, and V controlled substances can be stored together in Section 3c of Binder 2.

**B. Receipt Records**

Registrants must maintain an accurate receipt record of all controlled substances on hand in each registered location from the date received. Receipt records must include:

<table>
<thead>
<tr>
<th>Table 4. Receipt Record Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receipt Record Information</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>2. Controlled Substance Name</td>
</tr>
<tr>
<td>3. Building</td>
</tr>
<tr>
<td>4. Lab Number</td>
</tr>
<tr>
<td>5. Vendor Name</td>
</tr>
<tr>
<td>6. Vendor Address</td>
</tr>
</tbody>
</table>

**C. Disposition Records**

Registrants and lab workers authorized to administer/dispense controlled substances must maintain disposition records. Records must include the following information:

1. Name of the registrant;
2. Name of the controlled substance;
3. Strength (e.g., 5mg, 5mg/ml);
4. Form of controlled substance (e.g., tablet, liquid, powder etc.);
5. Protocol number;
6. Date of administering/dispensing;
7. Time of administering/dispensing including AM or PM;
8. Manner of administering/dispensing (e.g., IP injection in mice);
9. Beginning total quantity (i.e., number of units or volume);
10. Quantity used (i.e., number of units or volume);
11. Remaining total quantity on hand (i.e., number of units or volume); and
12. Signature of the authorized lab worker dispensing on behalf of the registrant.

Disposition records must be kept in a secure location in Section 2 of Binder 1. The remaining total quantity on the disposition record must match the total physical quantity of controlled substance(s) on hand. Records must be retained in the lab for three years (EH&S recommends 5 years) from either the date of disposal or date the entire substance was used up.

D. Annual Inventory

Registrants must complete a documented annual inventory, including expired bottles, working solutions and unopened containers, of all controlled substances in possession within four days of the first day of May. New registrants must complete an initial inventory when controlled substances first enter the work area. EH&S will send out a notification in April of each year making registrants aware of the requirement.

Schedule I and II controlled substances must be listed together and on a separate annual inventory from Schedules III-V. Registrants with no controlled substances on hand must still complete the inventory to confirm no controlled substances are in their possession.

The annual inventory must be kept on file in Section 2 of Binder 2 for three years and be readily available for inspection upon request by the Drug Enforcement Administration, Department of Consumer Protection, Drug Control Division, or EH&S.

E. Lab Worker Authorization

Registrants should contact CT-DCP when authorized lab workers are added or removed from having access to controlled substances. Registrants and lab workers are also responsible for completing the Controlled Substance Lab Worker Authorization form. The form acknowledges agreement by the lab worker to comply with federal and state regulations and UConn Health requirements regarding controlled substances as well as authorization of the worker to access controlled substances by the registrant. The form must be stored in Section 4 of Binder 2 and updated when lab workers are added or removed from access to controlled substances.

XI. THEFTS, BURGLARIES OR OTHER LOSSES

Registrants and authorized lab workers are required to provide adequate control against the diversion, theft, and loss of controlled substances. Suspected misuse or theft of controlled substances must be reported upon discovery to:
1. Drug Enforcement Administration within 24 hours;
2. Commissioner of Consumer Protection (DCP.DrugLoss@ct.gov) within 72 hours;
3. UConn Police Department; and
4. Environmental Health and Safety

If theft, burglary, or other loss of controlled substances has occurred, the Commissioner of Consumer Protection may require additional safeguards for storage. If controlled substances are lost or destroyed through breakage of a container or other accident, the registrant shall make a signed statement detailing the accident and the quantities lost. The statement shall be forwarded to the Commissioner of Consumer Protection and a copy must be retained by the registrant.

XII. DISPOSAL

Registrants and/or authorized lab workers are responsible for properly disposing of controlled substances. When expired or unwanted controlled substances must be removed from approved storage locations, registrants must contact the EH&S Chemical Health Officer – Director EH&S coordinate disposal with CT-DCP. A CT-DCP agent will be escorted to the lab by an EH&S employee, witness the destruction of the controlled substances with the registrant or authorized lab worker, and complete the State of CT-Department of Consumer Protection Drug Control Division Record of Surrender or Disposal Form. The form will include the name and signature of the registrant or authorized lab worker and CT-DCP agent who witnessed the destruction. The original document will be provided to the registrant or authorized lab worker for inclusion in their accountability records and must be kept on hand in Section 6 of Binder 2 for three years.
Controlled Substance Receipt Record
(Use a separate receipt record for each controlled substance)

<table>
<thead>
<tr>
<th>Registrant:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Substance:</td>
</tr>
<tr>
<td>Building:</td>
</tr>
<tr>
<td>Lab Number:</td>
</tr>
<tr>
<td>Vendor Name:</td>
</tr>
<tr>
<td>Vendor Address:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Invoice Number</th>
<th>Date Received</th>
<th>Time and am/pm</th>
<th>Strength and Form</th>
<th>Total Quantity Received</th>
<th>Received By</th>
<th>Signature of Receiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: 190001</td>
<td>07-01-18</td>
<td>10:00am</td>
<td>5mg/ml liquid</td>
<td>10-5ml vials (50ml)</td>
<td>Jane Doe</td>
<td>Jane Doe</td>
</tr>
</tbody>
</table>

- Add more lines as necessary
Controlled Substance Working Solution  
(Use a separate record for each controlled substance)

| Registrant: |  |
| Controlled Substance: |  |
| Strength and Form: | Example: 10mg tablet or 10mg/ml liquid |

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Date of Disposition</th>
<th>Time and am/pm</th>
<th>Manner of Dispensing</th>
<th>Beginning Total Quantity</th>
<th>Quantity Used</th>
<th>Remaining Total Quantity</th>
<th>Signature of PI/Authorized Lab Worker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: A99-999</td>
<td>07-01-18</td>
<td>10:00am</td>
<td>IP Injection in mice</td>
<td>15ml</td>
<td>5ml</td>
<td>10ml</td>
<td>Jane Doe</td>
</tr>
</tbody>
</table>

- Add more lines as necessary
# Annual Controlled Substance Inventory Record (per UCONN Health Policy)

**Biennial Inventory Required by FDA**

(Schedule I and II controlled substances must be listed on a separate inventory record)

(Use a separate line for each container)

## CONTACT INFORMATION

<table>
<thead>
<tr>
<th>Registrant:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person Completing Inventory:</td>
<td>Time: and AM/PM (circle)</td>
</tr>
<tr>
<td>Signature of Person Completing the Inventory:</td>
<td></td>
</tr>
</tbody>
</table>

- [ ] Schedules I and II
- [ ] Schedules III, IV and V

## CONTROLLED SUBSTANCE ANNUAL INVENTORY

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Form</th>
<th>Strength</th>
<th>Quantity</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: Ketamine HCl</td>
<td>Solution</td>
<td>100mg/mL</td>
<td>10 mL</td>
<td>Unopened MDV</td>
</tr>
</tbody>
</table>

- Add more lines as necessary
Controlled Substance Lab Worker Authorization
(The authorization form must be updated when a lab worker is added or removed from access to controlled substances)

**AUTHORIZED LAB WORKER ACKNOWLEDGEMENT**

I agree to complete required trainings and comply with all federal and state regulations and UConn Health requirements regarding controlled substances.

<table>
<thead>
<tr>
<th>Lab Worker Name (Print)</th>
<th>Net ID</th>
<th>Signature</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td></td>
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- Add more lines as necessary

**REGISTRANT AUTHORIZATION**

I authorize the lab worker(s) listed above to access, use, and manage controlled substances under my Drug Enforcement Administration and CT Department of Consumer Protection registrations.

<table>
<thead>
<tr>
<th>Registrant Name (Print):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Registrant Signature:</td>
<td></td>
</tr>
<tr>
<td>Building:</td>
<td>Lab Number:</td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

Keep a copy of this form in Section 5 of Binder 2