# Controlled Substances Licensure

# Instructions for University of Connecticut Researchers (Non-Practitioners)

**January 1, 2017**

## 1. INTRODUCTION

These instructions apply to all University of Connecticut personnel who utilize controlled substances while conducting research. The University's Division of Environmental Health and Safety (EHS) has developed these instructions to provide assistance to researchers to ensure that research at the University of Connecticut is conducted in compliance with both state and federal regulations concerning the use and handling of controlled substances.

The Division of Environmental Health and Safety provides oversight and guidance to the research community as follows:

- Providing guidance for controlled substance registration;
- Providing assistance with compliance;
- Inspecting the security and recordkeeping requirements of the DEA Registrant;
- Providing guidance regarding disposal of expired or unwanted substances.

## 2. RESPONSIBILITIES

Compliance is the responsibility of the PI/DEA Registrant and will be accomplished by proper licensing and registration with the Connecticut State Department of Consumer Protection/Drug Control Division, the Federal Drug Enforcement Administration (DEA), proper recordkeeping, inventory, storage and handling. Personnel Utilizing Controlled Substances are responsible for:

- Obtaining proper state and federal registrations prior to the possession of controlled substances;
- Compliance with all requirements of those registrations in accordance with the applicable state and federal regulations;
- Maintaining all records for inventory, dispensing, and license maintenance

## 3. PROCEDURES

### 3.1. Registration

3.1.1 Registration Procedure

a. Obtain your Connecticut Controlled Substance License (CSL) first, using this URL.
http://www.ct.gov/DCP/cwp/view.asp?a=4332&q=273650

The CSL will be needed in order to complete the Federal DEA application and if filing electronically, the DEA will not let you advance without the CSL. The State inspector will make a site visit to your lab prior to issuing the state license.

b. Complete the DEA Form 225 application after you have received the state CSL. Physicians and veterinarians use DEA Form 224 for Practitioners. When completing the DEA registration form, make sure the name and address are identical to those on the state CSL. Use the link below.

www.deadiversion.usdoj.gov/drugreg/index.html

c. Complete the "Fee Exemption" section (Section 6) on the paper DEA 225 form (Section 1 of the electronic application). Exemption from payment of application fee is limited to federal, state or local government operated hospitals, institutions and officials. Enter the name of the University EHS official who can verify your status- this is the Chemical Health & Safety Manager.

d. If not completing an on-line form, the registrant must send the DEA application form to:

DEA HEADQUARTERS
ATTN: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

3.1.2 Registration Renewal
Federal DEA renewal applications are mailed to the registered location 60 days prior to the expiration. On-line renewal information and applications are found at:

http://www.deadiversion.usdoj.gov/drugreg/index.html#regapps

Click on “Renewal Applications” and you will be directed to the proper DEA Registration Renewal Form Login. You will need the following information as it appears on your original registration:

- DEA registration number;
- Last name or business name and first name;
- Social security number and/or **University tax identification number (10-6077216)**
- Registration expiration date; and
- State and zip code.

Note: Information from your original application will be filled in for you including the tax/fee exempt status of the University. Enter your name as the certifying applicant/official upon completion of the application.

### 3.2. Monitoring, license renewal, and Inspections

The PI whose name is listed as the registrant on the State & Federal license is responsible for monitoring the use, storage, & recordkeeping of controlled substances in his/her laboratories. They are also responsible for renewing their licenses, and informing EHS of any changes in the status, such as allowing their licenses to lapse. The PI is responsible for coordinating the removal and disposal of expired and/or surplus drugs in their labs, by contacting the State Drug Control Agent (860.713.6065). The PI and/or the designated researcher also named on the license shall be available for any inspections by the State Drug Control agent.

### 3.3. Security

3.3.1 Security requirements are based on the following, taken from **CT statute Sec. 21a-262-2:**

(a) Requirements for minimum security and safeguard standards for storage and handling of controlled substances may be determined for each registrant by the Commissioner of Consumer Protection after consideration of the protection offered from an overall standpoint in instances wherein other security

measures provided exceed those specifically stated. If the registrant has provided other safeguards which can be regarded in toto as an adequate substitute for some element of protection required of such registrant such as supervised watchman service, full electrical protection of the building, electric alarms, etc., such added protection may be taken into account in evaluating overall required security measures. In cases where special hazards exist such as extremely large stock, exposed handling, unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards will be required by the Commissioner of Consumer Protection which may include approved vault(s), approved safe(s), electrical alarm protection, and/or hold up button(s).

(b) In all instances, 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 employees absolutely essential for efficient operation. All controlled substances should be stored in such a manner as to prevent theft or diversion of these preparations.

(c) In all instances, registrants shall maintain all equipment used for storage of controlled substances such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc., securely locked except for the actual time required to remove or replace needed items. Locks shall be kept in good working order with keys removed therefrom. Keys to the locks shall not be left in a location accessible to other than specifically authorized personnel.

(d) Any controlled substance(s) stored at any location not stored in compliance with section 21a-262-1 through section 21a-262-10 inclusive, or at a location other than that for which the person, firm, or business activity is registered under the Federal Controlled Substances Act shall be subject to seizure by the Commissioner of Consumer Protection. This action of seizure shall be considered as being in the best interests of the general public and said Commissioner shall not be held liable for any loss of revenues suffered by the person surrendering the drugs.

(e) Any wholesaler, manufacturer, or laboratory licensed by the Commissioner of Consumer Protection, who after due process, has his license revoked or suspended by said Commissioner, or who does not within 30 days apply for re-licensure shall upon loss of said license dispose of his entire stock of controlled substances under conditions approved by the Commissioner or surrender his entire supply of controlled substances to said Commissioner. Any Licensed Pharmacy or any Practitioner who has his license revoked or suspended by his respective Licensing Board or who does not apply for re-licensure, shall dispose of his entire stock of Controlled Sub- stances under conditions approved by the Commissioner of Consumer Protection or shall surrender his entire stock of Controlled Substances to said Commissioner. This action of surrender shall be considered as being in the best interest of the general public, and said Commissioner shall not be held liable in any way for any loss of revenue suffered by the person surrendering these drugs.

(f) If any case where a loss, theft, burglary, or diversion of controlled substances has occurred, the Commissioner of Consumer Protection may require additional security safeguards which may include storage of any controlled substance(s) in an approved vault, approved safe, separate locked caged area, locked room or enclosure, or a substantially constructed locked steel or wood cabinet, or under effective electrical protection within 90 days of any such occurrence. In the case of hospitals, 180 days shall be allowed for this purpose.

(g) Registrants shall not maintain any stock of controlled substance(s) in excess of the quantity actually required for normal, efficient operation.

And

**Sec. 21a-262-7. Laboratories other than hospital clinical laboratories**

(a) Schedule I and II Controlled Substance Stock shall be stored in an approved safe except where schedule II stock of the barbiturate type is used solely for its sedative or anesthetic effect on animals and not more than No. 10 Controlled Substance units are stocked, in which cases security as outlined for schedule III controlled substances in Section 21a-262-7 (b) will apply. In instances in laboratories where schedule I or II stock may be unstable, of extremely small quantity, or of such a nature as to require special storage conditions, the Commissioner of Consumer Protection may approve of other security safeguards on an individual basis in lieu of those required by section 21a-262-1 through 21a-262-10 inclusive.

**3.4. Recordkeeping**

All records must be maintained for at least two years from the date of such inventory or records for inspection and copying by authorized employees of the DEA. Retaining records for five years is advisable due to the statute of limitations. These records must be in conformance with the recordkeeping and inventory requirements of federal law. This includes all purchasing records, all administering and dispensing records, all Schedules I and II Order Forms (DEA Form 222), and all physical inventories. Schedules I and II must be maintained separately from all other records of the registrant, and Schedule III, IV, and V must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. The phrase "readily retrievable" means they can be separated out from other records in a reasonable time.

3.4.1. Purchasing Records

Purchasing records can be:

- A copy of the invoice;
- A copy of the shipping document; or
- A copy of the packing slip.

Note: These are acceptable records for Schedules III, IV, and V controlled substances but DEA Form 222 is the only approved receipt record for Schedule I and II controlled substances.

Purchasing records must contain:

- The name, address, and DEA number of the company from which the
- controlled substance was purchased;
- The name of the controlled substance purchased;
- The size and strength of the controlled substance purchased; and
- The amount purchased (which should match the amount received).

The purchasing record (invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt.

3.4.2. Dispensing Records

Dispensing records must contain:

- The name and address of person (research subject) or identification numbers of animal subjects (or groups of animals) to whom it was dispensed;
- The date dispensed;
- The initials of person dispensing on behalf of registrant;
- The name of the controlled substance;
- The strength and size of the controlled substance; and
- The amount dispensed (number of units or volume).

This can be a running log with a starting amount followed by amounts dispensed. When requesting disposal services from the State agent, it is noted if there is a discrepancy between the amount in the log book, and what can be visually determined remaining in the vial, so attention to detail is imperative.

**Title 21 of the Code of Federal Regulations, Section 1304.22 (c)** Records for dispensers and researchers, states that:

> "Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser."

Researchers using animal subjects, and not humans, must use the animal species and identification instead of the requirement for recording the name and address of the person receiving the controlled substance.

3.4.3. Inventory Records

Controlled substance inventory is one of the most important aspects of the DEA program. A biennial inventory (at least every two years) in the month of May is required thereafter. The following form can be used for this biennial reporting: (next page)

## BIENNIAL CONTROLLED SUBSTANCE INVENTORY RECORD FORM

(use separate line for each container)

PRINCIPAL INVESTIGATOR: _____

INVENTORY PERFORMED BY: _____ DATE: _____

| Controlled Substance Name | Form/Strength | Quantity | Notes/Comments |
|---|---|---|---|
| 1. | | | |
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