I. General Information

The U.S. Department of Justice, Drug Enforcement Administration (DEA) and the State Department of Consumer Protection, Division of Drug Control (CT DDC) exercise authority, by statute, over the acquisition, storage, use and disposal of controlled substances. Classifications of controlled substances by name and code number exist in documents produced by DEA, in the Federal Register and in Connecticut Statutes. The classification will be one of five schedules. Schedule I substances are those of highest abuse potential, whereas schedule V substances are of lowest abuse potential. All scheduled drugs are controlled; Schedule I and II drugs are the most stringently controlled items. Informational websites such as https://www.deadiversion.usdol.gov/schedules/ will provide drug classifications.

Special regulations apply to drugs and chemicals in all Schedules. Separate Federal and CT Controlled Substance Registrations are necessary for research (laboratory) and clinical applications.

Practitioners authorized to prescribe controlled substances for patients as part of their clinical activities must do so under appropriate (practitioner) US DEA and CT DDC Controlled Substance registrations. Practitioners authorized to prescribe controlled substances clinically to patients cannot use the same authorization to use controlled substances in research.

II. Research and Laboratory Use of Controlled Substances

A. Controlled Substances Prescribed for Animal Care by Center for Comparative Medicine Veterinarians:

Control Substances prescribed by a Center for Comparative Medicine (CCM) Veterinarian acting as the healthcare provider for the CCM animal may be issued to and then administered to the animal(s) by a researcher not having CT DDC and DEA laboratory controlled substance registrations. In such cases, the researcher will maintain the documentation required by CCM. (If the research itself pertains to the controlled substance,
the P.I. must have appropriate CT DDC and DEA registrations as a laboratory/researcher. See paragraph IIB)

B. **Controlled Substances used in Research and Laboratory Activities:**

Laboratory research activities with Controlled Substances (e.g., Drug Schedules I-V) are common and require special US DEA and CT DDC Controlled Substance Registrations (unless such use is fully covered by paragraph IIA). These special registration and use requirements apply to the Principal Investigator (P.I.) or head of the laboratory activity directly responsible for using the scheduled drug(s).

1. **CT (State) Controlled Substance Registration as a Laboratory.** Such a registration as a laboratory is needed. For medical providers with a CT Controlled Substance Registration as a “Practitioner”, an additional CT DDC Controlled Substance Registration as a “Laboratory” is necessary. In order to obtain your CT controlled substance laboratory registration, complete the application form on-line and available at www.ct.gov/dcp/cwp/view.asp?a=1620&9=512944. Provide the completed Application along with a check or money order for the permit fee (made payable to “Treasurer, State of Connecticut) with a copy to EH&S (MC1514).

   The CT license application must include a list of all persons (other staff, technicians, graduate students, etc.) handling the substances. As this list may change during the course of the licensing year, any additions or deletions to the list must be submitted promptly in writing to the CT DDC with a copy to EH&S.

   An inspection of laboratories and research facilities using Controlled Substances is made by agents of CT DDC as a part of the State’s DDC licensing procedure. CT DDC will have EH&S coordinate this inspection with the applicant. After the inspection, the license is normally processed and mailed to the applicant. Inspections may also be made by CT DDC periodically throughout the year as well as at the time for license renewal. A CT DDC research/laboratory license expires on January 31st of each year. Renewal forms are mailed by CT DDC to the applicant and applicant must complete the renewal form and submit it with the renewal fee to the Department of Consumer Protection (with copy to EH&S, MC1514). An on-line renewal option is available. Upon completion of the renewal process a print out of the certificate “must” be forwarded to EH&S (MC1514).

2. **US (Federal) DEA Controlled Substance Registration as a Researcher.** When the CT DDC license has been issued or the laboratory inspection has been completed, a DEA application form as a Researcher must be submitted. US DEA Controlled Substance Registration forms are available from EH&S. In filling out this application, please make sure that the top line of the address reads “University of Connecticut Health Center. Below this line enter your name, the department’s name and mail code, and the department’s mailing address. The DEA will waive payment of fees for Health Center registrations as a researcher. When the US DEA application is complete and the CT Laboratory Registration number has been received and entered on line 7(a) of the DEA form, the P.I. must return the DEA form to EH&S (MC1514). EH&S will complete
paragraphs 8 and 9 (if necessary) and mail the application to the DEA and send a copy to the P.I. If the registration will be for a Schedule I item(s), bring this to the attention of EH&S prior to filling out the form. If the registration will be for the use of Schedule I or II substances, the application form should be appropriately checked so that DEA Order Forms are requested.

III. Purchase, Records of Receipt and Disposition of Controlled Substances

Both the DEA and CT DDC Registrations described in the above paragraph must be obtained before controlled substances can be acquired, stored or used in teaching programs.

Purchase requisitions must be initiated by a licensed individual and the requisition must bear the individual’s DEA license number. In addition, requisitions for Schedules I and II controlled substances must be accompanied by a DEA order form. These forms are provided upon request to license holders by DEA. Purchase Requisitions for controlled substances should not include other chemical or supply items. In addition, Purchase Orders should be closely monitored for amount and frequency of material ordered.

The license holder’s department will be responsible for monitoring all Purchase Requisitions to ensure that only licensed persons are ordering controlled substances and that such requisitions are only for controlled substances.

Controlled substances must be received by the person issuing the Purchase Requisition. Receipt must be noted on a record form (see Attachment A) and the substance must be placed in the appropriate safe or locked cabinet. The detailed record that documents the use of controlled substances (Attachment A) must include: (1) date; (2) description of experiment, including number and species of animals; and, (3) signature of person using the container or package. A separate use record must be maintained for each container (bottle, ampoule or basic unit of packaging). In the case of Schedule I and II substances, the date of receipt of the material is entered in the appropriate block of the DEA order form.

If excessive quantities are withdrawn, a record of the manner of disposal must be recorded in the laboratory records.

If excessive stock accumulates and/or drugs become outdated, DEA or CT DDC agents will dispose of the material. Contact EH&S (x2723) and request that a CT DDC visit for drug disposal be scheduled. Outdated drugs should be clearly marked as outdated and segregated from other controlled substances so that they are not used; do continue to maintain the same level of security for such items. Stocks of controlled substances can only be transferred between authorized users by a CT DDC agent. If this becomes necessary, contact EH&S.

If the registered user of controlled substances leaves the Health Center, EH&S must be notified at least thirty days in advance so that arrangements can be made with CT DDC for them to destroy or transfer the drugs to another UConn Health authorized user.

By law, all records must be maintained for a period of three years.
IV. Storage and Use of Controlled Substances

Schedule I and some quantities of Schedule II substances must be stored in a safe. Such safes must be secured to the building. The funds for the purchase and securing of the safe will be provided by the activity that will be storing such controlled substances. The safe will be located close to the area in which the substances will be used. Location of the safe and/or the need for a safe to store certain quantities of Schedule II drugs is subject to agreement with CT DDC agents. Such issues will be resolved during the CT DDC agent visit and prior to registration approval. Additional security arrangements, as State or Federal agents require, must be complied with fully. It should be noted that security requirements for certain Schedule I substances may be costly as alarm systems may be required. Individual license holders using the same safe must maintain their substances in separately locked compartments within the safe. Only licensed individuals or their designated representatives can have access to the safe.

Schedule III-V substances must be stored in locked cabinets or drawers of substantial construction. Only licensed individuals or a designated representative should have keys to these cabinets. Substances must be kept in these secured areas at all times except when they are in use in laboratory experiments. Substances or preparations in use in experiments should not be left unattended in the laboratory. If faculty members or the staff involved in teaching and research activities leave a laboratory where controlled substances are in use, the substance or its preparation should be locked in a drawer or cabinet. Code names or numbers may be used for preparations in use in laboratory areas. Controlled substances may be transported to remote laboratories or other areas of use by licensed individuals or by designated (see paragraph III B1) individuals. Quantities transported for this purpose must be restricted to the amounts necessary for the experiment being conducted.

If Schedules I and II substances are stored in different locations, e.g., on different floors or in adjacent buildings, separate licenses must be obtained for each storage area.

Rooms and areas in which controlled substances are stored or are being used must have locks. Key control for these locks are vital for good security. The license holder working with the Department Head is responsible for controlling the issuance of keys, keeping a record of persons to whom they are issued, and obtaining their return when that person no longer will have access to the area, the drawer, or the room. A new lock or a new tumbler should be installed when there has been failure in key control or when keys is lost.

It is recommended that the combination of the safe containing Schedule I and II substances should, in general, be limited to the license holder and perhaps no more than one other person. If the combination is to be on record elsewhere, for emergencies, it is suggested that it be held only by the Department Head.

V. Inventory

A perpetual inventory (Attachment A) is obtained through the proper maintenance of records of receipt and of withdrawal as indicated above. This is the registered user’s responsibility. This record is subject to inspection and validation by CT DDC and Federal agents at any time.
special inventory noting exact quantities (exact count of tablets, vials, etc., and exact weight or volume of bulk material) shall be made on May 1 + 10 days of each odd-numbered year, as mandated by Controlled Substance regulations. This biennial inventory will be kept on file in the laboratory and a copy must be provided to EH&S.

VI. The Responsibility of the Vice President for Research Compliance Services

These responsibilities as they pertain to controlled substances include:

1. Supplying Federal and State license applications and assisting in their preparation.

2. Maintaining records on all of the applications and licenses granted.

3. Acting as the UConn Health’s interface with Federal and State Drug agents.

4. Providing assistance in insuring the proper security for controlled substances.

5. Maintaining and disseminating information on substances that are controlled and on Schedule changes.

6. Monitoring compliance by the license holders and reviewing inventory records maintained by the license holders.

7. EH&S will provide assistance to the Assistant Vice President for Research Compliance Services on the above controlled substance issues. Questions on such issues may be directed to EH&S (MC1514), X2723.

________________________________________
Signature, Date

Attachments

A. Laboratory Controlled Substance Inventory and Registration Form
Attachment A
LABORATORY CONTROLLED DRUG DISPOSITION RECORD

<table>
<thead>
<tr>
<th>NAME OF DRUG:</th>
<th>FORM:</th>
<th>STRENGTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE</td>
<td>NAME OF PRINCIPAL INVESTIGATOR</td>
<td>PROJECT NUMBER</td>
</tr>
</tbody>
</table>

NOTE: These records must be kept for three years.