FAQ’s
Managing Controlled Substances in Research

BACKGROUND

What are “controlled substances”?

Narcotic and non-narcotic drugs under the jurisdiction of the Federal Controlled Substances Act (CSA) and the State of Connecticut Controlled Substances Act, including, but not limited to, those substances listed in 21 CFR parts 1308.11-1308.15. These are known as scheduled controlled substances or scheduled drugs under the CSA.

What does the controlled substance program include?

The major elements of the controlled substance program include project registration, procurement, storage and security, usage and disposal of unused, expired and waste containing controlled substances, and inventory procedures.

What are the DEA schedules or code numbers for the controlled substances?

The DEA assigns each controlled substance a schedule number (I through V) according to its medicinal value, harmfulness, and potential for abuse or addiction. A higher schedule number indicates the substance has more medicinal value and less potential for abuse or addiction. The letter "N" following the schedule number signifies the substance is non-narcotic (e.g. III N). The DEA code is a 4-digit number assigned to each controlled substance. Please check your registration information with CT DCP (State of Connecticut Department of Consumer Protection) and the DEA (Federal – Drug Enforcement Agency) for the specific substances that are registered under your license.

DEA schedule numbers and corresponding DEA codes. DEA orange book.

The most common controlled substances used in research and respective schedule numbers and DEA codes are listed below.
### Controlled Substance Schedule

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Schedule</th>
<th>DEA Code</th>
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<tbody>
<tr>
<td>Buprenorphine</td>
<td>III</td>
<td>9064</td>
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<tr>
<td>Diazepam</td>
<td>IV</td>
<td>2765</td>
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<tr>
<td>Ketamine</td>
<td>III</td>
<td>7285</td>
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<tr>
<td>Pentobarbital (e.g., Nembutal)</td>
<td>II</td>
<td>2270</td>
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### Who is considered a Licensed Researcher?

‘Licensed Researcher’ refers to the Principal Investigator (PI) throughout this document and is someone who possesses a ‘Researcher’ category license through the DEA and CT DCP.

### Who is an Authorized Agent?

An Authorized Agent is an individual who has the complete trust of a DEA registered individual (licensed researcher). An authorized agent (with authorization from the licensed researcher) may oversee the ordering, dispensing and management of the controlled substances in the absence of the licensed researcher. To minimize the risk of drugs being diverted, only 1-2 individuals in a laboratory should be provided the status of an authorized agent. Licensed researchers are ultimately responsible for the management of controlled substances acquired under their DEA registration or license. Only the licensed researcher and authorized agents can have a key or the combination to access a safe or locked cabinet where controlled substances are stored. Only authorized agents are permitted to know the licensed researcher’s respective registration number and order controlled substances on her/his behalf.

### Who are Authorized Laboratory Personnel?

Authorized Laboratory Personnel are research staff, including graduate students and postdoctoral scholars that work under the direct supervision of a licensed researcher. In addition to the licensed researcher and authorized agents, the authorized laboratory personnel (also known as daily users) may participate in working with controlled substances as part of the approved experiments or treatments involving research animals. Authorized laboratory personnel can perform these functions without keys or combination access to the safe or cabinet where bulk quantities of controlled substances are stored. Licensed researchers or their authorized agent must take responsibility for dispensing limited quantities of controlled substances to authorized laboratory personnel for daily use and maintaining unused substances in the safe or locked cabinet for proper storage. Licensed researchers are ultimately responsible for the management of controlled substances acquired under their DEA registration or license.

### What type of Connecticut registration and DEA registration should a non-practitioner researcher apply for if schedule II-V controlled substances are needed for research purposes?

A non-practitioner researcher must first acquire a State of Connecticut ‘Laboratory/Researcher’ Controlled Substance License (CSL) for using schedule II-V substances. After a CT CSL is acquired (anticipate 4 to 8 weeks for processing), submit your application for the DEA registration.
Researchers must use the DEA Form 225 for classification as a licensed researcher. Please refer to 21 CFR Section 1301.18 for additional information on research protocols to conduct research with controlled substances.

**Where can I find application information for registration of controlled substances?**


I have an office in the “L” building, but my laboratory is located at the Cell and Genome Science Building (400 Farmington Avenue). What should I use as the address for my DEA registration?

- The DEA regulations require that licensed researchers have a separate DEA registration for each location where controlled substances are received, stored or used.
- If you are using DEA-controlled substances in different rooms within the same building, but only storing controlled substances at one location within a specified building, then your registration need only reflect the storage location.
- If you are planning to receive, store or use DEA-controlled substances in more than one building or you are storing DEA-controlled substances in more than one location within the same building, then you must have a separate DEA registration for each building and storage location.
- To minimize the need for transferring controlled substances between multiple registrations held by a single licensed researcher, they should order the controlled substances that they will need for each separate building/building location under the appropriate registration for such building/building location.

I am a licensed healthcare professional in UConn Health and have a practitioner’s registration with the DEA. Can I use this registration to cover my non-clinical research that involves the use of DEA controlled substances, or should I obtain a separate DEA registration for research use?

*Clinical practitioners must maintain a separate ‘Researcher’ category license to conduct nonclinical research.*

While a DEA registration held by a practitioner may permit research use of the specified DEA-controlled substance(s), the DEA registration is specific to a certain location where the controlled substances are received and stored. If you do not store controlled substances at your practice location, you may be able to maintain the single registration for the research location where the chemicals are received and stored. However, controlled substances acquired under the ‘Researcher’ category license must not be used in clinical practice.

**Do I qualify for the fee exemption for DEA registration as a research investigator?**

Yes. As an employee of a state university, you are qualified for fee exemption. The Associate Vice President for Research Compliance and Regulatory Affairs or his/her designee (Director of Environmental Health & Safety) is required to place her or his signature on Item #10 in the DEA registration form as an assurance of your employment. Note: your registration is not transferable to another institution. [http://www.deadiversion.usdoj.gov/drugreg/categories.htm#research](http://www.deadiversion.usdoj.gov/drugreg/categories.htm#research)
Do I qualify for the fee exemption for the CT DCP registration for controlled substances?

No. Neither practitioners nor research investigators are EXEMPT from registration fees. Research investigators are required to submit the registration fee for both an initial registration ($80.00) and annual renewal ($80.00) via a personal check or money order. Credit cards and departmental vouchers are not accepted.

Do I have to apply for separate registrations for Schedule I controlled substances and Schedule II-V Substances?

Yes. Research investigators must apply for a separate DEA registration if the research involves both schedule I and schedule II-V controlled substances. For registration with DEA, separate applications must be submitted for schedule I substances and schedule II-V substances. For registering with CT-DCP, a single application should be sufficient for schedule I and schedule II-V substances.

Do I need to notify EH&S prior to registration and registration renewal?

Yes. You are required to notify EH&S prior to your registration. EH&S has been charged with maintaining the institutional database of all active controlled substance license holders. EH&S acts as the institutional contact for CT DCP and subsequently plays a critical role in the methods of handling and disposal. EH&S works collaboratively with UConn Health’s IACUC to verify the proper/ethical use of these agents in animal research.

How often do I need to renew my registration?

Both the DEA and the CT DCP renewals are annual. The renewal process can be completed on-line. Approximately 30-45 days prior to the expiration you will be mailed a renewal document. The document will provide you with instructions, a user name and password to renew online or you can mail in the document with the appropriate fee. Regardless of how the renewal process was completed a printed copy of the renewal must be sent to EH&S MC-1514 for record keeping purposes.

I had an active DEA registration for a research protocol I was working on last year which has now ended. Can I just renew my registration in case I start another protocol which uses DEA regulated substances?

When licensed researchers are no longer conducting studies under an approved research protocol that authorizes use of DEA-controlled substances, they should promptly surrender their respective DEA registration to the DEA to avoid potential civil or administrative penalties. DEA only approves registration to research investigators who have a current need to access controlled substances for use in their research. Similarly, you should keep the schedules of controlled substances specified on your DEA registration current with the DEA, and promptly remove any controlled substances that are not authorized in your on-going research. It is against the CT DCP and DEA rules and regulation to share or transfer the controlled substances to ‘other research investigators’ without the prior DEA approval. Other research investigators include faculty members in different collaborative projects working within your building, department or college. Similarly, licensed researchers must not store
or use the controlled substances purchased under another investigator’s license without a DEA approved transfer.

**Can a registration be transferred to someone else once a licensed researcher leaves the campus?**

No. Registration and authority to use controlled substances are not transferable. Individuals who want to use a controlled substance in his/her research are required to be registered individually with the DEA and CT DCP. DEA approval must be obtained prior to transferring any controlled substances to another research investigator. The transfer process is the same as one would use to purchase substances from an approved vendor or request a reverse distribution.

**Must each individual research investigator obtain her or his own registration(s) or can a designated departmental investigator obtain registration(s) on behalf of many other investigators within the same department?**

No. Registration and authority to use controlled substances are for individual researchers, not the department. Please be aware that transfer of controlled substances between two licensed researchers are the same as the purchase of controlled substances from an approved vendor and therefore proper DEA procedures must be followed. If two different principal investigators are using the same controlled substances for the specified purpose as stated in the registration and the substances are used within the building and stored in a single location within that building, then the primary licensed researcher can assign the other investigator as the authorized agent, if the usage falls within the work described in the DEA application.

**Can I charge the registration fees to my grants, if any?**

Yes. Controlled substance registration fees can be charged as a direct cost to a sponsored fund, if the licensed researcher’s sponsored project requires use of controlled substance.

**BACKGROUND SCREENING**

**Who must undergo a security screening, and how does the screening process work?**

As part of the DEA registration, every ‘Researcher’ category registrant is required to undergo a DEA background check/screening. No additional screening is required by the University. Staff members working under a licensed researcher are not required to complete a DEA background/security screening.

**Do research investigators applying for DEA registration(s) undergo background screening through University Human Resources?**
No. As part of the application for registration, a background check/screening is conducted by the DEA when the application is submitted. For any questions related to background checks of University employees, please contact Human Resources or Public Safety.

I am a Principal Investigator (PI) and will be identified as a ‘Researcher’ in the DEA application for a research study, but I don’t plan to personally use the controlled substances. Do I still need to complete a DEA background check?

Yes. If you are listed as the ‘Researcher’ in the DEA application you must answer all liability questions in the DEA application form (Section 5- Liability) and your application will be screened by the DEA. As the licensed researcher, you have the primary responsibility for the research project and for overseeing the safety and security of all research materials; consequently, you must fully answer the liability questions in the initial and renewal applications.

Do authorized agents and authorized laboratory personnel (known as daily users) undergo a DEA background check or screening?

No. Authorized agents and authorized laboratory personnel are not required to go through a DEA background check or screening. Licensed researchers are ultimately responsible for the management of controlled substances acquired under their DEA registration or license. Therefore, each licensed researcher is responsible for checking staff’s credentials, authorizing specific roles, and providing required training for handling controlled substances.

I am I a licensed researcher with the DEA? Do my trainees or graduate students need a DEA background check?

No. Any individual employed in research studies conducted in the licensed researcher’s laboratory who has access to the controlled substance(s) must be approved by the licensed researcher. Licensed researchers are ultimately responsible for checking each staff’s credentials for handling the controlled substances.

As the licensed researcher, do I need to notify anyone if an authorized agent or authorized laboratory personnel transfers to another lab or leaves the University?

No. There is no need to notify the DEA or EHS if an authorized agent or authorized laboratory personnel terminates employment with a given laboratory or with the University. However, licensed researchers are ultimately responsible to ensure the security of the controlled substances under their license and maintain an up-to-date inventory.

Authorized agents and authorized laboratory personnel in my laboratory are not University employees. Do they need a background check?

Maybe. This scenario will be handled on a case by case basis.
PURCHASING CONTROLLED SUBSTANCES

How do I order controlled substances?

PIs with a ‘Researcher’ license or their authorized agents must determine the need for the controlled substances and sign all requisitions for controlled substances, regardless of dollar value. Manufacturers, suppliers or distributors such as Sigma-Aldrich require that all purchase orders for schedule I and schedule II substances be submitted using a DEA form 222. DEA 222 forms are provided to the individual licensed researchers by DEA upon an online request. Instructions for ordering DEA form 222 Purchase orders for schedule III-V drugs should be placed by providing a copy of the investigator’s DEA registration to the distributor.

I am attempting to order antibiotics from a distributor, but they need a “verification documentation” to prove that I am authorized to receive the drugs. How do I obtain this verification documentation?

Controlled substances distributors can be a chemical supplier, pharmaceutical vendor, or drug manufacturer. Licensed researchers must work directly with the distributor and provide the necessary information to establish that s/he is indeed authorized to receive controlled substances or drugs and that the research activities are within the scope of a DEA approved research protocol. A licensed distributor must exercise due diligence and obtain verification documentation from licensed researchers to ensure controlled substances are shipped only to individuals authorized for such access by the licensed researcher.

Can I transfer controlled substances to another authorized PI at UConn Health?

Yes, but only after receiving approval from CT DCP and only if the following criteria are met: (1) the authorized PI who is to receive the substance(s) must be an authorized user and (2) both parties maintain proper documentation for any approved transfers. The transfer process is very similar to the purchase of controlled substances from an authorized distributor.

Can I transfer controlled substances to another individual at another University or institution?

No. Such transfers are not allowed under any circumstances. Controlled substances procured under a specific research investigator’s DEA registration cannot be transferred to another individual who is not at the same location as the licensure process is location based.

STORAGE AND SECURITY

The DEA says that I need to double-lock my controlled substances. What does this mean?

This means that two locks must be in place to adequately secure the controlled substances. A laboratory door that is locked when authorized personnel (the licensed researcher, authorized agent(s) of the licensed researcher, or authorized lab personnel) are absent can serve as one of the
“locks.” Within the laboratory, controlled substances must be secured within a locked cabinet or safe that cannot be moved or transported.

- Schedule I and schedule II controlled substances must be secured within a specific type of safe or steel cabinet. The DEA regulations provide specifications regarding such enclosures.
- A narcotics cabinet (double lock, double door, which must be bolted to a wall) is recommended for drug storage. The safe or cabinet must remain locked at all times when controlled substances are not being dispensed from or returned to storage. Details regarding security requirements can be found in 21CFR Section 1301.71.

Please discuss with the CT DCP representative prior to installing a safe or cabinet for storing the controlled substances. Facilities Management can help you install a locked cabinet or safe that is required to be bolted in a secured fashion.

**Can I charge the purchase of a new safe to my grant?**

Yes. The costs of securing the controlled substance in a secured cabinet or lockbox could vary substantially between labs. Please contact the Office of Sponsored Programs to address this issue on a case-by-case basis.

**How do I store controlled substances?**

Controlled substances must be stored securely. Controlled substances should be separated from other drugs or other hazardous chemicals. This practice will help to prevent loss by limiting access to only those who are assigned to work specifically with controlled substances. It is recommended that access be limited to a minimum number of approved personnel as possible. When in use, controlled substances should never be left unattended. Please review the DEA requirements at [http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm)

**How do I store controlled substances during field work?**

Controlled substances must be stored in a locked box either under direct control of an authorized agent or authorized lab personnel or in a locked building or vehicle when not in use during field work. An example of field work could be when the authorized work is performed in a fume hood located in a different room within the building or in an animal research area on a different floor of the same building.

**My colleague and I have separate DEA registrations in a shared laboratory. Can I share the drug locker of my colleague in the department?**

No. Each licensed researcher should maintain her or his own secured lockbox or other secured cabinet for storage of DEA-controlled substances that are permitted by the individual license.

**How do I report if I discover a loss or theft?**

Authorized personnel are expected to report missing controlled substances to their supervisor, and the Public Safety Office as soon as the loss is discovered. Public Safety and law enforcement officials
will investigate the diversion, loss, or theft of controlled substances. If any imminent safety threat exists, contact Public Safety directly at X-7777. Notification to CT DCP and DEA DEA form 106 of loss or theft is required.

**What are the consequences of engaging in illicit activities?**

It is the position of the DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to a State or Federal prosecution for any illicit activity, but shall also immediately become subject of independent action by the University regarding their continued employment. The University will assess the violation and determine whether to suspend, transfer, terminate or take other action against the employee.

**What are the fines and penalties if I am non-compliant with either the CT DCP or the DEA controlled substance regulations?**

Actions may include administrative, civil, or criminal prosecution. The DEA can fine a licensed researcher for each and every violation that it finds. Loss or suspension of a controlled substance license and DEA registration could be catastrophic for a research investigator.

**What is the definition of ‘access to controlled substances’?**

Anyone who has the ability to access or can gain access to controlled substances: a person who is responsible for (1) obtaining, assuring secure storage, managing the initial or annual inventory, (2) completing the aliquot logs and recordkeeping, (3) distributing controlled substances or a dilution thereof to other approved laboratory personnel, and (4) dispensing to an animal or disposing of controlled substances waste.

**What are acceptable storage and security practices?**

Regardless of the source of the controlled substance, materials must be securely locked. A two key security system must be in place. Existing casework may be sufficient to limit inappropriate access if a cabinet or drawer is locked in a non-glass cabinet or drawer integral to the casework. Controlled substances must be accessible only to those who passed the background check by the DEA and their authorized personnel and are used only for legitimate research purposes. Order and store only the minimum amount of controlled substances necessary for planned experiments.

**SPILL**

I dropped a bottle containing DEA regulated substances and all of the material spilled. What paperwork do I need to fill out and how do I document this event?

You must document (date, time, volume, concentration, witnesses (if applicable) and a brief narrative of the circumstances pertaining to the event) in the respective drug accountability record
and in select situations you must submit a [DEA form 106 detailing the loss to the DEA](https://www.deadiversion.usdoj.gov/forms/106). Materials from such a spill should be packaged for collection by EH&S as a chemical waste spill (hazardous waste). Please contact EH&S at X-2723 for more information.

## DISPOSAL

### How do I dispose of partially used, unused or expired injectable vials containing controlled substances?

Expired containers of controlled substances (with any contents remaining) must be separated from non-expired containers of controlled substances, and must be clearly labeled as being expired. The expired containers of controlled substances must remain in the locked controlled substances cabinet or safe. The licensed researcher must request the Director of EH&S remove this material from the laboratory and arrange for destruction by a CT DCP representative. Final disposition of the expired quantity of the controlled substance must be documented in the respective controlled substance accountability record. The EH&S Director will visit your lab and with the authorized user witnessing, an inventory (Surrender of Controlled Substances document) of the material will be completed with both parties signing and dating. Upon final destruction, the CT DCP representative will sign and date the original inventory testifying to this destruction. This original document will then be provided to the authorized user for inclusion in their accountability records with a copy maintained by EH&S.

Please contact EH&S at X-2723 for disposal services.

### Is there any difference in the procedures for discarding empty vials (injectable drugs) of controlled substances vs. residual quantities of expired controlled substances?

Empty vials of controlled substances (injectable drugs) can be disposed of in red bag biohazardous waste containers, although the label should be removed or rendered unreadable. In addition, the disposal of the empty vial must be recorded in the respective controlled substances accountability record.

### Who are the ‘reverse distributors’?

Use of a reverse distributor is forbidden by CT DEEP and University policy.

### How do I dispose of my controlled substance?

Licensed researchers wanting to dispose of controlled substances that are mixed with hazardous chemical waste should contact EH&S at x-2723 to ensure compliance with RCRA regulation. There is no charge for disposal of this waste stream.

## DISPOSAL OF ORPHAN CONTROLLED SUBSTANCES

### How can I dispose of controlled substances left behind by a previously-licensed researcher or other investigator?
It is the responsibility of DEA-licensed researchers to dispose of all controlled substances before they leave the University. If the original licensed researcher is not available, then you, the current owner, is responsible for contacting the Director of EH&S. The EHS office can assist you with the destruction of the controlled substance(s).

### RECORDKEEPING AND INVENTORY

<table>
<thead>
<tr>
<th>Could I be subject to an inspection?</th>
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<tr>
<td>Yes. Both the DEA and CT DCP have the authority to oversee and inspect facilities before and after registration approval.</td>
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<tr>
<th>What specific records must be maintained after obtaining CT DCP license and DEA registration for receiving, storing, and administering controlled substances?</th>
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<tr>
<td>It is imperative that each licensed researcher adheres to all CT DCP and DEA record keeping requirements to ensure proper security controls are in place and complied with.</td>
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<tr>
<th>What are the elements of inventory requirements for controlled substances?</th>
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<tr>
<td>Each licensed researcher is responsible for his/her own annual inventory. Typical inventory checks include: 1) hands-on counting inventory and not a database check; 2) must be completed in a single business day, i.e., before the start of the work day or at the end of the work day; 3) at least two authorized personnel (licensed researcher and authorized agent or authorized lab personnel); and 4) use of an in-house developed initial inventory form, dispensation/disposal records, monthly inventory checks and annual inventory form.</td>
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<th>Is it true that I need to keep separate logs for aliquoting a controlled substance?</th>
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<tr>
<td>Yes. Once a controlled substance is used to make a dilution, it is important to track the usage, disposition and disposal of the new dilution which contains a controlled substance. An appropriate entry should be recorded on the original stock bottle's controlled substance aliquot log and a new dilution log. A separate controlled substance aliquot log should be generated and maintained by the investigator to record activities associated with the diluted aliquot.</td>
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<th>How long do I keep the copies of my controlled substance usage logs?</th>
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<tr>
<td>You must keep these at least two years after the final disposition of the controlled substance. The logs must be readily available for periodic review by CT DCP and/or DEA.</td>
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<th>What is the biennial inventory?</th>
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<tr>
<td>Every two years, each licensed researcher and their authorized agent must inventory the controlled substances under their possession during a one-day institutional inventory at either the opening or close of business (21 CFR 1304.11(b))</td>
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LISTED CHEMICALS

What are “listed” chemicals and “precursor” chemicals?

Certain chemicals and solvents can be used to manufacture a controlled substance. There are two [DEA regulated lists, List I and List II](#), which differ by import/export/sales reporting thresholds. The list I typically represents precursor reagents. The list II represents the solvents that are used in the synthesis and purification steps.

Are individuals who use DEA “listed” chemicals or “precursor” chemicals included in the DEA controlled substance registration?

No. The requirements of the controlled substance program apply only to DEA “scheduled” drugs.

How do I order listed/precursor chemicals, such as iodine?

Contact your purchasing representative for assistance. Store managers in Chemistry and BioChem stores may also be able to help you with this process. To meet the specific vendor requirements for the purchase of chemicals above the reporting thresholds, you will need to receive a registration form from your vendor, complete the form with appropriate authorization/approval signature from your departmental officer and then mail a hardcopy or email as a pdf attachment to the vendor. Fax copies may not be accepted by your vendor.

How do I store the listed/precursor chemicals?

Listed/precursor chemicals must be stored according to hazard class, following the EHS hazardous material storage requirements. These chemicals must not be stored with controlled substances.

REFERENCE DOCUMENTS

Why did EHS create the guidance document for handling controlled substances?

- The DEA and CT DCP regulations, as well as University policies are designed to assure that PIs (owners of registrations) have written policies and procedures to use controlled substances and prevent the inappropriate diversion or inadvertent access to controlled substances.
- EH&S has been developed guidelines as a resource for research personnel. Laboratory Guideline for Managing Controlled Substances in Research Laboratories clarifies the roles and responsibilities of the individual PIs (‘Researcher’ category DEA registration) with access to controlled substances in their research projects and describes proper disposal of partially used
and expired substances, or orphan controlled substances, and the wastes containing controlled substances.

- This EH&S guidance document helps to ensure compliance with the Federal and State regulations; therefore, the guidance document is an important resource with regard to safety and security of controlled substances stored in research labs.

**Who should I contact for questions regarding the use of controlled substances for research purposes at UConn Health?**

The Office of the Vice President for Research (OVPR) has designated EH&S as a resource to assist in matters relating to controlled substances guidance. EH&S staff will provide guidance for laboratories who use, store and/or attempting to dispose of expired and/or orphan DEA regulated materials. Please call EH&S at X-2723