



The University of Vermont

DEA Controlled Substances

Registrant and Authorized User Training

Introduction

- Due to their potential for misuse and abuse, items listed by the U.S. Department of Justice, Drug Enforcement Administration (DEA), scheduled drugs (controlled substances) are subject to special procurement, storage, use and disposal requirements.
- It is the responsibility of individual researchers and other staff using these materials to obtain appropriate registrations and licenses.



Controlled Substances Act

- **The Controlled Substances Act (CSA)** Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain narcotics, stimulants, depressants, hallucinogens, anabolic steroids and other chemicals is regulated.
- The DEA implements the CSA and may prosecute violators of these laws at both the domestic and international level.

DEA Schedules

- Controlled substances are divided into **five** schedules, based on:
 - Whether they have a currently accepted medical use in the United States
 - Their relative abuse potential
 - Safety and likelihood of causing dependence when abused
- Since 1970, many substances have been added, removed, or transferred from one schedule to another.
- An updated and complete list of the schedules is published annually in [Title 21 Code of Federal Regulations \(C.F.R.\) §§1308.11 through 1308.15.](#)

Schedule I Controlled Substances

No currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Examples:

- Heroin
- Lysergic acid diethylamide (LSD)
- Marijuana (cannabis)
- Peyote
- Methaqualone
- 3,4-methylenedioxymethamphetamine ("Ecstasy")

Schedule II/IIN Controlled Substances (2/2N)

High potential for abuse which may lead to severe psychological or physical dependence.

Examples:

- Methadone (Dolophine®)
- Oxycodone (OxyContin®, Percocet®)
- Fentanyl (Sublimaze®, Duragesic®)
- Morphine
- Opium
- Codeine
- Cocaine
- Amphetamine (Dexedrine®, Adderall®)
- Methamphetamine (Desoxyn®)
- Methylphenidate (Ritalin®)
- Pentobarbital

Schedule III/IIIN Controlled Substances (3/3N)

Potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples:

- Products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®)
- Benzphetamine (Didrex®)
- Phendimetrazine
- Ketamine
- Anabolic steroids such as Depo®-Testosterone

Schedule IV Controlled Substances

Low potential for abuse relative to substances in Schedule III.

Examples:

- Alprazolam (Xanax®)
- Carisoprodol (Soma®)
- Clonazepam (Klonopin®)
- Clorazepate (Tranxene®)
- Diazepam (Valium®)
- Lorazepam (Ativan®)
- Midazolam (Versed®)
- Temazepam (Restoril®)
- Triazolam (Halcion®).

Schedule V Controlled Substances

Low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples:

- Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®)
- Ezogabine
- Lomotil
- Motofen
- Lyrica
- Parepectolin

UVM Controlled Substances Committee

- Establish and review policies and procedures on all matters relating to the purchase, storage, usage, and disposal of controlled substances by members of the University Research community
- Review and authorize UVM researchers to purchase and use controlled substances
- Develop standards for monitoring compliance and responding to non-compliance with regulations and/or institutional procedures.
- If necessary, terminate a user's authority to use controlled substances at UVM

Approval Process

- Register with the DEA
- Designate authorized users in the lab
- Complete a background check
- Complete UVM Controlled Substances Training
- Submit registration to the UVM Controlled Substance Committee for final approval
 - Registrations can be submitted to the CSC through [UVMClick](#)
 - Please watch this short [how-to video](#) for instructions

Investigator Responsibilities

- Each registrant who orders, handles, or stores controlled substances must be registered with the DEA to perform these functions.
 - Maintain accurate inventories and records of controlled substances for a minimum of 2 years
 - Designate **Authorized Users**: An Authorized User is a member of the research team who has completed training and is approved to handle controlled substances in the laboratory.
 - Ensure that controlled substances are stored in a manner that prevents their theft or misuse
 - Supervise use of controlled substances in the lab
 - Ensure the appropriate disposal of controlled substances
 - Comply with DEA and UVM reporting requirements
 - Renew registrations annually



Registration



- If you are applying for a DEA registration, you will need to request a new application form. The application form required depends upon the type of activity you intend to conduct.
- Applications can be completed online:
<https://www.deadiversion.usdoj.gov/drugreg/index.html>
- Renewal Applications
 - **DEA Form 225a** – Manufacturer, Distributor, **Researcher**, Analytical Laboratory, Importer, Exporter
- New Applications
 - **DEA Form 225** – Manufacturer, Distributor, **Researcher**, Canine Handler, Analytical Laboratory, Importer, Exporter

Renewals

- Registrations must be renewed on an annual basis
- DEA policy and procedures with respect to renewal and reinstatement of registration:
 - If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
 - DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
 - Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Purchasing

- Controlled substances may only be purchased with a purchase order.
- Purchasing cards may not be used to purchase controlled substances.
- The purchasing record (invoice, shipping document, or packing slip) must be annotated with the handwritten date of receipt and when logged into drug usage log.
- The amount purchased must match the amount received.

Background Checks



- DEA background checks are required for all registrants
- At time of initial DEA screening, DEA conducts a background check on the Registrant.
- It is the responsibility of the Registrant to administer the "Questionnaire for Access to Controlled Substances for Research Purposes" to all Authorized Users.
 - The information captured on this form is considered "private personal information" and as such must be protected from unauthorized individuals and stored in a locked cabinet by the Registrant.

Security Requirements

- Controlled substances must be stored in a way that prevents their theft or misuse
- Registrants must store controlled substances at the location specified in the registration, in a **double-locked, substantially constructed cabinet that is fixed in place.**
- Registrants must institute a key access procedure and keep the key in a secure key safe or a locked drawer.
- Registrants must ensure that only authorized users have access to controlled substances.
- The storage area must remain locked when not in use
- No bicycle locks, clasp locks, or any other locking structure that can be easily cut off the cabinet may be used



Theft or Loss

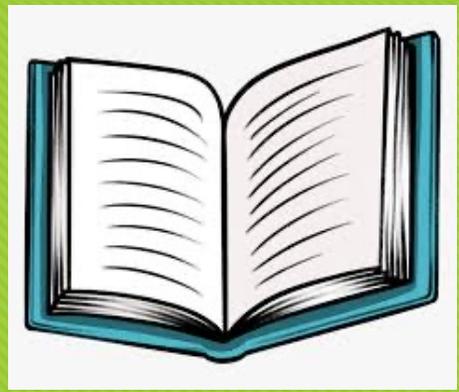
- All employees and students are required to report diversion of controlled substances. Any suspected theft, loss, or diversion must be immediately reported to:
 - UVM Police Services at (802)656-3473 or police@uvm.edu,
 - UVM Office of Compliance Services at (802) 656-3086 or at compliance@uvm.edu, and
- Area DEA Field Division Office must be notified in writing within one business day of discovery of loss or theft. Completion and submission of the DEA Form 106, "Report of Theft or Loss of Controlled Substances" is also required.
- Anonymous reports can be made through Ethicspoint <https://secure.ethicspoint.com/domain/media/en/gui/24544/>

Spills



- Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost.
- This type of loss must be documented by the **registrant and witness** on the inventory record.
- Controlled substances that can be recovered after a spill, but cannot be used because of contamination (such as tablets), must be disposed of in accordance with disposal procedures.

Record Keeping



- Each registrant must maintain inventories and records of controlled substances for a minimum of two years
- Records for schedule I and II substances should be kept separate from records for schedule III – V substances
- Inventories for all locations must be updated at least biennially. The inventory will:
 - Consist of a hands-on counting of inventory and not a database check
 - Be completed in a single business day, i.e., either the before the opening or after the close of business
 - Be completed by at least two authorized personnel (licensed registrant and authorized agent or authorized lab personnel).
- **Usage Logs** - Registrants are required to maintain a usage log of controlled substances at each physical location of controlled substances that can be reconciled to both purchasing and inventory records.
- Non-DEA Registrant screening forms must be kept on file for the duration of the person's employment within the lab. Forms are to be kept in a locked cabinet with access limited to the DEA Registrant or his/her authorized delegates.

Disposal Considerations



A registrant may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by:

- Administering the drug to an animal carcass and documenting the administration on the usage log. A second authorized user must be present to witness and sign the usage log.
- Destruction via a UVM approved vendor (requires DEA Form 41). Contact waste@uvm.edu.
- Reverse Distribution - Contact the CSC for guidance

If an unregistered controlled substance must be disposed of, contact waste@uvm.edu. See CSC Policy 9.0 Disposal for more information.

Inspections



- **DEA** - The DEA makes periodic **unannounced** inspections of registered controlled substance storage locations. Additionally, reporting of a loss or theft may result in a DEA inspection or visit. The DEA is a law enforcement agency, with the ability to assess civil and criminal penalties.
- **Controlled Substance Committee** – CSC representatives will conduct inspections to monitor the status of DEA registration & UVM authorization, security of controlled substances, completion of training for authorized users, and a review of inventory documentation.
- **IACUC** - As part of the federally required IACUC semi-annual inspections, representatives will review storage areas, use/logs, and security controls. Registrants are required to address inspection deficiencies within 14 days of receipt.

Non-Compliance

- The CSC will respond to observations of non-compliance, and recommend corrective actions to appropriate personnel including Department Chair, Dean, Vice President for Research, UVM Police, and/or U.S. DEA.
- Consequences of non-compliance may include loss of authorization to use CS at UVM, revocation of the DEA registration, termination of employment, or referral to law enforcement agencies.

Important: Document Your Training

Thank you for your attention!

Please proceed to the online quiz
to document your training.

- Log in with your UVM netID and password
- From the “Specific Hazards” box, choose “DEA Controlled Substances Quiz”

More information can be found on the [UVM Controlled Substances](#) web page