The University of Vermont

OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

UNIVERSITY OPERATING PROCEDURE

Title: Controlled Substances in Research

Overview

Researchers who use controlled substances as part of an approved research project must obtain a registration from the Drug Enforcement Agency (DEA) and authorization from the UVM Controlled Substance Committee (CSC). Access to the controlled substances must be limited to those individuals authorized in the DEA registration. This University Operating Procedure (UOP) provides requirements for the use of controlled substances associated with animal research, the administration of controlled substances administered to human subjects as part of a research protocol, and when using controlled substances for in vitro or analytical research. This policy does not apply to controlled substances administered or dispensed to a patient by a licensed practitioner in the course of professional medical, dental, or veterinary practice.

The Vice President for Research appoints the Controlled Substance Committee with authority to authorize researchers' use of controlled substances at UVM, and to review researcher activities for compliance with safety and security requirements.

Applicability of the Procedure

This Operating Procedure applies to those participating in research at the University of Vermont, involving the use of DEA controlled substances.

Definitions

Authorized User: Each registrant must designate and document those individuals who will be given authority to access and use controlled substances. Authorized users must complete training as described below. Registrants should limit the number of authorized users to the minimum necessary. Authorized users shall not be any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.

Controlled Substance (CS): Compounds containing any quantity of substances with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and have the tendency to promote abuse or physiological or psychological dependence, as designated under the Controlled Substance Act.

Controlled Substance Committee (CSC): Established by the Vice President for Research, the CSC reviews applications from UVM researchers who have valid DEA registrations, and may grant authority for them to purchase and use controlled substances in research at UVM. The CSC reviews policies and procedures regarding controlled substances, develops

tools to assist researchers to comply with requirements, and develops standards for inspection, compliance monitoring, and responses to non-compliance. Any employee of the University utilizing controlled substances for research must apply for authorization with this committee and undergo a review of plans to meet regulatory requirements.

Controlled Substance Schedule: The drugs and substances covered under the Controlled Substance Act are organized into five schedules. The DEA Website maintains a current schedule of which substances are controlled as well as their classification. Schedules are codified in 21 CFR§1308.

Schedule I: No accepted medical use.
- Schedule I compounds are classified as illicit drugs along with their chemical precursors.
- The DEA requires a Schedule I registration application for use of these substances.

Schedules II-V: Accepted medical uses.
- Schedule II substances have a high potential for abuse with severe psychological or physical dependence.
- Schedule III-V substances have a lower potential for abuse than substances in Schedules I or II.
- The DEA requires a Schedule II-V registration application for use of these substances.

Drug Enforcement Administration (DEA): Federal department that regulates the use of substances that have a high potential for diversion or abuse. DEA regulations are codified in 21 CFR§1300.

DEA Registrant (the Registrant): A person who holds a DEA Registration and who is responsible for the use, security, and disposal of controlled substances in accordance with DEA regulations. The DEA registrant is responsible for maintaining a list of authorized users, limiting access to the CS, and for ensuring all security measures. The Registrant is solely responsible for the controlled substance from receipt until destruction.

DEA Registration: DEA Registration grants practitioners (defined as physicians, dentists, veterinarians, pharmacies, or hospitals), researchers, and others, federal authority to handle controlled substances in the course of professional practice

Procedures

1. **DEA Registration** – Researchers conducting protocols that use controlled substances must have their own DEA registration and a separate registration is required for each location where the CS is being used. Researchers are prohibited from ordering CS for other researchers' protocols. Researchers obtain a DEA Registration using appropriate DEA forms and procedures available at www.deadiversion.usdoj.gov . Key personnel who are given access to CS must be listed as authorized users at the time of DEA registration application. At time of initial DEA screening, DEA conducts a required background check on both the registrant and anyone listed as authorized users on the registration. Registrants are responsible for registration, costs, requesting approval for changes in approved protocol, and applying for renewals in accordance with 21 CFR§1301.18.

   Licensed practitioners must register with the DEA for a separate research registration; however, they should use their Vermont license information when requesting a DEA registration for the purpose of doing research. This reduces the risk to medical or dental practice registrations in the event of

noncompliance with research regulatory requirements by state and federal agencies. Vermont is a one-license requirement state, meaning that individuals who already possess a state practitioner license (i.e., physicians, veterinarians, dentists) and who wish to also use controlled substances for research can use their state license to apply for a DEA registration.

Non-licensed researchers - The Vermont Office of Professional Regulation has waived the Vermont State Board of Pharmacy license requirement for UVM research faculty and individual investigators that do not have a state practitioner's license. With this exemption, non-licensed researchers may apply directly for a DEA registration.

2. **UVM Authorization (Approval)** - Researchers apply for and obtain authorization from UVM Controlled Substance Committee (CSC) to purchase, store and use CS. The CSC reviews applications and approves or denies authorization within 30 days.

3. **Adding Authorized Users After Registrant Has an Approved** Registration - Before a non-DEA Registrant (e.g. key personnel) is allowed to access to CS, to sign the Authorized Users Signature Log, and to use controlled substances in the lab, they must first complete the Questionnaire for Access to Controlled Substances for Research Purposes by Non-DEA Registration Holders and return it to the lab manager. Further information is available in the Instructions for the Questionnaire [forthcoming].

   Registrant is required to update their registration with the new users at time of renewal, at time of a DEA onsite inspection or when new protocols are submitted, whichever comes first.

4. **Training** – DEA Registrants and authorized users complete UVM controlled substance use training as outlined below. DEA Registrants are further subject to requirements of other UVM lab safety programs. Registrants are responsible for ensuring that all authorized users of CS are aware of the security and safety requirements associated with these materials.

5. **Purchasing** – UVM only allows the purchase of controlled substances through a purchase order. UVM prohibits the use of purchasing cards to purchase controlled substances (Purchase order requirements are on the Department of Risk Management & Safety - Controlled Substances webpage under the Forms and Guidance tab). 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.

6. **Storage and Safeguarding Access** –Registrants must store controlled substances at the location specified in the registration, in a double-locked, substantially constructed cabinet that is fixed in place. Each registrant is required to store CS in their own lock box. 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 and are not allowed to share a lock box for CS with other researchers.

7. **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. Usage logs must be kept within a bound notebook and follow the template provided at the end of this policy.

8. **Inventory** – The DEA requires that each registrant inventories the controlled substances under their possession as detailed at 21 CFR 1304.11. This requires a physical inventory of controlled substances to be completed on the date the registrant first engages in business with controlled substance(s) (initial inventory). In addition, an inventory must be taken on the effective date that the substance being used becomes controlled by DEA. A separate inventory must be performed at each registered location. The inventory must be updated as needed and at least biennially. Each registered researcher is responsible for his/her own periodic inventory.

The inventory will:

1. consist of a hands-on counting of inventory and not a database check;
2. be completed in a single business day, i.e., either the before the opening or after the close of business; and
3. be completed by at least two authorized personnel (registrant and authorized agent or authorized lab personnel).

9. **Record Retention** – As specified in 21 C.F.R. §1304.04, the registrant **must keep** at least two years of inventory records after the final disposition of the controlled substance. All records and logs must be readily available for periodic review by the DEA. Registrants must also maintain associated documents including approval letters, DEA & FDA approvals, certificates of registration, supplemental protocol applications, list of authorized users, purchasing, and destruction documentation. All DEA certificates of registration and all documentation related to the disposal or destruction of the CS must be maintained at each registered location in a readily retrievable manner and kept for official inspection.

10. **Disposal** - To minimize waste, DEA Registrants should only purchase quantities they intend to use within a reasonable timeframe (e.g. shelf-life of drugs, and not more than 1-year). Damaged, expired, unwanted, unusable, or non-returnable controlled substances must be accounted for, retained, and disposed of in accordance with applicable regulations. Controlled substances that are wastes remain subject to security regulations and supervision by the PI/registrant. The DEA registrant is the person who "owns" and is responsible for the controlled substance from receipt until destruction.

    Registrants must dispose of controlled substances obtained for research by one of the following methods:

    - DEA Registrant can personally administer the drug to an animal carcass or the University Veterinarian can administer the drug to an animal carcass while the DEA Registrant is present. Registrant remains responsible for CS from receipt to destruction so it is important that the Registrant remain present for this method of destruction. The Registrant remains responsible to properly log the administration activity; or
    - Reverse distribution back to the vendor. This requires paperwork be completed by the Registrant. The drug must stay in the possession of the DEA registrant, it cannot be handed to Risk Management and Safety to manage; or
    - Disposal by UVM Approved Vendor. To utilize this method, contact UVM Risk Management & Safety at waste@uvm.edu to schedule pick-up and disposal by UVM's approved vendor. The Registrant must maintain control of the CS until it has been properly transferred to the disposal vendor. Procedures for disposal are specific to each circumstance and may incur costs that are the responsibility of the individual researcher. This process may take several months, during which the registrant must maintain the CS in their inventory.

      Documentation of the disposal is required. Registrants are required to complete the online "Registrant Record for Controlled Substances Destroyed", online Form DEA- 41, to notify the DEA of controlled substance destruction. This form may be found on the DEA Forms website.

11. **Theft, Loss or other Diversion** – All employees and students are required to report diversion of controlled substances immediately upon discovery as follows:

    a. **Non-Registrants:** Any suspected theft, loss or diversion must be immediately reported to the Registrant unless the Registrant is suspected to be responsible for the theft, loss or diversion of the CS. Registrants are then responsible to report as indicated in section b. below.

       Exception: If the Registrant, after a reasonable inquiry, is suspected of the theft, loss or diversion of CS, reports shall be made immediately to one of the following:

i. UVM Police Services at (802)656-3473 or police@uvm.edu,
ii. UVM Office of Compliance Services at (802) 656-3086 or at compliance@uvm.edu, and
iii. Anonymous reports can be made through Convercent https://www.uvm.edu/compliance/helpline

b. **Registrants**: Federal regulations require that Registrants notify the Field Division Office of the Administration in their area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. To initiate a report, the Registrant may first contact the Office of General Counsel at General.Counsel@uvm.edu or (802) 656-8585. The Registrant shall also complete and submit to the Field Division Office in their area, the DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)). The DEA Form 106 can be completed via the Theft/Loss Reporting Online Form or by downloading the fillable PDF version and submitting it to the Local Diversion Field Office. These forms are only available to Registrants. All others must notify Police Services or the Office of Compliance Services as specified above. The Registrant must notify the Office of General Counsel or the Office of Compliance Services as soon as practicable for all reports made by the Registrant directly to the DEA.

When determining whether a loss is significant, a registrant should consider, among others, the following factors: The actual quantity of controlled substances lost in relation to the type of business; The specific controlled substances lost; whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances; a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known, whether the specific controlled substances are likely candidates for diversion; local trends and other indicators of the diversion potential of the missing controlled substance.

12. **Spills** - Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost but need to be reported immediately to UVM Risk Management & Safety. 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 (tablets), must be disposed of in accordance with disposal procedures.

13. **Inspections** - Registrants must be prepared at any time for internal and external, announced and unannounced 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. Background checks may be conducted by the DEA as part of the inspection.
    - **Controlled Substances Committee** – CSC representatives will conduct inspections to monitor the status of DEA registration and UVM authorizations, security of controlled substances, completion of training for authorized users, and a review of inventory documentation. Inspections will occur not less than annually. These inspections may be unannounced. Registrants are required to address inspection deficiencies within an appropriate and specific time period (usually 14 days).
    - **Institutional Animal Care and Use Committee (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.
    - **Please notify the** Vice President for Research **immediately if your lab is being subjected to an unannounced external investigation**.

14. **Renewals** – DEA research registrations are valid for one year. Renewals are completed through the DEA website. The DEA will conduct background checks as part of the renewal. DEA sends an electronic reminder to renew to the email address associated with the DEA registration. Registrants are responsible to ensure their registration remains current and active. Researchers are required to renew their authorization with the CSC following DEA renewal. The VPR/CSC will send an annual reminder to register with the CSC.

15. **Termination** – Registrants leaving the University must notify the DEA of the change in their registration, or dispose of their controlled substances in accordance with this UOP, and notify the CSC.

16. **Findings of 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.

Contacts

Questions concerning the daily operational interpretation of this UOP should be directed to the following:	
Title(s)/Department(s):	**Contact Information:**
Risk Management & Safety	Sarah.Roy@uvm.edu
Ida Washington, UVM Veterinarian	Ida.Washington@uvm.edu
Research Protections Office	Donna.Silver@uvm.edu

Forms/Flowcharts/Diagrams

All of the following found on the Department of Risk Management & Safety - Controlled Substances webpage under the Forms and Guidance tab:

- Information Needed for Registration
- Example Controlled Substance Log
- Example Controlled Substance Inventory Form
- Use of Controlled Substances in Research Flow
- Purchase Order Requirements
- DEA Unannounced Inspection
- Instructions and Questionnaire for Access to Controlled Substances for Research Purposes by Non-DEA Registration Holders
- Pharmacy Permit Waiver

Related Documents/Policies

- Controlled Substance Committee By Laws
- Title 21 United States Code (USC) Controlled Substance Act (link is external) U.S. Department of Justice - Drug Enforcement Administration (DEA) outline of the federal Controlled Substance Act
- Title 21 Code of Federal Regulations, Part 1300-End (link is external) Index listing the links to the sections of DEA policy for controlled substance registration

Training/Education

Training related to this is as follows:

Training Topic:	Registrants and Authorized Users of Controlled Substances		
Training Audience:	Registrants and Authorized Users of Controlled Substances	**Delivered By:**	Risk Management & Safety
Method of Delivery:	Online (in development)	**Frequency:**	Upon receipt of DEA Registration and triennial thereafter.

About This Procedure

Responsible Official:	Vice President for Research	**Approval Authority:**	Vice President for Research
Affiliated Policy Number(s):	None	**Effective Date:**	December 18, 2020
Revision History:	None		