OLD DOMINION UNIVERSITY

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Policies and Procedures for Using Controlled Substances in Research

Administered by

Division of Research & Economic Development (DivRED)

&

Environmental Health and Safety Office

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Old Dominion University
Policies and Procedures for Using Controlled Substances in Research

Table of Contents

I. PURPOSE

In conducting research and teaching activities with controlled substances, Old Dominion University's (ODU) registrants and authorized personnel shall comply with Federal and State laws and regulations regarding their uses, including registration with the Drug Enforcement Administration (DEA) and the Virginia Board of Pharmacy (VBP), specified storage requirements, inventory maintenance and substance disposal. Failure to comply with this policy can result in disciplinary action, as well as suspension or termination of research by the University. The Division of Research and Economic Development and the Environmental Health and Safety Office (EHSO) are responsible for monitoring compliance.

II. DEFINITIONS

Authorized Personnel:
Any employee authorized to use controlled substances under the direct supervision of a Registrant.

Controlled Substance:
Any substance listed in the Controlled Substances Act, Code of Federal or Substance Regulations (21 CFR, part 1300 to end), Virginia Statue §54.1 3422, and the Virginia Board of Pharmacy Policies and Procedures.

Department:
A Department is any administrative unit or structure that by size, location, or nature of activity requires separate registration.

Disposal:
The removal and destruction of controlled substances that are in their original containers or original form and that are outdated, surplus or no longer intended for use. Disposal also applies to small quantities of controlled substances that are residual (often referred to as "waste") or that have been adulterated through use.

Disposition Records:
An accurate, continuous and current record used to track the acquisition, use and disposal of controlled substances.

Drug Enforcement Administration (DEA):
The section of the United States Department of Justice that establishes regulations for the handling and use of controlled substances.

Employee/Member of the University:
This term refers to faculty, staff, and any other individuals employed by ODU or ODU Research Foundation who use ODU resources or facilities or receive funds administered by ODU, and volunteers and representatives who may speak or act as agents for ODU. Members do not include students taking courses, attending classes or enrolled in an academic program unless they meet one of the other criteria.

Environmental Health and Safety Office (EHSO):
The Old Dominion University Environmental Health and Safety Office.

Institutional Animal Care and Use Committee (IACUC):
The Institutional Animal Care and Use Committee for review of projects using animal subjects.

Institutional Review Board (IRB):
The Institutional Review Board for review of research involving human subjects.

Location:
A building, room, or set of contiguous or adjacent rooms where controlled substances are stored or used.

Division of Research and Economic Development:
The Division of Research and Economic Development (DivRED) is responsible for ensuring compliance with internal research policies and with local, State and Federal regulations related to research.

Registration:
Formal grant of specific authority by the DEA and/or Virginia Board of Pharmacy (VBP).

Registrant:
A University employee authorized by his/her Department to hold both a VBP registration and DEA license to obtain controlled substances and to store, use and properly dispose of controlled substances at a single location.

Research:
Any investigative activity conducted by ODU personnel using University facilities or resources regardless of funding source.

Teaching:
Teaching activities include classroom demonstrations, laboratory exercises and research projects that are required for completion of a course at the undergraduate, graduate or professional level. This policy does not cover any teaching activity performed within a clinical environment. However, clinical teaching activities must still comply with DEA and VBP regulations applicable to practitioners and pharmacies.

Virginia Board of Pharmacy (VBP):
The agency authorized by the Virginia statute to regulate controlled substances.

III. RESPONSIBILITIES

Authorized Personnel
Must properly use and maintain disposition records of controlled substances in accordance with this policy.

Department Chair
Determines whether to give an individual university employee in his/her Department authorization to maintain a VBP registration and DEA license to obtain controlled substances and to store, use and properly dispose of controlled substances at a single location.

Registrant
1. Maintains a VBP registration.
2. Maintains a DEA license.
3. Submits protocol review form to Department Chair for approval and signature.
4. Submits protocol review form to DivRED for review and approval.
5. Shall have protocol approved by the IRB and/or IACUC, if applicable.
6. Shall properly store and use controlled substances, maintain appropriate disposition records, supervise use by authorized personnel, and conduct an annual inventory of controlled substances used at that location.
7. Uses appropriate record keeping in accordance with regulatory requirements.
8. Notifies Department Chair and DivRED of discrepancies found in the inventory.
9. Can exercise signature authority to purchase and dispose of controlled substances used within that Department and for which a justification is on record

Division of Research & Economic Development (DivRED)
1. Maintains a current list of all registration holders.
2. Monitors acquisition of controlled substances and verifies registration and justification for use. Provides training in controlled substances policies and procedures.
3. Promulgates instructions on the use, storage, disposal, and reporting of the theft or loss of controlled substances.
4. Conducts inspection when a registration holder or registration address becomes inactive.
5. Conducts annual review of registrant’s purchasing process, disposition and inventory records, and security measures.
6. Reviews research protocols involving the use of controlled substances.
7. Performs periodic site reviews.

Environmental Health and Safety Office (EHSO)
1. Coordinates disposal activities for waste or unused controlled substances.
2. Approves security of storage facilities of all registrants.
3. Serves as back-up program coordinator to DivRED.

Old Dominion University Research Foundation (ODURF)
Requires that the Research Proposal Transmittal Form include a category for the use of controlled substances in research and that DivRED is sent a copy of research proposals that involve the use of controlled substances for review and comment.

IV. PROCEDURES FOR USING CONTROLLED SUBSTANCES Registration

Any Principal Investigator intending to use controlled substances for research or teaching must be registered with both the Drug Enforcement Agency (DEA) and the Virginia Board of Pharmacy (VBP). The Registrant shall purchase controlled substances using his/her own registration number. The Registrant shall not purchase controlled substances for other personnel.

For DEA registration, researchers should use Form 225 "New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter." DEA registration can be completed online: https://www.deadiversion.usdoj.gov/online_forms_apps.html

For VBP registration, researchers should use "Application for a Controlled Substance for Various Entities." This form can be obtained online at: http://www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm#csr

Application for Use

Controlled substances may not be procured, possessed, stored or used by an individual until the DivRED has approved the registrant's "Controlled Substances Protocol Review Form" (See Appendix A). Authorization to possess and use controlled substances expires two years from the date of final approval. Amendments to the original approval requested prior to the expiration date of the original authorization must be submitted to DivRED using the "Controlled Substances Protocol Review Form." Actions requiring amendments include:

1. Addition of controlled substance(s) to the experimental protocol
2. Significant change(s) in the experimental design
3. Change(s) in the location(s) or storage and/or use
4. Change(s) in Authorized Personnel

Purchasing

A Federal DEA license and DEA requisition number are required for purchasing controlled substances. The Federal Drug Administration (FDA), in the Controlled Substances Act, has established strict ordering procedures that must be followed before a vendor is permitted to fill an order. Orders must be accompanied by the appropriate DEA Form, which can be obtained from the DEA's Diversion Control Program Office.

Orders for DEA Schedule I and Schedule II drugs must be accompanied by DEA Form 222. This form is numbered sequentially and issued only to holders of DEA registration numbers.

Schedule III and IV controlled substances can be purchased by citing the DEA requisition number from Form 223. The three-part form must be completed as the directions on the back of the form specify.

The licensee must keep Part 3 of the form and have it available for inspection by enforcement officers for a period of two years from the date the order was placed. Space is provided on Part 3 for receiving information.

For assistance with registration or purchases, contact the Old Dominion University Division of Research & Economic Development at 757-683-3460.

Storage
The Registrant must provide effective controls and procedures to guard against theft and diversion of controlled substances. Controlled substances must be stored separate from other drugs or materials. Controlled substances should be stored in a securely locked, substantially constructed cabinet as stipulated in 21CFR Section 1301.75. Expired or unwanted controlled substances must be separated from the working stock, and "outdated" or "expired" shall be written in indelible ink on each vial, bottle or container to be discarded and on any outer container in which the item is placed. These substances can be placed in a bag or box and put in the same storage space as the working stock.

Maintenance of Records and Inventories
The VBP Controlled Substance Registration (CSR) Certificate must be posted in a conspicuous location within the facility in which the controlled substances are used, such as in the Registrant's office or laboratory.

The Registrant must keep accurate, continuing and current records of the acquisition, use and disposal of controlled substances at each location. Inventories and other records shall be kept and made available for inspection for at least two years from the date of such inventories or records. The Registrant must maintain separate inventories and records for each registered location and for each independent activity for which he/she is registered.

The schedules of Controlled Substances are listed in Appendix B. There are six schedules (I through VI). Inventories and records of Schedule I and II controlled substances must be maintained separate from all other records. Inventories and records of controlled substances listed in Schedules III – 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 Registrant must conduct an annual inventory and reconciliation of all stocks of controlled substances on hand. The date and time of the inventory and the Registrant's signature must be recorded. To prevent unauthorized persons from ordering controlled substances, DEA order forms must be numbered for each schedule drug, and the numbers must be recorded on a separate sheet. Both the DEA forms and the record of numbers must be stored in the safe/cabinet with the controlled substances.

The Registrant must include the following information in the inventory:

- Name of the substance for each finished form of the substance
- Number of units or total volume of each finished form in each commercial container
- Number of commercial containers of each finished form received
- Expiration date and lot numbers of the containers received
- Name, address and registration number of source from which the containers were received

- Amount of each finished form transferred or used, including the name and address of the person(s) to whom it was given, the date of transfer, the name of the individual who used the substance and the reason it was used
- If controlled substances are compounded or aliquoted, each new container must be labeled and tracked as with the original container. Federal law and IACUC guidelines prohibit use of non-pharmaceutical grade drugs for anesthesia, analgesia, euthanasia or for any survival procedures in live animals, unless there is no adequate commercial preparation available.
- Number of units or volume of finished forms and/or commercial containers disposed of in any other manner, as well as the date and manner of disposal

Security Controls
Rooms where controlled substances are used and/or stored shall be secured at all times. Access to these areas shall be limited to the registrant and authorized personnel. Door locks shall not be keyed to the University's master key system. A combination lock is preferable.

Persons who have 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 surrendered a DEA registration for case are prohibited from using controlled substances.

Theft or Loss
If a Registrant discovers a theft or any other unusual loss of any controlled substances, he/she must immediately report such theft or loss to the University Police and to DEA. Further, the Registrant must file a DEA Form-106 "Report of Theft of Controlled Substances" with the DEA. This form can be obtained online at:
https://www.deadiversion.usdoj.gov/21cfr_reports/theft/theft-loss.html

Disposal
To minimize waste, DEA registrants should only purchase quantities they intend to use. Damaged, expired, unwanted, unusable, or non-returnable Controlled Substances must be accounted for, retained, and disposed of in accordance with applicable State and Federal regulations

Environmental Health & Safety personnel are NOT DEA registered and therefore cannot collect, hold or dispose of Controlled substances without proper DEA paperwork from the PI (DEA form 41).

DEA controlled substances must be disposed of through an authorized **Reverse Distributor** or **On-Site Disposal**. Reverse distributors are companies licensed and permitted to recycle and/or destroy controlled substances. Contact EHSO (ehsdept@odu.edu) to help determine disposal method.

A Registrant Record of Controlled Substances Destroyed (DEA Form 41) must be completed prior to disposing of any DEA controlled substance. Copy of Form 41 should be retained by the registrant for at least 2 years.

Controlled substances that are mixed with radioactive waste, chemical waste or regulated medical waste are not eligible for disposal under these guidelines. Such substances must be disposed of through the EHSO as radioactive waste, chemical waste, or regulated medical waste, respectively. Contact the EHSO (ehsdept@odu.edu) to help determine disposal method.

Oversight

The Division of Research and Economic Development reviews each Registrant's purchasing and disposition records, and inventory and security measures on an annual basis and conducts a final inspection when the Registrant becomes inactive. This oversight review is required for the continued use of controlled substances in research.

APPENDIX A

CONTROLLED SUBSTANCES PROTOCOL REVIEW FORM
OLD DOMINION UNIVERSITY

Directions: Researchers planning to use controlled substances as part of their research must complete this form. Researchers must have a current DEA license and VBP Registration. This form should be returned to the Division of Research & Economic Development, Attention Research Compliance Coordinator. The Research Compliance Coordinator will review the application and contact the applicant if there are any questions or concerns. The applicant will receive confirmation to proceed with the project.

Administrative Information	
Name of Researcher	
Type of Application □ Initial Application □ Renewal Application □ Amendment	
Department	
Campus Address	
Office Phone	Emergency/After Hours Phone
Fax	Email
Title of Research or Teaching Project	
Please list all personnel authorized to work with controlled substances under your supervision.	
Proposed Starting Date	
Grant Number (if applicable)	
Does the research involve the administration of drugs to live animals? □ Yes □ No If yes, has the project been reviewed by the IACUC? □ Yes (indicate the protocol number) □ No	
Does the research involve the administration of drugs to human subjects? □ Yes □ No If yes, has the project been reviewed by the IRB? □ Yes (indicate the protocol number) □ No	
Controlled Substances	
Current DEA license expiration date	Current VBP registration expiration date

List the name(s) and amount(s) of controlled substance(s) to be used in the research project.

Which controlled substance schedule(s) are you planning to use? (Please check all that apply)
☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI

Where will the controlled substances be stored? (Please include building name(s) and room number(s)).

Describe security measures to prevent theft or loss of controlled substances.

Is a securely locked, substantially constructed cabinet used for storage of controlled substances?
□ Yes
□ No

Where will the controlled substances be used? (Please include building name(s) and room number(s)).

Describe security measures to prevent theft or loss of controlled substances during use.

Describe the proposed use(s) of the controlled substance in research. Please include the number and species of research subjects, dose to be administered, the route and method of administration, and duration of the project. (Attach an extra sheet if necessary.)

Certification

The signature below affirms that the researcher will comply with all of the rules and regulations outlined in the Old Dominion University Policy and Procedures for Using Controlled Substances in Research.

Signature	Date

Authorization by Department Chair

I authorize the use of controlled substances as outlined in this protocol submission and certify that the researcher possesses appropriate licensure through DEA and VBP.

Signature	Date

Authorization by Division of Research & Economical Developemt

Signature	Date

APPENDIX B

SCHEDULES OF CONTROLLED SUBSTANCES
VIRGINIA CODE OF LAW

Be sure to check the following links for updated Schedules:

- **DEA**: http://www.deadiversion.usdoj.gov/schedules/
- **VA Board of Pharmacy**: http://www.dhp.virginia.gov/Pharmacy/