



Using Controlled Substances for Research

Policy Type: Administrative

Responsible Office: Office of Vice President for Research and Innovation

Initial Policy Approved: 05/28/2013

Current Revision Approved: 10/26/2016

Policy Statement and Purpose

Certain research activities conducted under the auspices of Virginia Commonwealth University require the use of controlled substances. In conducting research with controlled substances, authorized university members must comply with federal and state laws and regulations regarding appropriate use. These regulations cover the topics of obtaining and maintaining Drug Enforcement Agency (DEA) Registrations, storage requirements, inventory maintenance, substance disposal and reporting and record keeping requirements as outlined by both the DEA and the Code of Virginia.

University members using VCU resources, including facilities, or receiving funds administered by the university must comply with this policy and federal and state regulations relating to controlled substances.

Principal investigators using controlled substances in research must obtain a Virginia Board of Pharmacy Controlled Substances Registration and a Drug Enforcement Administration Registration prior to ordering or using controlled substances. Responsibilities associated with controlled substances are detailed and regularly enforced by VCU, Virginia Board of Pharmacy and the DEA. Those individuals not comfortable with assuming the responsibility and maintaining the required records are discouraged from applying for registration. Delegation of the administrative responsibilities is permitted; however, only the DEA registrant is permitted to have access to the inventory of controlled substances and to dispense controlled substances. Only full-time faculty members can be DEA registrants under this policy. Responsibility is individually based. Individuals who are fined or individuals suspected or found to have violated the law will not be reimbursed nor defended by VCU for criminal actions.

The vice president for research and innovation (VPRI) is the institutional official with ultimate responsibility for ensuring appropriate conduct of research at VCU. The VPRI is vested with the authority to suspend, revoke, or deny any researcher registration application submitted or registration issued through the state or federal processes, if necessary.

The senior associate vice president for research administration and compliance is the authorized official with responsibility for reviewing and approving DEA registration applications.

Exclusions

This policy does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license.

This policy does not cover teaching activity performed within a clinical environment.

Employee Responsibility to Report Drug Diversion

An employee who has knowledge of drug diversion associated with the actions of a fellow employee, student, or supervisor has an obligation to report such information to the Office of Research Subjects Protection or the VCU helpline.

Noncompliance with this policy may result in disciplinary action up to and including termination. Additionally, the university may suspend or terminate individuals or research, refer for academic misconduct proceedings and/or report to external licensing authorities. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth good faith concerns, asks clarifying questions, or participates in an investigation is prohibited.

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Who Should Know This Policy

All university members using controlled substances in research are responsible for knowing this policy and familiarizing themselves with its contents and provisions. University members using VCU resources or facilities or receiving funds administered by the university must comply with this policy and federal and state regulations relating to controlled substances.

Definitions

Authorized Official

The individual(s) formally authorized to be the “approver” of DEA registration applications on behalf of the institution. The authorized official for VCU is currently the senior associate vice president for research administration and compliance.

Authorized User

A university member authorized to use controlled substances by a DEA registrant.

Controlled Substance

Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end) and Title 54.1, Section 3400 of the Code of Virginia. Controlled substances are identified in the schedules contained within the “Controlled Substance Inventory List” published by the DEA.

DEA Registrant

A university member who holds a DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of controlled substances on his/her VCU Controlled Substance Research Protocols or DEA protocols.

Dispense

Prepare and distribute controlled substances to authorized users

Drug Enforcement Administration (DEA)

The agency within the United States Department of Justice that enforces the controlled substances laws and regulations.

Institutional Official

The vice president for research and innovation

Principal Investigator

The individual with final responsibility for the conduct of research or other activity described in a proposal or an award.

Registration

Formal grant of specific authority for controlled substances activities by the DEA and by the Virginia Board of Pharmacy. Often referred to as a license.

Research

A systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Researcher

Any university member who conducts research at VCU.

Teaching Activity

Activities that include classroom demonstrations, laboratory exercises and research projects which are required for completion of a course at the undergraduate, graduate or professional level.

Teaching Institution Registration

A DEA registration awarded to a teaching institution (for Schedules II-V only) overseen by an institutional practitioner.

University Member

All VCU full- and part-time faculty, classified employees, administrative staff, paid student assistants, students (under certain conditions as described in this policy), volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by sponsored program agreements or other contractual arrangements are considered university members for purposes of this policy.

Virginia Board of Pharmacy

The agency authorized by the Commonwealth of Virginia to implement and regulate Virginia statutes and Board of Pharmacy rules and to oversee the conduct and professional competency of Virginia Board of Pharmacy registrants.

Contacts

The Office of the Vice President for Research and Innovation officially interprets this policy. OVPRI is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the Office of Research and Innovation. Questions regarding the implementation of this policy may also be sent to controlsub@vcu.edu.

Policy Specifics and Procedures

Principal investigators using controlled substances in research must obtain a Virginia Board of Pharmacy Controlled Substances Registration and a Drug Enforcement Administration Registration prior to ordering or using controlled substances. An individual must be named and designated as providing research oversight on an approved DEA Research Protocol or VCU Controlled Substance Research Protocol to serve as a registrant for that protocol.

Activities associated with the use of controlled substances are outlined in the *Use of Controlled Substances in Research Manual*, which details procedures and provides instructions and suggested forms for complying with this policy.

Use of Controlled Substances in Research Manual

Topics include:

- Definitions
- Controlled Substance Definitions
- Registration and Inspection
- Institutional Registration
- Authorized Users
- Personnel Screening
- Roles and Responsibilities
- Training
- Ordering Controlled Substances
- Recordkeeping and Inventory Requirements
- Storage and Security
- Transporting Controlled Substances between University Buildings
- Disposal
- Theft or Significant Loss
- Virginia Board of Pharmacy and DEA Visits
- Diversion
- Close Out of Registration
- Forms

Please refer to this document for complete information. See Related Documents section.

Teaching Institution Registration

VCU's Division of Animal Resources (DAR) maintains an institutional registration. DAR will order veterinary controlled substances when a veterinary license is required and appropriately transfer them to a DEA registrant's inventory. DAR will not dispense controlled substances.

Oversight

The Office of Research Subjects Protection will assist DEA registrants in complying with applicable rules and regulations and provide information regarding regulatory requirements. The Office of Research Subjects Protection Research liaison analysts will review DEA registrants' controlled substance records and security measures as a part of post-approval monitoring.

Questions regarding the implementation of this policy should be sent to controlsub@vcu.edu.

Forms

1. DEA Form 225 – for Controlled Substances Registrations - online
(<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>)
2. Virginia Board of Pharmacy Application for a Controlled Substances Registration
(https://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm#csr)
3. DEA Form-222 Books – Purchasing and Transferring Substances I and II
(<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>)

4. DEA Form 106 – Reporting Theft or Loss
(<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>)
5. DEA Form 41 – Disposal of Unwanted Controlled Substances
(http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/)

All internal forms and templates listed below are located online at
http://www.research.vcu.edu/controlled_substances/index.htm

6. Personnel Screening Form
7. Authorized Users Signature Log – Schedule I Controlled Substances
8. Authorized Users Signature Log – Schedule II-V Controlled Substances
9. Controlled Substance Inventory Record
10. Controlled Substance Dispensing Record
11. Controlled Substance Usage Log
12. Controlled Substances Disposal Log
13. Controlled Substance Transfer Invoice

Related Documents

1. [21 CFR 1300 – 1399](#)
2. [Code of Virginia, Title 54.1, Section 3422](#)
3. [DEA Storage and Security requirements](#)
4. [Use of Controlled Substances in Research Manual](#)
5. [DEA Disposal Requirements](#)
http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/
6. Controlled Substances Training Modules – Blackboard Log-in site
<https://blackboard.vcu.edu/webapps/portal/frameset.jsp>
7. [DEA Practitioner's Manual](#)
<http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>

Revision History

This policy supersedes the following archived policies:

05/28/2013	<i>Interim Policy</i>
12/09/2013	<i>Using Controlled Substances for Research</i>
05/24/2017	<i>Using Controlled Substances for Research (updated hyperlink; uses updated policy template)</i>

FAQ

1. What are the DEA schedules or code numbers for the substances we are using?

A list of federally controlled substances is located here:

<http://www.deadiversion.usdoj.gov/schedules/index.html>

2. Who do I contact if I have questions relating to this policy?

Questions relating to this policy or implementation of controlled substances activities at VCU should first be posed to controlsub@vcu.edu.

3. What is the contact information for our local DEA office? Individuals assigned to VCU routinely change.

Please contact controlsub@vcu.edu for current contact information.

4. What are the names and addresses of some Controlled Substance sources?

NIDA Drug Supply For Class I-V 6001 Executive Boulevard, Rm 4262 Bethesda, MD 20892	Butler Schein, Inc. For Class III, IV & V 135 Duryea Road Melville, NY 11747	Butler Schein, Inc. For Class II 3820 Twin Creeks Dr. Columbus, OH 43204	Sigma-Aldrich, Inc. For Class I-V P.O. Box 18817B St. Louis, MO 63160
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5. Is there a supplier of double lock storage cabinets for controlled substances?

You can find standard narcotic cabinets by searching the internet for "Narcotic Cabinets." Please be aware that DEA regulations require that the cabinet be secured. Regulatory inspection officers checking drug storage facilities will confirm that cabinets/safes are secured properly.

6. I am retiring or leaving VCU. What do I do with my controlled substances?

All controlled substances must be transferred to another registrant who is authorized to receive such substances or disposed of in accordance with DEA regulations. Please see our [Disposal of Controlled Substances](#) webpage for detailed disposal information.

7. When do I start counting the two-year time frame required for the retention period of my records?

Records should be maintained for two years from the date of the last transaction on the record.