RES-013

Regulation of Controlled Substances in University Research

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Contact Office Vice President for Research (Office of the)

Oversight Executive
Vice President for Research

Applies To Academic Division, the Medical Center, and the College at Wise.

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Reason for Policy

The University has established requirements for the acquisition, storage, security, use, recordkeeping, and disposal of controlled substances in research. Due to stringent federal and state regulations, these substances require strict oversight. This policy mitigates key risks - such as diversion, unauthorized access, and misuse - which carry severe legal and professional consequences. Ultimately, these measures protect the integrity of the University's research mission by adhering to the Federal Controlled Substances Act, Drug Enforcement Administration, Virginia Board of Pharmacy, and institutional safety standards.

Definition of Terms

Controlled Substance (CS)

Description

Any drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of the Federal Controlled Substances Act (21 U.S.C. § 812), or any drug, substance, or immediate precursor listed in Schedules I through VI of the Virginia Drug Control Act (§ 54.1-3400 et seq.), including controlled substance analogs placed into Schedule I or II by the Virginia Board of Pharmacy.

Controlled Substance Database

Description

The University-maintained database containing all research-controlled substance registrations and associated compliance documentation.

Controlled Substance Program Manager

Description

The individual designated by the University to oversee the Controlled Substances Program and ensure compliance with Drug Enforcement Administration, Virginia Board of Pharmacy, and University requirements.

Controlled Substance Storage Locker

Description

A secure storage location for controlled substances inspected and approved by the Virginia Board of Pharmacy and/or the Drug Enforcement Administration in connection with a controlled substance registration application, with the approved storage location listed on the corresponding registration.

Drug Enforcement Administration (DEA) Registration

Description

A registration issued by the Drug Enforcement Administration to an individual to authorize activities involving controlled substances. There are two types of registrations:

DEA Practitioner Registration: Issued to an individual who is authorized under state law to prescribe, dispense, or administer controlled substances in the usual course of professional practice. Provides no authorization for activities involving Schedule 1 controlled substances.

DEA Researcher Registration: Issued to an individual to authorize them to purchase, possess, store, administer, dispense, or conduct research with one or more controlled substances. May authorize activities involving Schedule I controlled substances.

Registrant (1)

Description

An individual who holds a Drug Enforcement Administration and/or a Virginia Board of Pharmacy research-controlled substance registration.

Policy Statement

The University of Virginia (University) maintains this policy to ensure centralized awareness and oversight of all controlled substance (CS) registrations and controlled substance activities conducted under the University's authority. The objectives of this policy are to: (1) confirm that individuals seeking to obtain or maintain Drug Enforcement Administration (DEA) and/or Virginia Board of Pharmacy (VBP) controlled substance registrations are eligible and have a legitimate, documented need, as demonstrated through established and approved University research protocols; and (2) establish clear operational requirements that support compliance with applicable federal and state-controlled substance regulations.

The principles and requirements in this policy are intended to standardize and streamline the registration and compliance process, reduce administrative delays in obtaining and maintaining registrations, and promote consistent practices across the research community. These requirements also serve as safeguards to prevent diversion and other unsafe or non-compliant activities that may result in enforcement action, including civil or criminal penalties and the suspension or revocation of controlled substance registrations from federal and state agencies.

This policy applies to all persons who conduct or support University research involving controlled substances, including research conducted at University-operated field stations, e.g., Mountain Lake Biological Station. It governs the acquisition, possession, storage, security, recordkeeping, administration, and use of controlled substances maintained or used for University research, as well as the federal or state controlled substance registrations associated with those activities.

This policy also applies to research involving substances classified in Schedule I under the federal Controlled Substances Act, which may not be conducted under a DEA practitioner registration. **Specifically, a DEA practitioner registration does not authorize the registrant to purchase, possess, store, administer, dispense, or conduct research with a Schedule I controlled substance.** A University investigator needing to obtain, possess, or use a Schedule I controlled substance for research purposes must hold the appropriate DEA researcher registration authorizing the Schedule I research activity, as well as a Virginia Board of Pharmacy controlled substances registration authorizing Schedule I research at the applicable registered location (the physical address listed on a Drug Enforcement Administration and/or Virginia Board of Pharmacy Controlled Substance Registration where controlled substances must be shipped and securely stored when not in use).

Licensed veterinarians within the Office of Comparative Medicine who hold DEA practitioner registrations are also subject to this policy when controlled substances are acquired, possessed, stored, administered, or otherwise used in support of University research involving animals.

Physicians and other practitioners are not subject to this policy solely because they prescribe or administer controlled substances, other than Schedule 1, to human research participants as part of human clinical research approved by an Institutional Review Board and conducted through University-approved clinical pharmacy systems. ***Note:*** *Such clinical activities are subject to other applicable University requirements (e.g., Medical Center and Health System policies) and federal and state laws and regulations.* However, all other controlled substance research activities conducted by those individuals (e.g., laboratory-based or using live animals) remain subject to the requirements of this policy.

I. **Eligibility, Justification of Need, and Controlled Substance Registration Amendments:**
   Prior to VBP and DEA CS registration submission, the controlled substance program manager must review and approve all controlled substance registration applications and any amendments/changes to existing registrations for the following registration types:
   - **DEA (applications submitted on DEA Form 225):** Type of activity, including (but not limited to): manufacturer, importer, exporter, distributor, reverse distributor, researcher, canine handler, and analytical laboratory.
   - **Virginia Board of Pharmacy Controlled Substances Registration Certificate:** Type of activity, including (but not limited to): researcher, wholesale distributor, and analytical laboratory.
   - This review-and-approval requirement also applies to any request to modify an existing DEA or VBP registration, including (but not limited to) a change of location, change of responsible party, change of ownership, or change to authorized drug schedules.

II. **Appropriate Use and Security of Controlled Substances:**

Registrants may purchase, possess, and use controlled substances only for the research activities authorized under their own DEA and/or VBP research registration, as described in the registration application and associated research protocol submitted to and approved by the registering authority. Such authorization is limited to the specific purpose, scope, and activities identified in the approved application and does not extend to other research projects, protocols, or registrations. Sharing, supplying, or transferring controlled substances between unaffiliated research projects or registrations is strictly prohibited. Registrants may only purchase controlled substances for use on projects covered by their own DEA and/or VBP research registration application.

Controlled substances must be stored in a secure, DEA and VBP compliant storage locker at the registered location.

Access to controlled substance storage lockers must be controlled by a minimum four-digit combination locking mechanism. Use of a keyed locker is permitted only if the key is maintained in a separate lockbox secured by a minimum four-digit combination lock. Keys may not be hidden, unsecured, or stored within laboratory spaces, as such practices do not provide adequate security.

When an individual authorized by the registrant to access controlled substances is no longer authorized due to a change in employment, change in title, or for any other reason, the combination to the key lockbox and/or the controlled substance storage locker must be changed immediately. In addition, any electronic key card access, laboratory key access, or other physical or electronic access controls that permit entry to controlled substance storage areas must be revoked promptly, where applicable, for individuals who are no longer authorized to access controlled substances.

III. **Controlled Substance Use, Inventories, Disposal, and Incident Reporting:**

Accurate records of controlled substance receipts, use, disposal, and biennial inventories must be maintained and retained for a minimum of two years in accordance with applicable federal and state recordkeeping requirements. Records must be retained beyond this minimum period when required by University Policy IRM-017: Records and Information Management and the applicable University records retention schedules.

Any suspected or confirmed loss, theft, or diversion of controlled substances must be reported immediately upon discovery to the controlled substance program manager, who will provide guidance and coordinate required reporting to the UVA Police Division, the Drug Enforcement Administration, and the Virginia Board of Pharmacy in accordance with the Theft / Loss Reporting – DEA Form 106 Guidance Standard Operating Procedure (SOP).

Controlled substances must be disposed of only with the guidance of the controlled substance program manager.

Individuals will report suspected non-compliance or other concerns directly to the CS Program Manager for expeditious handling; alternative reporting methods, including ones that allow the reporter to remain anonymous, are available on the University Office of Audit & Compliance website.

IV. **Controlled Substance Database Compliance Requirement:**

The Controlled Substance Program maintains a database of all controlled substance research registrants at the University of Virginia. This database supports compliance monitoring, including registration status, authorized location(s), schedules, authorized personnel, expiration/renewal dates, and current contact information, and it enables timely communication regarding changes that may affect a registrant's requirements under federal and state regulations. The database is also accessed by the DEA to support annual renewal approval of DEA research registrations.

Each registration holder is solely responsible for keeping their database records accurate and up to date, including promptly updating renewal/expiration information and uploading revised DEA and VBP registrations when they are renewed or amended. Maintaining current information in the CS database is a condition of holding a CS registration at the University. Participation is mandatory.

V. **Standard Operating Procedures Supporting Controlled Substances in Research:**

Procedures supporting this policy are maintained by the controlled substance program manager, in coordination with the Office of the Vice President for Research. These procedures define the University's operational requirements for controlled substances, including registration and amendments (DEA and VBP), required training and authorization, procurement and receiving, secure storage and access control, recordkeeping and inventory, compliance checks/inspections and corrective actions, and disposal/destruction processes for unwanted or expired controlled substances.

Detailed procedures (e.g., SOPs, forms, checklists, and guidance documents) are maintained separately from this policy, reviewed periodically, and may be revised as needed to reflect changes in federal or state regulations, agency guidance, University requirements, and audit or compliance findings.

All controlled substance activities must be conducted in accordance with established University of Virginia SOPs and policy and applicable federal and state regulations, including (but not limited to) authorized use by approved personnel, record-keeping, storage, security, and disposal. Compliance is required.

VI. **Compliance with Policy:**

Consequences of non-compliance with UVA established Policy and state and federal regulations regarding controlled substances include:

A. **Institutional Action:**

Non-compliance with University of Virginia SOPs and Policy, or with applicable state and federal regulations regarding controlled substances, may result in referral to the Office of the Vice President for Research for review and consideration of appropriate disciplinary action, up to and including termination or expulsion, in accordance with University policies and procedures.

B. **Regulatory Referral:**

In cases of serious or egregious violations of these requirements, referrals may be made to the Drug Enforcement Administration and/or the Virginia Board of Pharmacy for review and possible disciplinary action at the federal and/or state level. Such actions may include (but not limited to) suspension or revocation of controlled substance registrations and may also subject individuals or entities to civil or criminal penalties as provided by applicable federal and state law.

Direct question about this policy to the Office of the Vice President for Research or contact the controlled substance program manager at controlledsubstances@virginia.edu.

Procedures

Procedures/SOPs (behind Netbadge)
CS Database (behind Netbadge)

Related Information

Controlled Substances Act (21 U.S.C. § 801 et seq.) 21 CFR Parts 1301, 1304, 1308, and 1317
Virginia Drug Control Act (§ 54.1-3400 et seq.)
Virginia Board of Pharmacy Regulations (18VAC110-20)
Virginia Board of Pharmacy Regulations (18VAC110-20-720)
University Policy IRM-017: Records and Information Management

Major Category Research Administration

Next Scheduled Review Friday, October 12, 2029

Revision History

This is a new policy.

Approved Date Tuesday, October 6, 2026