Use of Controlled Substances In Research Manual

June 2021

This manual and all forms are posted online at:

https://research.vcu.edu/integrity-and-compliance/compliance/controlled-substances/

Questions about the information in this manual can be sent to:

controlsub@vcu.edu

Contents

Introduction

This manual describes the procedures for complying with Virginia Commonwealth University's (VCU's) policy, *Use of Controlled Substances in Research*.

All individuals involved in the use of controlled substances for research must know and comply with all state and federal regulations regarding the procurement, record keeping, inventory, storage, use, and disposal of those substances.

Principal Investigators (PIs) using controlled substances in research must obtain a Virginia Board of Pharmacy (VBOP) Controlled Substances Registration and a Drug Enforcement Administration (DEA) Controlled Substance Registration Certificate prior to ordering or using controlled substances. Only individuals named and designated as providing research oversight on an approved VCU Institutional Animal Care and Use Committee (IACUC) or Controlled Substance Research protocol may serve as a registrant for that protocol. The responsibilities associated with controlled substances are numerous, detailed, and regularly enforced by VCU, VBOP, and the DEA. Delegation of the administrative responsibilities is permitted; however, the registrant is ultimately responsible for all activities occurring under their registration. For this reason, the Office of the Vice President for Research and Innovation (OVPRI) strongly discourages individuals from applying for registrations if those individuals are not comfortable with or do not have the capacity to assume the responsibility of ensuring that procedures are properly followed and that the required records are properly maintained. Individuals who are fined or who have violated the law will not be reimbursed by VCU for their legal defense.

VCU will not pay any fines or damages resulting from noncompliance with federal, state, and local regulations, or resulting from noncompliance with university policies; such fines or damages are the sole responsibility of the individual.

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 or deny any researcher's controlled substances registration application or to suspend or revoke any researcher's controlled substances registration.

Questions about obtaining controlled substances, secure storage, use, disposal, required documentation, or regulatory questions regarding controlled substances in research should be directed to controlsub@vcu.edu.

The OVPRI offers controlled substances education sessions for employees (including faculty) and students.

Definitions

Authorized User
An individual authorized by a registrant to use controlled substances under the registrant's direction. Completion of appropriate training is required.

Bulk Form
A controlled substance, as received from the manufacturer or supplier, "to be used in, or capable of use in, or being used in, the manufacture of the same or other Controlled or non-Controlled Substances in Finished Form." (21 CFR §1304.22(a)(1)) Bulk form substances may be dispensed to authorized users for a single day. Unused bulk form substances must be returned to the registrant at the end of each day.

Controlled Substance
Any substance listed in the Controlled Substances Act (21 CFR, part 1300 to end) or Title 54.1, Section 3400 of the Code of Virginia. Lists of Scheduling Actions, Controlled Substances, and Regulated Chemicals are published by the DEA.

Dispense
The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject. (21 USC §802(10))

Disposal
Relinquishment of contaminated, expired, excess, residual (or waste), or unwanted controlled substances.

Division of Animal Resources (DAR)
A division of the Office of the Vice President for Research and Innovation that provides a humane and high quality animal care and use program to facilitate research and teaching at VCU.

Drug Enforcement Administration (DEA)
The agency within the United States Department of Justice that enforces the controlled substances laws and regulations.

Expired and/or Unusable Substances
Controlled substances for which the expiration date has passed. Or tablets, injections, liquid, or preparations compounded in error that contain controlled substances that can no longer be used for research due to contamination, etc.

Finished Form
A controlled substance altered from bulk form (diluted, compounded, etc.) that will be used for research, i.e. bulk form diluted 1:10 becomes finished form. Finished form substances may be retained by authorized users until depleted.

Principal Investigator
The individual with overall responsibility for the conduct of research or other activity described in a proposal, protocol, or an award, and/or the individual with fiduciary responsibility for award management.

Recordkeeper
An individual assigned by the registrant to assist with the registrant's records. The recordkeeper is not authorized to dispense substances, enter new substances into inventory, or dispose of substances. The

recordkeeper provides only data entry services. The registrant is responsible for all actions and records of the recordkeeper.

Registrant
A full-time faculty member who holds a DEA or VBOP registration and who is responsible for ordering, storing, using, record keeping, and disposing of controlled substances on their IACUC or VCU Controlled Substance Research protocols. Completion of appropriate training is required.

Registration
Formal grant of specific authority for controlled substances activities by the DEA and by the VBOP. Often referred to as a license or certificate.

Research
A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research may be defined in additional detail in certain contexts.

Reverse Distribute
To acquire controlled substances from another registrant or law enforcement for the purpose of:
(1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or
(2) Destruction. (21 CFR §1300.01)

Reverse Distributor
A person registered with the [Drug Enforcement] Administration as a Reverse Distributor. (21 CFR 1300.01)

Transfer
To move a controlled substance from the inventory of one DEA registrant to another DEA registrant. In Virginia, those holding a controlled substances researcher registration can transfer controlled substances only to a reverse distributor.

Usage Log
A document completed by each registrant and authorized user tracking usage of controlled substances. The registrant must keep controlled substances usage logs for a minimum of two (2) years from the date of the last transaction.

Virginia Board of Pharmacy (VBOP)
The regulatory board under the Department of Health Professions with “authority to license and regulate the dispensing of Controlled Substances by practitioners of the healing arts.” (§ 54.1-3304.1.)

VCU Controlled Substances Inspection Information Form
The form used by the OVPRI to gather the information required by the local DEA office prior to scheduling inspections related to the registration application process.

Controlled Substance Definitions

According to the DEA Diversion Control Division, "[d]rugs and other substances that are considered Controlled Substances under the Controlled Substances Act (CSA) are divided into five schedules. […] Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused." Definitions of Controlled Substance schedules can be found here: https://www.deadiversion.usdoj.gov/schedules/#define.

Both the DEA and VBOP use Schedules I-V to classify controlled substances. In addition, Virginia has a Schedule VI class of controlled substances. The classes of drugs and devices that fall under Schedule VI can be found at § 54.1-3455 of the Code of Virginia. See here for the full regulation: https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3455/

Template Forms

When using controlled substances in research, registrants are required to complete and maintain specific documentation. They must keep records regarding their authorized users (Personnel Screening Form – Authorized User, Authorized Users Signature Log) and regarding their controlled substances (inventory, dispensing, usage, and disposal). Template forms can be found on our website at https://research.vcu.edu/forms/#d.en.412602

Although the OVPRI does not require the use of these specific forms, it does recommend the use of these templates because they incorporate all required elements from the applicable regulations. Any forms used must meet the requirements of all regulations.

To ensure best compliance practices, registrants should establish a consistent documentation process. Documents may be maintained electronically, so long as they can be printed and presented to DEA investigators as requested.

Who Must Register

Full-time faculty members who store, administer, or order controlled substances for VCU IACUC or Controlled Substance Research protocols on which they are a contributing investigator must register with both the VBOP and the DEA (for Schedules I-V) or the VBOP only (for Schedule VI). To be a registrant, the individual must have oversight of the research on a protocol.

Those needing only a Schedule VI registration from the VBOP do not need to complete the VCU registrant training titled "Use of Controlled Substances in Research." In addition, those with only a Schedule VI registration do not need to complete a Personnel Screening Form – Authorized User for each of their authorized users.

Separate Registrations for Separate Locations

Registrations must be for the specific location where the controlled substances are stored. This means that a registrant seeking to store controlled substances in multiple locations (labs) must have multiple registrations.

Registrants Holding Clinical Practitioner Registrations

A practitioner registration from the DEA allows for **clinical** research and instructional activities with the controlled substances for which the registration was granted. A practitioner registration does not authorize use of controlled substances for animal research or chemical analysis! A separate researcher registration is required for these activities.

Registration and Inspection

It is the responsibility of each registrant to obtain the required registrations and to comply with applicable state and federal regulatory requirements when working with controlled substances. Registrants must maintain current registrations until all of their controlled substances are spent or disposed of.

The registrations must be for the specific location where the controlled substances are stored. Use the street address and room number of where the controlled substances will be stored and include the proper six-digit VCU Box Number. A registrant seeking to store controlled substances in multiple locations (labs) must have multiple registrations. To request a copy of a sample completed application or form, email controlsub@vcu.edu.

The information that appears on your VBOP and DEA researcher registrations must match each other and should reflect the controlled substances you use in your research. Registrations should cover the schedules you need for your approved research protocol.

To Obtain a New Virginia Board of Pharmacy Registration

1) Print the application and complete it. The VBOP requires an original signature, so do not fax or scan it. To request a copy of a sample completed application, email controlsub@vcu.edu.

   Here is a link to the application form:
   http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm#csr

2) Check the "New" box.
   There is a fee for a new application.

3) Be sure to include the proper six-digit VCU Box Number in addition to the street address, so the registrations do not get lost in the mail - this has been an issue for a number of registrants. According to the VBOP, they can send mail only to the controlled substances storage location address or to a building box.

4) Check the boxes for all “Controlled Substance Schedules” you require.

5) Attach to the application a brief write-up summarizing your protocol (its purpose), listing the controlled substances you will be using, and explaining how you will be using those controlled substances (the purpose of the controlled substances in your protocol). **Do NOT submit your full IACUC protocol** - whatever you submit becomes public.

6) Attach your CV.

7) Mail the completed application to the VBOP address at the top of the application.

8) Prior to issuance of a Controlled Substances Registration, the VBOP will schedule a time for inspection. The registrant must be present for the inspection and must be prepared to answer questions regarding the entire path of the controlled substance from when and where it is ordered to how it is safely brought to and secured in the location/lab.

Unlike for Schedules II-VI, a request for a Schedule I registration must be approved by the DEA prior to VBOP approval. A copy of the DEA registration must be sent to the VBOP, so that the Virginia Controlled Substance Registration can be updated to reflect Schedule I.

To Obtain a New DEA Registration

1) Complete the online application (DEA Form 225) at:
https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm

To request a copy of a sample completed application, email controlsub@vcu.edu.

Note that there is a separate application for Schedule I registrations. This means that those needing a registration for Schedule I-V controlled substances must complete two applications - one for Schedule I and one for Schedule II-V.

In addition, applications for Schedule I registrations must address the federal requirements that appear in 21 CFR §1301.18. Here is a link to the applicable regulation:
https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_18.htm

We have developed a template form that can be used to address the 21 CFR §1301.18 requirements. To request the template form, email controlsub@vcu.edu.

2) Be sure to include the proper six-digit VCU Box Number in addition to the street address, so the registrations do not get lost in the mail - this has been an issue for a number of registrants.

3) On DEA applications, you can include a separate mailing address. Again, include the proper six-digit VCU Box Number.

4) Be sure to check the box for “CERTIFICATION FOR FEE EXEMPTION” on page 2 of Form 225. To obtain fee exemption, the VCU Authorized Official (Sr. Associate VP for Research Compliance) must be listed on the "Fee Exempt Details" page of DEA Form 225.

VCU Controlled Substances Inspection Information Form
The local DEA has established a process for gathering information and scheduling inspections for registration applicants. Those seeking a DEA registration must complete a VCU Controlled Substances Inspection Information form. Once notified that the DEA requests a completed VCU Controlled Substances Inspection Information form, registration applicants should submit the completed and signed form and all required attachments to controlsub@vcu.edu as soon as possible.

To request a copy of a sample completed VCU Controlled Substances Inspection Information form, email controlsub@vcu.edu.

Be sure to use the sample as your guide! When completing the form, also keep in mind the following:

- Be sure to attach all requested documents, including: completed Personnel Screening Form – Authorized User for all authorized users, current CV, copy of drug logs (if not using OVPRI's template), copy of VBOP registration, and picture of the storage location/container.
- Be sure to include which supplier(s) you intend to use to obtain your controlled substances. DAR cannot act as a supplier at any time!
- Be sure to sign and date the form! Typing in one's name is not a signature.

When compiling the packet of information to be sent to the local DEA, OVPRI will include floor plans based on the registration address listed on your form, copies of log templates (if the appropriate box is checked), and information regarding VCU's procedures for reverse distribution.

The local DEA will schedule inspections, through OVPRI, *only after* receipt and review of the completed inspection packet.

DEA Inspections
The OVPRI coordinates the scheduling of DEA inspections. Prompt responses to requests for availability are not only appreciated, but also may expedite the inspection process.

The registration applicant must be present for the inspection.
Registration applicants must be prepared to answer questions regarding the entire path of the controlled substances listed in their application from when and where it is ordered to how it is safely brought to and secured in the location/lab.

After Receiving the Registrations

As each registration is received, send a copy to controlsub@vcu.edu. The OVPRI maintains a database of all controlled substances researcher registrations.

DEA and VBOP researcher registrations are active for a one (1) year period.

Changes to Registrations

If any aspect of a registration changes, such as address or schedule, etc., the DEA and VBOP must be notified.

If a registration must be updated because the controlled substances will be stored in a new location, the controlled substances cannot be moved to the new location until after the DEA and VBOP have inspected the new location and approved of the change.

For changes to a DEA registration, registrants must submit a DEA Registration/Application Update Request online. The link to the "Make Changes to My DEA Registration" form can be accessed here: https://www.deadiversion.usdoj.gov/drugreg/index.html#2

For changes to a VBOP registration, registrants must submit an application form with the appropriate "change" boxes checked. Here is a link to the application form: https://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm#csr

After submitting a request for changes to your registration, notify OVPRI of the submitted request by sending an email to controlsub@vcu.edu.

If any aspect of a registration changes, such as address or schedule, etc., the DEA and VBOP will issue updated registrations. Send copies of the updated registrations to controlsub@vcu.edu for our records as soon as each is received.

Adding Controlled Substances to Already Approved Registrations

If a registrant is already approved for a specific schedule (Schedules II-VI) and would like to add a controlled substance within the same schedule to their research protocol, no additional submissions/requests need to be made to the DEA or to VBOP for changes in specific controlled substances under those schedules. However, the registrant should ensure that their research protocols have been updated to reflect any changes in controlled substances.

Any changes in controlled substances for a Schedule I registration require the submission of supplemental research protocols and DEA Headquarters approval. Registrants must log in to their DEA registrations online and request modification to their current Schedule I researcher registration by adding the needed/requested drug codes. Supplemental research protocols are processed the same way as original research protocols. If needed, the DEA will request additional information regarding the supplemental research protocol.

After submitting a request for changes to your registration, notify OVPRI of the submitted request by sending an email to controlsub@vcu.edu.

Registration Renewals

Virginia Board of Pharmacy Registrations
The VBOP researcher registration covers a one (1) year period. There is an annual fee. A late fee is charged for late renewals.

Although the VBOP registrations no longer show expiration dates, be aware that VBOP registrations expire at the end of February each year.

In mid-January, the registrant should receive a renewal notice from VBOP with instructions on how to renew. If the registrant does not receive such a notice by the end of January, the registrant should contact VBOP.

If you are a new user or have forgotten your login information, you will need to sign up to create a user ID and password using the license number and temporary PIN you received in the mail. Click the New User button to get started.

Please note that because VCU registrants are categorized as facilities (Controlled Substances Registration (CSR) Businesses), the facilities/CSR screens need to be used when renewing the VBOP registration online. On the default page, be sure to click "Facility Sign Up."

If you would like to make changes to your VBOP registration, email controlsub@vcu.edu.

If you do not intend to renew your VBOP registration, you must email controlsub@vcu.edu. DEA registrants will need to coordinate the immediate termination of their DEA registrations. A valid VBOP registration is a prerequisite for a DEA registration; a DEA registrant who does not maintain a valid VBOP registration is in violation of federal regulations and can be issued a Letter of Admonition by the DEA.

DEA Registrations
For DEA researcher registration renewals, complete Form 225a online. See here: https://www.deadiversion.usdoj.gov/drugreg/index.html#regapps

Be sure to check the box for “CERTIFICATION FOR FEE EXEMPTION” on page 2 of Form 225a. To obtain fee exemption, the VCU Authorized Official (Sr. Associate VP for Research Compliance) must be listed on the "Fee Exempt Details" page of DEA Form 225a.

Make sure that registrations are renewed in a timely manner. Expired registrations are inactivated by the DEA after one (1) month. This means that the registrant will need to re-apply to get a new registration.

Registrants should place a renewal reminder on their calendar three (3) and two (2) months prior to expiration. The issuing of DEA reminder notices by mail and email can be inconsistent.

Send copies of renewed registrations to controlsub@vcu.edu for our records as soon as each is received.

Federal law prohibits the handling of controlled substances under an expired registration.

If you do not intend to renew your DEA registration, or you would like to make changes to it, email controlsub@vcu.edu.

Authorized Users

The registrant is individually responsible for adhering to federal and state regulations and to university policies pertaining to the possession and use of controlled substances. If needed, the registrant may identify individuals to be authorized users. The registrant must ensure that Human Resources (HR) has completed a background check for the authorized user (if required) and that any findings were evaluated. In addition, the registrant must complete an annual review of the Personnel Screening Form – Authorized User for each authorized user.

Personnel Screening Form – Authorized User

To comply with DEA guidance, VCU requires that all authorized users complete the Personnel Screening Form – Authorized User prior to the handling of any controlled substances and on a yearly basis (such as at the time of renewal of the VBOP registration). (21 CFR §1301.90)

The Personnel Screening Form – Authorized User includes the following questions:

1) Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date, and sentence on a separate page.
2) In the past three years, have you ever knowingly used any controlled substances (marijuana, narcotics, amphetamines, or barbiturates, etc.) other than those prescribed to you by a physician? If the answer is yes, furnish details on a separate page.
3) Have you ever been denied a DEA registration, had a DEA registration revoked or surrendered a DEA registration for cause? If yes, please describe the basis for the DEA's action and provide the date this action occurred on a separate page.

If the answer to any of the above questions is "Yes," the registrant must email controlsub@vcu.edu immediately regarding next steps, and the applicant authorized user cannot sign the Authorized Users Signature Log.

Authorized users must notify the registrant immediately if the answer to any of the Personnel Screening Form – Authorized User questions changes to a "Yes."

The registrant must retain this completed form in a secure confidential file.

Roles and Responsibilities

OVPRI:

- Provide guidance to faculty members for registering with VBOP and DEA.
- Provide guidance on storage of controlled substances.

- Provide guidance on disposal of controlled substances.
- Provide training on VCU's policies and procedures regarding use of controlled substances in research.
- Increase awareness of and accountability for compliance when using controlled substances in research.

Registrants:

- Comply with federal and state regulations and university policy pertaining to the possession and use of controlled substances. The registrant is individually responsible for adherence to VCU policies, VBOP regulations, and DEA regulations.
- Obtain and maintain VBOP and DEA registrations.
- Retain a record of having completed the VCU registrant training titled "Use of Controlled Substances in Research." See "Training" section below.
- If needed, identify and document individuals as authorized users.
- Ensure that HR has completed a background check for the authorized user(s) (if required) and that any findings were evaluated.
- Complete an annual review of the Personnel Screening Form – Authorized User for each authorized user.
- Maintain documentation for current authorized users.
- Provide and maintain documentation on training of laboratory-specific operations involving controlled substances.
- Ensure proper storage of controlled substances; maintain strict control over security of location and of inventory of records.
- Obtain VBOP and DEA approval for schedule changes prior to ordering, inventorying, dispensing, or disposing of such substances.
- Dispense no more than daily usage amounts of bulk form substances to authorized users. Finished form substances can be retained until depleted. Usage logs must be maintained for both types.
- Schedule I, Schedule II, and Schedule III-V controlled substances cannot be stored together! For each of these three categories, the registrant must maintain a separate storage area and a separate set of drug logs (inventory, usage logs, etc.).
- Schedule VI drugs should be kept out of sight when not in use and behind a locked door or cabinet when the registrant is not present. Schedule VI drugs do not need to be locked in a safe and do not require a usage log.
- Receive, store, use, and dispose of controlled substances properly.
- Complete all drug logs contemporaneously as controlled substances are received, used, and disposed.
- Retain drug logs (inventory record, dispensing record, usage log, wastage record, and disposal log) for two (2) years after complete use or disposal of controlled substances.
- Exercise signature authority for purchases and disposal of controlled substances.
- Conduct an initial inventory.
- Conduct a biennial inventory.
- Report the theft or loss of any controlled substance to the DEA Field Division (using Form 106), VBOP, VCU Police, and controlsub@vcu.edu within one (1) business day of discovery of such loss or theft.
- Dispose of unwanted controlled substances using a reverse distributor in accordance with DEA regulations.
- Dispose of controlled substances no longer supported by an approved protocol.

- Upon receipt, send copies of current VBOP and DEA registrations to controlsub@vcu.edu.
- Report lapse of VBOP or DEA registration to controlsub@vcu.edu immediately.
- Report VBOP or DEA inspections to controlsub@vcu.edu immediately.

Authorized Users:

- Complete the "Use of Controlled Substances in Research" course in Canvas and provide record of completing the course to the registrant. See "Training" section below.
- Complete the Personnel Screening Form – Authorized User before commencing use of controlled substances. Thereafter, annually review Personnel Screening Form – Authorized User, as needed.
- Sign the Authorized Users Signature Log (Note: separate logs are kept for Schedule I and Schedule II-V controlled substances).
- Complete Usage Log sheets – Controlled Substance Usage Log and Wastage Record.
- Store controlled substances in an individual lockbox, marked with the authorized user's name, or a laboratory-level lockbox, in a locked cabinet.
- Return any unused bulk form controlled substances and the usage log sheet to the registrant after each day.
- Return usage log sheets for finished form controlled substances when a substance has been fully used or is no longer needed.
- Immediately report any discrepancy or suspected theft to the registrant.
- Receive laboratory-specific training from the registrant or other authorized user before using controlled substances.
- Immediately report to the registrant any felony or misdemeanor violations/convictions.

Training

All individuals involved in the use of controlled substances (Schedules I-V) must complete training prior to handling any controlled substance. Individuals can self-enroll on the Canvas site. The Canvas course is titled "Use of Controlled Substances in Research." After completion of the training course, registrants should save or print the page reflecting their passing score and retain it for their records. Authorized users must provide registrants with the page reflecting their passing score, so that it can be kept with the authorized users' Personnel Screening Forms.

Ordering Controlled Substances

Registrants can order only the controlled substances used in their research – the registrations should cover only the schedules needed for the registrants' approved research protocols.

Stocks of controlled substances must be kept to the smallest quantity needed.

DAR cannot dispense controlled substances. DAR cannot act as a supplier at any time.

Orders for controlled substances must include a request signed by a registrant and go through standard VCU procurement processes.

Controlled substances can be ordered through standard procurement processes with the following additional requirements:

Schedule I or II
Any person registered to conduct research with controlled substances in Schedule I or II must use DEA Form 222. DEA Form 222 can be requested here:
https://www.deadiversion.usdoj.gov/online_forms_apps.html

Along with the order request and the DEA Form 222, a copy of the DEA registration must be included.

Schedule I Controlled Substances That are not Commercially Available
Requests to obtain Schedule I controlled substances that are not commercially available must be made to the National Institute on Drug Abuse.

National Institute on Drug Abuse (NIDA) Drug Supply Program (DSP)
The NIDA Drug Supply Program (DSP) provides for research purposes various controlled drugs, other chemical substances, marijuana, and nicotine research cigarettes to research investigators working in the area of drug abuse, drug addiction, or related disciplines at academic institutions. To obtain research chemicals and controlled substances from the NIDA DSP, research investigators must prepare a Request Package. Complete details are available at Ordering Guidelines for Research Chemicals and Controlled Substances.

Schedules III-V
Schedules III-V controlled substances may be ordered by a registrant through standard procurement processes.

Record Keeping and Inventory Requirements

The following records must be maintained at the DEA registrant's location (the address that appears on the DEA registration):

- Training completion records for registrant and authorized user(s)
- Personnel Screening Form – Authorized User for each authorized user(s)
- Executed order forms
- Receiving record or purchase receipt that is verified, signed, and dated
- Inventory records (Must be kept a minimum of two (2) years from date of last transaction. After the two (2) years have passed, the records may be shredded.)
- Controlled Substance Usage Logs (Must be kept a minimum of two (2) years from the date of last transaction. After the two (2) years have passed, the records may be shredded.)

All controlled substance records must be kept separately from all other records, in or near the primary work area, and must be available for inspection at any time by VCU representatives, DEA, or VBOP inspectors.

Registrants may identify an individual to assist with record keeping requirements. The recordkeeper cannot dispense controlled substances, enter new controlled substances into inventory, or dispose of

controlled substances. The registrant remains responsible for all actions and records of the registrant's recordkeeper.

Controlled Substance Receiving
Controlled substances must be shipped directly to the registrant at the address that appears on the registration. Once received, the controlled substances must be opened and the contents verified by the person receiving the controlled substance. Any discrepancies must be rectified with the supplier and/or shipper. If discrepancies cannot be rectified, the registrant must contact the DEA and email controlsub@vcu.edu to report this within five (5) business days.

Once the registrant has verified that the shipment is correct, the registrant must sign and date the purchase receipt and file it with the registrant's controlled substances records.

Controlled Substance Dispensing and Tracking
The DEA registrant is the only individual who can dispense controlled substance from inventory. From the time a controlled substance is received on campus until it is fully used or disposed of, a record of the chain of custody and usage must be kept. Each point at which the controlled substance changes hands or is used must be documented. The documentation must be completed at each point by the registrant dispensing the controlled substance and must include the controlled substance, quantity, date dispensed, and the recipient's initials.

Each quantity of a controlled substance must be accounted for in the dispensing records. Template Controlled Substance Dispensing Record, Controlled Substance Usage Log, and Wastage Record forms can be found in the "Forms" section of the Controlled Substances web page.

Controlled Substances Cannot Be Transferred
As set forth in 21 CFR 1307.11, a practitioner/researcher who is registered to dispense may distribute limited amounts of controlled substances to another practitioner/researcher for the purpose of general dispensing, if certain conditions are met. Among these conditions is that the amount a practitioner so distributes to other practitioners during a calendar year cannot exceed five percent of the total number of dosage units of all controlled substances that the practitioner/researcher dispenses and distributes during that year. *Id*. at 1307.11(a)(1)(iv). This provision of the regulations is often referred to as the "five percent rule."

According to the deputy executive director of the Virginia Board of Pharmacy, the five percent rule does not extend to researchers in Virginia; the five percent rule applies only to pharmacies.

The federal five percent rule does not supersede state regulations that prohibit such distributions.

Inventory Procedures
After a DEA registration is first issued, a registrant must take an initial inventory. An inventory is a count of all controlled substances in the registrant's possession. The inventory must reflect a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count. ***On the initial inventory, a registrant should start by recording a zero inventory. On the initial inventory, the table will be blank because the registrant should have zero inventory. Once controlled substances are ordered and received, a new inventory must be created.***

Each DEA registrant must maintain an inventory. The inventory must be:

- Maintained at the registered location.
- Available for two (2) years after the controlled substance is used or is disposed.
- Completed every two (2) years (biennially) to comply with DEA regulations. (21 CFR 1304.11) The biennial inventory may be taken on any date within two (2) years of the previous biennial inventory date and must show whether it was performed at the opening or closing of the day.
- Updated on the effective date when a controlled substance is added to any schedule (List of Controlled Substances).

Inventories of Schedule I and Schedule II controlled substances must be maintained separately from those for all other controlled substances, i.e., a registrant with Schedules I-V controlled substances must keep three separate inventories – one for Schedule Is, one for Schedule IIs, and one for Schedules III-V.

The inventory must contain the following information:

- Date of inventory
- Exact time of inventory and whether at start or close of business
- Name of DEA registrant and DEA registration number
- Location of inventory

The person conducting the inventory and a witness must sign and date the inventory record.

- **For controlled substances in bulk form**, the inventory record must include:
    - Name of controlled substance
    - Lot #
    - Schedule
    - Drug form (bulk or finished)
    - Number of units/volume
    - Supplier
    - Date acquired

- **For controlled substances in finished form**, the inventory record must include:
    - The name of the substance
    - Each finished form of the substance (e.g., 10-milligram (mg) tablet or 10 mg concentration per fluid ounce or milliliter (ml))
    - The number of units or volume of each finished form in each container (e.g., 100-tablet bottle or 3 ml vial)
    - The number of containers of each such finished form (e.g., four 100-tablet bottles or six 3 ml vials)

- **For each substance that is expired, damaged, defective, or impure awaiting disposal; or held for quality control purposes; or maintained for extemporaneous compounding**, the inventory record must include:
    - Name of substance
    - Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form (e.g., fifty 10 mg tablets or 10 ml of 50 mg/ml)

- Reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.
- Best practice is to store substances in this category separately within the registrant's inventory, i.e., a separate compartment, box, or bag within the storage area.

The template Controlled Substances Inventory Record form should be used for the above described purposes.

Labeling Requirements
All containers of controlled substances must be properly labeled. If the laboratory re-packages, compounds, or dilutes controlled substances, appropriately label the repackaged, compounded, or diluted substance and store it in the safe. The label on diluted or combined controlled substances that will be stored in the safe overnight or longer must include the following information:

- Name of controlled substance
- Final concentration of controlled substance
- Volume per container
- Expiration date (must be no more than 30 days after dilution)

Storage and Security

DEA registrants are responsible for establishing and maintaining effective controls and procedures against unauthorized access to controlled substances.

The storage, handling, and documentation of controlled substances must adhere to all applicable state and federal laws.

The DEA registrant must restrict access to locked rooms and locked storage cabinets containing controlled substances.

Schedule I, Schedule II, and Schedules III-V controlled substances cannot be stored together! For each of these three categories, the registrant must maintain a separate storage area and a separate set of drug logs (inventory, usage logs, etc.).

Safes/storage containers for controlled substances cannot be shared with other registrants!

All controlled substances must be stored in a "securely locked, substantially constructed cabinet" as per federal regulations. If storing Schedule I or Schedule II controlled substances, the cabinet must be permanently constructed or attached to a building structure to prevent physical removal. Registrants can find standard narcotic cabinets by searching for "narcotic cabinets" on the internet. DEA regulations require that the cabinet be secured so that it cannot be removed. A locked drawer in a lab bench that is bolted to the floor or wall is generally sufficient.

DEA registrants must keep controlled substances in a substantially constructed, securely locked cabinet (safe) that meets DEA requirements.

- For Schedule I, the controlled substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled controlled substances, with the cabinet secured to a wall or otherwise not removable, as per federal regulations.
- For Schedule II, the controlled substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled controlled substances, with the cabinet secured to a wall or otherwise not removable, as per federal regulations.
- For Schedules III-V, the controlled substance must be in a locked cabinet or safe.

All controlled substances must be kept locked in their storage location except for the actual time required to remove, legitimately work with, and replace them.

All controlled substance shipments must be processed and stored in a secure cabinet as soon as possible after receipt. The controlled substances must be opened and the contents verified by the person receiving the controlled substance. The inventory record also must be updated at this time.

Each registrant must determine how their authorized users will access substances. Authorized users must store controlled substances in an individual lockbox, marked with the individual's name, in a locked cabinet when not being legitimately worked with. Multiple individuals can use the same cabinet and/or laboratory-level lockbox, but access to individual lockboxes must be by the named individual only. Usage logs must be completed for each lockbox and returned to the DEA registrant upon completion.

Authorized users must return usage logs and unused bulk form substances to the DEA registrant on a daily basis. Finished form substances can be retained until depleted.

Authorized users must record all activity for each substance on a controlled substances usage log.

Schedule VI drugs should be kept out of sight when not in use and behind a locked door or cabinet when the registrant is not present. Schedule VI drugs do not need to be locked in a safe and do not require a usage log. Here is a link to the relevant Virginia Administrative Code section - 18VAC110-20-710. Requirements for storage and security for controlled substances registrants.
https://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section710/

Carrying Controlled Substances Between University Buildings

Registrants can carry controlled substances between buildings as long as the locations are on the same campus and within walking distance. Controlled substances cannot be transported by car.

Controlled substances must be stored at their registered location. This means that any unused controlled substances must be returned to the storage location at the end of the day.

Disposal

A DEA registrant must dispose of out-of-date, damaged, or otherwise unusable or unneeded controlled substances by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as reverse distributors. The OVPRI has contracted with a DEA-authorized

reverse distributor who can assist registrants with the proper disposal of controlled substances. Currently, there is no cost to VCU registrants for this service. Although OVPRI covers the cost of reverse distribution, OVPRI does not cover the cost of shipping the substances to the reverse distributor. OVPRI expects the registrant to cover that cost.

Please see Disposal of controlled substances for complete information.

When disposing of Schedule I and II controlled substances, DEA Form 222 must be used with the reverse distributor. Schedules III-V controlled substances may be transferred via invoice.

Expired or unusable substances must be labeled, separated, and stored in a cabinet or safe that meets DEA requirements for the highest level schedule, until ready for disposal. Maintaining these substances in a separate box or container within the same cabinet where inventory is stored is acceptable.

The controlled substances inventory record must be updated and copies of the records documenting the transfer and disposal of controlled substances must be kept for a period of two (2) years from the last recorded transaction. The controlled substances disposal log can be used for documentation purposes.

Theft or Significant Loss

If theft is suspected, the DEA registrant must immediately notify the OVPRI (controlsub@vcu.edu), VCU Police, and the DEA. The DEA requires that theft or loss of controlled substances be reported on DEA Form 106, Report of Theft or Loss of Controlled Substances. A copy of Form 106 must be kept in the registrant's records, and copies must also be sent to VBOP and to OVPRI.

DEA registrant must notify VBOP and the local DEA office in writing of the theft or significant loss of any controlled substances within one (1) business day of discovery of such loss or theft.

If a container of a controlled substance is broken, it must be documented in the inventory record, and a witness must sign and date the record.

Monitoring Inspections by VBOP and DEA

The VBOP normally will call to schedule a time for their inspections. The DEA can inspect an existing registrant at any time.

If desired by a registrant, a representative from OVPRI will attend a registrant's VBOP inspection. Send an email to controlsub@vcu.edu to request a representative. Routine DEA inspections will be coordinated through OVPRI.

The OVPRI is obligated to report inspections conducted by external entities to the central VCU Integrity & Compliance Office. Therefore, if you are the subject of such an inspection from VBOP or the DEA, you must notify the OVPRI via email to controlsub@vcu.edu. In addition, you must email to controlsub@vcu.edu copies of your inspection reports, your responses, and the inspector's responses, if any.

Institutional Monitoring

VCU environmental health & safety (EHS) include a controlled substances review as a part of their routine lab consultations. The controlled substances reviews occur at the time of each lab's annual lab safety consult and are documented in BioRAFT.

For registrants without designated lab space, the OVPRI conduct an annual controlled substances monitoring visit to ensure that the federal and state record keeping and inventory requirements are being met.

Employee Responsibility to Report Drug Diversion

From 21 CFR §1301.91:
"Reports of drug diversion by fellow employees are not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information."

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 controlsub@vcu.edu or to the VCU helpline at 1-888-242-6022 or www.vcuhelpline.com.

VCU's *Duty to Report and Protection from Retaliation* policy protects anyone from retaliation for making a good faith report of unlawful activity.

Close Out of Registration

Registrants wishing to terminate their active registration(s) must inform the DEA and VBOP of their intent to terminate. Contact controlsub@vcu.edu for the form that must be submitted to the DEA and VBOP when closing out a registration. Addresses for where the form must be sent are included on the form.

In addition, along with the form, the registrant must return their original VBOP and DEA registrations, respectively.

Be sure to email copies of the forms to controlsub@vcu.edu for OVPRI's records. After terminating their registrations, registrants must keep their own records for the two-year record keeping requirement.

If, in the future, the registrant intends to work with controlled substances again, the registrant will need to submit new applications to obtain new VBOP and DEA registrations, respectively.

Under no circumstances are controlled substances to be abandoned by a DEA registrant. Registrants are expected to properly dispose of controlled substances inventory when controlled substances are no longer required or prior to departure from a university position. Contact controlsub@vcu.edu when preparing to close out a registration.

Any person who is registered with the DEA who violates record keeping requirements or abandons controlled substances will be subject to the civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Abandoning substances is equivalent to distributing a controlled substance to an unauthorized person.

Forms

All forms can be found on our web page at: https://research.vcu.edu/forms/#d.en.412602

Checklist – Applying for Virginia Board of Pharmacy and DEA Registrations
Personnel Screening Form – Authorized User
VCU Controlled Substances Inspection Information Form for DEA
Authorized Users Signature Log – Schedule I Controlled Substances
Authorized Users Signature Log – Schedule II-V Controlled Substances
Controlled Substance Inventory Record
Controlled Substance Dispensing Record
Controlled Substance Usage Log and Wastage Record
Controlled Substance Disposal Log

To request a copy of a sample completed application or form, or a Word version of the form, please email controlsub@vcu.edu.

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