Use of Controlled Substances In Research Manual

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This manual and all forms are posted online at:

http://www.research.vcu.edu/controlled_substances/cs_manual.pdf

Questions about the information in this manual should be addressed to:

controlsub@vcu.edu

Contents

Introduction

This manual provides detailed information required by the VCU Policy entitled "*Using Controlled Substances for Research*."

Virginia Commonwealth University (VCU) and federal regulations require Principal Investigators conducting activities with Drug Enforcement Administration (DEA) Controlled Substances in basic and applied research settings be licensed with the Virginia Board of Pharmacy and registered with the DEA.

All individuals shall comply with state and federal regulations regarding the acquisition, record keeping, inventory, storage, use, and disposal of those substances.

Principal Investigators using Controlled Substances in research must obtain a Virginia Board of Pharmacy Controlled Substance 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 VCU IACUC or Controlled Substance Research Protocol to serve as a Registrant for that protocol. Responsibilities associated with Controlled Substances are detailed and regularly enforced by both VCU and the DEA. Those individuals not comfortable with assuming the responsibility of maintaining the required records are discouraged from applying for registration. Delegation of the administrative responsibilities is permitted; however, the DEA Registrant is ultimately responsible for all activities occurring under his/her Registration. Responsibility is individually based. Individuals who are fined or individuals who have violated the law will not be reimbursed by VCU nor defended 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's registration application or registration issued through the state or federal processes, if necessary.

Office of Research Subject Protection (ORSP)

Questions about procurement, secure storage, use, disposal, required documentation, or regulatory questions regarding Controlled Substances in research should be directed to the Office of Research Subjects Protection (ORSP) at controlsub@vcu.edu. The ORSP offers Controlled Substances education sessions for faculty, staff, and students.

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. Appropriate training completion is required.

Building
A structure with an official street address.

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 non-Controlled Substances in Finished Form. 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, Code of Federal Regulations (21 CFR, part 1300 to end) or 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 DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of Controlled Substances on his/her IACUC or VCU Controlled Substance Research protocols. Appropriate training completion is required.

DEA Research Protocol
A protocol to conduct research with Schedule I Controlled Substances in the form described in 21 CFR 1301.18. For Schedule II-V substances, see VCU Controlled Substances Protocol below.

Dispense
Prepare and distribute Controlled Substances to Authorized Users

Disposal
Relinquishment of contaminated, expired, excess, residual (or waste), or unwanted Controlled Substances.

Division of Animal Resources (DAR)
A division of the Office of 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 or expired.

Institutional Official
The Vice President for Research and Innovation.

Institutional Practitioner
A hospital or other entity (other than an individual) licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices, to dispense a Controlled Substance in the course of professional practice, but does not include a pharmacy.

Location
A room or designated area in a building where Controlled Substance inventory is stored.

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

Recordkeeper
An individual assigned by the DEA Registrant to assist with Registrant 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 DEA Registrant remains responsible for all actions and records of the Recordkeeper.

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 or certificate.

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 that 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. At VCU, the Division of Animal Resources (DAR) holds this registration.

Transfer
To move a Controlled Substance from the inventory of one DEA Registrant to another DEA Registrant. Transfer of Controlled Substances between VCU registrants must be less than 5% of registrant's annual

total Controlled Substance inventory or usage unless written permission is obtained from the Richmond DEA office to transfer more than 5%.

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. Only full-time faculty members can be DEA Registrants under this Policy.

Usage Log
A document completed by each Registrant and Authorized User tracking usage of Controlled Substances. Completed documents are maintained in the DEA Registrant records.

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.

VCU Controlled Substances Inspection Information Form
A VCU Form providing the information required by the DEA to apply for a Schedule I application and/or prior to scheduling an inspection for a registration application.

Controlled Substance Definitions

Controlled Substances are drugs or other chemicals that have the potential to be addictive or habit forming. The Drug Enforcement Administration (DEA) has divided Controlled Substances into 5 schedules based on their potential to be habit forming and on their usefulness in medicine as a drug. For a more comprehensive listing, see http://www.deadiversion.usdoj.gov/schedules/. Schedule VI substances are those identified by the Code of Virginia, and this scheduling designation is not utilized by the DEA.

- **Schedule I**
  - Drugs or other substances that have a high potential for abuse; no currently accepted medical use in the United States; and have a lack of accepted safety for use under medical supervision. Examples include: Heroin, LSD, Tetrahydrocannabinols (Delta-9-THC), Marijuana, Cathinone

- **Schedule II**
  - Drugs or other substances that have a high potential for abuse; currently have an accepted medical use in treatment in the United States, or have a currently accepted medical use with severe restrictions; abuse may lead to severe psychological or physical dependence. Examples include: Morphine, Cocaine, Amphetamine, Oxycodone, Methadone, Pentabarbital.

- **Schedule III**

- Drugs or other substances that have a potential for abuse less than Schedule I or II; currently have an accepted medical use in treatment in the United States; abuse may lead to moderate or low physical dependence and high psychological dependence. Examples include: Anabolic steroids, Ketamine, Euthasol (Pentobarbital/phenytoin mix), Buprenorphine.

- **Schedule IV**
  - Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence relative to those in Schedule III. Examples include: Chloral hydrate, Phenobarbital, Benzodiazepines.

- **Schedule V**
  - Drugs or other substances that have a low potential for abuse relative to Schedule IV; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence relative to those in Schedule IV. Examples include: Zolpidem, Zopiclone, Pregabalin, some Codeine cough preparations (*Robitussin*)

- **Schedule VI** (Virginia Board of Pharmacy only)
  - Drugs or other substances recognized by Code of Virginia 54.1-3455. Schedule VI contains any stimulant or depressant exempted from Schedules III, IV, V, or any drug not in Schedules I–Vthat because of potential tox*icity must* be prescribed by a physician. Examples include: Toluene, Amyl nitrite, Nitrous oxide. *Note: This is specific to the Commonwealth of Virginia. The federal DEA does not utilize this scheduling designation.

Sample Forms

Using Controlled Substances requires specific documentation. Sample forms to authorize specific users, maintain required inventory, and record use of Controlled Substances are included on our website at http://www.research.vcu.edu/forms/index.htm#cs_forms. Use of these specific forms is not required, but these templates do incorporate all required elements from the applicable regulations. Any format used must meet the requirements of all regulations. Individuals should determine a consistent documentation process to ensure best compliance practices. Documents may be maintained electronically, so long as they can be printed and presented to DEA Investigators as requested.

Who Must Register

University Members, who are also 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 Virginia Board of Pharmacy and the Drug Enforcement Administration. The registrations must be for the laboratory and specific address where the Controlled Substances are stored. University Members must have oversight of the research to serve as the DEA Registrant on a protocol.

Current Registrants Holding Clinical Practitioner Registrations

A Practioner Registration from the DEA allows for research and instructional activities with the Controlled Substances for which registration was granted. Therefore, a Practitioner may conduct clinical research under his/her Practioner Registration. A Clinical Practitioner is not authorized to conduct 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 appropriate annual licenses and registrations and to adhere to applicable state and federal regulatory requirements when working with Controlled Substances. Registrations must remain current until all Controlled Substances are spent, disposed of, or transferred to another Registrant. Registrants must obtain separate registrations for each address where Controlled Substances will be used. SAMPLES OF COMPLETED APPLICATION FORMS ARE INCLUDED ON OUR WEBPAGE.

Virginia Board of Pharmacy Registration
Each individual desiring registration must complete a Virginia Board of Pharmacy Application for Controlled Substance Registration Certificate. Virginia Board of Pharmacy licensing is for a one (1) year period . There is an annual fee. The online forms are here: http://www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm#DEA)

Virginia Board of Pharmacy Applications should be sent to:

Commonwealth of Virginia
Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233

and a copy of the application sent to controlsub@vcu.edu.

Inspection: Prior to issuance of a Controlled Substances Registration, Virginia Board of Pharmacy representatives will conduct an interview and an inspection to ensure that appropriate safeguards are in place to protect Controlled Substances.

DEA Registration
A DEA Form 225 Application for Registration is required. The Senior Associate Vice President for Research Administration and Compliance is responsible for approval of Schedule I applications and certification of tax-exempt status.

Schedule I applications
Schedule I applications cannot be submitted online. The completed paper application must be forwarded to the Office of Research Subjects Protection (PO Box 980568 or controlsub@vcu.edu) for review and approval. Following approval, the application must be sent to:

U.S. Department of Justice
Drug Enforcement Administration
Attn: Registration Section ODR
8701 Morrissette Drive
PO Box 2639
Springfield, VA 22152-2639

Registrants requiring the use of Schedule I substances also must include a VCU Controlled Substances Inspection Form that meets the requirements described in 21 CFR 1301.18 and included below:

(1) Investigator:

- Name, street address, building name,room number, and DEA registration number, if any.
- Institutional affiliation.
- Qualifications, including a curriculum vitae (Biosketch), and an appropriate bibliography (list of publications).

(2) Research project:

- Title of project.
- Statement of the purpose.
- Name of the Controlled Substances involved and the amount of each needed.
- Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
- Location where the research will be conducted (same as Registrant address)
- Statement of the security provisions for storing the Controlled Substances (in accordance with 21 CFR 1301.75) and for dispensing the Controlled Substances in order to prevent diversion.
- If the Principal Investigator desires to manufacture or import any Controlled Substance, include a statement of the quantity to be manufactured or imported and list the sources of the chemicals to be used or the substance to be imported.

(3) Authority:

- Institutional approval. The Authorized Official must approve your registration application.
- Approval of the Institutional Review Board for human studies.
- Approval of the Institutional Animal Care and Use Committee for animal studies.
- Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number), if applicable.
- Indication of an approved funded grant (FP number), if any.

Schedule II-V Applications:
Schedule II-V applications can be completed online. The online forms are here:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

VCU Controlled Substances Inspection Information Form
DEA Applicants must complete a VCU Controlled Substances Inspection Form. This form must be completed and, along with the required attachments, must be sent to controlsub@vcu.edu within two (2) weeks of DEA Application submission. OVPRI will attach floor plans based on the address on your form, copies of log forms if the appropriate box is checked, and reverse distribution information to the package. When the DEA notifies us that they are ready to schedule an inspection, the complete, approved package will be forwarded to the DEA. Applicants will be cc'd on this e-mail.

DEA Inspections
DEA Inspections will be coordinated through the OVPRI office. Applicants must provide a prompt response to requests for availability.

Registration Certificates

As each Registration Certificate is received, a copy should be sent to controlsub@vcu.edu for our Controlled Substances database.

DEA and Virginia Board of Pharmacy registrations remain active for a one (1) year period.

Registration Amendments

Registrants may require the addition of new substances and protocols throughout the life of the registration. An amendment must be submitted in accordance with the instructions below:

For Schedule I substances, a letter with a revised VCU Controlled Substances Protocol, specifically highlighting the changed information should be forwarded to the Office of Research Subjects Protection (PO Box 980568 or controlsub@vcu.edu) for review and approval. Following approval, the application should be sent to:

U.S. Department of Justice
Drug Enforcement Administration
Attn: Registration Section ODR
PO Box 2639
Springfield, VA 22152-2639

For Schedule II-V substances, you will need to submit a change request online. Go to https://www.deadiversion.usdoj.gov/drugreg/index.html and under Registration Tools select the hyperlink for Registration Changes (Address, Drug Code, Name, Schedule). Complete the request form and submit.

After the field office receives the submitted Registration Changes form, the request will be reviewed and go through a process of being approved or denied. The DEA agent reviewing the request may ask for

additional information so including as much information as possible with the original change request is in your best interest.

Please notify controlsub@vcu.edu that a Registration Changes request has been submitted.

Registration Renewals

Annual renewals for both Virginia Board of Pharmacy and DEA registrations can be completed online (Use Form 225A). See https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp

The Virginia Board of Pharmacy will send a reminder notice approximately two months prior to expiration providing a website link and passcode to enter your renewal online.

The DEA will send a reminder notice approximately three (3) months prior to expiration.

Separate Registrations for Separate Buildings

Individuals with a need to use Controlled Substances in different buildings must obtain a separate registration for each building. Separate storage, inventory, usage records, etc. must be maintained for each location.

Institutional Registration

VCU's Division of Animal Resources (DAR) maintains an institutional registration. DAR will obtain veterinary Controlled Substances and appropriately transfer them to a DEA Registrant's inventory. DAR will not dispense Controlled Substances.

Authorized Users

The DEA Registrant is responsible for managing the Controlled Substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions. Authorized Users (designated employees) of the registrant may engage in approved activities under the direction of the registrant. The registrant is required to screen employees prior to authorization of work with Controlled Substances using the Personnel Screening Form and verify that the Controlled Substances Training module has been completed.

Personnel Screening

The DEA Registrant should ensure that each potential Authorized User fulfills the screening process by completing the *Personnel Screening Form – Authorized User* (21 CFR 1301.90). The screening form includes the following questions:

1. Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense?

2. In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
3. Have you ever been denied a DEA registration, had a DEA registration revoked or surrendered a DEA registration for cause?

Make copies of the form as needed for each employee who will be working with these substances.
If the answer to any of the questions is "yes", the person should not be allowed to sign the Authorized Users Signature Log and the Office of Research Subjects Protection (controlsub@vcu.edu) should be contacted.
Keep these questionnaires on file at the registered location. This form must also be completed by new hires before they are allowed to handle DEA Controlled Substances.

Roles and Responsibilities

Office of Research Subjects Protection Roles and Responsibilities:

- Provide guidance to faculty members for registering with state and federal agencies
- Provide guidance on storage of Controlled Substances
- Provide guidance on disposal of Controlled Substances
- Provide training on VCU's policies and procedures for use of Controlled Substances

Units or Departments which Process Orders for Controlled Substances for Registrants Roles and Responsibilities:

- Be in compliance with federal and state regulations
- Ensure only DEA Registrants order Controlled Substances using the appropriate forms
- Assure Controlled Substances ordered through the department are stored in accordance with VCU, federal, and state regulations

DEA Registrants Roles and Responsibilities:

- 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 Policy, Virginia Board of Pharmacy regulations and DEA regulations.
- Obtain and maintain Virginia Board of Pharmacy and Drug Enforcement Administration registrations
- Complete the "Controlled Substances Training – Registrant" module and maintain a copy of the quiz score in his/her records. See Training Topic outlined below.
- Identify and document individuals as Authorized Users
- Maintain documentation for Authorized Users
- Provide and maintain documentation on training of laboratory-specific operations involving Controlled Substances
- Maintain strict control over inventory and security and ensure proper storage of Controlled Substances
- Obtain DEA approval, via amendment, for substances not currently approved under their Registration prior to ordering, inventorying, dispensing, or disposing of such substances
- Dispense no more than weekly usage amounts of Bulk Form substances to Authorized Users
- Obtain and retain usage log sheets for Bulk and Finished Form substances

- Maintain separate storage areas, logs and inventory for Schedule I Controlled Substances in their possession
- Maintain separate storage areas, logs and inventory for Schedule II Controlled Substances in their possession
- Maintain separate storage areas, logs and inventory for Schedule III-V Controlled Substances in their possession
- Receive, store, use, and dispose of Controlled Substances properly and continually maintain usage log sheets.
- Maintain usage log sheets for two years after complete use or disposal of Controlled Substances
- Exercise signature authority for purchase and disposal of Controlled Substances
- Conduct an initial inventory
- Conduct a biennial inventory per DEA regulations
- Report in writing the theft or loss of any Controlled Substance to the DEA Field Division (using Form 106), Virginia Board of Pharmacy, VCU Police and Office of Research Subjects Protection within one business day of discovery of such loss or theft
- Dispose of unwanted Controlled Substances in accordance with DEA regulations using DEA Form 41, supplied by an authorized Reverse Distributor
- Dispose of Controlled Substances no longer supported by an active, approved protocol
- Upon receipt, send copy of registration, registration renewal or notice of lapse of registration to controlsub@vcu.edu.
- Report DEA inspection and audit findings to controlsub@vcu.edu within 5 business days of notice received by Registrant

Authorized Users Roles and Responsibilities:

- Complete the "Controlled Substances Training – Authorized Users" Module and provide completion certificate to the DEA Registrant. See Training topic below.
- Complete the *Personnel Screening Form – Authorized User* before commencing use of Controlled Substances.
- Sign the Authorized Users Signature Log (Note: separate logs are kept for I and II-V substances)
- Complete usage log sheets – *Controlled Substance Usage Log and Wastage Record*
- Store Controlled Substances in an individual lockbox, marked with the individual's name, or a laboratory-level lockbox, in a locked cabinet at the Registrant's Location
- Return unused Controlled Substances in Bulk Form and usage log sheet to the DEA Registrant after each day
- Return usage log sheets of Finished Form substances when substance has been fully used or is no longer needed
- Immediately report any discrepancy or suspected theft to the DEA Registrant
- Receive laboratory-specific training on procedures before using Controlled Substances
- Immediately report to the DEA Registrant any felony violations/convictions.

Training

All individuals involved in the use of Controlled Substances must complete training prior to handling any Controlled Substance. Individuals can self-enroll on the Blackboard Training site, located at https://blackboard.vcu.edu/webapps/portal/frameset.jsp. Registrants should enroll in "Controlled

Substances Training - Registrant" and Authorized Users should enroll in "Controlled Substances Training – User." Following completion of training, each individual should print their score in accordance with the instructions. Registrants should retain a copy in their records. Authorized Users should attach a copy of the score sheet to the completed Personnel Screening Form as proof of completion and the original should be retained in their records.

Ordering Controlled Substances

Registrants (or their Authorized Users) can order only substances approved under their current registration.

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 send, in triplicate, DEA order form # 222. Instructions for ordering DEA Form #222 can be found at: **http://www.deadiversion.usdoj.gov/faq/dea222.htm**.

Schedule I (substances that are not commercially available)
Requests to obtain Schedule I Controlled Substances not commercially available must be made to the National Institute on Drug Abuse (301-443-1124 or **http://www.nida.nih.gov/**).

Schedule III-V
Schedule III-V Controlled Substances may be ordered by a Registrant through standard procurement processes and maintenance of procurement records.

NIDA Drug Supply Program
The NIDA Drug Supply Program (NDSA) provides various controlled drugs, other chemical substances, and marijuana and nicotine research cigarettes for research purposes to research investigators working in the area of drug abuse, drug addiction, and related disciplines at academic institutions. In order to obtain these substances from NIDA, research investigators and other users are required to submit their requests along with necessary documents to the NIDA drug supply program for consideration. Complete details can be found at:
http://www.drugabuse.gov/sites/default/files/files/OrderingGuidelinesUS.pdf.

Controlled substances must be ordered and maintained in the smallest quantity needed.

Record Keeping and Inventory Requirements

The following records should be maintained at the registrant's Location (as identified on the registration):

- Personnel Screening Forms and training records for Registrant and Authorized Users
- Executed order forms

- Receiving record that is verified, signed and dated
- Inventory records (must be kept a minimum of two years from date of last transaction)
- Controlled substance usage records (must be kept a minimum of two years from the date of last transaction)

All Controlled Substance records must be kept separately from all other records, in or near the primary work area, and shall be available for inspection by VCU representatives, DEA, or state inspectors at all times.

The DEA Registrant may assign a Recordkeeper to assist with record keeping requirements. The Recordkeeper cannot dispense Controlled Substances.

Controlled Substance Receiving

Controlled substances must be shipped to the DEA Registrant and address as indicated on the DEA Registration. Once received, the Controlled Substances must be opened and the contents verified by the Registrant. Any discrepancies must be rectified with the supplier and/or shipper. If discrepancies cannot be rectified, the DEA Registrant must contact the Office of Research Subjects Protection at controlsub@vcu.edu and the DEA to report this within five business days. The DEA Registrant must sign and date the purchase receipt and file it with the Controlled Substances records.

Controlled Substance Dispensing and Tracking

The DEA Registrant (or their Authorized User) is the only individual that 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 substance, quantity and the signature of the authorized user or Registrant receiving it.

Every ml, mg, or tablet of a Controlled Substance should be accounted for in the dispensing records. Sample *Controlled Substances Dispensing Record* and *Controlled Substances Usage and Waste Log* forms are available in the Forms section.

Controlled Substance Transfer

If needed, researchers with an active DEA registration can transfer small quantities (up to 5% of their current Controlled Substance inventory) to other DEA registrants at VCU. The transferor must ensure that the transferee has a valid DEA registration for the category of substances to be transferred and approval, via an approved DEA protocol (if Schedule I) or VCU Controlled Substances Inspection Information Form (if Schedule II-V), to receive the substance.

Transfers of schedule I or II Controlled Substances must be accompanied by a DEA Form 222 completed by the registrant receiving the substance(s).

Transfers of schedule III-V Controlled Substances must be documented, be maintained in the appropriate records of both the recipient and supplier and include:

- Name, address, and DEA registration number of recipient
- Name, address, and DEA registration number of supplier
- Name, concentration, and quantity of Controlled Substances transferred
- Transfer date

The sample *Controlled Substance Transfer Invoice* can be used for this purpose.

It is a felony to transfer a Controlled Substance to a person who is not registered with the DEA.

Inventory Procedures

When issued a DEA registration, a registrant shall take an initial inventory, which is an actual physical count of all Controlled Substances in their possession. ***The registrant should make a record showing a zero inventory upon initial receipt of registration.***

Each person registered to handle Controlled Substances must maintain an inventory. The inventory should be:

- Maintained at the registered location (unless a notification has been sent to DEA notifying that records will be maintained at a specified central location).
- Available for 2 years after the substance is used or is disposed.
- Completed every 2 years (biennial) to meet DEA regulations (21 CFR 1304.11). The inventory may be taken on any date which is within two years of the previous biennial inventory date and must indicate whether it was performed at the opening or closing of the day.
- Updated on the effective date of a rule (from the DEA) when a substance is added to the Schedule (list of Controlled Substances).

The inventory should have the following information:

- Name, address, and DEA registration number.
- Date the inventory was taken and whether it was at the beginning or end of the day.
- Sign and date form.

For Controlled Substances in Bulk Form

- Name of substance;
- The total quantity of the substance to the nearest metric unit weight consistent with unit size.

For Controlled Substances in Finished Form

- the name of the substance;
- Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

- The number of units or volume of each finished form in each container (e.g., 100-tablet bottle or 3-milliliter vial); and
- The number of containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

For each substance that is expired, damaged, defective or impure substances awaiting disposal, or substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

- Name of substance;
- Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form (i.e. 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 maintain substances in this category separately within your inventory, i.e., a separate compartment, box, or bag within the storage area

The sample *Controlled Substances Inventory Record* can be used for these 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 at least overnight in the safe must include the following information:

- Name of Controlled Substance
- Lot number from the supplier
- Final concentration of Controlled Substance
- Volume per container
- Expiration date

Storage and Security

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 shall be kept locked in their storage location except for the actual time required to remove, legitimately work with, and replace them. You can find standard narcotic cabinets by searching for "narcotic cabinets" on the internet. Please be aware that 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.

Access to locked rooms and locked storage cabinets containing Controlled Substances shall be restricted by the DEA Registrant.

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 or at the Registrant's location for overnight storage. For Finished Form only substances, laboratory-wide lockboxes, can be established and utilized but must be stored at the Registrant's location for overnight storage. Usage logs must be completed for each lockbox and returned to the DEA Registrant upon completion.

Transporting Controlled Substances between University Buildings

Controlled substances cannot be transported between buildings (separate street addresses). Buildings connected by above-ground bridges or steam/non-public tunnels can not be considered the same building. Example: A Registrant cannot walk down the sidewalk or across the street to another building with Controlled Substances in his/her pocket.

Disposal

Expired, damaged or otherwise unusable or unneeded Controlled Substances can be disposed of by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as Reverse Distributors. A DEA authorized reverse distributor to assist registrants with the proper disposal of Controlled Substances has been established. There is currently no cost to VCU Registrants for this service. Please see Disposal of Unwanted, or Expired, Controlled Substances for complete information.

Schedule I and II Controlled Substances must be disposed of via DEA Form 222 with the Reverse Distributor. Schedule 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 maintained for a period of two years. The *Controlled Substance Disposal Log* can assist with this documentation.

Theft or Significant Loss

If theft is suspected, the DEA Registrant shall immediately notify the Office of Research Subjects Protection, 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 disposition records, and a copy must also be sent to the Office of Research Subjects Protection.

If a container of a Controlled Substance is broken, it shall be documented in the record and a witness must sign and date it.

Virginia Board of Pharmacy and DEA Inspections

The Virginia Board of Pharmacy normally will call to schedule a time for their inspections. The DEA can inspect an existing Registrant at any time. In preparing for their inspections, the DEA will refer to their database for the list of substances approved for the Registrant, so ensuring that DEA is notified via the amendment process is extremely important. Substances in a Registrant's inventory that do not match the DEA's database is cause for a finding.

If desired by a Registrant, a representative from the Office of Research Subjects Protection will accompany DEA Registrants during Virginia Board of Pharmacy. Send an e-mail to controlsub@vcu.edu to request a representative. DEA Inspections will be coordinated through the Office of Research Subject Protection.

Institutional Monitoring

The Office of Research Subjects Protection, as a part of its Post-Approval Compliance Monitoring (PACM) program, will review Registrant records and facilities in accordance with its standard inspection schedule. Separate reports will be issued for Controlled Substance monitoring.

Employee Responsibilities 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 serve the public interest at large. It is, therefore, the position of DEA than 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 the Office of Research Subjects Protection or the VCU helpline at 1-888-242-6022 or www.vcuhelpline.com.

Close Out of Registration

Registrants wishing to terminate their registration(s) should prepare individual letters to the Virginia Board of Pharmacy and the DEA providing a date of termination. The original registration certificate should be included in the letter to each agency.

Under no circumstances are Controlled Substances to be abandoned by a DEA registrant. Registrants are expected to properly transfer or dispose of Controlled Substance inventory when Controlled Substances are no longer required or prior to departure from their University position. Contact controlsub@vcu.edu when preparing to close out.

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. Please note that abandoning substances is equivalent to distributing a Controlled Substance to an unauthorized person.

Forms

All forms can be found on our website at: http://www.research.vcu.edu/forms/index.htm#cs_forms
Personnel Screening Form – Authorized User
Authorized Users Signature Log – Schedule I Controlled Substances
Authorized Users Signature Log – Schedule II-V Controlled Substances
VCU Controlled Substances Inspection Information Form
Controlled Substance Inventory Record
Controlled Substance Dispensing Record
Controlled Substance Usage Log
Controlled Substance Disposal Log
Controlled Substance Transfer Invoice
Sample “Completed” Virginia Board of Pharmacy Application Form
Sample “Completed” DEA Application Form

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