



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

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Introduction

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

Virginia Commonwealth University (VCU) requires Principal Investigators conducting activities with Drug Enforcement Agency (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 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 and maintaining the required records are discouraged from applying for registration. Delegation of the administrative responsibilities is permitted; however, only the DEA Registrant should have access to their inventory of controlled substances and dispense substances. 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 (VPR) is the Institutional Official with ultimate responsibility for ensuring appropriate conduct of research at VCU. The VPR is vested with the authority to suspend, revoke, or deny any researcher registration application submitted or registration issued through the state or federal processes, if necessary.

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 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.

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 seven (7) days. Unused Bulk Form substance must be returned to the Registrant after seven (7) days.

Controlled Substance

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

DEA Registrant

A University Member that holds DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of controlled substances on his/her VCU Controlled Substance Research or DEA 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) and unwanted controlled substances.

Division of Animal Resources (DAR)

A division of the Office of Research 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 which 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.) which 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.

Institutional Official

The Vice President for Research

Institutional Practitioner

A hospital or other person (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 should only provide 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 that conducts research at VCU.

Teaching Activity

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

Teaching Institution Registration

A DEA registration awarded to a teaching institution (for Schedules II-V only) overseen by an Institutional Practitioner. 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 registrants must be less than 5% of registrant's annual total controlled substance inventory or usage.

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 log kept by each registrant and authorized user of controlled substances tracking usage that is returned to the DEA Registrant for his/her 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 Substance Research Protocol

A VCU form meeting the requirements of a DEA protocol for use with research projects using Schedule II-V controlled substances.

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 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, Pentobarbital.
- **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 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 containing any stimulant or depressant exempted from Schedules III, IV, V, or any drug not in Schedules I–V, which, because of potential toxicity *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 at the end of this manual. 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, that store, administer or order controlled substances for VCU 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 for the laboratory and specific address where 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 Practitioner Registration from the DEA does allow for the following coincident activities: research and instructional activities with those substances for which registration was granted. Therefore, a Practitioner may conduct clinical research under their Practitioner registration. A 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. Registrants shall not allow the registration to lapse until all controlled substances are spent, disposed of, or transferred to another Registrant. SAMPLES OF COMPLETED APPLICATION FORMS ARE INCLUDED IN THE FORMS AT THE END OF THIS MANUAL.

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 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 paper application should be completed and forward 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
8701 Morrissette Drive
PO Box 2639
Springfield, VA 22152-2639

Registrants requiring the use of Schedule I substances must also include a VCU Controlled Substances Protocol which meets the requirements described in [21 CFR 1301.18](#) and included below:

• (1) Investigator:

- Name, street address, building name and room number and DEA registration number; if any.
- Institutional affiliation.
- Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).
- (2) Research project:
 - Title of project.
 - Statement of the purpose.
 - Name of the controlled substances or 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.
 - 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 investigator desires to manufacture or import any controlled substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and 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 (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

Inspection

DEA Investigators will conduct a pre-registration interview with all pending registrants. Information or documentation that will be required is:

- Curriculum Vitae/Resume
- Copy of State License
- Copy of Certifications
- Summary of Controlled Substance Protocol (the VCU Controlled Substances Protocol can be used, if desired)

- List of Controlled Substances to be used
 - Quantity of controlled Substance to keep on hand
 - List of Suppliers for Controlled Substances
 - How the Controlled Substances will be used in your research
 - Source of Funding
 - Length of Research
- List of people who will have access to the Controlled Substances
 - Full name
 - Home Address
 - Home Telephone Number
 - Date of Birth
 - Social Security Number
 - E-mail Address
- Supplier Source for the Animals (if applicable)
- Copy of the controlled Substances Log
- Copy of the Lab's floor plan
- Specifications for Safe or Controlled Substances storage cabinet (lock information)
- Lab/Area Security Summary

Once received, a copy of each license/registration should be submitted to controlsub@vcu.edu for our records.

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

Registration Certificates

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

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, a revised VCU Controlled Substance Research Protocol, specifically highlighting the changed information should be submitted to controlsub@vcu.edu for review. Upon approval by the Office of Research Subjects Protection, the form will be forwarded to the Richmond Office for updating in their database. The Richmond DEA Office will not issue specific approvals for additional Schedule II-V substances. A copy of the ORSP approval forwarded to the Richmond DEA Office will be sent to the Registrant.

Registration Renewals

Annual renewals for both Virginia Board of Pharmacy and DEA registrations can be completed online.

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. DEA renewals can be completed online at:

<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp>

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 should be contacted. Keep these questionnaires on file at the registered location. Keep a blank copy of this form in your files for new hires to be completed 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
- 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 seven (7) 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 can only order substances appearing on approved DEA Protocols (for Schedule I), and VCU Controlled Substance Research Protocols (for Schedule II-V) 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 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 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 Research Protocol (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;

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.

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. Buildings connected by above-ground bridges can be considered the same building. Buildings connected by steam or non-public tunnels are considered separate buildings and/or Locations. Example: A Registrant cannot walk down the sidewalk or across the street to another building with controlled substances in his/her pocket.

There is one limited exception:

- 1) A registrant transferring a substance from their inventory to another registrant's inventory (via a Form 222 or invoice) can transport the substance, with the proper documentation, between buildings to the new inventory location.

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 pilot program with a DEA authorized reverse distributor to assist registrants with the proper disposal of controlled substances has been established. There is currently no cost to Registrants for this service.

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 or DEA inspections. Send an e-mail to controlsub@vcu.edu to request a representative.

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

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

Personnel Screening Form – Authorized User

Authorized Users Signature Log – Schedule I Controlled Substances

Authorized Users Signature Log – Schedule II-V Controlled Substances

VCU Controlled Substance Research Protocol

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

Attachments

List of Approved DEA Registered Reverse Distributors

Version 9-19-14

Use of Controlled Substances In Research

Attachments and Sample Forms

Checklist – Applying for Schedule I Registration

Checklist – Applying for Schedule II-V Registration

Personnel Screening Form – Authorized User

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

Controlled Substance Disposal Log

Controlled Substance Transfer Invoice

Sample “Completed” Virginia Board of Pharmacy Application

Sample “Completed” DEA Application Form – Hard Copy (Schedule I)

Sample “Completed” DEA Application Form – Electronic (Schedule II-V)
List of Approved DEA Registered Reverse Distributors

.....K

Checklist
Obtaining Virginia Board of Pharmacy and DEA Registrations
For Schedule I Controlled Substances

| Date | Action Item | | | | | | | | | | |
|------|--|--|---|--|---|--|---|--|----------------|--|---|
| | Read the VCU Policy and Manual | | | | | | | | | | |
| | Take the "VCU Controlled Substances – Registrant" training module on Blackboard | | | | | | | | | | |
| | Apply for a Virginia Board of Pharmacy Controlled Substances Registration Certificate <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td><td>Fill out application form http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm Sample form is available in Manual</td></tr> <tr> <td></td><td>Submit application along with fee</td></tr> </table> | | Fill out application form http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm Sample form is available in Manual | | Submit application along with fee | | | | | | |
| | Fill out application form http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm Sample form is available in Manual | | | | | | | | | | |
| | Submit application along with fee | | | | | | | | | | |
| | Prepare proper storage location and paperwork prior to VBP inspection | | | | | | | | | | |
| | Attend inspection, answer questions | | | | | | | | | | |
| | Receive Virginia registration certificate | | | | | | | | | | |
| | Apply for a DEA Registration <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td><td>Complete paper application (Form 225) at http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm Sample form is available in Manual</td></tr> <tr> <td></td><td>Apply for "Individual Registration"</td></tr> <tr> <td></td><td>Use Sample Form as a guide for sections 1, 2, and 6</td></tr> <tr> <td></td><td>Skip Section 7</td></tr> <tr> <td></td><td>Send signed paper application and all required attachments to: controlsub@vcu.edu. Following signature by the Authorized Official in Section 6, the application will be sent to the U.S. Department of Justice in Springfield, VA</td></tr> </table> | | Complete paper application (Form 225) at http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm Sample form is available in Manual | | Apply for "Individual Registration" | | Use Sample Form as a guide for sections 1, 2, and 6 | | Skip Section 7 | | Send signed paper application and all required attachments to: controlsub@vcu.edu. Following signature by the Authorized Official in Section 6, the application will be sent to the U.S. Department of Justice in Springfield, VA |
| | Complete paper application (Form 225) at http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm Sample form is available in Manual | | | | | | | | | | |
| | Apply for "Individual Registration" | | | | | | | | | | |
| | Use Sample Form as a guide for sections 1, 2, and 6 | | | | | | | | | | |
| | Skip Section 7 | | | | | | | | | | |
| | Send signed paper application and all required attachments to: controlsub@vcu.edu. Following signature by the Authorized Official in Section 6, the application will be sent to the U.S. Department of Justice in Springfield, VA | | | | | | | | | | |
| | Prepare for DEA Pre-Registration Interview <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td><td>Assemble required documents: CV, State License, Protocol Information, Inventory Documentation</td></tr> <tr> <td></td><td>Create Security Plan and Specifications for Safe/Storage Location</td></tr> <tr> <td></td><td>Meet with DEA Inspectors and answer questions</td></tr> </table> | | Assemble required documents: CV, State License, Protocol Information, Inventory Documentation | | Create Security Plan and Specifications for Safe/Storage Location | | Meet with DEA Inspectors and answer questions | | | | |
| | Assemble required documents: CV, State License, Protocol Information, Inventory Documentation | | | | | | | | | | |
| | Create Security Plan and Specifications for Safe/Storage Location | | | | | | | | | | |
| | Meet with DEA Inspectors and answer questions | | | | | | | | | | |
| | Receive DEA Registration | | | | | | | | | | |
| | Send copy of VBP and DEA registration to controlsub@vcu.edu | | | | | | | | | | |
| | Order controlled substances and create inventory record | | | | | | | | | | |
| | Confirm documentation and training of authorized users; approve and file documentation | | | | | | | | | | |

Checklist

Obtaining Virginia Board of Pharmacy and DEA Registrations For Schedule II-V Controlled Substances

| Date | Action Item | | | | | | | | |
|------|--|--|---|--|---|--|---|--|---------------------------|
| | Read the VCU Policy and Manual | | | | | | | | |
| | Take the "VCU Controlled Substances – Registrant" training module on Blackboard | | | | | | | | |
| | Apply for a Virginia Board of Pharmacy Controlled Substances Registration Certificate <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td><td>Fill out application form (http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm Sample form is available in Manual)</td></tr> <tr> <td></td><td>Submit application along with fee</td></tr> </table> | | Fill out application form (http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm Sample form is available in Manual) | | Submit application along with fee | | | | |
| | Fill out application form (http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm Sample form is available in Manual) | | | | | | | | |
| | Submit application along with fee | | | | | | | | |
| | Prepare proper storage location and paperwork prior to VBP inspection | | | | | | | | |
| | Attend inspection, answer questions | | | | | | | | |
| | Receive Virginia registration certificate | | | | | | | | |
| | Apply for a DEA Registration <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td><td>Complete application (Form 225) at http://www.deadiversion.usdoj.gov/drugreg/reg_.apps/onlineforms_new.htm Sample form is available in Manual</td></tr> <tr> <td></td><td>Apply for "Individual Registration"</td></tr> <tr> <td></td><td>Use Sample Form as a guide for sections 1, 2, and 6</td></tr> <tr> <td></td><td>Skip Section 7 and Submit</td></tr> </table> | | Complete application (Form 225) at http://www.deadiversion.usdoj.gov/drugreg/reg_.apps/onlineforms_new.htm Sample form is available in Manual | | Apply for "Individual Registration" | | Use Sample Form as a guide for sections 1, 2, and 6 | | Skip Section 7 and Submit |
| | Complete application (Form 225) at http://www.deadiversion.usdoj.gov/drugreg/reg_.apps/onlineforms_new.htm Sample form is available in Manual | | | | | | | | |
| | Apply for "Individual Registration" | | | | | | | | |
| | Use Sample Form as a guide for sections 1, 2, and 6 | | | | | | | | |
| | Skip Section 7 and Submit | | | | | | | | |
| | Prepare for DEA Pre-Registration Interview <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td><td>Assemble required documents: CV, State License, Protocol Information, Inventory Documentation</td></tr> <tr> <td></td><td>Create Security Plan and Specifications for Safe/Storage Location</td></tr> <tr> <td></td><td>Meet with DEA Inspectors and answer questions</td></tr> </table> | | Assemble required documents: CV, State License, Protocol Information, Inventory Documentation | | Create Security Plan and Specifications for Safe/Storage Location | | Meet with DEA Inspectors and answer questions | | |
| | Assemble required documents: CV, State License, Protocol Information, Inventory Documentation | | | | | | | | |
| | Create Security Plan and Specifications for Safe/Storage Location | | | | | | | | |
| | Meet with DEA Inspectors and answer questions | | | | | | | | |
| | Receive DEA Registration | | | | | | | | |
| | Send copy of VBP and DEA registration to controlsub@vcu.edu | | | | | | | | |
| | Order controlled substances and create inventory record | | | | | | | | |
| | Confirm documentation and training of authorized users; approve and file documentation | | | | | | | | |

PERSONNEL SCREENING FORM – AUTHORIZED USER

To comply with federal Drug Enforcement Agency guidance, Virginia Commonwealth University requires that all persons who will have access to controlled substances during work or research activities to answer the following questions. By signing below, you authorize inquiries of courts and law enforcement agencies for possible pending charges or convictions. Any false information, omission of information, or misuse of controlled substances will jeopardize your position with the University. Information included herein will not preclude employment but will be considered as part of the overall evaluation of qualifications for the use of controlled substances. The protection of an individual's right to privacy will be upheld in all confidential inquiries. The Controlled Substances Training module must be completed and a copy of the score (minimum of 80%) must be attached to this form.

Full Name: _____
Circle: Faculty Staff Student Other: _____
Home Address: _____
Home Phone: _____ Date of Birth: _____
Lab/Office location: _____
Work Phone: _____ Work E-mail: _____

Answer 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. Yes* No
- 2) In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details on an additional page. Yes* No
- 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 the date this action occurred on an additional page. Yes* No

Applicant Signature: _____ Date: _____
Controlled Substances Training Completion Date: _____ (Attach copy)

DEA Registrant authorization for the person identified above to handle controlled substances:

DEA Registrant Signature: _____ Date: _____

The DEA Registrant should retain this completed questionnaire in a secure, confidential file.

*If the answer to any of the questions is "Yes," the individual should not be allowed to sign the Authorized Users Signature Log and the Office of Research Subjects Protection (controlsub@vcu.edu) contacted for further evaluation.

VCU Controlled Substance Research Protocol

| | |
|--------------------------------|--|
| DEA Registrant/Applicant Name: | DEA Registrant No. (if applicable): |
| Street, City, Zip: | Building Name and Room Number: |
| Protocol PI: | Controlled Substance Schedules to be Used: |

| |
|--|
| Title of Project: |
| Period of Performance: Start: _____ End: _____ |
| Statement of Purpose: |
| Brief description of the research to be conducted - include number and species of research subjects, dosage to be administered, route and method of administration (continued on the next page): |

VCU Controlled Substance Research Protocol

Location where the research will be conducted:

Statement of the security provisions for storing the controlled substances and for dispensing the controlled substances in order to prevent diversion:

Will the investigator manufacture or import any controlled substance listed above? Yes No
If Yes, include a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported:

Check all that apply. Enter all HM/AM protocols that are applicable (use commas to separate)

| | |
|--------------------------|---|
| <input type="checkbox"/> | IRB Approval - Protocol# |
| <input type="checkbox"/> | IACUC Approval - Protocol #: |
| <input type="checkbox"/> | Notice of Claimed Investigational Exemption Number: |
| <input type="checkbox"/> | Funded grant number: |

VCU Controlled Substance Research Protocol

Schedule and Drug Codes

Listed below are examples of schedules 1-5 codes. Check all drugs you handle as required. For substances not listed, visit http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf for additional codes.

If you bulk manufacture a substance, check the 'Bulk?' column after the applicable class code.

| Schedule 1 Narcotic & Non-Narcotic | | Code | Bulk? | | Pentobarbital (bulk) (Nembutal) | 2100/2329 | |
|--|--|-------------|--------------|--|--|------------------|--|
| 3,4-Methylenedioxymethamphetamine (MDMA) | | 7400 | | | Phencyclidine (PCP) | 7295 | |
| 3,4-Methylenedioxymethamphetamine (MDMA) | | 7405 | | | Secobarbital (Seconal, Tuinal) | 2315 | |
| 4-Methyl-2,5-Dimethoxyamphetamine (DOM, STP) | | 7395 | | | Schedule 3 Narcotic & Non-Narcotic | | |
| 4-Methylaminorex (cis isomer) (U4Euh, McN-422) | | 1590 | | | Anabolic Steroids | 4000 | |
| Alphacetylmethadol (except LAAM) | | 9603 | | | Barbituric acid derivative | 2100 | |
| Bufotenine (Mappine) | | 7433 | | | Benzphetamine (Didrex, Inapetyl) | 1228 | |
| Cathinone | | 1235 | | | Buprenorphine (Buprenex, Temgesic) | 9064 | |
| Diethyltryptamine (DET) | | 7434 | | | Butabarbital | 2100/2175 | |
| Difenoxin 1MG/25UG AlSO4 /DU (Motofen) | | 9167 | | | Butalbital | 2100/2165 | |
| Dimethyltryptamine (DMT) | | 7435 | | | Codeine combo product (Empirin) | 9804 | |
| Etorphine (except HCL) | | 9056 | | | Dihydrocodeine combo product (Compal) | 9807 | |
| Gamma Hydroxybutyric Acid (GHB) | | 2010 | | | Dronabinol in sesame oil soft cap (Marinol) | 7369 | |
| Heroin (Diamorphine) | | 9200 | | | | | |
| Ibogaine | | 7260 | | | Gamma-Hydroxybutyric Acid preparations (Zyrem) | 2012 | |
| Lysergic acid diethylamide (LSD) | | 7315 | | | Hydrocodone combo products (Lorcet, Vicodin) | 9806 | |
| Marijuana | | 7360/7372 | | | Ketamine (Ketaset, Ketalar) | 7285 | |
| Mescaline | | 7381 | | | Morphine combo product | 9810 | |
| Methaqualone (Quaalude) | | 2565 | | | Nalorphine (Nalline) | 9400 | |
| Methylene | | 7540 | | | Opium combo product (Paregoric) | 9809 | |
| MDPV | | 7535 | | | Pentobarbital suppository dosage (FP3) | 2270 | |
| Mephedrone | | 1248 | | | Pentobarbital | 2271 | |
| Normorphine | | 9313 | | | Phendimetrazine (Plegine, Bontril) | 1615 | |
| Peyote | | 7415 | | | Thiopental | 2100/2329 | |
| Psilocybin | | 7437 | | | Tiletamine & Zolazepam Combination (Telazol) | 7295 | |
| Tetrahydrocannabinols (THC) | | 7370 | | | Schedule 4 Narcotic & Non-Narcotic | | |
| Schedule 2 Narcotic & Non-Narcotic | | Code | Bulk? | | Alprazolam (Xanax) | 2882 | |
| Amobarbital (Amytal, Tuinal) | | 4000 | | | Barbital (Veronal, Plexonal) | 2145 | |
| Amphetamine (Dexedrine, Adderall) | | 2100 | | | Chloral Hydrate (Noctec) | 2465 | |
| Cocaine (Methyl benzoyleccgonine) | | 1228 | | | Chlordiazepoxide (Librium) | 2744 | |
| Codeine (Morphine methyl ester) | | 9064 | | | Clonazepam (Klonopin) | 2737 | |
| Dextropropoxyphene (bulk) | | 2100/2175 | | | Clorazepate (Tranxene) | 2768 | |
| Diphenoxylate | | 2100/2165 | | | Diazepam (Valium) | 2765 | |
| Fentanyl (Duragesic) | | 9804 | | | Flurazepam (Dalmane) | 2767 | |
| Hydrocodone (Dihydrocodeinone) | | 9807 | | | Lorazepam (Ativan) | 2885 | |
| Hydromorphone (Diaudid) | | 7369 | | | Meprobamate (Milltown, Equanil) | 2820 | |
| Levo-Alphacetylmethadol (LAAM) | | | | | Midazolam (Versed) | 2884 | |
| Levorphanol (Levo-Dromoran) | | 2012 | | | Oxazepam (Serax, Serenid-D) | 2835 | |
| Meperidine (Demerol, Mepergan) | | 9806 | | | Phenobarbital (Fastin, Zantryl) | 2285 | |
| Methadone (Dolophine, Methadose) | | 7285 | | | Phentermine | 1640 | |
| Methamphetamine (Desoxyn) | | 9810 | | | Temazepam (Restoril) | 2925 | |
| Methylphenidate (Concerta, Ritalin) | | 9400 | | | Zolpidem (Ambien, Stilnox) | 2783 | |
| Morphine (MS Contin, Roxanol) | | 9809 | | | Schedule 5 Narcotic & Non-Narcotic | | |
| Opium, powdered | | 2270 | | | Codeine preparations (Robitussin A-C, Pediaco) | 9050 | |
| Oxycodone (Oxycontin, Percocet) | | 2271 | | | Pyrovalerone (Centroton, Thymergix) | 1485 | |
| Oxymorphone (Numorphan) | | 1615 | | | | | |

Write in additional Codes: (attach a separate sheet if needed)

VCU Controlled Substance Research Protocol

All listed IRB/IACUC approvals include the substances listed and have been approved by the appropriate committee. I certify that the foregoing information is true and correct:

| | |
|-----------------------------------|-------|
| DEA Registrant/Applicant : | Date: |
|-----------------------------------|-------|

| | |
|---|-------|
| Protocol PI: (if different from Registrant) | Date: |
|---|-------|

THE DEA REGISTRANT/APPLICANT MUST SEND A COPY OF THIS COMPLETED FORM TO
controlsub@vcu.edu FOR RECORDS PURPOSES.

Authorized Users Signature Log

Schedule I Controlled Substances

Signatures of all persons designated by the Registrant as Authorized Users of Schedule I Controlled Substances for this Location are required according to Virginia Commonwealth University's policy.

Lab Location Address (Street, Building and Room #): _____

Registrant Name (Print): _____

| Date Signed | Name (Print) | Job Title | Signature | Initials As Used in CS Records | Date Departed |
|-------------|--------------|-----------|-----------|--------------------------------|---------------|
| | | | | | |
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I hereby certify that I have designated the person(s) listed above as Authorized Users for this location. Person is no longer an Authorized User when a "Date Departed" is entered.

Registrant's Signature*: _____ **Date:** _____

*Strike through unused lines to avoid addition of names after signature.

Instructions: Maintain in Registrant Records. Questions should be addressed to: controlsub@vcu.edu

Authorized Users Signature Log

Schedule II-V Controlled Substances

Signatures of all persons designated by the Registrant as Authorized Users of Schedule II-V Controlled Substances for this Location are required according to Virginia Commonwealth University's policy.*

Lab Location Address (Building and Room #): _____

Registrant Name (Print): _____

| Date Signed | Name (Print) | Job Title | Signature | Initials As Used in CS Records | Date Departed |
|-------------|--------------|-----------|-----------|--------------------------------|---------------|
| | | | | | |
| | | | | | |
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| | | | | | |

I hereby certify that I have designated the person(s) listed above as Authorized Users for this location. Person is no longer an Authorized User when a "Date Departed" is entered.

Registrant's Signature: _____ **Date:** _____

*Strike through unused lines to avoid addition of names after signature.

Instructions: Maintain in Registrant Records. Questions should be addressed to: controlsub@vcu.edu

Initial or Biennial Controlled Substances Inventory (Circle one)*

Date (MM/DD/YY): _____ Time (00:00 a.m./p.m.): _____ Start of Business _____ Close of Business _____

Street Address of Registrant: _____

VCU Building Name and Room Number:

DEA Registrant Name (Print): _____ **DEA Registration #:** _____

Inventory Conducted by: _____ **Date:** _____

Inventory Witnessed By: _____ **Date:** _____

Instructions: Complete an initial inventory of zero upon receipt of initial registration. An inventory must be completed **at least** biennially (per DEA regulations). Send copy of biennial inventory to controlsub@vcu.edu.

*This record may be kept electronically.

CONTROLLED SUBSTANCE USAGE LOG

1. One log sheet must be completed for each container of Controlled Substance. If the material is converted or diluted, start a new log form to track that usage; reference the original container's lot or serial # and original bottle #.
 2. Controlled Substance usage must be tracked on a per dose (use) basis and only by an Authorized User. Record total quantity of the substance to the nearest metric unit weight/volume or the total number of units finished form.
 3. Controlled Substances Dispensed in Bulk Form must be returned to the DEA Registrant within seven (7) days*.

| | | | |
|------------------|------------------|--|------------------------------|
| DEA Registrant: | Building: | Room: | |
| Drug Name: | Lot or Serial #: | Container Amount: | |
| Expiration Date: | Strength: | Form: Bulk* Finished (Circle One) | |
| Date Received: | Date Returned: * | Unique Bottle Number assigned by DEA Registrant**: | Date Remainder was Disposed: |

****This information is a unique number added to the controlled substance bottle in some labs. This is not required.**

***Number of Animals and Species, i.e., (5 mice) or describe other administration.

DEA Registrant Signature: _____ Date: _____

Instructions: Registrant should maintain completed form in his/her records for at least two years from the date of the last transaction.

CONTROLLED SUBSTANCE WASTAGE RECORD

Controlled Substance Dispensing Record

| DEA Registrant Name | DEA Registrant # | Controlled Substance | Schedule |
|---------------------|---------------------------------|-------------------------------------|---------------|
| Lot # | Finished Form & Number of Units | Acquired From (Name, Address, DEA#) | Date Acquired |

Instructions: Complete one form for each substance in inventory. Maintain in Registrant records. Document must be retained for two years from the last date of activity.

Controlled Substances Disposal Log

DEA Registrant: _____

DEA Registration #: _____

Storage Cabinet Location: _____

Schedule(s)¹: _____

| Lot # or Tracking # | Drug and Concentration | Amount Disposed | Reason for Disposal | Disposal Route ² | DEA # of recipient ⁴ | Returned Date | Returned by (Print name) | Returned by (Signature) |
|---------------------|------------------------|-----------------|---------------------|-----------------------------|---------------------------------|---------------|--------------------------|-------------------------|
| | | | | | | | | |
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| | | | | | | | | |

¹Disposal Logs for Schedule I & II must be maintained separately from Schedules III-V

²If disposal is conducted by any manner other than return to supplier or reverse distributor, circumstances should be fully described and documented

³RD = Reverse Distributor

⁴DEA number of the RD³ or supplier who will be accepting the substances for disposal

Instructions: When substance has expired or is no longer usable or needed, add to this log and store separately from other inventory. Record disposal information when disposal occurs. Maintain completed form in records for at least two years and date of last transaction.



VCU

VIRGINIA COMMONWEALTH UNIVERSITY

CONTROLLED SUBSTANCE* TRANSFER INVOICE

FROM [Registrant Name]

[DEA Registration Number]

DATE: JULY 31, 2013

[Registrant Street Address, City, ST, Zip]
Phone [000.000.0000] Fax [000.000.0000]
[e-mail]

TO [Registrant Name]
[DEA Registration Number]
[Registrant Street Address]
[City, ST ZIP Code]
[Phone]

SHIP TO [Registrant Name]
[DEA Registration Number]
[Registrant Street Address]
[City, ST ZIP Code]
[Phone]

| QUANTITY (ML, MG,ETC.) | SCHEDULE | CONTROLLED SUBSTANCE DESCRIPTION | CONCENTRATION OR STRENGTH | LOT # | RECEIPT VERIFIED (ENTER DATE TRANSFERRED) |
|------------------------------|----------|----------------------------------|------------------------------|-------|--|
| | | | | | |
| | | | | | |
| | | | | | |
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| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Transferring Registrant Signature: _____ Date: _____

Recipient Registrant Signature: _____ Date: _____

*To be used to transfer Schedule III-V Controlled Substances between DEA registrants. Each registrant must retain a copy in their records.



COMMONWEALTH OF VIRGINIA

Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
www.dhp.virginia.gov/pharmacy

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)
pharmbd@dhp.virginia.gov (email)

APPLICATION FOR A CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Check Appropriate Box(es):

| | | | |
|--|----------|---|--------|
| <input checked="" type="checkbox"/> New | \$90.00 | <input type="checkbox"/> Change to Drug Schedule | No Fee |
| <input type="checkbox"/> Change of Ownership | \$50.00 | <input type="checkbox"/> Change of Trade Name | No Fee |
| <input type="checkbox"/> Change of Location | \$150.00 | <input type="checkbox"/> Change of Responsible Party | No Fee |
| <input type="checkbox"/> Remodel | \$150.00 | <input type="checkbox"/> Change of Supervising Practitioner | No Fee |
| <input type="checkbox"/> Reinstatement | | | |

The application fee is not refundable.

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials

| | | | | |
|--|--|--|--|--|
| Type of Activity— | | <input type="checkbox"/> Alternate Delivery Site ^{1&6} | <input type="checkbox"/> Ambulatory Surgery Center ¹ | <input type="checkbox"/> Analytic Laboratory ² |
| Check only one: | | <input type="checkbox"/> Animal Shelter or Pound ¹ | <input type="checkbox"/> EMS Agency ¹ | <input type="checkbox"/> Government Official ² |
| <input type="checkbox"/> Hospital ¹ | | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Out-patient Clinic ¹ | <input checked="" type="checkbox"/> Researcher ² |
| <input type="checkbox"/> Teaching Institute ² | | <input type="checkbox"/> Warehouser | <input type="checkbox"/> Wholesale Distributor | <input type="checkbox"/> Other ^{1 or 2} |
| Name of Entity VCU Department of _____ | | | Controlled Substance Schedules Requested: <input type="checkbox"/> I ³ <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> VI | |
| Street Address Researcher Street Address (where substances will be stored) | | | Telephone Number () Researcher Phone | Fax Number () Researcher Fax |
| City Richmond | | | State VA | Zip Code 23219 |
| Name of Responsible Party Researcher Name | | Email Address of Responsible Party Researcher E-mail | | |
| Type of Professional License to administer drugs (if applicable) Respond | | Professional License Number of Responsible Party (if applicable) Respond | | VA Controlled Substance Number of entity (if applicable) Respond |
| Signature of Responsible Party Sign | | | Date | |
| Name of Supervising Practitioner (if applicable) ¹ Leave Blank | | | Area Code and Telephone Number Leave Blank | |
| Street Address of Supervising Practitioner Leave Blank | | | Professional License Number Leave Blank | |
| City Leave Blank | | State Leave Blank | Zip Code Leave Blank | DEA Number of Supervising Practitioner ⁴ Leave Blank |
| Signature of Supervising Practitioner | | | Date | |
| Expected Opening Date Enter Date | | Requested Inspection Date ⁵ Enter Date | | |
| Assigned Inspection Date⁵: | | (For Board Use Only) | | |
| IMPORTANT: Please Read and complete page 2 of this application | | | | |

Controlled Substances Registration Application, Page 2

OWNERSHIP TYPE—check one: Corporation Partnership Individual Other

Name of ownership entity if different from name of application: Virginia Commonwealth University

Street Address: 800 East Leigh Street, Suite 3000 Phone No. (804) 827-0479

City: Richmond State: VA Zip Code: 23219

State(s) of incorporation:

List all other trade or business names used by this facility

Name: _____ Name: _____

LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED

| | | |
|------------------------|-----------------------------------|-----------------------------|
| Name: _____ | Francis Macrina | Vice President for Research |
| Contact Address: _____ | 800 East Leigh Street, Suite 3000 | Title: _____ |
| Name: _____ | Susan Robb | Assoc. VP for Research |
| Contact Address: _____ | 800 East Leigh Street, Suite 3000 | Title: Admin. & Comp. |

AREA BELOW FOR OFFICE USE ONLY

| Application Number Assigned | Date Processed | Date Issued | CSRC Number |
|--|--|-------------|-------------|
| If reinstatement, date registration expired: | Reinstatement is following the: <input type="checkbox"/> Lapse of registration <input type="checkbox"/> Suspension/Revocation <input type="checkbox"/> Period of inactivity | | |
| Approved for Controlled Substance Schedules: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> VI <input type="checkbox"/> DEA Approval for Schedule I received (DEA Number): _____ | | | |

1. Entities applying under this activity code must submit a description of the processes/business practices for which this registration is being sought, and must have a supervising practitioner as follows:

A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

- In a hospital without an in-house pharmacy, a pharmacist shall supervise.
- In an emergency medical services agency, the operational medical director shall supervise
- In an animal shelter or pound, a licensed veterinarian shall supervise
- For any other person or entity approved by the board, a practitioner of pharmacy, medicine, osteopathy, podiatry, dentistry, or veterinary medicine whose scope of practice is consistent with the practice of the person or entity and who is approved by the board shall provide the required supervision.

2. Persons applying under this activity code must submit, with the application, a protocol which specifically names the controlled substances to be used and provides details as to the intended use of these controlled substances within the work. Additionally, persons applying under this activity code must provide documentation showing competence (curriculum vitae, educational credentials, professional licensure, training documentation) to use the controlled substances within the scope of this activity.

3. Schedule I must be approved by DEA prior to Board approval. A copy of the DEA license must be sent to the Board in order for the Virginia controlled substance registration to be updated to reflect Schedule I.

4. If supervising practitioner is a pharmacist, give DEA number of the provider pharmacy supplying drugs.

5. A 14-day notice is required for scheduling an opening or change of location inspection.

An inspector will call the responsible party prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at (804) 367-4691 to verify the inspection date with the inspector.

APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

APPROVED OMB NO 1117-0012
FORM DEA-225 (04-12)
FORM EXPIRES: 4/30/2015

INSTRUCTIONS

Save time - apply on-line at www.deadiversion.usdoj.gov

1. To apply by mail complete this application. Keep a copy for your records.
2. Mail this form to the address provided in Section 7 or use enclosed envelope.
3. The "MAIL-TO ADDRESS" can be different than your "PLACE OF BUSINESS" address.
4. If you have any questions call 800-882-9539 prior to submitting your application.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ON-LINE.

DEA OFFICIAL USE:

| | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|

Do you have other DEA registration numbers?

NO YES

MAIL-TO ADDRESS

Please print mailing address changes to the right of the address in this box.

FEE FOR ONE (1) YEAR - see Section 2
FEE IS NON-REFUNDABLE

*Answer question
Do not enter any
number.*

SECTION 1 APPLICANT IDENTIFICATION

Individual Registration

Business Registration

Name 1 (Last Name of individual -OR- Business or Facility Name)

LAST

Name 2 (First Name and Middle Name of individual - OR- Continuation of business name)

FIRST M

PLACE OF BUSINESS Street Address Line 1

STREET ADDRESS + ROOM # OF INVENTORY

PLACE OF BUSINESS Address Line 2

VCU DEPARTMENT OF -----

City

State Zip Code

RICHMOND

VA 23219

Business Phone Number

Point of Contact

804------

Business Fax Number

Email Address

804------

eid@vcu.edu

DEBT COLLECTION INFORMATION
Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number (*if registration is for business*)

Provide TIN or SSN.
See additional information note #3 on page 4.

Social Security Number (*if registration is for individual*)

COMPLETE

SECTION 2**BUSINESS ACTIVITY**

Check one business activity box only

Researcher w/Sched I.....fee for one year is \$244
 Researcher w/Sched II - V.....fee for one year is \$244

Researcher - See page 4 for required attachments

Canine Handler.....fee for one year is \$244
 Distributor.....fee for one year is \$1523

Exporter.....fee for one year is \$1523
 Importer.....fee for one year is \$1523
 Reverse Distributor.....fee for one year is \$1523
 Manufacturer.....fee for one year is \$3047
 Manufacturer BULK.....fee for one year is \$3047

SECTION 3 *COMPLETE***A. DRUG SCHEDULES**

Check all that apply

List 1 (L1) - manufacturers & importers ONLY
 Schedule 1 Schedule 2 Narcotic
 Schedule 2 Non-Narcotic (2N) Schedule 3 Narcotic
 Schedule 3 Non-Narcotic (3N) Schedule 4
 Schedule 5

Enter drug codes on page 2.

Check this box if you require official order forms - for purchase of schedule 2 controlled substances.

B. MANUFACTURERS ONLY

Mark each box with an 'X' to indicate which drug schedule is handled in each manufacturing stage

L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 1 Bulk synthesis/extraction

L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 2 Dosage form manufacture

L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 3 Package / Repackage Label / Relabel

L1 1 2 2 NON narcotic 3 3 NON narcotic 4 5 STAGE 4 Non-human consumption NEW - Page 1

C. SCHEDULE AND DRUG CODES
COMPLETE

Listed below are examples of schedules 1-5 and List 1 codes. Check all drug codes you handle as required.

For more information, see our website at www.deadiversion.usdoj.gov, 21 CFR 1308, or call 1-800-882-9539.

| | | | |
|----------------|--|------------------------|---|
| Canine Handler | must mark schedule 1 | Distributor | must mark all schedule 1, drug code 2012 |
| Exporter | must mark all schedule 1-5 | Reverse Distributor | must mark all schedule 1, drug code 2012 |
| Importer | must mark all schedule 1-5 & List 1 codes | Researcher w/Sched 1 | must mark schedule 1 |
| Manufacturer | must mark all schedule 1, 2 & List 1 codes | Researcher w/Sched 2-5 | must mark schedule 2 to be manufactured or imported as part of research |

If you bulk manufacture a substance, check the 'BULK?' column after the applicable class code.

| SCHEDULE 1 NARCOTIC & NON-NARCOTIC | CODE | BULK? | SCHEDULE 2 NARCOTIC & NON-NARCOTIC | CODE | BULK? |
|--|-----------|-------|---|------|-------|
| 3,4-Methylenedioxymphetamine (MDA) | 7400 | | Amobarbital (Amytal, Tuinal) | 2125 | |
| 3,4-Methylenedioxymethamphetamine (MDMA) | 7405 | | Amphetamine (Dexedrine, Adderall) | 1100 | |
| 4-Methyl - 2,5 - Dimethoxyamphetamine (DOM, STP) | 7395 | | Cocaine (Methyl benzoylcgonine) | 9041 | |
| 4-Methylaminorex (cis isomer) (U4Euh, McN-422) | 1590 | | Codeine (Morphine methyl ester) | 9050 | |
| Alphacetylmethadol (except LAAM) | 9603 | | Dextropropoxyphene (bulk) | 9273 | |
| Bufotenine (Mappine) | 7433 | | Diphenoxylate | 9170 | |
| Marijuana / Cannabidiol | 7360/7372 | | Fentanyl (Duragesic) | 9801 | |
| Diethyltryptamine (DET) (| 7434 | | Hydrocodone (Dihydrocodeinone) | 9193 | |
| Difenoxin 1MG/25UG AISO4 /DU (Motofen) | 9167 | | Hydromorphone (Diauid) | 9150 | |
| Dimethyltryptamine (DMT) | 7435 | | Levo-Alphacetylmethadol (LAAM) | 9648 | |
| Etorphine (except HCL) | 9056 | | Levorphanol (Levo-Dromoran) | 9220 | |
| Gamma Hydroxybutyric Acid (GHB) | 2010 | | Meperidine (Demerol, Mepergan) | 9230 | |
| Heroin (Diamorphine) | 9200 | | Methadone (Dolophine, Methadose) | 9250 | |
| Ibogaine | 7260 | | Methamphetamine (Desoxyn) | 1105 | |
| Lysergic acid diethylamide (LSD) | 7315 | | Methylphenidate (Concerta, Ritalin) | 1724 | |
| Mescaline | 7381 | | Morphine (MS Contin, Roxanol) | 9300 | |
| Marijuana | 7360 | | Opium, powdered | 9639 | |
| Methaqualone (Quaalude) | 2565 | | Oxycodone (Oxycontin, Percocet) | 9143 | |
| Normorphine | 9313 | | Oxymorphone (Numorphan) | 9652 | |
| Peyote | 7415 | | Pentobarbital (bulk) (Nembutal) | 2270 | |
| Psilocybin | 7437 | | Phencyclidine (PCP) | 7471 | |
| Tetrahydrocannabinols (THC) | 7370 | | Secobarbital (Seconal, Tuinal) | 2315 | |
| SCHEDULE 3 NARCOTIC & NON-NARCOTIC | CODE | BULK? | SCHEDULE 4 NARCOTIC & NON-NARCOTIC | CODE | BULK? |
| Anabolic Steroids | 4000 | | Alprazolam (Xanax) | 2882 | |
| Barbituric acid derivative | 2100 | | Barbital (Veronal, Plexonal) | 2145 | |
| Benzphetamine (Didrex, Inapetyl) | 1228 | | Chloral Hydrate (Noctec) | 2465 | |
| Buprenorphine (Buprenex, Temgesic) | 9064 | | Chlordiazepoxide (Librium) | 2744 | |
| Butabarbital | 2100/2175 | | Clonazepam (Klonopin) | 2737 | |
| Butalbital | 2100/2165 | | Clorazepate (Tranxene) | 2768 | |
| Codeine combo product (Empirin) | 9804 | | Diazepam (Valium) | 2765 | |
| Dihydrocodeine combo product (Compal) | 9807 | | Flurazepam (Dalmane) | 2767 | |
| Dronabinol in sesame oil soft cap (Marinol) | 7369 | | Lorazepam (Ativan) | 2885 | |
| Gamma-Hydroxybutyric Acid preparations (Zyrem) | 2012 | | Meprobamate (Milltown, Equanil) | 2820 | |
| Hydrocodone combo products (Lorcet, Vicodin) | 9806 | | Midazolam (Versed) | 2884 | |
| Ketamine (Ketaset, Ketalar) | 7285 | | Oxazepam (Serax, Serenid-D) | 2835 | |
| Morphine combo product | 9810 | | Phenobarbital (Fastin, Zantyl) | 2285 | |
| Nalorphine (Nalline) | 9400 | | Phentermine | 1640 | |
| Opium combo product (Paregoric) | 9809 | | Temazepam (Restoril) | 2925 | |
| Pentobarbital suppository dosage (FP3) | 2270 | | Zolpidem (Ambien, Stilnox) | 2783 | |
| Phendimetrazine (Plegine, Bontril) | 1615 | | LIST 1 REGULATED CHEMICALS | CODE | BULK? |
| Thiopental | 2100/2329 | | ** ONLY manufacturers & importers may select List 1 | | |
| SCHEDULE 5 NARCOTIC & NON-NARCOTIC | CODE | BULK? | | | |
| Codeine preparations (Robitussin A-C, Pediocof) | 9050 | | Ephedrine | 8113 | |
| Pyrovalerone (Centroton, Thymergix) | 1485 | | Phenylpropanolamine | 1225 | |
| | | | Pseudoephedrine | 8112 | |

WRITE IN ADDITIONAL CODES

You may write in additional drug codes in this section. Attach a separate sheet if needed.

SECTION 1. APPLICANT IDENTIFICATION - Information must be typed or printed in the blocks provided to help reduce data entry errors. A physical address is required in address line 1; a post office box or continuation of address may be entered in address line 2. Fee exempt applicant must list the address of the fee exempt institution. Applicant must enter a valid social security number (SSN), or a tax identification number (TIN) if applying as a business entity.

Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.

SECTION 2. BUSINESS ACTIVITY - Indicate only one. Each type of business activity requires a separate application. You are required to register as a "manufacturer" if you manufacture a controlled substance or list 1 chemical and then distribute it.

SECTION 3A. SCHEDULES - Applicant should check all schedules to be handled. However, applicant must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you intend to purchase or to transfer schedule 1 and 2 controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration.

3B. MANUFACTURER ONLY - Mark the chemical/controlled substance schedule(s) handled in each manufacturing stage listed.

3C. SCHEDULE CODES - Report all chemical/drug codes as required for your business activity. Controlled substances manufacturers and importers must obtain a separate chemical registration if they handle chemicals other than an FDA-approved drug product containing 1225, 8112, or 8113.

SECTION 4. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant's compliance with applicable state and local laws. Applicant should contact the local state licensing authority prior to completing this application. If your state requires a license, provide that number on this application.

SECTION 5. LIABILITY - Applicant must answer all four questions for the application to be accepted for processing. If you answer "Yes" to a question, provide an explanation in the space provided. If you answer "Yes" to several questions, then you must provide a separate explanation describing the date, location, nature, and result of each incident. If additional space is required, you may attach a separate page.

SECTION 6. EXEMPTION - Exemption from payment of application fee is limited to federal, state or local government official or institution. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided. The address of the fee exempt institution must appear in Section 1.

SECTION 7. METHOD OF PAYMENT - Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. **FEES ARE NON-REFUNDABLE**.

SECTION 8. APPLICANT'S SIGNATURE - Applicant MUST sign in this section or application will be returned. Card holder signature in section 7 does not fulfill this requirement.

ATTACHMENTS: Researcher or canine handler must attach 3 copies of protocol, including curriculum vitae, to conduct research with schedule 1 controlled substances. For clinical investigations, researcher must first submit to FDA a "Notice of Claimed Investigational Exemption for New Drug (IND)". See DEA web site or CFR 1301.18 for details.

NOTICE TO REGISTRANTS MAKING PAYMENT BY CHECK

Authorization to Convert Your Check: If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

Insufficient Funds: The electronic funds transfer from your account will usually occur within 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two more times.

Transaction Information: The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions". You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights: You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

ADDITIONAL INFORMATION

No registration will be issued unless a completed application form has been received (21 CFR 1301.13).

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is 1117-0012. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.

The Debt Collection Improvements Act of 1996 (31 U.S.C. §7701) requires that you furnish your Taxpayer Identification Number (TIN) or Social Security Number (SSN) on this application. This number is required for debt collection procedures if your fee is not collectible.

PRIVACY ACT NOTICE: Providing information other than your SSN or TIN is voluntary; however, failure to furnish it will preclude processing of the application. The authorities for collection of this information are §§302 and 303 of the Controlled Substances Act (CSA) (21 U.S.C. §§822 and 823). The principle purpose for which the information will be used is to register applicants pursuant to the CSA. The information may be disclosed to other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes, State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes, and person registered under the CSA for the purpose of verifying registration. For further guidance regarding how your information may be used or disclosed, and a complete list of the routine uses of this collection, please see the DEA System of Records Notice "Controlled Substances Act Registration Records" (DEA-005), 52 FR 47208, December 11, 1987, as modified.

**Your Local
DEA Office**

CONTACT INFORMATION

All offices are listed on web site
(800, 877, and 888 are toll-free)

INTERNET:
www.deadiversion.usdoj.gov

TELEPHONE:
HQ Call Center (800) 882-9539

WRITTEN INQUIRIES:
DEA
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

SAMPLE SCREENSHOTS FROM ONLINE 225 APPLICATION FORM

HELP

Contact Name: Enter the name of the person the DEA should contact in case of necessity. This field is primarily for businesses to nominate a point of contact for the DEA.

[General Instructions](#)

1. General Information (Page 1)

| | |
|---|----------------------------------|
| * Last Name | Last |
| * First Name, Middle Initial, (Degree) | First |
| Additional Company Information | Virginia Commonwealth University |
| * Business Address Line 1 | Street Add. & Room# of Inventory |
| Address (Line 2) | VCU Department of _____ |
| * City | Richmond |
| * State | VA- VIRGINIA |
| * Zip | 23219 - _____ |
| * Business Phone Number | (804) _____ - _____ Ex. _____ |
| Fax Number | (804) _____ - _____ |
| * Business Email Address | eid@vcu.edu |
| Contact Name | _____ |
| Mailing Address <input checked="" type="checkbox"/> (Check if same as business address) | |
| Additional Company Information | Virginia Commonwealth University |
| * Mail to: Address Line 1 | Street Add. & Room# of Inventory |
| Mailing Address (Line 2) | VCU Department of _____ |
| * City | Richmond |
| * State | VA- VIRGINIA |
| * Zip | 23219 - _____ |

-Cancel- **Next->**



U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

HELP

Social Security Number:
The Debt Collection Improvement Act of 1996 (PL 104-134) requires that you furnish your federal Taxpayer Identifying Number to DEA. This number is required for debt collection procedures should your fee become uncollectable. If you do not have a Federal Taxpayer Identifying Number, use your Social Security Number.

[General Instructions](#)

1. Personal Information (Page 2)

Enter a Social Security Number or Taxpayer Identifying Number
If you are Fee Exempt, check the Fee Exempt box below and supply the required information.

Tax ID (No dashes or spaces.)

SSN (No dashes or spaces.)

For Fee Exempt applicants ONLY:

By checking this box, the applicant hereby CERTIFIES that they are a Government employee (not a contractor) of a federal, state, or local government agency, or if an institution, it is OPERATED by a government agency and is exempt from the payment of the application fee.

CERTIFICATION FOR FEE EXEMPTION - Government Only

If you select Fee Exempt, the next page will prompt you to provide the Name, Title, and phone number of the Certifying Official (applicants must not certify themselves).

[**<-Previous**](#)

[**Next->**](#)

[**-Cancel-**](#)



U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

HELP

Certifier's Approval
Checkbox: Click here to indicate that the certifying official agrees to the terms outlined on the Fee Exempt page.

[General Instructions.](#)

1. Personal Information (Page 3 - Fee Exempt Details)

Please provide the Name, Title, and phone number of the Certifying Official (applicants must not certify themselves).

| | |
|---|--------------------------------|
| * Name of Fee Exempt Institution (Must be a Federal, State, or County Agency) | Virginia Commonwealth Universi |
| * Certifying Official Name (other than applicant) | Susan E. Robb |
| * Certifying Official Title | Assoc. VP for Res. Adm. & Comp |
| * Certifying Official Phone Number | (804) 827 - 0479 Ex. |

By checking the following box, the applicant states that the certifying official listed above has consented to be named on this application for the purpose of certifying the applicant's Fee Exempt status.

I have read the above, and agree.

Fields with a () are required.*

[<-Previous](#)

[Next->](#)

[-Cancel-](#)



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

HELP

Drug Schedule

Checkboxes: Click a checkbox to request authorization for that schedule. At least one schedule must be checked to proceed.

[General Instructions](#)

2. Business Activity/Schedules

Your business activity is: RESEARCHER (II-V)

DRUG SCHEDULES [see schedules](#)

Select all that apply

- | | |
|---|--|
| <input type="checkbox"/> Schedule II Narcotic | <input type="checkbox"/> Schedule III Non Narcotic |
| <input type="checkbox"/> Schedule II Non Narcotic | <input type="checkbox"/> Schedule IV |
| <input checked="" type="checkbox"/> Schedule III Narcotic | <input type="checkbox"/> Schedule V |

Check here if you require order forms to only purchase Schedule I and II from suppliers.

Fields with a () are required.*

[<-Previous](#)

[Next->](#)

[-Cancel-](#)



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

HELP

Expire Date: Enter the date that your state license expires. This is a required field.

General Instructions.

3. State Licenses

All applicants are required to answer the following:

You must be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate.

Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn WITHOUT refund

* State License Number:

* State License State:

* Expire Date:

Sections with a () require all data fields to be entered.*



U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

HELP

Questions Applicants must answer all questions.
NOTE: If question 4 is not applicable to you, select 'No.'

[General Instructions.](#)

4. Background Information

All applicants are required to answer the following 4 questions:

(1) * Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or any such action pending?

Yes No

(2) * Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?

Yes No

(3) * Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?

Yes No

(4) * If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?

Yes No

Fields with a () are required.*

[<-Previous](#)

[Next->](#)

[-Cancel-](#)

Form 225/225A - Drug Code Selection - Windows Internet Explorer

https://www.deadiversion.usdoj.gov/webforms/background.do

File Edit View Favorites Tools Help
Convert Select

Google

Form 225/225A - Drug Code Selection

Select a schedule to add drug codes for that schedule.

Schedule I *

You have not selected any schedules which require drug code input. You may select "Next" below to continue.

Schedule II Narcotic *

More details regarding drug schedules can be found in [21 CFR 1308](#).

Schedule II Non Narcotic *

Schedule III Narcotic *

Schedule III Non Narcotic *

Schedule IV *

Schedule V *

List I Chemicals *

Schedules marked with a '*' do not require drug codes to be entered.

You have not selected any schedules which require drug code input. You may select "Next" below to continue.

Select Drug Codes

Drug Codes Selected
- No Codes Selected -

<-Previous
Next->
-Cancel-

Done

Internet 100%



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Summary of Information

Please review your responses. Click the change buttons on the left to make any required changes, then submit the application using the Submit button below.

| STEP - 1 PERSONAL INFO | | |
|------------------------|--------------------------------|---|
| Change | | |
| | First Name, MI: | Susan E. |
| | Last Name: | Robb |
| | Address: | Virginia Commonwealth University 800 East Leigh Street |
| | City: | Richmond |
| | State: | VA |
| | Zip: | 23219 |
| | Phone: | 804 827 0479 |
| | Fax: | 804 828 2521 |
| Business Email: | sarobb@vcu.edu | |
| Contact Name | | |
| Change | | |
| | SSN: | 111223333 |
| | Tax ID: | |
| | Fee Exempt: | Yes |
| | | |
| | Institution Name: | |
| | Virginia Commonwealth Universi | |

Review summary. Submit button is at the bottom of this page.

DEA Registered Reverse Distributors



ARIZONA

Environmental Pharmaceuticals, LLC – (480) 659-9611

CALIFORNIA

EXP Pharmaceutical Services Corporation – (800) 350-0397 or (510) 476-0909

Far West Returns – (530) 872-1758

Veolia Es Technical Solutions, LLC – (626) 945-6003

FLORIDA

Pharmacy Returns Logistics – (386) 935-0876

PharmaLink, Inc. – (727) 669-8187

Pharmatech Services, Inc. – (813) 749-7113

Rx Reverse Distributors, Inc. – (772) 388-1212

SAI Transport – (863) 858-7110

Woodfield Distributor LLC – (561) 998-3885

GEORGIA

Burke Horton, Inc. dba The Rx Exchange – (687) 306-1866

Danox Environmental Services Inc. – (404) 671-9163

Maximum Rx Credit, Inc. – (770) 985-2136

Pharmamate dba Return Co – (727) 861-1100

Return Logistics – (912) 748-5100

Stericycle, Inc – (707) 409-1500

ILLINOIS

Pharma Logistics, Ltd. – (888) 729-7427 or (847) 837-1224

Pharmaceutical Returns Services – (800) 215-5878 or (630) 892-8740

Progressive Returns, Inc. – (773) 622-9584

Qualanex – (847) 775-7256

INDIANA

Stericycle, Inc. – (317) 860-1200

IOWA

National Pharmaceutical Returns, Inc. – (800) 470-7725 or (515) 252-7722

KENTUCKY

Infectious Disease Control, Inc. – (502) 847-4989

MICHIGAN

Drug and Laboratory Disposal, Inc. – (800) 685-9824 or (269) 685-9824

EQ Detroit, Inc. – (313) 347-1350

U S Industrial Technologies, Inc. – (734) 462-4100

MINNESOTA

EZ Pharmacy Returns, LLC – (800) 440-0613

NEW JERSEY

Advanced RX Returns – (201) 222-3800

December 2012

This list of reverse distributors does not constitute an endorsement by the DEA of these companies or their products or services.

DEA Registered Reverse Distributors



NEW YORK

**ARK Business Services Inc – (347) 590-2779
Devos, Ltd. dba Guaranteed Returns – (800) 473-2138 or (631) 689-0191
Reliable RX Returns – (631) 589-4249**

NORTH CAROLINA

**ALMAC Clinical Services, Inc. – (919) 479-8853
Assured Waste Solutions, LLC – (704) 224-6083
Pharmaceutical Dimensions – (336) 664-5287
Republic Environmental Systems – (704) 391-2805**

OHIO

**Achieva Group Returns, Inc. – (513) 474-9900
Chemtron Corporation – (440) 933-6348
Heritage – WTI – (330) 3895-7336**

OKLAHOMA

Total Returns – (580) 276-3056

PENNSYLVANIA

**Chesapeake Waste Solutions, Inc. – (717) 653-8882
HDS Returns LLC – (724) 658-0206
Pharmareturns – (215) 651-7400
Republic Environmental Systems (Pennsylvania), LLC – (215) 822-8995
Prestigious RX Returns DBS PRX Returns – (570) 578-0136**

SOUTH CAROLINA

Advanced Environmental Options, Inc. – (864) 488-9111

TENNESSEE

**Pharmaceutical Credit Corp. – (615) 373-4262
Quality RX Returns – (865) 660-6558
Reliable Pharmaceutical Returns, LLC – (615) 361-8856
Return Solutions, Inc. – (865) 675-1355**

TEXAS

**Med-Turn, Inc. – (817) 868-5300
Sharps Compliance, Inc. – (903) 693-2525**

UTAH

**Clean Harbor Aragonite, LLC – (435) 884-3100
MD Returns – (801) 562-2498
National Products Sales – (801) 972-4132**

WASHINGTON

P.S. Industries, Inc. – (206) 749-0739

WISCONSIN

**Capital Returns, Inc. – (800) 950-5479 or (414) 967-2800
Veolia ES Technical Solutions, LLC – (262) 255-6655**

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