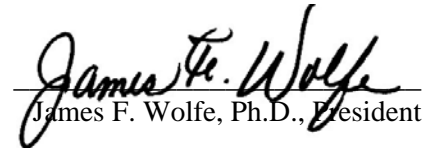


## Edward Via Virginia College of Osteopathic Medicine

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Dixie Tooke-Rawlins, Dean  
And Chief Administrative Officer

  
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### VCOM Policy on Using Controlled Substances for Research

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## 1. PURPOSE

Certain research activities conducted under the auspices of the College require the use of controlled substances. Controlled substances are identified in the schedules contained within the “Controlled Substance Inventory List” published by the US Drug Enforcement Agency (DEA). In conducting research with controlled substances, authorized College employees must comply with federal and state laws and regulations regarding their use. These regulations include DEA registration, Code of Virginia, storage requirements, inventory maintenance, substance disposal and reporting and record keeping in accordance with Title 21, Part 1300 to end of the Code of Federal Regulations and Title 54.1, Section 3422 of the Code of Virginia.

VCOM employees and any other individuals using College resources or facilities or receiving funds administered by the College must comply with this policy and federal and state regulations relating to controlled substances.

Failure to comply with this policy may be grounds for discipline by the College, suspension or termination of research by the College Institutional Review Board, referral for academic misconduct proceedings and/or reporting to external licensing authorities.

## 2. DEFINITIONS

**Authorized Personnel:** A College employee authorized to use controlled substances by an authorized registrant who also serves as his/her direct supervisor.

**Authorized Registrant:** A College employee holding a DEA registration and responsible for ordering, storing, using and disposing of controlled substances.

**Chief of Operations:** The Chief of Operations at VCOM oversees functions related to building and property operations, all current and future planned building construction and the facilities and information technology departments.

**Controlled Substance:** Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21.CFR.1300 to end) and the Code of Virginia, Title 54.1, Section 3422.

**Disposition Record:** An accurate, continuous and current record to track the acquisition, use and disposal of controlled substances.

**Drug Enforcement Administration (DEA):** The unit with the United States Department of Justice that establishes and enforces regulations for the handling and use of controlled substances.

**Institutional Biosafety Officer:** The Biosafety Officer is responsible for ensuring compliance of VCOM personnel with internal policies and procedures and with local, state and federal regulations.

**Research:** Any investigative activity engaged in by College personnel using College facilities or resources regardless of funding source.

## 3. RESPONSIBILITIES

### 3.1. Authorized Registrant

Authorized registrants of DEA licensure, principal investigators or supervisors of research in which controlled substances are used, bear full responsibility for complying with federal and state laws and regulations and with VCOM policy regarding their use. Specifically, authorized registrants are responsible for:

1. Obtaining and maintaining appropriate licensure from the DEA.
2. Ensuring proper use, storage and disposal of controlled substances and maintenance of disposition records.

3. Establishing security measures for the purchase, acceptance, use and ultimate disposal of the controlled substances used in research.
4. Providing the VCOM Biosafety Officer with copies of the appropriate DEA registration.
5. Carrying out an annual inventory of controlled substances.

If applicable, the authorized registrant shall be responsible for obtaining approval for use from the VCOM Institutional Review Board or the Virginia Tech Animal Care and Use Committee as well as reporting intentions to use controlled substances to external funding sponsors upon submission of grant applications.

### **3.2. Institutional Biosafety Officer**

The VCOM Biosafety Officer shall maintain a current list of all registration holders. The Biosafety Officer shall approve and periodically review security of controlled substances storage facilities. In addition, the Biosafety Officer shall periodically perform site reviews and reviews of registrant's purchasing process, disposition and inventory records as well as verify justification for use of the controlled substances. Training in controlled substances policies and procedures for registrants and authorized personnel will be the responsibility of the Biosafety Officer.

### **3.3. Authorized Personnel**

Authorized personnel are those authorized to use controlled substances by an authorized registrant who also serves as their direct supervisor. Authorized personnel shall be responsible for properly using controlled substances and maintaining disposition records. Authorized personnel are allowed to perform activities with controlled substances as directed by the authorized registrant of the laboratory in which the authorized personnel are working. Authorized Personnel must sign the Authorized Personnel Signature Log within each Laboratory.

### **3.4. Office of Research Administration**

The Office of Research Administration shall be responsible for assisting the Biosafety Officer in collecting information on authorized use of controlled substances by investigators using animal or human subjects.

## **4. REGISTERING**

The authorized registrant, any VCOM faculty member conducting research involving controlled substances, must obtain a DEA registration for his/her laboratory where the controlled substances will be used. Authorized registrants should use DEA Form-225. Application information and forms can be found at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

The Biosafety Officer and Office of Research Administration must be notified when licensure is requested.

Contact the Biosafety Officer or the Office of Research Administration for assistance with the DEA registration process.

### **4.1. Maintaining Registration**

DEA registrations must be renewed every year. The Office of Research Administration and the Biosafety Officer must be notified by the authorized registrant when a registration becomes inactive.

## **5. PURCHASING, RECEIVING AND STORAGE OF CONTROLLED SUBSTANCES**

### **5.1. Purchasing**

Orders for controlled substances by authorized registrants must be submitted to the Purchasing Department on a Purchase Order Form signed by the authorized registrant or authorized personnel. The signature of the authorized registrant's associate dean is also required on this form. DEA Form-222 and a copy of the DEA registration must accompany the order request.

DEA Form-222 books can be requested at: <https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>.

## **5.2. Receiving**

Controlled substances must be shipped to the authorized registrant and address as indicated on the DEA registration. Once received, the controlled substances must be opened to verify the contents and any discrepancies must be rectified with the shipper. If discrepancies cannot be rectified, the authorized registrant must contact the Biosafety Officer and the DEA. The authorized registrant must sign and date the purchase receipt and file it with the controlled substances records. A copy of the receipt must be provided to the Purchasing Department.

From the time a controlled substance is accepted on campus until it is consumed or disposed of, a disposition record of the chain of custody must be kept at each point where the controlled substance changes hands or is used. The record is completed at each point by the individual delivering the controlled substance and includes the substance, quantity and the signature of the individual receiving it. The individual making the withdrawal shall sign all records of withdrawals of controlled substances from storage.

## **5.3. Labeling**

If controlled substances are removed from original packaging and compounded, diluted or combined, each new container must be labeled and tracked. The label must include:

1. The name of the controlled substances,
2. The lot number,
3. The final concentration,
4. The amount per container, and
5. The expiration date (not more than 30 days after dilution date).

## **5.4. Storage and Security**

Controlled substances must be stored in a safe place separate from other drugs or materials. The safe must be bolted to an immovable object.

All authorized registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. The following are some of the considerations in determining security requirements:

- Type of activity,
- Type and form of controlled substance,
- Quality of controlled substance,
- Location of the premises,
- Type of vault, safe and secure enclosure, and
- Adequacy of supervision of employees with access.

Specific outlines for the storage and security for controlled substances are to be found in 21.CFR.1301.71 – 1301/74 (<http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm>).

## **6. USING AND DISPOSING OF CONTROLLED SUBSTANCES**

### **6.1. Disposition Records**

In accordance with 21.CFR.1304.21 and 1304.24, each authorized registrant must document all actions taken with the controlled substance, which include receiving, using, diluting/combining, transferring or disposing of expired and waste controlled substances. Such record of use of controlled substances should be written in disposition records. The authorized registrant must maintain the records for at least three years. Other contracts or regulations may require longer retention periods. A Controlled Substance Disposition Record must be completed and filed in a binder. All fields in the Disposition Record must be completed.

### **6.2. Inventory**

At least once a calendar year, authorized registrants must complete an inventory to compare the actual count of controlled substances in the safe to the amount in the written disposition records. More frequent inventories are recommended for laboratories using Schedule II drugs, higher volumes, multiple controlled substances or with many authorized personnel. The Controlled Substance Inventory Record contains all the required information to

meet the DEA regulations. For guidance regarding damaged, defective or impure substances awaiting disposal, see 21.CFR.1304.15(d). Note that all Schedule I and II controlled substances must be maintained separately from all other records.

### **6.3. Reporting**

Within 14 days of completing annual inventory as discussed in 6.2, the authorized registrant shall send a copy of the inventory to the Biosafety Officer. Any discrepancy in the disposition record or inventory of controlled substances must be reported to the Biosafety Officer immediately. A copy of the completed inventory must be retained for at least three years and be made available to the College or regulatory authority when requested.

### **6.4. Disposal**

Each authorized registrant shall dispose of the controlled substances in his/her custody in accordance with College and federal policy. The disposal of controlled substances must be recorded on a Controlled Substances Disposal Form. Any questions or difficulties regarding disposal of controlled substances should be directed to the Biosafety Officer.

### **6.5. Reporting Theft or Loss**

If theft is suspected, the authorized registrant shall immediately notify the Biosafety Office and the Chief of Operations. 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 Biosafety Officer.

If a container of a controlled substances is broken, it shall be documented in the disposition record and a witness must sign and date it. A DEA Form-41 must be completed for the amount of the substance lost, and “unintentional destruction” must be written on the form. Signatures of the person who broke the container, the witness and the authorized registrant are required on Form-41. A copy of Form-41 must be kept in the disposition records, and a copy must be sent to the Biosafety Officer.

## **7. OVERSIGHT**

The Biosafety Officer will assist authorized registrants in complying with applicable rules and regulations and provide information regarding regulatory requirements. The Biosafety Officer and the Chief of Operations will review authorized registrants’ controlled substance records and security measures periodically. The Office of the Associate Dean for Biomedical, Academic and Research Affairs may also review security measures as needed.