

Use and Disposal of Controlled Substances in Research

Contents

I. Purpose	3
II. Definitions	3
III. Responsibilities	6
a. Registrants	6
b. Authorized Users	7
c. Environmental Health and Safety (EHS)	7
IV. Exclusions	7
V. Registration	8
a. Who Must Register	8
b. Registration Locations	8
c. Drug Enforcement Administration Registration	8
d. Virginia Board of Pharmacy Registration	9
e. Upon Successful Registration	10
f. DEA and VBP Inspections	10
VI. Changes to Registrations	10
a. Adding Controlled Substances to Approved Registrations	11
VII. Record Keeping and Inventory Requirements	11
a. Controlled Substance Receiving	12
b. Controlled Substance Dispensing and Tracking	12
c. Inventory Procedures	12
i. Bulk Form Controlled Substance Inventories	13
ii. Finished Form Controlled Substance Inventories	13
iii. Expired/Damaged/Defective/Awaiting Disposal Controlled Substances Inventories	14
d. Labeling Requirements	14
VIII. Storage and Security	14
IX. Disposal	15
X. Theft or Significant Loss	16
XI. Employee Responsibility to Report Drug Diversion	17
XII. Close Out of Registration	17
XIII. Review and Revision	18
XIV. Employee Acknowledgement	18

Use and Disposal of Controlled Substances in Research

XV. Appendix A: Authorized Users Signature Log	19
XVI. Appendix B: Controlled Substance Use Log	20



Use and Disposal of Controlled Substances in Research

I. Purpose

Certain research activities conducted under the auspices of Virginia Tech require the use of controlled substances. The use of controlled substances in research is governed by both state and federal regulations. The intent of the regulations is to maintain a closed system of distribution wherein a controlled substance is tracked from its acquisition through to its use and/or disposal.

It is required that all individuals involved in the use of controlled substances for research comply with all state and federal regulations regarding the procurement, record keeping, inventory, storage, use, and disposal of those substances.

The responsibilities associated with controlled substances are numerous, detailed, and regularly enforced by the Virginia Board of Pharmacy (VBP) and the Drug Enforcement Administration (DEA).

This manual provides information and guidelines regarding responsibilities of individuals involved in controlled substances research; licensing and registration through both VBP and DEA; controlled substance security; reporting loss, theft, or unauthorized use; record keeping and inventorying; and proper controlled substance disposal.

For all other inquiries related to controlled substance use or licenses associated with the Virginia Tech School of Medicine or the Virginia-Maryland College of Veterinary Medicine, please consult VBP, DEA, and/or those individual entities.

II. Definitions

Authorized User

An individual authorized by a Registrant to temporarily possess and use controlled substances under oversight by the Registrant who procures it. An Authorized User form must be kept on file containing the signature of each Authorized User and the signature of the Registrant documenting when the Authorized User was given authorization by the Registrant. The form must be kept on file by the Registrant for a period of two years **after** the Authorized User leaves the University. Authorized Users must understand their role and be trained in proper handling and use of controlled substances.

Controlled Substance

Any substance listed in the Controlled Substances Act (21 CFR, Part 1300) or Title 54.1, Section 3400 of the Code of Virginia. Lists of Scheduling Actions, Controlled Substances, and Regulated Chemicals are published by the DEA. These drugs and other substances are placed in respective [schedules](#) based on whether they have a currently accepted



Use and Disposal of Controlled Substances in Research

medical use in treatment in the United States; their relative abuse potential; and likelihood of causing dependence when abused.

Both DEA and VBP use Schedules I-V to classify controlled substances. In addition, Virginia has a Schedule VI class of controlled substances which fall under [§54.1-3455](#) of the Code of Virginia.

Dispense

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

Disposal

Relinquishment of contaminated, expired, excess, residual (or waste), unusable, or unwanted controlled substances. Registrants are responsible for working with Environmental Health and Safety (EHS) to ensure destruction of controlled substances by reverse distribution through an authorized reverse distributor.

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 or mixtures containing controlled substances for which the expiration date has passed; or tablets, injections, liquid, or preparations compounded in error that contain controlled substances that can no longer be used for research due to contamination, etc.

Finished Form

A controlled substance altered from bulk form (diluted, compounded, bound, etc.) that will be used for research (i.e. bulk form diluted 1:100 becomes finished form). Finished form substances may be retained by authorized users until depleted. All containers of finished form substances must be properly labeled and have a Use Log.

Principal Investigator

The individual with overall responsibility for the conduct of research or other activity described in a proposal, protocol, or grant.



Use and Disposal of Controlled Substances in Research

Registration

Formal grant of specific authority for controlled substances activities by the DEA and/or VBP, sometimes referred to as a registration certificate or license. The registration is specific to a single physical location. If multiple controlled substance storage locations are needed, then multiple registration certificates / licenses are required. The Registrant is responsible for maintaining their controlled substance registration current and active.

Registrant

A University member who holds a DEA and/or VBP registration and who is ultimately responsible for ordering, storing, using, record keeping, and disposing of controlled substances kept in their specified physical location (21 USC §823 or §958). The VBP often refers to this individual as the “Responsible Party”. The Registrant must be responsible for the individuals (Authorized Users) using and having access to their controlled substances.

Reverse Distribution

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

Reverse Distributor

A person or company registered with the Drug Enforcement Administration as a Reverse Distributor (21 CFR §1300.01).

Transfer

To move a controlled substance from the inventory of one DEA/VBP Registrant to another DEA/VBP Registrant.

Use Log

A document completed by each Registrant and Authorized User to track usage of controlled substances. The Registrant must keep controlled substances Use Logs for a minimum of two (2) years from the date of the last transaction. Note: the logs should be kept for 2 years from the date of last controlled substance **use** – *NOT the purchase date*.

Virginia Board of Pharmacy (VBP)

The agency authorized by the Commonwealth of Virginia to administer the Drug Control Act and enforce State laws and regulations overseeing the conduct and professional competency of Virginia Board of Pharmacy Registrants.

Use and Disposal of Controlled Substances in Research

III. Responsibilities

It is the responsibility of each Registrant to notify the DEA and VBP of any changes in registration (i.e. schedule, etc.) immediately.

Registrants are responsible for the safe and secure management of all controlled substance inventories in accordance with federal regulations and any Virginia Tech procedures.

a. Registrants

- Obtain and maintain DEA and VBP registrations to include submission of application, amendments, and renewals involved with their registration(s).
- Must be present for initial inspection by DEA and VBP.
- Comply with federal and state regulations pertaining to the possession and use of controlled substances. The Registrant is individually responsible for adherence to DEA and VBP regulations.
- A signed copy of these guidelines must be uploaded to the EHS Safety Management System (SMS). This will serve as training for work with controlled substances.
- Identify, train, and document Authorized Users.
- Provide and maintain documentation on training of laboratory-specific operations involving controlled substances.
- Ensure proper storage of controlled substances including maintaining strict control over security in the storage location and inventory of records.
- Supervise inventory, dispensing, and disposal of controlled substances when used *in vivo* or *in vitro* by Authorized Users.
- Obtain DEA and VBP approval for schedule changes prior to ordering, inventorying, dispensing, or disposing of such substances.
- Receive, store, use, and dispose of controlled substances properly.
- Complete all substance logs concurrently as substances are received, used, and disposed.
- Retain substance logs (inventory records, dispensing records, Use Logs, waste records, and disposal records) for two (2) years after complete use or disposal of controlled substances. These logs should remain with the Registrant, even if leaving the University.
- Conduct an initial inventory.
- Conduct a biennial inventory.



Use and Disposal of Controlled Substances in Research

- Report the theft or loss of any controlled substance to the DEA Field Division in your area through the Theft Loss Reporting (TLR) system (using [Form 106](#)), VBP, and Virginia Tech or Carilion Police within one (1) business day of discovery of such loss or theft.
- Dispose of unwanted or unnecessary controlled substances using a reverse distributor in accordance with DEA and VBP regulations through Virginia Tech EHS.
- Report theft or loss of any controlled substances to the DEA and VBP.
- Upon receipt, notify EHS of current DEA and VBP registrations.
- Report DEA and VBP inspections to EHS.

b. Authorized Users

- A signed copy of these guidelines must be uploaded to the EHS Safety Management System (SMS). This will serve as training for work with controlled substances.
- Sign the Authorized Users Signature Log (Note: separate logs are kept for Schedule I, Schedule II, and Schedule III-V controlled substances).
- Complete Use Log sheets – Controlled Substances Use Log and Waste Record.
- Store controlled substances in a lockbox, either individual or laboratory-level, marked with the Registrant's name.
- Return any unused bulk form controlled substances and the Use Log sheet to the Registrant at the end of each workday.
- Return any unused finished form (see definition in Section II) controlled substances and their Use Log sheets when a substance has been fully used or is no longer needed.
- Immediately report any discrepancy or suspected theft to the Registrant.
- Receive laboratory-specific training from the Registrant before using controlled substances.
- Per DEA mandate, immediately report to the Registrant any felony violations or convictions.

c. Environmental Health and Safety (EHS)

- Provide guidance on storage of controlled substances.
- Facilitate disposal of controlled substances through reverse distribution.
- Increase awareness of and accountability for compliance when using controlled substances in research.

IV. Exclusions



Use and Disposal of Controlled Substances in Research

These guidelines do not apply to controlled substances dispensed by a practitioner to a patient (human or animal) in the course of professional practice as authorized by the practitioner's license, nor does it cover medical teaching activities performed within a clinical environment.

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

V. Registration

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

a. Who Must Register

Faculty members who store, administer, or order controlled substances for research protocols on which they are a contributing investigator must register with both the VBP and the DEA (for Schedules I-V) or the VBP only (for Schedule VI). To be a Registrant, the individual must have oversight of the research on a protocol.

b. Registration Locations

Registrations must be for the specific location where the controlled substances are stored. This means that a Registrant considering storing controlled substances in multiple locations (labs) must have multiple registrations.

Use the street address and room number of where the controlled substances will be stored. The information that appears on your VBP and DEA researcher registrations should match each other and should reflect the controlled substances used in your research, as well as covering the schedules you need for your research protocols.

c. Drug Enforcement Administration Registration

1. Complete the [online application](#) for new registrations or [renewals](#).



Use and Disposal of Controlled Substances in Research

Note that there is a separate application for Schedule I registrations. Researchers requesting registration for Schedule I-V controlled substances must complete two applications – one for Schedule I and one for Schedule II-V.

In addition, applications for Schedule I registrations must address the federal requirements that appear in [21 CFR §1301.18](#).

2. Attach any requested documents (dependent upon Schedule, but **may** include)
 - a. Personnel Screening Form – Authorized User (for all authorized users)
 - b. Curriculum vitae for authorized users
 - c. Copy of VBP registration (if in-hand)
 - d. Photo of the storage location and container
 - e. Supplier/Vendor from which to purchase controlled substances
 - f. Signature and date on form
3. Prior to issuing a Controlled Substances Registration, the DEA will schedule a time for inspection. The Registrant must be present for the inspection and must be prepared to answer questions regarding the entire life cycle of the controlled substance (i.e. from procurement to lab storage to disposal). The Chemical Hygiene Officer can be available to discuss disposal if needed.
4. Ensure registrations are renewed in a timely manner. Expired registrations are inactivated by the DEA after one (1) month. This means the Registrant would need to re-apply for a new registration. DEA typically sends a reminder notice approximately three (3) months prior to the annual expiration. Registrants should place a renewal reminder on their calendar (2) months prior to expiration as reminder notices, (both by mail and email) can be inconsistent. Note that federal law prohibits the possession of controlled substances under an expired registration.

d. Virginia Board of Pharmacy Registration

1. Print and complete the [application](#). The VBP requires an original signature; fax or scan will not be accepted.
2. Check the “new” or “reinstatement” box. Note that there is an annual fee for each application. Registrations expire one year from date of application receipt.
3. Check the boxes for all “Controlled Substances Schedules” required.
4. Attach a synopsis or abstract describing your protocol, listing the controlled substances to be used (and briefly explaining the purpose of the controlled substances). **Keep it brief and do NOT submit a full protocol or proposal**, as this information becomes public knowledge.

Use and Disposal of Controlled Substances in Research

5. Attach a Curriculum Vitae and mail the completed application package to the address at the top of the application.
6. Prior to issuing a Controlled Substances Registration, the VBP will schedule a time for inspection. The Registrant must be present for the inspection and must be prepared to answer questions regarding the entire life cycle of the controlled substance (i.e. from procurement to lab storage to disposal). The Chemical Hygiene Officer can be available to discuss disposal if needed.
7. Ensure registrations are renewed in a timely manner. VBP typically sends a reminder notice to the Registrant approximately two (2) months prior to the annual expiration and provides the website link and passcode to enter in the renewal site.

Unlike Schedule II-VI substances, a request for a Schedule I registration must be approved by the DEA prior to VBP approval. A copy of the DEA registration must be sent to the VBP with the application packet.

e. Upon Successful Registration

Once registration is successful and received by the Registrant, please send a copy to Environmental Health and Safety (EHS) at mail code 0423 so that the information can be noted and stored for facilitating reverse distribution of waste. Note: registration and licensing will not be managed by EHS; however, the license information will be needed by EHS to manage disposal.

DEA and VBP registrations are valid for a one (1) year period.

f. DEA and VBP Inspections

The DEA and VBP typically call the Registrant listed on the application to schedule a time for their initial inspection. The Registrant must be present for the initial inspection. After the initial inspection, both the DEA and VBP may conduct unannounced routine inspections.

VI. Changes to Registrations

It is the responsibility of each Registrant to notify the DEA and VBP of any changes in registration (i.e. name, address, telephone, schedules, etc.) immediately. Changes must be submitted within six (6) days of the change.



Use and Disposal of Controlled Substances in Research

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

For changes to a DEA registration, submit a [DEA Registration/Application Update Request](#) online.

For changes to a VBP registration, a [printed application](#) form with the appropriately marked “change” boxes should be mailed to the address at the top of the application.

a. Adding Controlled Substances to Approved Registrations

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

Any changes in controlled substances for a Schedule I registration require the submission of supplemental research protocols and DEA approval. Registrants must log in to their DEA registrations online and request modifications to their current Schedule I registration by adding the required drug codes. Supplemental research protocols are processed the same as original research protocols – additional information will be requested if required.

Please notify EHS after submitting a request for changes in registration.

VII. Record Keeping and Inventory Requirements

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

- DEA and VBP licenses
- Signed copies of these guidelines to serve as training confirmation.
- Executed order forms
- Receiving record or purchase receipt that is verified, signed, and dated
- Inventory records (must be kept a minimum of two (2) years from the date of last transaction)
- Controlled Substance Use Logs (must be kept a minimum of two (2) years from the date of last transaction (use – NOT purchase))

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



Use and Disposal of Controlled Substances in Research

To ensure best compliance practices, Registrants should establish a consistent documentation process. Records must be readily retrievable for immediate inspection by DEA and/or VBP. Use Logs should be hard-copy and maintained on the containers. Once a log is complete, it may be scanned to archive electronically and the hard copy filed away.

a. Controlled Substance Receiving

Controlled substances must be shipped directly to the Registrant at the address that appears on the registration. Once received, the controlled substances must be opened and the contents verified by the person receiving the substance. Any discrepancies must be corrected with the supplier and/or shipper. If discrepancies cannot be corrected, the Registrant must contact the DEA to report this within five (5) business days. Once the Registrant has verified that the shipment is correct, the Registrant must sign and date the purchase receipt and file it with the Registrant's controlled substances records.

b. Controlled Substance Dispensing and Tracking

The DEA Registrant is responsible for all controlled substances dispensed from inventory from themselves and all Authorized Users. From the time a controlled substance is received until it is fully used or disposed of, a record of the chain of custody and usage must be kept. Each point at which the controlled substance changes hands or is used must be documented. The documentation must be completed at each point by the Registrant dispensing the controlled substance and must include the controlled substance, quantity, date dispensed, and the recipient's initials.

Each quantity of a controlled substance must be accounted for in the Use Logs.

c. Inventory Procedures

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

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

- Maintained at the registered location.
- Available for two (2) years after the controlled substance is used or disposed.



Use and Disposal of Controlled Substances in Research

- Completed every two (2) years (biennially) to comply with DEA regulations (21 CFR 1304.11). The biennial inventory date must be listed and must show whether it was performed at the beginning or closing of the day.
- Updated on the effective date when a controlled substance is added to any schedule (List of Controlled Substances).

Inventories of Schedule I and Schedule II controlled substances must be maintained separately from those for all other controlled substances. All inventories must contain the following information:

- Date of inventory
- Exact time of inventory and whether at beginning or closing of business
- Name of DEA Registrant and DEA registration number
- Location of inventory

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

i. Bulk Form Controlled Substance Inventories

Inventories must include:

- Name of controlled substance
- Lot #
- Schedule
- Drug form (bulk or finished)
- Number of units/volume
- Supplier
- Date acquired

ii. Finished Form Controlled Substance Inventories

Inventories must include:

- Name of controlled substance
- Each finished form of the substance (e.g., 10-milligram tablet or 10 mg 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 mL vial)
- The number of containers of each of such finished form (e.g., four 100-tablet bottles or six 3 mL vials)



Use and Disposal of Controlled Substances in Research

iii. Expired/Damaged/Defective/Awaiting Disposal Controlled Substances Inventories

Inventories must include:

- Name of controlled substance
- Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form (e.g., fifty 10 mg tablets or 10 mL of 50 mg/mL)
- Reason for the substance being maintained by the Registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form
- Best practice is to store substances in this category separately within the Registrant's inventory (i.e., a separate compartment, box, or bag within the storage area).

d. Labeling Requirements

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

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

VIII. Storage and Security

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

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

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

Schedule I, Schedule II, and Schedules III-V controlled substances may be stored together, as long as storage requirements are met for the most stringent Schedule (i.e. Schedule I and Schedule IV may be stored together, as long as they are stored per Schedule I

Use and Disposal of Controlled Substances in Research

requirements). For each Schedule, the Registrant must maintain a separate set of Use Logs.

Safes/Storage containers for controlled substances **cannot** be shared with other Registrants.

All controlled substances must be stored in a “securely locked, substantially constructed cabinet” as per federal regulations.

- **Schedule I** controlled substances 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.
- **Schedule II-V** controlled substances 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.
- **Schedule VI** controlled substances do not require a Use Log but should still be secured in a locked cabinet. Schedule VI substances may be stored with other Schedule II-V substances (see [18 VAC 110-20-710](#)).
 - If Schedules are to be stored together, items must be stored at the highest Schedule’s level (e.g. storing Schedule I and Schedule IV together is fine, as long as they are stored in a safe or steel cabinet rated for Schedule I storage).
 - Inventory records for Schedule I must be kept separately from Schedule II, which must also be kept separately from Schedules III-V (do not list Schedule III drugs on a Schedule I inventory). Each container of controlled substance should have its own individual Use Log.

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

Controlled substances **must** be stored at their registered location, so any unused controlled substances must be returned to their registered storage location at the end of the day.

IX. Disposal

DEA and VBP Registrants must dispose of empty containers and out-of-date, damaged, or otherwise unusable or unneeded controlled substances by transferring them to a Registrant who is authorized to receive such materials. These Registrants are referred to as reverse distributors. EHS has contracted with a DEA-authorized reverse distributor who can assist Registrants with the proper disposal of controlled substances.



Use and Disposal of Controlled Substances in Research

When disposing of Schedule I and II controlled substances, [DEA Form 222](#) must be used with the reverse distributor.

Registrants should contact EHS to request disposal of controlled substances via reverse distribution. The Registrant should provide a copy of the DEA and/or VBP registration.

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

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

Schedule VI substances may include any prescription medications used in research, inhalation anesthetics, some analgesics, and other substances. Any substance with the following statements on the label should be disposed of through reverse distribution:

- Rx Only
- Caution: Federal Law prohibits dispensing without prescription
- Caution: Federal Law restricts this drug to use by or on the order of a Veterinarian
- Caution: Federal Law restricts this device to sales by or on the order of a Physician/Dentist/Veterinarian/Professional Designation of Licensed Practitioner

X. Theft or Significant Loss

If theft is suspected, the DEA Registrant must immediately notify the Virginia Tech or Carilion Police, VBP, and the DEA Field Division (using [Form 106](#)), VBP within one (1) business day of discovery of such loss or theft.

Virginia State law requires a theft or unusual loss to be immediately reported to the VBP using the DEA Form 106 (see above link) with a written itemization of the substances lost or stolen within 30 days (54.1-3404 of the Drug Control Act). Retain a copy of DEA Form 106 with the inventory records.

Requirements of Registrants when Breakage or Spillage Occurs:

Per [21 CFR 1301](#), “[I]f controlled substance containers are broken or damaged, or controlled substances spilled, the substances are not considered “**lost**” because they can be accounted for. When breakage, spillage, or damage of controlled substances occurs, the affected controlled substances must be disposed of according to DEA [and VBP] requirements”.

However, if the breakage or spillage “is clearly observed but the controlled substances are not recoverable, then the Registrant must document the circumstances of the breakage in



Use and Disposal of Controlled Substances in Research

their inventory records. Two individuals who witnessed the breakage must sign the inventory records, indicating what they witnessed”.

XI. Employee Responsibility to Report Drug Diversion

From 21 CFR §1301.91:

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

Failure to report information regarding drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a controlled substances security area. The PI/Registrant shall inform all employees concerning this policy.

XII. Close Out of Registration

Registrants wishing to terminate their active registration(s) must inform DEA ([21 CFR §1321.01](#)) and VBP (in writing) of their intent to terminate. In addition, along with the form, the Registrant must return their original DEA and VBP registrations. Any controlled substances must then be disposed of via reverse distribution.

Under no circumstances are controlled substances to be abandoned by a Registrant. Registrants are expected to properly transfer or dispose of controlled substances inventory when controlled substances are no longer required or prior to departure from a university position.

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

Use and Disposal of Controlled Substances in Research

XIII. Review and Revision

EHS shall review this procedure annually or as DEA and/or VBP requirements change.

02/01/2021	Guidelines developed based on DEA and Virginia Board of Pharmacy information; based on disposal SOP created by Rachel Layman (10/26/17)
03/15/2021	Incorporation of comments and items submitted by EHS reviewers
04/09/2021	Incorporation of comments from EHS reviewers
04/12/2021	Editing for finalization of document

XIV. Employee Acknowledgement

I have read and understand Virginia Tech Environmental Health and Safety's guidelines on Controlled Substances in Research and agree to abide by these guidelines.

Name (Print) Date

Signature Date

PI/Registrant Name (Print) Date

PI/Registrant Signature Date

XV. Appendix A – Authorized Users Signature Log

Authorized Users Signature Log

Signatures of all persons designated by the DEA and/or VBP Registrant as Authorized Users for this Location are required according to the Virginia Tech Use and Disposal of Controlled Substances in Research guidelines.

Lab Name: (PI) _____ **Department** _____

Lab Location Address: (Street address and Building) _____

DEA Registrant Name: (print) _____ **DEA/VBP#** _____

Date Signed	Name (Please print)	Job Title	Signature	Initials	Date Departed

I hereby certify that I have designated the persons listed above as Authorized Users for this location. Person is no longer an Authorized User when a “Date Departed” is entered.

DEA Registrant’s Signature: _____ **Date:** _____

Controlled Substance Use Log

Complete a log sheet for each container of Controlled Substance. If the material is diluted, start a new log form to track usage of each new container and use the original container's log or serial # and original bottle # assigned by the laboratory.

Principal Investigator	Building:	Room
Drug Name:	Lot or Serial Number:	Amount Received:
Expiration Date:	Strength:	Form:
		<input type="checkbox"/> Liquid <input type="checkbox"/> Powder
Date Received:	Unique Container Number:	Date/time disposed (if applicable)

When content has been consumed, save and file use logs for a period of two years from consumption.

Date	Amount removed (mL mg, etc.)		Amount Remaining in Vial (mL, mg etc.)	Protocols, Species and/or identification of Usage	Name of Person Withdrawing Controlled Substance	
	Used	Loss ¹			(Printed Name)	Initials

¹Material drawn up for dosing that was not used or could not be fully extracted; e.g., syringe hub loss.

*Medication that has been drawn up and not administered should be labeled as DEA or VBP Waste - Do Not Use, and secured until it can be properly disposed of via reverse distribution facilitated by Environmental Health and Safety.

Receiving Information

*A copy of the invoice must be retained (either electronically or hard-copy) for two years from date of receipt..

Purchase Order:	Requisition:	Vendor:

Controlled Substance Use Log Continuation Page Page _____ of _____

Complete a log sheet for each container of Controlled Substance. If the material is diluted, start a new log form to track usage of each new container and use the original container's log or serial # and original bottle # assigned by the laboratory.

Principal Investigator	Building:	Room
Drug Name:	Lot or Serial Number:	Amount Received:
Expiration Date:	Strength:	Form:
		<input type="checkbox"/> Liquid <input type="checkbox"/> Powder
Date Received:	Unique Container Number:	Date/time disposed (if applicable)

When content has been consumed, save and file use logs for a period of two years from consumption.

[illegible]

¹Material drawn up for dosing that was not used or could not be fully extracted; e.g., syringe hub loss.

* Medication that has been drawn up and not administered should be labeled as DEA or VBP Waste - Do Not Use, and secured until it can be properly disposed of via reverse distribution facilitated by Environmental Health and Safety.