Use of Controlled Substances in Research and Scholarly Activities Program

West Virginia University

Environmental Health and Safety

Table of Contents

1.0 Purpose

This procedure addresses compliance with federal regulations regarding registration, acquisition, use, storage, and disposal of U.S. Drug Enforcement Agency (DEA) listed Controlled Substances being used in West Virginia University research, teaching, and service activities. This program manual was developed pursuant to WVU Policy on Use of Controlled Substances in Research and Scholarly Activity.

2.0 References

WVU Controlled Substance Website: https://www.ehs.wvu.edu/controlled-substance-use-in-research

DEA Forms and Applications: deadiversion.usdoj.gov/online_forms_apps.html

West Virginia Board of Pharmacy Forms and Applications:
https://www.wvbop.com/practitioners/facilities/instatecontrolledsubstancepermit.asp

3.0 Responsibilities

3.1 Environmental Health & Safety

3.1.1 EHS will aid all University Member DEA Registrants in maintaining compliance with applicable laws, policies and procedures. To support the lawful possession and use of Controlled Substances by University Members, EHS will maintain this program manual and supporting practice aids/for templates, as well as conduct training sessions, consultations, and audits in conjunction with the EHS Chemical Hygiene and Controlled Substance programs.

3.1.2 The EHS Controlled Substances Manager will perform Registrant monitoring functions to maintain a complete and accurate roster of Controlled Substances University Member registrants. Monitoring activities include:

> 3.1.2.1 Maintaining copies of University Member registration certificates, renewals, and authorized personnel forms.
> 3.1.2.2 Access to the IACUC protocol database, which enables the ability to observe animal care and use activities which have been approved to utilize Controlled Substances.
> 3.1.2.3 Workflow approval responsibilities in the WVU Mountaineer Marketplace e-procurement system for system-tagged Controlled Substances.
> 3.1.2.4 Laboratory safety audits and inspections, close-out procedures, and surveys and coordination with college and department level chemical hygiene officers.
> 3.1.2.5 Liaison contacts and periodic registrant information inquiries with DEA and WVBOP contacts.

3.1.2 EHS staff will escort DEA inspectors during their inspections of labs and act as a liaison between the inspectors and the DEA Registrant or authorized users.

3.1.3 EHS Controlled Substance Manager will approve all purchases via PCPS procurement processes, oversee disposal and destructions of controlled substances on campus, and coordinate with Registrants at end of license and lab close-outs.

3.2 Registrant

3.2.1 Apply for and maintain WVBOP and DEA registrations, including compliance to submitting any changes and registration renewals.

3.2.2 Be present for inspections by WVBOP and DEA.

3.2.3 Manage the Controlled Substances in their possession in accordance with the requirements of federal and state regulations.

3.2.4 Select, screen, and train Authorized Users. Create and document laboratory-specific training as needed to train Authorized Users. Supervise the use of Controlled Substances by all Authorized Users.

3.2.5 Ensure that only the Registrant submits orders (acquisition) for Controlled Substances using appropriate forms. Registrants must exercise signature authority for purchases of Schedule I and II drugs (see Ordering section of this procedure).

3.2.6 Must submit copies of in-date WVBOP and DEA Registration to OLAR office if acquiring Controlled Substances from OLAR.

3.2.7 Ensure that Controlled Substances are secured and stored in accordance with federal and state regulations. Maintain strict control inventory (see Storage & Security section of this procedure).

3.2.8 Maintain all required deduction cards, usage logs and documentation (see 5.11 Documentation section of this procedure).

3.2.9 Conduct and document initial and biennial (every two years) inventory as per DEA regulations (see Documentation section of this procedure).

3.2.10 Report theft, loss, or significant inventory discrepancies of any Controlled Substances to the DEA, WVBOP, and EHS. (see 5.10 Controlled Substance Loss section of this procedure).

3.2.11 Report DEA and WVBOP inspection audit findings of non-compliance to WVU EHS within two (2) business days of notice received by the Registrant.

3.3 Authorized User

Authorized Users must be identified, screened, and certified by each Registrant who allows the individual to engage in approved activities under the Registrant's registration. Examples of Authorized Users: post-doctoral fellows, university staff, classified staff, and graduate students. Typically, the Authorized User reports directly to the Registrant or is funded by the Registrant.

3.3.1 Complete the Personnel Screening Form for Authorized Users prior to commencing use of Controlled Substances for the Registrant.

3.3.2 Complete laboratory-specific training on procedures for using Controlled Substances prior to working with them.

3.3.3 Once certified by the Registrant, sign the Authorized Users Signature Log specific to the Schedule of authorized use.

3.3.4 Comply with university, federal, and state regulations, policies, and procedures pertaining to proper registration, acquisition, storage, use, and disposal of Controlled Substances under the direct supervision of the DEA Registrant.

3.3.5 Complete all required documentation on deduction cards and usage logs (see Documentation section of this manual).

3.3.6 Store Controlled Substances appropriately in the location listed on the Registration and based on the Registrant's requirements for securing them by the end of each workday or when not in use.

3.3.7 Immediately report any theft, loss, or significant inventory discrepancies to the DEA Registrant, and, if necessary, EHS, the university police department, DEA, and other relevant authorities as required by federal law, state law, and University procedures (see 5.10 Controlled Substance Loss section of this manual).

3.3.8 Immediately report to the Registrant any felony violations or convictions.

4.0 Definitions and Terminology

For purposes of this procedure, the following terms are defined as:

Administration: the act of dosing, injecting, or applying a controlled substance.

Authorized User: a university member authorized to temporarily possess and use Controlled Substances for research under oversight by the DEA Registrant who procures it. An authorized user should be a direct report of the Registrant or be funded by the Registrant. An authorization 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 termination of Controlled Substance use by the Authorized User.

Bulk Form: a controlled substance as received from the manufacturer or supplier to be used in, or capable of use in, the manufacture of the same or other non-controlled substances in finished form (diluted or working form). Depending on the concentration of the Bulk Form, this form may be a concentrated stock which is compounded by dilution or combination with other drugs into a Finished Form for administration to an animal or for *in vitro* use.

Cactus Sink: a secure waste solution for unused portions or partial doses of Controlled Substances.

Controlled Substance (CS): any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end) and West Virginia Code 60A (Uniform Controlled Substances Act). Controlled Substances (CS) are drugs or other chemicals that have the potential to be addictive or habit forming. Controlled Substances are divided into five schedules based on their potential to be habit forming (I = greatest, V = least habit forming) and usefulness in medical treatment. The DEA and WVBOP jointly regulate these substances. For a list of Controlled Substances refer to "List of: Scheduling Actions, Controlled Substances, Regulated Chemicals (Aug 2021)" (https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf) published by the DEA.

Schedule I

Substances that have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Examples: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), methaqualone, 3,4-methylenedioxymethamphetamine ("Ecstasy")

Schedule II

Drugs or other substances that have a high potential for abuse, abuse may lead to severe psychological or physical dependence. Currently have an accepted medical use in treatment in the United States or have a currently accepted medical use with severe restrictions.

Examples of schedule II narcotics: hydromorphone (Dilaudid ®), methadone (Dolophine ®), meperidine (Demerol ®), oxycodone (OxyContin ®, Percocet ®), fentanyl (Sublimaze ®, Duragesic ®), morphine, opium, codeine, hydrocodone.

Examples of schedule IIN stimulants: amphetamine (Dexedrine ®, Adderall ®), methamphetamine (Desoxyn ®), methylphenidate (Ritalin®).

Examples of other schedule II substances: amobarbital, glutethimide, pentobarbital

Schedule III

Drugs or other substances that have a potential for abuse less than Schedule I or II, abuse may lead to moderate or low physical or high psychological dependence. Currently have an accepted medical use in treatment in the United States.

Examples of schedule III narcotics: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine ®), buprenorphine (Suboxone ®)

Examples of schedule IIIN non-narcotics: benzphetamine (Didrex ®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone

Schedule IV

Drugs or other substances that have a low potential for abuse relative to substances listed in Schedule III, abuse may lead to limited physical or psychological dependence. Currently have an accepted medical use in treatment in the United States.

Examples: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril ®), and triazolam (Halcion ®), phenobarbital.

Schedule V

Substances that have a low potential for abuse relative to substances listed in Schedule IV. Consist primarily of preparations containing limited quantities of certain narcotics.

Examples: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

Controlled Substance Research Protocol: a document submitted to WVU EHS, the DEA and WVBOP which describes the need for and use of Controlled Substances in the Registrant's research. For schedule II through V substances, use the form provided- "University of West Virginia Controlled Substances Research Protocol" on the WVU EHS website. To register to conduct research with Schedule I controlled substances, the Registrant must compete and submit the protocol described in 21 CFR 1301.18.

Compounding: the mixing or diluting of pharmaceutical agents into a Finished Form for administration for which no similar Bulk Form is available. Compounding of pharmaceutical agents for use in experiments is allowed.

DEA Registrant: Often, but not always, the principal investigator, the DEA Registrant is a university employee designated to hold DEA registration who is responsible for ordering, storing, using, and disposing of Controlled Substances within his or her inventory.

Deduction Card: document provided to DEA Registrants, by WVU EHS, to record use of Bulk Form Controlled Substances.

Disposal/Destruction: Expired, unusable, or unwanted Controlled Substances must be disposed of using a DEA and WVBOP approved method.

Diversion: a transfer of a Controlled Substance from a lawful to an unlawful channel of distribution or use. This includes administration of a Controlled Substance by an individual that is not listed as an Authorized User associated with the Registrant.

Drug Enforcement Administration (DEA): the agency within the United States Department of Justice that enforces the federal Controlled Substances laws and regulations.

Environmental Health and Safety (EHS): the university unit responsible for working with academic, research, and administrative units to promote compliance and responsible behavior as required by health, safety, and environmental standards, codes, regulations, and University programs.

Expired and/or Unusable Substances: Controlled Substances or mixtures containing Controlled Substances for which the expiration date has passed for tablets, injections, liquid, powders, or preparations compounded. This also includes Controlled Substances that can no longer be used for research due to contamination, animal care and use requirements, remaining quantity, etc.

Finished Form: A Controlled Substance altered (e.g., diluted, compounded) from Bulk Form which will be administered for research. For example, Bulk Form diluted 1:10 becomes a Finished Form. Finished Form substances may be retained and secured by Authorized Users until depleted or unusable. All vials of Finished Form substances must be properly labeled and have a usage log.

Institutional Animal Care and Use Committee (IACUC): the university committee charged with oversight of the use of vertebrate animals in research and instruction.

Location: a room or designated area where inventory of Controlled Substances is securely stored. A location is managed by a single DEA Registrant and has a single building and room address with which it is associated. All Controlled Substances must be returned at the end of their use each day to the storage area on the registration.

Office of Animal Welfare (OAW): facilitates the review of research protocols and grants involving live vertebrate animals.

Office of Laboratory Animal Resources (OLAR): WVU Health Sciences Center unit charged with providing guidance, support, and training for animal care and use in the laboratory setting.

Principal Investigator (PI): the individual with final responsibility for the conduct of research or other activity described in a research proposal.

Power of Attorney: the Registrant is the only individual who may order, dispense, or dispose of Controlled Substances listed in their registration. The Registrant must generate a Limited Power of Attorney (POA) document in order to allow an Authorized User to perform specific functions specifically involving Schedule I or Schedule II substances. The person(s) having a Limited Power of Attorney (POA) may perform the following functions on behalf or in the absence of the Registrant: sign the DEA Form 222 to receive Schedule I and II substances, transfer Schedule I or II substances for destruction, or perform biennial inventory. The Registrant must show the Limited Power of Attorney documents to the DEA upon request. A copy of the POA documents must be provided to WVU EHS and OLAR (if obtaining

Schedule II substances from OLAR). See 21 CFR part 1305.05 (https://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_05.htm) for generating a POA document. A POA document is not needed for Schedule III-VI substances.

Registration: formal grant of specific authority for Controlled Substance activities by the DEA and/or WVBOP sometimes referred to as a Registration Certificate. The Registration is specific to a single physical location. If multiple Controlled Substance storage locations are needed, then multiple Registration Certificates are required. The Registrant is responsible for maintaining their Controlled Substance Registration in a current and active state.

Research: Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Teaching Institution Registration: attending veterinarians hold this registration for the administration of Controlled Substances to research animals while providing veterinary care. A DEA registration to a teaching institution (for Schedules II-V only) is overseen by an Institutional Veterinary Practitioner.

Transfer: an informal term used to describe the process to affect change in the possession of a Controlled Substance from the inventory of one DEA Registrant to another DEA Registrant.

University Member: all WVU full- and part-time faculty, classified or University staff, administrative staff, paid student assistants, students, 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 complying with Controlled Substances regulations.

Usage Log: document available on the WVU EHS website, to record use of Finished Form Controlled Substances.

Usage Records: maintaining accurate, continuous, and current records reflecting the acquisition, administration, disposal, and biennial inventory of Controlled Substances is necessary to properly document the use of the Controlled Substances within a closed system of distribution. Controlled Substance usage records are completed by each Registrant and Authorized User.

WV Board of Pharmacy (WVBOP): the agency authorized to carry out the WV Uniform Controlled Substances Act (WV Code, Chapter 60A).

5.0 Procedure

5.1 Registration

5.1.1 The researcher responsible for projects involving Controlled Substances (ordering, storing, usage, disposal) must register with WVBOP and DEA. This researcher is referred to as the "DEA Registrant".

5.1.2 Registrants are typically principal investigators and are linked to an individual laboratory. Registration is linked to a specific physical address (a single physical location) where Controlled Substances are stored. The Registrant must have oversight of the Controlled Substance use to serve as the DEA and WVBOP Registrant.

5.1.3 A summary table of DEA registration requirements and limitations is available at 21 CFR 1301.13 (e)(1). University Members conducting research with Controlled Substances will typically qualify to obtain a Research/Researcher DEA registration, which also allows certain coincident activities such as instructional activities and chemical analysis. DEA Practitioner registrations for physicians, dentists, veterinarians, and other health care professionals permit certain coincident research and instructional activities, but it is the understanding of EHS that Practitioner registrations cannot be used for animal or human research protocols. WVU and DEA require a separate DEA Research registration for non-clinical research for Practitioners. University Members, who are licensed veterinarians, may obtain a DEA Practitioner registration pursuant to their lawful licensed practice of veterinary medicine. Other DEA registration business activities, such as Chemical Analysis, may require additional consultation with the EHS Controlled Substances Manager.

5.1.4 Each individual Registrant (principal investigator) is responsible for obtaining appropriate registrations and adhering to applicable state and federal regulatory requirements when working with Controlled Substances. Registrants will be responsible for the oversight of all Controlled Substances on their applications.

5.1.4.1 PIs must complete the *West Virginia University Controlled Substances Research Protocol* and submit it to WVU's EHS department via the Controlled Substance Manager. Protocols will be used to establish initial communication to inform EHS of intent to pursue a Controlled Substance registration by the PI and to begin other documentation. Furthermore, it will be used by EHS to consult, provide recommendations and guidance, and update DEA registrants, as needed.

5.1.4.2 PIs must complete and submit the West Virginia Board of Pharmacy (WVBOP) Application for Permit or Renewal to Handle Controlled Substances. The DEA application will not be approved without a WVBOP license. The DEA registration is predicated on state authority.

5.1.4.2.1 University Employees ware considered state/government employees and as such qualify for fee waiver for DEA license fees (West Virginia Code of State Rules §15-2-4.2.2, 15 CSR 2). WVU Research Corporation Employees do not meet the state rule requirements for WVBOP fee exemption.

5.1.4.2.2 The WVBOP application contains an entry field for a DEA registration number. For initial applications, an applicant will not have a valid DEA registration since a state BOP registration must first be obtained. Applicants are typically permitted to note this on the initial application. For applicants who were previously registered elsewhere, prior

DEA registration numbers should not be entered, as they are not valid for a new WVU location.

5.1.4.2.3 The WVBOP application contains an entry field for a "Consultant Pharmacist". It is the understanding of EHS that supplying an information for this field is not necessary for the application. Consult with EHS for the appropriate information to enter.

5.1.4.3 After receiving the WVBOP permit, PIs must complete and submit DEA-225 (new application for registration). For Schedules II-V, DEA Form 225 can be completed online. For Schedule I substances, DEA Form 225 and the protocol in 21 CFR 1301.18 must be submitted (cannot apply online for initial Schedule I application).

5.1.4.3.1 University Employees are considered state/government employees and as such qualify for fee waiver for DEA license fees (21 CFR 1301.21). WVU Research Corporation Employees do not meet the federal regulation requirement for DEA fee exemption. In order for University employees to obtain a DEA fee waiver, they will need information from an institutional "certifying official". Consult with EHS to obtain this certification.

5.1.4.4 Prior to issuance of a registration, an inspector will schedule an inspection with the applicant (Registrant) to ensure that appropriate safeguards are in place to secure Controlled Substances. Notify WVU EHS of the DEA inspection time and schedule a preview of the storage site prior to DEA arrival.

5.1.4.5 Upon receiving their DEA registration certificate, PIs are required to send a copy to WVU EHS.

5.1.4.6 Registrants must not allow their registration to lapse until all Controlled Substances are used or transferred.

5.1.4.7 DEA and WVBOP registrations are valid for one year and must be renewed annually. Complete DEA Form 225A for renewal. Notify WVU EHS of renewal status. Renewals for both WVBOP and DEA Registrations are completed online:

WVBOP: wvbop.com/facilities/csp/renew

DEA: deadiversion.usdoj.gov/online_forms_apps.html (see "Renewal Applications")

5.1.4.7.1 Renewal applications will require similar input or information consistent with initial applications explained in 5.1.4.2 and 5.1.4.3.

5.1.4.8 Agencies (WVBOP & DEA) must be notified of any changes to drug code, schedule, name, address (address change requires approved state license for the new address first) or any information required on the application or Registration. Changes can be submitted to the DEA at: deadiversion.usdoj.gov/online_forms_apps.html (see "Make changes to DEA Registration").

5.1.4.9 In addition to the initial inspection conducted during the application process, following registration approval, the DEA and/or WVBOP may conduct unannounced routine inspections. Notify WVU EHS immediately if DEA officials arrive for an inspection. In preparing for an inspection, the DEA will refer to their database for the list of substances approved for the Registrant, so ensuring that the DEA is notified of changes is extremely important. Substances in

a Registrant's inventory that do not match the DEA's database is cause for a finding of violation of the law.

During inspection the DEA may inspect for:

-Expired Controlled Substances

-Documentation is available, complete, and correct

-Vial inventory numbers have a corresponding Deduction Card/Usage Log

-The remaining quantity per Deduction Card/Usage Log and the actual physical quantity is approximately the same

-Verification that all drug invoices present have a large red "C" on them, date of receipt, and signature of the person receiving the shipment (see section 5.4.3).

-Verification that DEA Form 222 order forms for Schedule I or II are present for each compound (unused DEA 222 Forms should be stored in a secured location).

-Verification that DEA Form 222 order forms have the number of packages received and the date received columns completed at the time of receipt (An incomplete DEA-222 form can incur a $10,000 fine from the DEA) (refer to section 5.3.3).

-Verification of appropriate security and storage based on Schedule and license type

5.1.4.10 Under no circumstances are Controlled Substances to be abandoned by a DEA/WVBOP Registrant. Registrants are expected to properly dispose of Controlled Substances inventory when Controlled Substances are no longer required or prior to departure from their University position. See "Controlled Substance Disposal" section 5.9 in this procedure. Any person who is registered with the DEA who violates record-keeping requirements or abandons Controlled Substances is subject to the civil penalties outlined in the United States Code (USC): 21 USC Sec. 842. Note that abandoning substances is equivalent to diversion of a Controlled Substance to an unauthorized person.

5.1.4.11 Registrants seeking to modify or terminate their research laboratory use license and/or registration must notify WVU EHS prior to any changes. If appropriate, registrants must follow the WVU EHS close-outs procedures timeline. See "Controlled Substance Disposal" section 5.9 in this procedure.

5.1.4.12 The OAW, as part of the animal care and use post-approval monitoring program and members of the Animal Care and Use Committee (IACUC), as part of the semi-annual inspection of animal use areas will review Controlled Substances, storage, and usage records for compliance with USDA regulations and NIH guidelines. These institutional inspections do not constitute a review of a Registrant's compliance with DEA and/or WVBOP regulations. The OAW and IACUC inspections are mandated under the University's Public Health Service assurance to NIH and required by the USDA for research using regulated species.

5.1.5 Important Points for Application Forms

A. Addresses for state and federal registrations must be the same.

B. Address must be a single physical geographic location (building name and room number) for secure storage of the Controlled Substances.

C. Postal Address vs Physical Address: if the specific location does not have a US Postal delivery (the storage location is a lab bench in the back room), then list the nearest postal delivery address, and on the next line list the geographic location by building/room number. Addresses must have the geographic location of the Controlled Substance storage cabinet.

D. Shipping Address: The "Ship To" address is the address on the federal DEA registration. It is a violation to ship to any address other than the federal DEA address listed on the Registration certificate. This address must be the storage location (not a PO Box).

E. The Schedules of substances listed on one registration (federal DEA) must be the same as the Schedules listed in the other registration (WVBOP).

5.2 Registrant Screening and Selection Process for Authorized Users

5.2.1 Having Authorized Users associated with the WVBOP and DEA Registration is not required; however, it is necessary if anyone other than the Registrant will have access to the Controlled Substances storage or administration under the Registration. Every University Member identified by the Registrant as being an Authorized User must compete the screening process/forms.

5.2.2 The Registrant is solely responsible for the compliance of their Authorized Users associated with their Registration in accordance with DEA and/or WVBOP Regulations.

5.2.3 Personnel Screening Form (21 CFR 1301.90) - This form (on WVU EHS website) must be completed prior to the Registrant authorizing the individual to work with Controlled Substances. If the answer to any of the three (3) questions below is "yes", then the person should not be allowed to possess or administer Controlled Substances.

> 5.2.3.1 Question 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 charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial).
>
> 5.2.3.2 Question 2: In the past three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
>
> 5.2.3.3 Question 3: Have you ever been denied a DEA registration, had a DEA registration revoked or surrendered a DEA registration for cause?

5.2.4 A copy of the personnel form must be sent to the WVBOP and DEA during the initial application process. Both new hires and students must complete the form prior to becoming an Authorized User. Keep the questionnaires in a separate secured file at the registered location for two years after the termination of the individual being an Authorized User. These documents are considered sensitive and should be locked securely as with other sensitive employment information held by the Registrant.

5.2.5 The DEA Registrant and Authorized Users must conduct an annual review of the Screening Form for the duration of a given Authorized User's involvement in Controlled Substances work.

5.2.7 Authorized Users Signature Log– This form must be initially completed by each Authorized User after the Registrant screens and then certifies the person is an Authorized User associated with their Registration. The Signature Log is kept with the Registrant's Controlled Substance notebook. Scan a copy of the signature log to WVU EHS when there is an update (new or terminated authorized user).

5.2.8 The "termination date" on the Personnel Screening Form and Authorized Users Signature Log is completed by the DEA Registrant once the Authorized User is no longer authorized to come in contact with the Registrant's Controlled Substances. Once the termination date is documented and the Registrant and Authorized User (previously) have signed the forms, scan a copy of the Signature Log to WVU EHS. Once an Authorized User status has been terminated, the location of the key to open the Controlled Substance storage cabinet and/or any codes needed to access the Controlled Substances need to be changed.

5.3 Acquisition: Purchasing Controlled Substances

5.3.1 Registrants may only acquire Controlled Substances within the schedule listed on their approved WVBOP and DEA Registrations. Controlled Substances can be obtained through the purchasing methods and vendor sources in this section or through a permissible Registrant-to-Registrant transfer described in Section 5.8.

5.3.2 Controlled Substances may be ordered/purchased through standard WVU PCPS procurement processes via Mountaineer Marketplace catalog and non-catalog ordering, such as through Wholesale Distributor and Pharmacy vendors.

> 5.3.2.1 The WVU/WVURC PCard Manual prohibits purchases of Controlled Substances. Ordering/purchasing exceptions require the approval of PCPS and EHS Controlled Substance Manager.

5.3.3 WVU OLAR is a Wholesale Distributor and stocks some commonly used veterinary Controlled Substances in Schedules II-V. Examples of Schedule II substances that OLAR dispenses include pentobarbital and Fatal-Plus. OLAR will only sell Controlled Substances to Registrants that have provided OLAR with scanned copies of their valid DEA Registration and WVBOP Registration Certificate. Purchases are made within the OLAR purchasing system. Additionally, the purchasing database only allows purchasers to select substances within the schedules on their Registration.

> 5.3.3.1 Before OLAR can dispense any Schedule II Controlled Substance to a Registrant, a completed DEA Form 222 must be received.

5.3.4 The National Institute on Drug Abuse (NIDA) has a Drug Supply Program (DSP) to provide Controlled Substances, other chemical substances, marijuana, and nicotine research cigarettes for research purposes to investigators working in the area or drug abuse, drug addiction, prevention, and treatment at academic institutions.

> 5.3.4.1 To obtain substances from NIDA, research investigators are required to submit their requests along with necessary documents to the NIDA Drug Supply Program for consideration. Ordering guidelines can be found at https://www.drugabuse.gov/research/research-data-

measures-resources/nida-drug-supply-program/ordering-guidelines-research-chemicals-controlled-substances

5.3.4.2 If ordering Schedule I or II Controlled Substances from NIDA, DEA Form-222 is required.

5.3.5. Registrants can also obtain Controlled Substances through the DEA's Controlled Substance Ordering System (CSOS) (https://www.deaecom.gov/). Registering with DEA CSOS enables electronic ordering without the need to prepare a paper Form 222 in order to purchase Schedule I and II substances.

5.3.6 Purchasing Documentation - Schedule I and II Controlled Substances

5.3.6.1 DEA and WVBOP Registrants can obtain Schedule I and II Controlled Substances using a completed and signed DEA Form 222. The Registrant must make a copy of the completed, original DEA Form 222 for their records and then submit the original to the supplier. The supplier retains the original DEA Form 222 in their files.

5.3.6.2 Registrants can request official order forms (Form 222) (*Schedule I & II Registrants Only*) from deadiversion.usdoj.gov/online_forms_apps.html.

5.3.6.3 DEA Form 222 is unique to each Registrant. DO NOT share DEA Form 222 with other Registrants.

5.3.6.4 NO corrections are to be made on DEA Form 222. If a mistake is made, the form must be voided and a new form used. To void the form, draw a line across it and write "Void", sign and date underneath the line. Retain voided forms for two years.

5.3.6.5 DEA Form 222 must be completely filled out. However, the National Drug Code (NDC) number is not required. If it is available from the manufacturer, it can be inserted in the appropriate box.

5.3.6.5.1 Only one item may be entered on each numbered line. An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance.

5.3.6.5.2 The number of lines completed must be noted at the bottom of the form.

5.3.6.5.3 DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine, must contain only these substances.

5.3.6.5.4 The name and address of the supplier from who the Controlled Substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

5.3.6.5.5 A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

5.3.6.6 When the ordered substances are received, the purchaser must record on their copy of DEA Form 222 the number of commercial or bulk containers furnished for each item and the dates on which the containers are received.

5.3.6.7 A limited Power of Attorney document must be used if the Registrant plans to give another individual signatory authority to sign DEA Form 222 and obtain Schedule I and II Controlled Substances on their behalf (21 CFR 1305.05). If the Registrant personally orders and obtains the Schedule I and II Controlled Substances, then a Power of Attorney document is not needed. For instructions on creating a Power of Attorney, see https://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_05.htm.

The power of attorney must be available for inspection together with other order records.

5.3.6.9 DEA Form 222 must be maintained separately, in a secure location, from all other records. The Registrant is responsible for securing the forms and retaining executed (copy, supplier will have original) unexecuted, voided, unaccepted, and defective forms.

5.3.6.9.1 Forms should be retained for two years and be available for inspection.

5.3.6.9.2 Executed DEA Forms 222 (copy, supplier will have original) and any attached statements or other related documents must be secured at the registered location printed on the DEA Form 222.

5.3.6.9.3 Unexecuted DEA Forms 222 may be kept (securely) and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by an officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding Controlled Substances (21 CFR 1305.12e)

5.3.6.9.4 The Registrant should make a list of the unique form numbers and record the date when each is used. If any used or unused DEA Forms 222 are lost or stolen, it must be reported to the Special Agent in charge of the DEA in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

5.3.6.9.5 If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business, surrenders the registration), is suspended or revoked, or the name or address on the registration changes for all Schedule I & II Controlled Substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 (21 CFR 1301.52).

5.3.6 Purchasing Documentation Schedule III - V Controlled Substances – Orders and purchases by a Registrant can be documented through standard procurement processes. A copy of the Registrant's Certificate should be attached to the requisition. –

5.4 Receiving Controlled Substances

5.4.1 Controlled Substances must be shipped directly to the DEA Registrant at the address indicated on the DEA Registration. The Controlled Substance(s) must be opened, and the contents verified by the Registrant. Any discrepancies must be rectified with the supplier and/or vendor. If discrepancies cannot be rectified, the DEA Registrant must contact the DEA and WVBOP to report the discrepancy within five (5) business days.

5.4.2 The DEA Registrant must sign (full name) and date the purchase receipt (packing slip) and keep it with the Deduction Card (provided by WVU EHS). Document a red "C" on the purchase receipt to signify that Controlled Substances are listed. Ensure the quantity and name/lot # of Controlled Substance received is on the purchase receipt.

5.4.3 Once received, Controlled Substances must be immediately secured in the location indicated on the Registration and in accordance with federal and state regulations (see Storage and Security section of this procedure).

5.5 Storage and Security

5.5.1 Registrants must keep Controlled Substances in a substantially constructed, not easily moved, and securely locked steel cabinet (or safe) that meets DEA (https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm) /WVBOP requirements. Controlled Substances must **not be visible** through a glass panel.

5.5.1.1 Schedule I-II: Securely locked, substantially constructed safe or steel cabinet that is anchored to a wall or the floor.

5.5.1.2 Schedule III-V: Securely locked, substantially constructed safe or steel cabinet

5.5.1.3 Schedule I-V substances can be stored together as long as security measures meet Schedule I-II requirements.

5.5.1.4 Ensure two levels of security (e.g., locks) are in place and always used.

5.5.1.5 Portable storage boxes or storage in high-activity areas (e.g., corridors) are not allowed.

5.5.1.6 Controlled Substances requiring refrigeration must be locked in a container securely fastened within a refrigeration unit unless the refrigeration unit can be locked from the outside.

5.5.2 The Registrant must restrict access to locked rooms and locked storage cabinets (safes) containing Controlled Substances. The Controlled Substance storage areas shall be accessible only to an absolute minimum number of specifically authorized individuals. The Registrant must determine how their Authorized Users will access substances.

5.5.2.1 Keys to Controlled Substance storage must be secured such as establishing a key control system (e.g., a log to track who has a key). Keys should be limited to a minimum number of Authorized Users.

5.5.2.2 If using combination locks, the combination should be giving to a minimum number of Authorized Users and the combination should be changed as Authorized Users (with knowledge of the combination) terminate use of Controlled Substances.

5.5.3 Records and documentation on Controlled Substances must also be secured.

5.4.4 All Controlled Substances must be kept locked in their storage location except for the actual time required to remove and actively work with them. They must then be replaced back into the approved secure storage location listed in the Registration. ***It is absolutely required that Controlled Substances, when not in use, are located in the secure location at the address on the Registration.*** Do NOT leave Controlled Substances unattended.

5.4.5 Standard narcotic cabinets can be purchased through various vendors. Remember that DEA regulations (https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm) require that the cabinet (safe) be secured so that it cannot be easily removed.

5.4.6 The steel cabinet or safe, if necessary, depending on the quantities and type of Controlled Substances stores, needs equipped with an alarm system which, upon attempted unauthorized entry, transmits a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

5.6 Administering (Dispensing) Controlled Substances

5.6.1 The DEA/WVBOP Registrant and their Authorized Users are the only individuals permitted access to the Controlled Substances in the inventory.

5.6.2 Administering or dispensing Controlled Substances occurs when an Authorized User obtains the required quantity of Controlled Substance from the Controlled Substances storage for administration during an experiment. The Authorized User must complete documentation of Controlled Substances use by making a written record of the substance administered, quantity used, and any wastage. Every ml, mg, tablet, etc. of a Controlled Substances must be accounted for in the records.

5.6.3 Use of a Bulk form Controlled Substance is documented on the Deduction Card (provided by WVU EHS when substance is received).

5.6.4 If a Finished Form of the Controlled Substance will be used multiple times (e.g. vial of diluted Controlled Substance provides several doses) record the quantity of the Bulk Form used to make the Finished Form, and the Finished Form inventory number on the Deduction Card. Document use of the Finished Form of the Controlled Substance on a Usage Log (can be printed from: https://www.ehs.wvu.edu/hsc/controlled-substance-use-in-research).

5.6.5 At the end of each research use, Authorized Users must return all Controlled Substances to the secure approved storage area at the physical location on the Registration Certificate.

5.7 Transport of Controlled Substances between University Buildings

5.7.1 Small quantities of Finished Form substances for administration may be transported between different building addresses for use (e.g.: from lab to vivarium, vet clinic to field animal). Controlled Substances must always be stored in accordance with DEA and WVBOP regulations.

5.7.2 Bulk Form substances cannot be transported between University buildings unless being distributed (via Form 222, packing slip, transfer) to a Registrant.

5.7.3 A DEA Registrant cannot give his or her Controlled Substance to another researcher to have it compounded, diluted, tested, disposed, etc., unless the recipient researcher is a Registrant authorized to receive the Controlled Substance, and the substance has completed a permissible Transfer (see Section 5.8).

5.8 Disposal and Destruction of Controlled Substances

5.8.1 Controlled Substances that are no longer supported by an active approved protocol, or are expired, damaged, contaminated, residual (waste) or otherwise unusable or unneeded must be appropriately disposed of. Coordination with WVU EHS Controlled Substances Manager is required for any disposal actions to be performed by University Member Registrants. The most common disposal methods available to University Member Registrants are destruction and reverse distribution.

> 5.8.1.1 Destruction of Controlled Substances is performed and documented by the Registrant and must be destroyed by a mechanism rendering them unusable, irretrievable, and unrecoverable by an approved DEA and WVBOP method. The EHS Controlled Substances Manager can provide witnessing and other assistance for Registrant-performed destructions upon request.
>
> 5.8.1.2 Reverse distribution is the process by which a Registrant has its Controlled Substances inventory collected by a company/vendor possessing a Reverse distributing DEA Registration. The reverse distribution is documented in a manner similar to a Registrant-to-Registrant transfer, with the Reverse distributing Registrant then responsible for performing and documenting destruction. Use of a reverse distributor vendor can be cost-prohibitive for an individual Registrant. Coordinating Controlled Substances disposal needs with EHS enables advanced planning for hosting periodic Reverse distribution events which can service multiple University Member Registrants if/as warranted.

5.8.2 Bulk (Stock) Vials

Registrants are responsible for disposing of sealed or partially used Bulk (stock) Controlled Substances by Reverse Distribution or Controlled Substance Destruction. DEA Form 41 must accompany any on site destructions.

Disposal can be accomplished by transferring the sealed or partially used Bulk (stock) Form Controlled Substance (in original container) directly to a Reverse Distributor or via Registrant-performed destruction.

5.8.2.1 Complete WVU Controlled Substance Registrant Transfer for Disposal Form available on the EHS website at: http://www.ehs.wvu.edu/environmental/waste-management/controlled-susbstance-disposalform

5.8.2.2 E-mail completed forms to the Controlled Substance Manager (Subject line: Controlled Substance Disposal Form) to coordinate disposal with EHS Hazardous Materials team and Reverse Distributor, as needed.

5.8.2.3 The Deduction Card must document Reverse Distribution and retain Reverse Distribution documentation.

5.8.2.4 Bulk/Stock vials containing less than 10% of the original volume may be rendered unusable and discarded into a Cactus Sink. This wastage must be documented on the Deduction Card as well as on the documentation located at the Cactus Sink and be witnessed by another Authorized User.

5.8.2.5 Completed DEA for 41 for registrant record of Controlled Substance Destructions available on the EHS website at: https://www.ehs.wvu.edu/controlled-substance-use-in-research

5.8.3 Finish (Compounded) Form Vials

Finished Form or compounded drugs (anesthetic mixtures or Controlled Substance dilutions) that are expired or no longer usable must be destroyed by a comparable method rendering the substance unusable, unrecoverable, and irretrievable.

5.8.4 Labeling Expired Drugs Awaiting Reverse Distribution or Destruction

Expired or unusable substances must be labeled, separated, and stored securely according to DEA requirements for the highest-level Schedule associated with the Controlled Substances that require disposal. Each vial must be labeled as “expired” or “waste” and placed into a separate box or bag labeled as “DO NOT USE-EXPIRED” clearly on the outside of the box. The closed, labeled box must be kept within the same cabinet where inventory is stored. Expired compounds must remain on the inventory until reverse distributed.

5.8.5 Controlled Substance waste cannot be combined into one bottle for consolidation. Each individual container of Controlled Substance must be maintained and tracked separately until disposal. At the time of disposal, an entry shall be made on each container’s Deduction Card/Usage Log documenting disposal.

5.8.6 Empty drug vials/containers may be disposed in the standard lab waste stream, after defacing the label as EMPTY.

5.8.7 Controlled Substances injected into animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures (contact WVU-EHS with any questions).

5.8.8 Orphaned Controlled Substances - Continued possession of Controlled Substances following the expiration of a DEA or Board of Pharmacy Registration is unlawful. Registrant University Members must eliminate all Controlled Substances inventory in their possession via approved disposal or by a permissible Registrant-to-Registrant transfer prior to Registration expiration. In the event that Controlled Substances are found on University premises for which a valid Registrant cannot be located (e.g. Registrant no longer with the University):

5.8.8.1 Ensure the Controlled Substance is secured.

5.8.8.2 Contact WVU EHS (Controlled Substances Manager 304-293-6925, Main 304-293-3792 or HSC 304-293-7953) and submit a Hazardous Waste Disposal Request Form (https://www.ehs.wvu.edu/chemical-waste/waste-management/hazardous-waste-disposal). Email form to EHS_Chemicals@mail.wvu.edu (Subject line: Orphaned Substance)

5.8.8.3 WVU EHS will notify UPD and arrange transfer of the Controlled Substance to UPD, who will secure the substance while awaiting DEA approval for destruction.

5.8.8.4 DEA Form 41 will be completed to document destruction of the orphaned Controlled Substance(s). The form must be kept as a record of destruction for at least two years in accordance with 21 U.S.C. 827.

5.9 Controlled Substance Loss

5.9.1 If any Controlled Substance has been stolen, misplaced, or lost from the lab's control, the Registrant will immediately notify WVU EHS (304-293-0952), university police (304-293-3036), and the DEA.

DEA-Charleston
2 Union Square Ste 300
Charleston, West Virginia 25302
(304)-347-5209
Fax: (304)-347-5212

5.9.2 This includes required reporting for unauthorized uses, unauthorized destruction, and a significant explained loss (e.g., dropped and broken bottle) of any Controlled Substance. Any discrepancies or losses of the material must be noted on the Deduction Card/Usage Log.

5.9.3 The DEA requires Registrants to notify the Field Division Office of the Administration in their area, in writing, of theft or significant loss of any Controlled Substance, disposal receptacles, or listed chemicals within one business day of discovery of such loss or theft (fax a report to the above DEA number).

5.9.4 For theft or loss in transit, the Registrant must also complete and submit to the Field Division Office in their area, DEA Form 106 "Report of Theft or Loss of Controlled Substances" regarding the loss or theft (21 CFR 1301.76 (b) and 21 USC 830 (b)(1)(c)).

5.9.5 For loss of Controlled Substances due to accidentally spilling or container breakage, the Registrant must complete and submit DEA Form 41. Witnesses must sign DEA-Form 41 for the loss of material.

5.9.6 DEA Form 106 can be found at https://www.deadiversion.usdoj.gov/online_forms_apps.html under the "Reporting Forms" section.

5.9.7 If a container of a Bulk Form Controlled Substance is stolen, broken or spilled, the loss must be documented on the Deduction Card and a witness(es) must also sign and date the deduction (preferably a member of WVU EHS and another Authorized User). If safe and feasible to do so, attempt to quantify the spilled material.

5.9.8 If a container of a Finished Form Controlled Substance is stolen, broken or spilled, the loss must be documented on the Usage Log and a witness(es) must sign and date the deduction (preferably a member of WVU EHS and another Authorized User). If safe and feasible to do so, attempt to quantify the spilled material.

5.10 Documentation

5.11.1 DEA Registrants must maintain complete and accurate inventory records for all Controlled Substances that demonstrate a closed system of distribution. Controlled Substances must be accounted for with documents that support acquisition (ordering), receiving, administration (use), inventory, and disposal. An accurate, continuous, and current record is required and necessary to validate proper use of Controlled Substances. Organization and retention of documentation are discussed in the Recordkeeping section of this procedure.

5.10.2 Receipt of Controlled Substance

> 5.10.2.1 When a Controlled Substance is received from a manufacturer or vendor, the accompanying paperwork (order form, shipping documents, and invoices) must be retained as part of the Controlled Substance official record.
>
> 5.10.2.2 You must maintain a record of the receipt of each Controlled Substance, indicating date received, date opened, name and address of supplier, the strength or concentration, and amount of the Controlled Substance received (will be documented on Deduction Card).
>
> 5.10.2.3 After receiving a Controlled Substance, contact WVU EHS who will provide a Deduction Card and WVU inventory number. Every vial/container must have its WVU inventory number clearly and indelibly marked onto it. The Deduction Card will also state the WVU inventory number. Do NOT use a Controlled Substance until it has a Deduction Card and WVU inventory number.

5.10.3 When a delivery of Controlled Substance is received from a vendor (bulk (stock) form), it must be issued a WVU inventory number. The following numbering convention will be used for consistency:

> 5.10.3.1 Lot number on container/package - MMDDYY of receipt - First & Last Initials of DEA Registrant. Example: a vial of Ketamine (lot # 123456) for DEA Registrant John Smith that arrived at WVU on June 8, 2020 would be listed as 123456-060820-JS
>
> 5.10.3.2 If multiple vials with the same lot # arrive on the same day, use lower case letters to distinguish specific vials. For example, if three vials of Ketamine (Lot# 123456) for DEA

Registrant John Smith arrived on June 8, 2020, the vials would be assigned WVU inventory numbers of 123456-060820a-JS, 123456-060820b-JS, 123456-060820c-JS. (It may be helpful for each vial to be given its own Deduction Card).

5.10.4 All containers of Controlled Substances must be properly labeled. If the research laboratory re-packages, compounds, or dilutes Controlled Substances (Finished Form), then appropriately label the repackaged, compounded or diluted substance and store it in the approved secure location listed on the Registration.

Note, compounded (Finished Form) Controlled Substances (mixed cocktails or diluted Controlled Substances) cannot be transferred between DEA Registrants.

5.10.5 Finished forms (mixtures, dilutions) must be labeled with their own unique inventory number that links the Finished Form vial back to the Bulk (stock) vial used to create the Finished Form.

5.11.5.1 Use the Bulk Form lot number, the date the Finished Form was made, and the abbreviation "FF" (for Finished Form). For example, if the Bulk Form vial had lot number "123456" and the Finished Form was made on 09/06/21, then the diluted vial would be numbered "FF-123456-09/06/21". If there are multiple vials of Bulk Form, include the lower-case letter from the Bulk Form WVU identification number in the Finished Form inventory number. For example:

Unique Tracking Number	Would Mean
FF-123456a-09/06/21	dilution of Controlled Substance Lot 123456, vial a on 09/06/21
FF-123456b-09/06/21	dilution of Controlled Substance Lot 123456, vial b on 09/06/21
FF-123456b-10/12/21	dilution of Controlled Substance Lot 123456, vial b on 10/12/21

5.10.5.2 If multiple Finished Form vials are made on the same day (from the same Bulk Form lot), include a suffix after the date:

Unique Tracking Number	Would Mean
FF-123456a-09/06/21.01	First dilution of Controlled Substance Lot 123456, vial a on 09/06/21
FF-123456a-09/06/21.02	Second dilution of Controlled Substance Lot 123456, vial a on 09/06/21
FF-123456a-09/06/21.03	Third dilution of Controlled Substance Lot 123456, vial a on 09/06/21
FF-123456b-10/12/21.01	First dilution of Controlled Substance Lot 123456, vial b on 10/21/21
FF-123456b-10/12/21.02	Second dilution of Controlled Substance Lot 123456, vial b on 10/21/21

5.10.5.3 Diluted or compounded Controlled Substances that will be stored at least overnight in the safe/secured location must be properly labeled with the following information:

- o Name of Controlled Substance
- o Unique inventory number
- o Final concentration
- o Volume per container
- o Expiration date (if applicable)

5.10.5.4 Each Finished Form vial must be issued a corresponding usage log to document use and disposal.
Exception: if a Controlled Substance dilution or mixture will be used for a single application, documentation on the Deduction Card is sufficient, a separate Usage Log is not required.

5.10.6 The Deduction Card (Bulk Form) and Usage Log (Finished Form) will state the starting quantity of the substance. Each use is a subtraction from the starting quantity, and the running (decreasing) amount should equal the total amount remaining on-hand. Each record of use must be documented and signed by the DEA Registrant or Authorized User working with the Controlled Substance. The Deduction Card/Usage Log should also include details of any Controlled Substance lost, destroyed, or stolen.

5.10.7 The following details should be documented on the Deduction Card/Usage Log every time a Controlled Substance is used in research:

Date
Building/Room
Specific Research Experiment
Strength/Quantity/Form of Controlled Substance
Controlled Substance Administration (Animal Species/Cell Culture/Equipment + ID)

5.11 Good Documentation Practices

5.11.1 Good Documentation Practices should be adhered to when documenting information for Controlled Substances. All documented information should be:

5.11.2 **Attributable** to a specific individual**.**

5.11.2.1 Sign and date documentation in a way that it is clear who has documented the data.

5.11.2.2 Full name should be printed/signed. Initials can only be used when they correspond to a full name on the same document. For example, if an individual will sign multiple columns of a table, sign the full name in the first column with initials in parenthesis, subsequent columns will require initials only.

5.11.2.3 Never sign for another individual on any document. Only sign for work performed yourself.

5.11.2.4 If any information/signature/date is to be repeated, the same should be rewritten. Ditto (--"---) marking or "as above" should NOT be used.

5.11.3 **Legible**: all recorded information (including signatures) should be identifiable.

5.11.4 **Contemporaneous**: record entries at the time of activity occurrence

5.11.5 **Original**: the first record made by the appropriate person

5.11.6 **Accurate**: consistent and real representation of facts

5.11.7 **Enduring**: long-lasting and durable

5.12.7.1 Use an indelible pen. DO NOT use pencil, erasable or water-soluble ink.
5.12.7.2 Do not discard or destroy any Controlled Substance documentation unless the retention period expiry has been reached.

5.11.8 Correction of entry errors

5.11.8.1 Incorrect entries in Controlled Substance documents should NOT be overwritten or blacked out to make it unreadable (DO NOT USE white out or correction tape)

5.11.8.2 Always use a single strike through the documentation to mark the incorrect entry in such a manner that the incorrect entry remains readable.

5.11.8.3 If possible, document the correct entry near the strikeout entry and sign and date the documentation change. Alternatively, using corresponding superscript numbers (enclose superscripts in a circle), document the correct entry at the bottom of the document and sign and date the documentation change.

5.11.8.4 If the error is not easily identifiable (e.g., misspelled word), document the reason for correcting the entry.

5.11.9 Blank/unused space in Controlled Substance documents should be NA'ed (make a single line striking through portions of unused tables), signed, and dated.

5.12 Controlled Substances Inventory Requirements (21 CFR 1304.11)

5.12.1 The Registrant is responsible for maintaining a Controlled Substances inventory for Schedule I – V substances. The inventory must be maintained at the registered location and made available for two (2) years after the substance(s) has been used or disposed.

5.12.2 Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location.

5.12.3 A separate inventory shall be made for each registered location and each independent activity registered. The inventory may be taken either at opening of business or at close of business on the inventory date and it shall be indicated on the inventory form.

5.12.4 Initial Inventory: Once a DEA Registration is issued, the Registrant must take an **initial inventory**, which is an actual physical count of all Controlled Substances in their possession. The Registrant will make a record showing what is on hand, typically zero, during the initial inventory.

5.12.5 **Biennial inventory**: After the initial inventory is taken, the registrant shall take a new inventory of all stocks of Controlled Substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

5.12.6 Inventory date for newly Controlled Substances: inventory must be updated on the effective date of a rule (from the DEA) when a substance is added to the Schedule (list of Controlled Substances). Every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the Registrant.

5.12.7 Inventory log sheets are available on the website associated with this procedure. The inventory must be maintained in the documentation notebook.

5.12.7.1 The inventory must document the Registrants name, DEA registration number, storage location, Controlled Substance(s) name, DEA Schedule, WVU inventory number, quantity (volume/weight/count), Container Quantity, Strength/Concentration, and Form (liquid, powder, tablets) for all Controlled Substances.

5.12.7.2 For any Controlled Substance that is damaged, defective, impure, or expired and awaiting disposal, this must be noted on the inventory along with the reason for the substance being maintained by the Registrant in such a state and whether such substance is capable of use in the manufacture of any Controlled Substance in Finished Form.

5.12.7.3 Any discrepancies identified between actual physical quantity and remaining quantity according to the Deduction Card/Usage Log should be reported to WVU EHS within one business day.

5.13 Recordkeeping Requirements

5.13.1 A Controlled Substances notebook must be maintained (file, folder, binder) containing the documentation of Controlled Substance transactions demonstrating a closed system of distribution.

5.13.2 An accurate, continuous, and current record reflecting the acquisition, administration (use), disposal, and biennial inventory of Controlled Substances in Schedules I – V is necessary to validate proper documentation of use of Controlled Substances.

5.13.3 Records must be maintained for two years after the depletion or destruction of the Controlled Substance.

5.13.4 Authorized User Forms

5.14.4.1 As described in section 5.2 of this manual, the Registrant must maintain clearance records for every Authorized User associated with the Registration. These forms contain sensitive information and should not be stored in the Controlled Substance notebook. Instead, the Personnel Screening Form should be locked securely as with other sensitive employment information maintained by the Registrant.

5.14.4.2 The Authorized User Signature Log must be maintained with the Controlled Substance notebook associated with the appropriate Schedule.

5.14.4.3 Forms must be retained for two (2) years after the Authorized User is no longer associated with the Registration.

5.13.5 Suggested Controlled Substances Notebook Sections Based on Required Documentation. Page dividers and plastic sheet protector pockets are very useful when organizing the different sections and individual vials.

1. **Background Information**

- Copy of current in-date DEA Registration and WVBOP Registration Certificate
- Controlled Substance Research Protocol
- Copy of amendments to Registration(s)

2. **Authorized Users**

- Authorized User Signature Log specific to Schedules in Registration(s)
-Documentation of any training given to the Authorized User by the Registrant.
- Copy of Power of Attorney (for Schedule I and II only)

3. **Inventory**

- Initial inventory
- Biennial inventories

4. **Acquisition/Purchasing**

- Purchasing log/Tracking form used to track Controlled Substance acquisition, numbering/tracking system, and disposal. Suggested columns include:
    - Date of purchase
    - Date of arrival
    - Name, manufacturer, lot number, concentration, WVU inventory number
    - Expiration date
    - Individual Authorized User assigned to bottle/vial (if needed)
    - Date of when vial/bottle was disposed/emptied

-For how to store DEA Forms 222, see section 5.3.3.9

5. **Controlled Substance Usage and Disposal Log form**

- *Stock (Bulk form) vial* log - Every vial must have a WVU inventory number and associated Deduction card. If multiple vials of the same Controlled Substance, with the same lot number arrive on the same day, they can be associated with a single Deduction Card (see Documentation section in this manual).

    - Maintain packing slips (signed and dated) with Deduction Cards – photocopy packing slip when multiple substances are purchased at once. Each Controlled Substance will need to be easily associated with its packing slip and making copies simplifies this process.

- Copy of completed DEA Form 222 – Required for Schedule I and II purchases. Keep blank originals locked.
- *Compounded/Dilution (Finished form) vial* log – each compounded vial created must have a usage log. The compounded vial must have a unique tracking number that references/links it to the original Stock/Bulk vial number (see Documentation section in this manual).

-Documentation of Controlled Substance use must be done **contemporaneously** on the Deduction Card/Usage Log.

-The last entry in the usage portion of the forms should refer to the record of disposal (e.g, vial empty (remaining balance should be ~0), expired-reverse distributed, waste-reverse distributed). Make a single line through any remaining (blank) columns of the usage portion, NA,, sign, and date.

6. **Reverse Distribution**

- Copy of WVU Controlled Substance Registrant Transfer for Disposal Form
- Maintain copies of Reverse Distribution confirmation.

6.0 Termination of License

If the DEA Registrant desires to terminate their work with Controlled Substances (e.g. the lab is closing or the DEA Registrant is retiring), the DEA Registrant must notify WVU EHS Controlled Substances Manager immediately for assistance in properly concluding Controlled Substance work. The Registrant must dispose of or transfer all Controlled Substances prior to closing the lab or before allowing the DEA registration to expire. The DEA should be notified to cancel the registration and will inform the Registrant of any additional requirements.

7.0 Associated Forms

Authorized User Screening Form (WVU EHS Website)
Authorized User Signature Log (WVU EHS Website)
DEA From 222 for transfer of Schedule I & II drugs
DEA Form 41 for documenting loss of material from spills/broken bottles
DEA Form 106 for documenting drug theft/loss during transit
Deduction Card (Issued by WVU EHS)
New Registrant Application
- *West Virginia University Controlled Substances Research Protocol*
- WVBOP *Application for Permit or Renewal to Handle Controlled Substances*
- DEA-Form 225 *New Application for Registration*

Schedule III-V Transfer Form (WVU EHS Website)
Transfer for Disposal Form (WVU EHS Website)
Usage Log (WVU EHS Website)

DEA Forms can be found at: https://www.deadiversion.usdoj.gov/online_forms_apps.html

8.0 Version History and Procedure Attributes

Attribute Type	**Detail**
Policy / Procedure Name	Use of Controlled Substances in Research and Scholarly Activities Program
Responsible Unit	Environmental Health and Safety
Adoption / Effective Date	12/01/2023
Most Recent Review Date	04/01/2024
Next Planned Review Date	Annual review of this program will be conducted to ensure accuracy and compliance with regulations.
Version History	Initial Procedure 04/01/2024