WEST VIRGINIA STATE UNIVERSITY
OFFICE OF RESEARCH & PUBLIC SERVICE

USE OF CONTROLLED SUBSTANCES IN RESEARCH

POLICIES AND PROCEDURES

Revised on ~~March 7~~ May 4, 2018

WEST VIRGINIA STATE UNIVERSITY BOARD OF GOVERNORS

West Virginia State University

BOG Policy # 63 (?)

Title: Policy on the Use of Controlled Substances in Research

1. Policy Introduction & Purpose

This policy is designed for substances used for medical and scientific research purposes, which are otherwise illegal. The Federal Controlled Substance Act (21 U.S.C. Chapter 13; implementing regulations at 21 CFR 1300-1399) and West Virginia Uniform Controlled Substances Act (WV Code 60 A, Article 9 - Controlled Substances Monitoring Act) regulates such use of these substances. Due to their potential abuse, drugs identified by the US Department of Justice, Drug Enforcement Administration (DEA) and Drug Control Division (DCD) as controlled substances are subject to extensive licensing, registration, storage, security, use, and disposal requirements. At the state level, the WV Board of Pharmacy coordinates with the **Division** of Justice and Community Services, and the Office of **Drug Control** Policy to enforce these regulations. The West Virginia State University's Office of Environmental Health and Safety (WVSU-EHS), under the auspices of the Research and Public Service Unit, has the responsibility for assisting researchers with navigating these requirements, including obtaining appropriate regulatory documents; WVSU-EHS officials can be contacted at 304-XXX-XXXX during regular business hours. Please note that this policy applies exclusively to the research use of controlled substances, including human subject studies.

Therefore, the purpose of these policies and procedures is to create an oversight support system upon which WVSU and associated researchers can comply with federal, state and institutional requirements regarding the use of controlled substances in research.

2. Operating Definition of "Controlled Substance"

Controlled substances are any "…drug, substance, or immediate precursor in schedules I to V, inclusive of the West Virginia Uniform Controlled Substances Act (WV Code, Chapter 60)

Commented [CN1]: Is this all of the definition? There's no end quote and it appears incomplete.

From DEA website - Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in **Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15**. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are listed below.

3. Applicability and Non-compliance

Principal Investigators (PIs) or Researchers, including WVSU faculty and approved staff engaged in research involving the use of DEA controlled substances, are required to register with the DEA and the WV Board of Pharmacy. Authorized users of controlled substances must comply with the DEA's requirements for secure storage, recordkeeping, inventorying, reporting loss, theft, or abuse, and safe disposal. Thus, authorized users will be responsible for updating the controlled substances records as described below, and for assuring compliance with all applicable state and federal regulations. The registrant must not allow the permit to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

Authorized users using controlled substances in their research are subject to extensive state and federal regulatory requirements, as outlined in this Policy. Note that these requirements (including licensing/registration with regulatory agencies) are separate from and in addition to requirements that apply to medical practice: therefore MDs and MD/PhDs conducting laboratory or non-therapeutic human subject research involving controlled substances must obtain licensure/registration for laboratory use of controlled substances in addition to licensure for their practice. Please further note that therapeutic research, in which the subjects are receiving controlled substance(s) as part of their treatment, requires only the medical practice license, and not a laboratory research license. (The inclusion of subjects receiving only a placebo does not invalidate this exception.)

The WVSU-EHS will assist individuals engaged in research in complying with applicable rules and regulations in the form of educating researchers about requirements and providing compliance oversight through the coordination of inspections. However, it is ultimately the registrant's responsibility to ensure compliance with state and federal regulations.

The State of WV and the DEA can impose administrative, civil, and criminal actions against a controlled substance licensee and DEA registrants for noncompliance and/or theft or loss associated with the storage, administration, recordkeeping, and other aspects of controlled substances.

Failure to comply with this WVSU Controlled Substance Policy, state, and federal regulations will automatically result in the termination of the researcher's controlled substance authorization and will also result in the suspension of controlled substance orders through the University or WVSU Research & Development Corporation.

Commented [CN2]: I would be careful in outlining only this variant of the license type. There are numerous types of licenses that could potentially be applied for. If you are discussing one other type, you should discuss all types that could potentially be applied for through WVSU, otherwise, keep the language vague.

See various application types - https://apps.deadiversion.usdoj.gov/webforms/

4. Schedules

Commented [CN3]: I would move this section right below the definition of controlled substances or combine them

Controlled substances are divided into five categories known as Schedules. Schedules are based on whether the substances have a currently accepted medical use for treatment in the U.S., their relative abuse potential, and likelihood of causing dependence when abused. Schedules I and II are the most stringently regulated, and both have high potential for abuse. However, Schedule II drugs have a currently accepted medical use in treatment, while those in Schedule I do not. Schedule III drugs include many stimulants and depressants, pain-killers and cough suppressants, the veterinary anesthetic ketamine, and anabolic steroids. Schedule IV substances cover the balance of lower abuse potential stimulants and depressants, and Schedule V includes therapeutic drug mixtures containing limited quantities of controlled substances. Researchers planning work with controlled substances must be aware of and responsible for complying with relevant state and federal statutes and regulations for these materials. The state and federal schedules of controlled substances are substantially similar, but not identical.

Commented [CN4]: You discuss drug types in this category, but not the others. I would either discuss examples in each schedule, or keep the language vague. Keep in mind that in the future new drugs may be added to these schedules or drugs may be moved from one schedule to another.

Commented [CN5]: I don't believe there are any stimulants in Schedule IV

Commented [CN6]: Do you need to identify the differences in schedules?

5. Licensing and Registration

Since the University cannot, by law, maintain "blanket" registration for controlled substances, it is the responsibility of individual Principal Investigators (PI) or Researchers to obtain appropriate licenses and registration, and to adhere to applicable state and federal regulatory

requirements when working with controlled substances. PIs must obtain research licensure from the WV Board of Pharmacy as well as registration from the federal DEA. A table summarizing the license and registration obligations by different research activities appears in Attachment A [Need to adapt table to WVSU needs]. Instructions for completing licensing/registration applications are summarized below:

A. **State Licensing**: PIs must complete both the WVSU-EHS Institutional Approval Form for Application for Controlled Substance Laboratory License and the State of West Virginia's Board of Pharmacy (WVBOP) Controlled Substance Permit, and submit them (with charging instructions and business office authorizing signature) to WVSU-EHS for processing. As part of the application process, the DCD (WVBOF?) will inspect the designated laboratory work area; a copy of the DCD (WVBOF?) inspection checklist is attached to facilitate PIs review of the items covered in their laboratory work areas to ensure that facilities and operations are consistent with DCD (WVBOF?) requirements. Approved applicants will receive a one-year license (Specified dates are from July 1 through June 30) to work with controlled substances in a manner consistent with the approved use(s) described in the application. The DCD (WVBOF?) also conducts periodic random inspections of licensees thereafter.

B. **Federal Registration**: After receiving state WVBOP Permit from WVSU-EHS, PIs will be provided with a research laboratory registration (Form DEA-225), along with charging instructions for the DEA license fee. These forms should be completed and returned to WVSU-EHS. where they will be processed for submission and payment to DEA. Note that for work with Schedule I substances, three copies of the research protocol must accompany the application form. Due to internal DEA protocols, PIs will receive their registration certificate (known as Form DEA-223) directly from DEA. Upon receipt of certificates, PIs are required to send a copy to WVSU-EHS for documentation. DEA registrations remain active for a 3-year period, at which time a renewal notice will be mailed to the PI. DEA has also implemented an on-line registration system that can be directly accessed upon successful state licensing.

C. **Renewals**: Notices of pending license and registration renewals will be sent out by WVSU--EHS several weeks prior to expiration. Renewals will be processed in the same manner as initial licenses. Registrants seeking to modify, transfer, or terminate their research laboratory use license and/or registration must submit a written request to WVSU-EHS for processing with the regulatory agencies.

Commented [CN7]: The WVBOP Permits are mailed to the PI as well

Commented [CN8]: Are they going to mail the application in and pay the fee or is the PI still going to need to do that? Will the PI be required to fill out a PO for approval for fees?

Commented [CN9]: None of this is part of the state licensing process. There is a fee associated with the WVBOP application as well.
Application form - http://www.wvbop.com/forms/ControlledSubstances.pdf

Commented [CN10]: After obtaining state licensure, you then have to apply for the DEA license using the application form online. Once an agent has reviewed the application, they will contact the PI with a series of questions that must be answered and returned to the agent. That's as far as I got in the process, but my understanding is that after that step, the agent will then inspect the facility for storage, security, etc. before giving approval of the application.

Commented [CN11]: Where did you see this information? The Form 225 states that the fee is good for one year only.

6. Purchasing Controlled Substances

Controlled substances are considered "restricted purchase items" at West Virginia State University and may only be ordered through the Purchasing Department or the Purchasing Department's approved designee. Researchers are required to provide a copy of their current license to the Purchasing Department at the time of each purchase. PIs involved in "human subjects" research must obtain their controlled substances by prescription from an approved Investigational Drug Service or research pharmacy. Please note that Medical Practitioners may NOT use their prescription privileges to order controlled substances for *in vitro* benchtop or *in vivo* animal laboratory research.

Commented [CN12]: Again, there are diff restrictions for different applications besides human research

7. Scope of Use

Controlled substances may be used only for duly authorized, legitimate medical or scientific research purposes, to the extent permitted by a registrant's license and registration, and in conformity with WVSU, state and federal statutes and regulations.[1]

8. Storage and Security Controls

Controlled substances must be maintained in a manner and location that comply with state and federal law. Any controlled substances maintained otherwise, are subject to seizure by and forfeiture to the state. Failure to comply with applicable requirements may also result in a suspension of the PI's purchasing privileges and disciplinary actions through the University Safety Committee (???).

Commented [CN13]: What actions? I'm not sure this falls under the University Safety Committee's rule. If there is failure to comply, it will result in actions by the DEA/WVBOP and loss of licensure.

In order to guard against theft or diversion, all controlled substances - regardless of schedule - must be kept under lock and key, and accessible only to authorized personnel. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stocks of controlled substances must be limited to the smallest quantity needed.

Commented [CN14]: There may be rules regarding how many people have access per the DEA and I'm not sure if drugs from more than one PI can be stored together or not.

Security requirements vary by drug schedule. Schedule I and II controlled substances are subject to the highest security requirements, and must be stored separately from other drugs in an approved safe (as defined below). Schedule III through V substances must also be stored separately from other drugs in a secure locked location. Regardless of schedule, all controlled substances must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

Safes for Schedules I and II:

Commented [CN15]: There is no description of requirements for other schedules

An approved safe is one approved by the DCD or DEA prior to January 1, 1975, or any safe that minimally conforms to *all* of the following standards:

a. Safe Manufacturer's National Association certified as being Class A, B or C.
b. Underwriters Laboratories certified as being inspected for one or two hours.
c. Underwriters Laboratories certified as being equipped with a relocking device.
d. Weight of 750 pounds or more, or rendered immobile by being securely anchored to a permanent structure of the building.

WVSU-EHS can provide recommendations for safes that comply with these requirements.

9. Export

Federal law prohibits the export of controlled substances unless certain requirements are met, including, in most cases, export and import permits. Violators of the law risk arrest at U.S. Customs or on airplanes, imprisonment, and fines both in the United States and foreign countries. Licensed brokers are available for transport of controlled substances. WVSU-EHS can provide assistance in arranging for any necessary transport of controlled substances.

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[1] Pursuant to the Drug-Free Workplace Act of 1988, West Virginia State University prohibits the unlawful manufacture, distribution, dispensation, possession, or use of any controlled substance at the workplace. In addition, the University prohibits the unlawful possession, use, or distribution of illicit drugs and alcohol by faculty, staff, and students on its property or as part of any of its activities in accordance with the Drug-Free Schools and Communities Act Amendments of 1989. Violation of these University's policies can lead to disciplinary action, up to and including termination.

10. Authorized Staff

PIs or Researchers may authorize members of their laboratory staff to work with controlled substances under their license/registration, provided staff members have been listed on the license and registration applications. In the case of non-therapeutic human subject research, authorized staff must also be appropriately credentialed to administer such materials to patients. Authorized staff members must follow all of the rules and regulations outlined and referenced in this Policy, and are also obliged by law to immediately report any loss or diversion of controlled substances to their PI, WVSU Police Department, and WVSU-EHS. Persons previously convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for "cause", may not be authorized for work with these materials. (In this instance, "cause" is the surrender of a license or registration resulting from a federal or state investigation into an individual's handling of controlled substances.)

Commented [CN16]: What constitutes staff? Do students fall under this designation?

Commented [CN17]: There is no place to do this on the application. I'm not sure this statement is true. The application is for one individual only.

11. Recordkeeping

PIs must maintain complete and accurate inventory records for all controlled substances. These records must be kept separately from all other records and documents, in or near the primary work area, and be readily available for inspection during regular work hours or at any other reasonable time. Records must be written, typewritten, or printed form. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited. Records should be kept in such a manner as to facilitate quick and accurate assessment of quantity on hand and history of use to the individual container level. In the event that any controlled substances are lost, destroyed, or stolen, the kind and quantity of the material and the date of discovery of such loss must be recorded in detail. All records must be maintained by PIs for a period of at least three years from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance. The recordkeeping system must include *at least* the following information maintained as prescribed in state and federal controlled substance laws and regulations:

Commented [CN18]: I believe that DEA requires schedule I & II records be kept separately from other schedules

A. **Receipt of Controlled Substance**: A separate and current record of the receipt of controlled substances, indicating date received, name and address of supplier, and the type, strength or concentration, and amount of the controlled substances received. Each record must be signed by the person receiving the controlled substance. DEA Forms 222 and invoices should be maintained as applicable.

B. **Use of Controlled Substances**: A separate and current record for the storage and use of each controlled substance (use means to administer, dispense, professionally use, or otherwise dispose of), indicating the date, building and room number, specific research experiment, controlled substance's application in the research, and type, strength, lot number, expiration date and quantity of each controlled substance used. The record must also include the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the substances were administered or dispensed. By noting starting volume or mass of substance in the container, 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 signed by the person working with the controlled substance. The inventory should also include a detailed list of any controlled substances lost, destroyed, or stolen, including the type, strength, and quantity of such substances, and the date of the discovery of such loss, destruction, or theft. See Section 13 for more information.

Commented [CN19]: How is this going to be handled since all orders get delivered to the warehouse? I have had multiple issues with packages not being delivered to Hamblin in appropriate time. We cannot have scheduled narcotics sitting at the warehouse all day for anyone to steal. This issue will need to be dealt with – I think the delivery of these items should only go directly to the researcher. No other personnel is licensed to accept these packages.

Commented [CN20]: I'm not sure what you mean here?

C. **Biennial Inventory of Controlled Substances**: A complete and accurate inventory of the stock of controlled substances within each PI's laboratory must be recorded when he/she first engages in research with controlled substances and then biennially thereafter, within four days of May 1 of each *odd numbered year* (2017, 2019, 2021, etc.). The inventory can be taken either as of the opening of business or the close of business on the inventory date and this should also be noted on the inventory. The type, strength, and quantity and lot number of all controlled substances must be recorded at this time in the manner prescribed in DEA regulations. The person conducting the inventory must also date and sign the record. Reminder notices and forms will be distributed by WVSU-EHS several weeks in advance. This biennial inventory must be retained on the laboratory premises for three years, separate from other business records and readily available for potential regulatory review as described above.

12. Disposal

Controlled substances from non-human research work may only be disposed under witness from the State DCD (WVBOF?) or Federal DEA, through a reverse distributor by documented return to the supplier or manufacturer, or as otherwise authorized or directed by regulatory agency personnel.

Commented [CN21]: Need to specify that these are controlled substances that have not been used for research, this does not apply to waste from experiments

Commented [CN22]: I think it's a DEA agent

Expired material, unused or unwanted product, or neat waste must be accumulated and stored under lock and key until ready for disposal. The WVSU-EHS should be contacted to arrange for a disposal visit or permission to otherwise dispose of controlled substances from the DEA. Controlled substances injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures available from WVSU-EHS and the WVSU IRB (?) (Yale Animal Resources Center).

Commented [CN23]: What do you mean by this? If we include waste here, this may be an issue for me....how am I to store gallons and gallons of water waste from experiments under lock and key?? I'm not sure that waste falls under this strict disposal policy.

Unused or unwanted controlled substances derived from human subject research must be returned to the WVSU-EHS (?) (Investigational Drug Service) for disposal, or locally disposed to sewer upon double-witness by authorized research staff.

Commented [CN24]: If drugs are returned to this person, won't they be required to hold a DEA license for all drugs too?

13. Reporting of Loss, Destruction, Theft, or Unauthorized Use

Any losses of any controlled substance, including thefts, unauthorized uses, or unauthorized destruction must be reported to the WVSU Police Department and WVSU-EHS immediately upon discovery. Registrants must also document the incident in writing for submittal to the State DCD (WVBOF?), (within 72 hours) and Federal DEA (within one business day). The written statement must describe the kinds and quantities of controlled substances in question, and the specific circumstances involved. If the circumstances are unknown, immediate notice should still be given to regulators and a complete statement provided thereafter if the loss is substantiated. Regulators should be kept apprised of any ongoing investigation and notified if the loss is not subsequently substantiated. In addition, where a controlled substance is stolen, lost, or destroyed in transit, the consignee (and consignor if within this state) is also required to prepare a loss report that includes documentary evidence that local authorities were notified. The registrant should retain a copy of the statement for at least three years.

14. Resources and References

Registration with the West Virginia Department of Agriculture (Industrial Hemp)

Cancellation of Registration

Authorized Use

Federal Drug-Free Workplace and School Compliance

Purchasing Controlled Substances

Storage and Security of Controlled Substances

Storage

Security

Inspections

Record-keeping Requirements

Controlled Substance Tracking

Inventory Procedures

Reporting Loss, Destruction, Theft or Unauthorized Use

Licensees terminating affiliation with WVSU

https://policies.utexas.edu/policies/controlled-substances-research

Registration Procedures

WVSU faculty or staff wishing to obtain controlled substances must proceed in the following order:

Institutional Application

1. Any staff or faculty wishing to register with the U.S. DEA or WV Board of Pharmacy to use controlled substances in research conducted on behalf of WVSU must first obtain institutional approval to do so. Please see the Office of Sponsored Programs' website or contact the OSP office for a current application form.

   The application form will help facilitate the process for the individual applying to the DEA and WV Board of Pharmacy, including identifying the research being conducted, location of research, storage site, and inspection plan.

   If a WVSU faculty or staff member already has a DEA Controlled Substance and/or a WV Board of Pharmacy license due to affiliation with a previous institution, that staff or faculty member still must request institutional approval before ordering, storing, or using controlled substances at a WVSU-affiliated location.

Commented [CN25]: There's no mention of OSP in the entire document until here? Everything seemed to go through WVSU-EHS.

Commented [CN26]: Licenses cannot be transferred from one institution to another

WV Board of Pharmacy Registration

2. After institutional approval is obtained, the next step in the registration process is to apply to the WV Board of Pharmacy. The WV Board of Pharmacy is the body charged with carrying out the WV Uniform Controlled Substances Act. Registration with the U.S. DEA requires the applicant to be registered with the state first.

   Registration with the WV Board of Pharmacy is required on an annual basis. The individual registering to use controlled substances in research is responsible for renewing and maintaining his or her registration with the WV Board of Pharmacy.

U.S. DEA Registration

3. The final step of registering to use controlled substances in research is to apply to the U.S. DEA using Form 225.

West Virginia State University

Policy: Use of Controlled Substances in Research

Annotated Review

(*April 6, 2018*)

Drs. Gerald Hankins, Carmen Nichols, and Ulises Toledo met on April 6, 2018 at 11:30 am to discuss the latest draft of the **Use of Controlled Substances in Research**. During this meeting the following issues and questions were identified; which needed further discussion, research and review.

Policy Jurisdiction:

- What administrative unit at the University should have jurisdiction or be in charge of the policy?
- Will a new (or existing office) be assigned to administer the policy? The current policy provides an example of a unit created at other university named: Environmental and Safety Office.
- Will the new position being hired as a Safety Compliance Officer be assigned to administer the policy?
- How often this position needs to conduct reviews and audits of records and facilities?
- Will the position assigned and office have the authority to cease and/or close facilities (temporary or permanent) for non-compliance issues?
- Will a special committee be assembled to assist and guide in terms of the policy and its functions?

Permit Applications:

- What are the differences between obtaining an individual lab (individual researcher) versus institutional permits?
- What will be the timeframe which will be required by the WVSU's policy as it relates to renewing permits (e.g. 3 months before expiration)?
- The policy currently establishes that the Office in charge will monitor the application process?
- Will the application fee (small fee) be paid by the Office in charge or each individual applicant?

Requirements for Storage Rooms:

- Can each researcher have and control her or his own storage room, especially for schedule III and above?
- For controlled substances classified as Schedule I and II, can a dedicated room be shared by 2 or more faculty?

- Is access to storage and storage room restricted to the researcher to whom the permit was issued?
- What type of training and documentation will be required for other research personnel (e.g. research assistants, graduate and undergraduate students, etc.) working in experiments using controlled substances?

Schedules:

- Do controlled substances' schedules differ between State and Federal jurisdictions? If so then the policy should state that both schedules must be followed.
- Does the WV Board of Pharmacy establish the Schedules within the state of WV (e.g. WV Code # 60)?
- Does the DEA establish the Schedules at the Federal level?

Records and Recordkeeping

- What is the period (years) records must be kept as it relates to controlled substances?
- It was suggested that the record also include the lot or batch numbers as it relates to the controlled substance (in addition to the ones already indicated in the policy)
- In addition to the researcher, who should have access to the records at WVSU?

Non-compliance and Discipline Issues

- Once a non-compliance issue is identified by the position assigned and office, which entity determines the disciplinary action and what will the process be?
- Will there be different levels of disciplinary actions taken, based on the non-compliance severity and how will these be determined?

Controlled Substances Disposal

- The policy currently indicates that the mechanism of disposal should be monitored by the Safety Officer and the new office. This current proposed mechanism is limited to those substances which are left over after an experiment is finished or is no longer utilized.
- How will waste be managed as it relates to disposal?
- What type of process and records are required for disposal?