
WVU POLICY
USE OF CONTROLLED SUBSTANCES IN RESEARCH AND SCHOLARLY
ACTIVITY

1. PURPOSE & SCOPE:

1.1. **PURPOSE.**

This policy addresses oversight and compliance with federal and state laws and regulations regarding lawful possession and use of U.S. Drug Enforcement Agency (“DEA”) listed Controlled Substances by West Virginia University (“University”) during the course of teaching, research, and service activities (“Research and Scholarly Activity”).

1.2. **SCOPE.**

- 1.2.1. This policy applies to all University Members who engage in the lawful possession and use of Controlled Substances for Research and Scholarly Activity of the University, and any related purposes necessary to support those activities.
- 1.2.2. This policy applies to all University-owned and controlled property and facilities being utilized for lawful possession and use of Controlled Substances, including divisional campuses and satellite locations.
- 1.2.3. This policy excludes the application of the lawful prescribing or administering of Controlled Substances to a human being during lawful practice by authorized clinician personnel.

2. POLICY:

- 2.1. In furtherance of the University’s mission to support University Members in their Research and Scholarly Activity, the University is committed to the lawful and compliant possession and use of Controlled Substances in its facilities and by its employees.
- 2.2. Utilization of University resources and infrastructure to support Research and Scholarly Activity is a privilege afforded to University Members. Controlled Substances are sensitive materials subject to specific federal and state legal and regulatory requirements.

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University Members are required to engage in safe and responsible stewardship of these materials in a manner that meets applicable requirements and mitigates risks of unlawful Diversion of Controlled Substances.

2.3. Pursuant to the Controlled Substances Registration requirements established by federal and state law, any University Member in lawful possession or any location being utilized for the lawful possession or use of Controlled Substances for Research and Scholarly Activity, or any other permissible purpose, must be covered by the appropriate state Board of Pharmacy and corresponding DEA Registrations.

2.3.1. The University does not maintain any institution-wide Controlled Substances Registrations or licenses to support individual teaching, research, or service endeavors. It is the responsibility of the individual University Member to apply for and maintain valid federal and state Controlled Substances Registrations for their University-supported physical location and/or activity.

2.4. As a general matter, the University does not impose any substance or activity-specific limitations for Research and Scholarly Activity requiring the lawful possession and use of Controlled Substances. However, University Members seeking to lawfully possess and use Controlled Substances remain subject to institutional approval requirements applicable to all Research and Scholarly Activity, including but not limited to, eligibility for research with a compliance requirement, sufficient resources and infrastructure necessary to maintain chemical hygiene standards, as well as Controlled Substances regulations, and appropriate department/unit, college, and administration approvals.

2.5. The West Virginia University Environmental Health and Safety Office (“EHS”) will aid and support University Members in maintaining compliance with the applicable Controlled Substances laws, regulations, policies, and procedures via implementation of a Controlled Substances Compliance Program. Responsibilities for the program will be vested in a Controlled Substances Manager or equivalent position.

2.5.1. The support and oversight role of EHS and its Controlled Substances Compliance Program do not supersede or replace a University Member’s responsibilities for compliance pursuant to their individual DEA and state Board of Pharmacy Registrations and this policy.

3. GENERAL RESPONSIBILITIES

3.1. EHS Controlled Substances Manager shall be responsible for the following:

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- 3.1.1. Primary responsibility and oversight for the University's institutional Controlled Substances Compliance Program. The program will be supported by a procedures manual ("EHS Controlled Substances Compliance Program") to assist University Members engaging in lawful possession and use of Controlled Substances.
 - 3.1.2. Maintain up-to-date copies of University Member registrant records (e.g. Registration certificates, renewals, and authorized personnel forms).
 - 3.1.3. Act as an institutional liaison and inspection escort for Registrant University Members during inspections or other contact with DEA and Board of Pharmacy representatives, as needed.
 - 3.1.4. Perform oversight monitoring and support for the lifecycle of Controlled Substances activity by University Members, as appropriate.
 - 3.1.5. Other oversight and support duties, as appropriate and articulated in the Controlled Substances Compliance Program Manual.
- 3.2. University Members shall be responsible for the following:
- 3.2.1. Identify and recognize teaching, research, or service activities necessitating federal and state Controlled Substances Registration.
 - 3.2.2. Notify EHS of all planned activities involving the lawful possession and use of Controlled Substances prior to engaging in the activity.
 - 3.2.3. Obtain all internal department/unit, college, and institutional approvals to pursue lawful possession and use of Controlled Substances for teaching, research, or service activities.
 - 3.2.4. Apply for and maintain all necessary Board of Pharmacy and DEA Registrations for University-supported locations and activities where lawful possession and use of Controlled Substances will occur, including timely submission of any changes for registered activities, possessed substances, and renewals.
 - 3.2.5. Comply with all applicable Controlled Substances Registration, security, recordkeeping/inventory, and disposal requirements.
 - 3.2.6. Procure, use, and store all Controlled Substances in a compliant and permissible manner.

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- 3.2.7. Maintain accurate records and screening to support Authorized Users with access to Controlled Substances.
 - 3.2.8. Timely notify EHS and cooperate fully with any externally or internally initiated inspections, records reviews, or enforcement actions pursuant to Controlled Substances Registration.
 - 3.2.9. Promptly report any known or suspected theft, loss, or other misuse/diversion of Controlled Substances to the DEA, Board of Pharmacy and EHS.
 - 3.2.10. Promptly notify EHS of Registration non-renewal/termination or departure from the University in accordance with applicable EHS procedures.
 - 3.2.11. Other recommended and best practices per the EHS Controlled Substances Compliance Program, as appropriate.
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4. INSTITUTIONAL EXPECTATIONS

4.1. Procurement of Controlled Substances

- 4.1.1. Registrants may only procure Controlled Substances authorized pursuant to their valid, unexpired state Board of Pharmacy and DEA Registrations.
- 4.1.2. Controlled Substances must be ordered or purchased through ordering and payment methods and vendors approved by WVU Procurement, Contracting and Payment Services (“PCPS”) or by a Registrant-to-Registrant transfer permitted by federal and state regulations. All Controlled Substances procurements (including any ordering/payment method exceptions or transfers) must be approved by PCPS and/or EHS Controlled Substance Manager, as appropriate.
- 4.1.3. Controlled Substances must be shipped directly to the Registrant University Member or Authorized User at the address indicated on the DEA Registration.
- 4.1.4. Once received, Controlled Substances must be immediately secured in the University Member’s registered location in accordance with federal and state regulations.

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4.2. Use, Transfer, and Disposal of Controlled Substances.

- 4.2.1. Registrant University Members must utilize Controlled Substances in their possession only in the manner authorized by their registration.
- 4.2.2. Registrant University Members are prohibited from releasing or otherwise transferring Controlled Substances in their possession to other University Members or outside parties who do not possess a valid Controlled Substances Registration. Registrant-to-Registrant transfers between University Members or outside parties must comply and be documented in accordance with applicable federal and state regulations.
- 4.2.3. Registrant University Members must dispose of any Controlled Substances in their possession that are no longer supported by an active approved protocol, or are expired, damaged, contaminated, residual (waste), or otherwise unusable or unneeded.
- 4.2.4. Controlled Substances must be disposed of by a mechanism rendering them unusable, irretrievable, and unrecoverable by an approved DEA and Board of Pharmacy method.
- 4.2.5. 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.
- 4.2.6. Coordination with EHS Controlled Substance manager is required for all Registrant University Member transfer and disposal activity.

5. DEFINITIONS:

- 5.1. **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 University Member 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.

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- 5.2. **Controlled Substances:** 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 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.
- 5.2.1. 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.
 - 5.2.2. 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.
 - 5.2.3. 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.
 - 5.2.4. 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 relative to the substances in Schedule III. Currently have an accepted medical use in treatment in the United States.
 - 5.2.5. Schedule V - Substances that have a low potential for abuse relative to substances listed in Schedule IV, abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Currently have an accepted medical use in treatment in the United States. Consist primarily of preparations containing limited quantities of certain narcotics.
- 5.3. **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.

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- 5.4. **Drug Enforcement Administration (“DEA”):** The agency within the United States Department of Justice that enforces the federal Controlled Substances laws and regulations.
- 5.5. **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.
- 5.6. **Registrant:** Also referred to in this policy as “DEA Registrant,” the University Member who is the designated authorized individual listed on a Controlled Substances Registration for a given location. The Registrant is the individual ultimately responsible for compliance with DEA and Board of Pharmacy requirements for lawful possession and use of the Controlled Substances under the Registration.
- 5.7. **Registration:** A 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.
- 5.8. **Research and Scholarly Activity:** Activities that are considered part of a University Member’s teaching, research (defined as also including scholarship and creative activity), and service. Research includes systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 5.9. **University Member:** All WVU and WVU Research Corporation full- and part-time faculty, 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.
- 5.10. **Board of Pharmacy:** The state-level agency authorized to enforce Controlled Substances regulations. As used in this policy, this term refers to the West Virginia Board of Pharmacy (“WVBOP”) pursuant to the West Virginia Uniform Controlled Substances Act (W. Va. Code, Chapter 60A), unless a University Member is in lawful possession and use of Controlled Substances outside of the State of West Virginia for Research and Scholarly Activity.

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6. AUTHORITY:

- 6.1. U.S. Drug Enforcement Agency (“DEA”) Diversion Control Division
- 6.2. Title 21 Code of Federal Regulations (“CFR”) Chapter II, Part 1300-1399, Drug Enforcement Administration, Department of Justice.
- 6.3. West Virginia Board of Pharmacy (“WVBOP”) Controlled Substances Monitoring Program
- 6.4. West Virginia Uniform Controlled Substances Act (W. V. Code, Chapter 60A).

7. CROSS REFERENCES:

- 7.1. DEA Forms and Applications: deadiversion.usdoj.gov/online_forms_apps.html
- 7.2. West Virginia Board of Pharmacy: <https://www.wvbop.com/practitioners/facilities/instatecontrolledsubstancepermit.asp>
- 7.3. WVU EHS & Controlled Substance Website: <https://www.ehs.wvu.edu/controlled-substance-use-in-research>