

Controlled Substance Management Program

Purpose and Scope

The use of controlled substances in research and teaching requires a federal Drug Enforcement Administration (DEA) registration. DEA registrations are issued to individual registrants, who are responsible for ensuring compliance with all federal DEA regulations.

This program is designed to assist registrants in adhering to controlled substance regulations and to help minimize their liability, as well as that of the university. It outlines the standards and expectations for those involved in research and teaching activities that involve controlled substances, while also establishing clear accountabilities for monitoring and enforcing these standards. The goal is to ensure compliance with all relevant state and federal laws, regulations, and university policies.

This program applies specifically to the use of controlled substances in research and teaching at West Chester University.

Responsibilities

- A. **DEA Registrant:** The DEA Registrant has primary responsibility for the safe and lawful conduct of their research or teaching laboratories, when using controlled substances. Below is the list of responsibilities:
- Comply with federal DEA regulations.
 - Provide a copy of most current controlled substance inventory to Environmental Health and Safety (EHS).
 - Provide a copy of most current DEA Registration to the Director of EHS, the Chairperson of the Department in which the research or teaching laboratory activity is intended to occur, and to the respective Dean of the College prior to a research project being undertaken, as well as notify these offices of any change in the status of their DEA registration, including suspensions, lapses and renewals of current DEA Registration.
 - Keep current with changing regulations and communicate regulatory and policy requirements associated with the program to authorized users and EHS.
 - Immediately notify the Department Chair and EHS of any DEA visit or inspection.
 - Contact EHS, the respective Department Chair, and Dean before registration expires.
 - Notify EHS immediately if found in possession of an Orphaned Controlled Substance.
 - Approve and oversee authorized users working under the registration.
 - Follow all procedures set forth in this program.
 - Notify the Department Chair and EHS before moving out of the laboratory and participate in Laboratory Closeout Inspection conducted by EHS.
 - Report theft, suspected theft, and loss of all controlled substances managed under registration to DEA and EHS.

- Ensure that anyone authorized to access or handle controlled substances is adequately trained in the security, recordkeeping, handling, and disposal of these substances and maintain record of training records.
- Notify the Purchasing Office whenever controlled substances are purchased through the university's SourcePoint catalog.

B. Authorized User:

- Conduct supervised research with controlled substances under a registrant in compliance with federal DEA regulations.
- Report any issues, loss, theft, or suspicious activity involving controlled substances to registrant immediately to the DEA Registrant.

C. Environmental Health and Safety: The Office of Environmental Health and Safety (EHS) is primarily responsible for overseeing compliance with DEA registration requirements for Registrants. This includes conducting annual and ad hoc reviews of Registrants' purchasing, inventory, and disposal records, as well as assessing the adequacy of security measures for controlled substances. Additionally, EHS to performs periodic site inspections of laboratory facilities, provides expert guidance and support to the University's DEA Registrants, coordinates the proper disposal of hazardous controlled substances, and acts as the initial point of contact for the DEA on non-criminal matters involving Registrants

- Develop and maintain the Controlled Substances Management Program.
- Assist researchers with the federal DEA registration application process as needed.
- Provide resources to researchers to facilitate compliance with the Controlled Substances Act requirements.
- Facilitate reverse distribution of controlled substances used for research and orphaned substance resolution.
- Review Institutional Animal Care and Use Committee (IACUC) protocols involving controlled substances.
- Partner with procurement to implement controls to prevent unauthorized purchases of controlled substances.
- Conduct inspections of research areas where controlled substances are used or stored focusing on compliance with recordkeeping, storage, security, and work practices, and providing recommendations for improvement as needed. Research areas to be inspected annually.
- Provide training on usage of controlled substances in research as needed.
- Maintain a record of all DEA research registrations at West Chester University.
- Conduct Lab Closeout Inspections when a Registrant changes locations or leaves the university.

D. Department Chair: The Academic Department Chairperson has primary responsibility for knowing who is using departmental laboratories and drug safes as well as the timely reporting of any concerns observed, suspected or reported, related to the use of controlled substances in research or teaching laboratory activities.

- Ensure EHS is up to date on all current and new registrants.

- Contact registrants if an Orphaned Controlled Substance is found left behind after they have left the university.
 - Ensure that a Laboratory Closeout Inspection has been completed before registrants relocates or leaves the university.
 - Provide timely reports of any concerns observed, suspected or reported, related to the use of controlled substances in research or teaching laboratory activities to the Dean's Office.
- E. **Dean's Office:** The Dean of the College has responsibility to ensure that the faculty member's work with controlled substances is aligned with their Statement of Expectations and that the faculty member is qualified to properly use controlled substances in their teaching or research. The Dean of the College has administrative responsibility for the proper use and security of laboratories and drug safes and is the first level manager responsible for pursuing reported concerns related to drugs used in research or teaching laboratory activities within the College, in cooperation with the Director of Environmental Health and Safety.
- Support and provide all necessary information needed to maintain the university's Controlled Substance Program.
 - Oversee Registrants and approve the use of controlled substances.
 - Notify EHS of any changes to registrant's status.
- F. **Procurement:** The Purchasing Office is responsible for establishing and ensuring that DEA Registrants know and comply with University procurement rules and policies and report any procurement-related violations to the Dean of the College.
- Maintain procedures for controlled substance purchases
 - Receive notice from Registrants whenever controlled substance are purchased through the SourcePoint catalog.
- G. **Department of Public Safety (DPS):** Any investigations of research or teaching laboratory activities where criminal violations relating to the use of controlled substances may have occurred must be investigated by the Department of Public Safety. The Public Safety Director will also be responsible for providing timely, simultaneous notice to the DEA, the Chief Academic Officer, the Chief Human Resources Officer, the Director of Environmental Health and Safety, University Legal Counsel and the President when a criminal investigation is undertaken, and when it concludes. The Public Safety Director is also the point of contact with the DEA in possible criminal matters involving use of controlled substances in research or teaching laboratory work on the campus.
- Conduct investigations into the theft or suspected theft of controlled substances.
 - Assist EHS as a witness to the destruction of orphaned controlled substances where needed.
- H. **Legal Counsel:** Legal Counsel is responsible for providing legal advice to University decision-makers when questions of law arise in association with the use of controlled substances in research and teaching laboratory work on campus.

Procedures

DEA Registrant Application Process

- Principal Investigators and faculty members who wish to use controlled substances in research or teaching must apply and obtain a current federal DEA registration.
 - Applications for research use of Schedule I controlled substances must be accompanied by a research protocol that includes the qualifications of the researcher (curriculum vitae), the purpose of the research, a description of the research to be conducted, and the security provisions for storage and dispensing. ([21 CFR 1301.18](#))
 - The DEA may inspect the lab as part of the application process. Applicants are responsible for ensuring all security measures, storage, paperwork, and protocols are complete and/or installed prior to inspection by the DEA.
- Provide a copy of DEA Registration to EHS and the Department Chair.
- Renew registration in a timely manner to avoid lapses in registration.
 - Contact EHS if controlled substances remain after a registration expires.
- Notify EHS and the Department Chair if the registration status changes.
- Employees who have been convicted of a criminal offense relating to controlled substances, or who have ever been denied DEA Registration after having filed an application, or who have been required to surrender their DEA registration as part of criminal prosecution that ultimately resulted in a conviction, even if the conviction is subsequently expunged based on the successful completion of a court-sanctioned offender program, are prohibited from conducting research at WCU involving controlled substances as a matter policy.
- DEA Registration Support may be obtained by calling the DEA's Office of Diversion Control at 1-800-882-9539, or by e-mail at DEA.Registration.Help@usdoj.gov. New application and renewal forms, as well as change forms, and registration validation service information can also be found on the site.

Storage of Controlled Substances

- Controlled substances must be properly stored to prevent diversion. ([21 CFR 1301.71](#))
 - Schedule I-II controlled substances must be stored in a securely locked, substantially constructed safe or steel cabinet (GSA Class 5 Rated Safe/Cabinet) that is anchored to a wall/floor or in excess of 750lbs, or an alternate containment device approved by the DEA.
 - Schedule III-V controlled substances must be stored in a stationary securely double locked, substantially constructed safe or steel cabinet.
 - Schedule I-V can be stored together provided the security measures meet Schedule I-II requirements.
 - Keys must be secured and access to keys is limited to the registrant and authorized users.

Access to Controlled Substances

- Access to controlled substances is limited to the registrant and authorized users approved by the registrant.

- The DEA requires non-practitioner (unlicensed) employees who will work with controlled substances answer the following questions as part of a screening process: ([21 CFR 1301.90](#))
 - 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 formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date, and sentence.
 - In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.
- Access to controlled substances is denied to any individual with known or confirmed substance abuse, a revoked or denied controlled substance registration, or a conviction of a crime involving controlled substances.
- Controlled substances must be stored separately from other drugs and materials. They must be kept in their original containers, and they may not be combined with different lots with different expiration dates.
- Quantities of controlled substances on hand for use must also be kept to a reasonable minimum necessary for efficient research to be conducted.
- Controlled substances must always be kept under lock and key in an approved drug safe, except when the controlled substances are in use. Keys and authority to access the drug safe is strictly limited to the DEA Registrant.
- Any controlled substances used in research or teaching labs that are not maintained in this manner are subject to seizure by the WCU Public Safety Department and the Department of Environmental Health and Safety, pending reverse distribution or other appropriate means of disposal consistent with WCU Department of Environmental Health and Safety and Department of Public Safety policies and procedures

Procurement of Controlled Substances

- Controlled substances can only be purchased by those authorized under an active registration.
 - The purchase of controlled substances requires the DEA registration information, including registrant name, address of the registered location, and registration number.
 - Ship to address for controlled substances must match the address on the registration and be addressed to the registrant. Vendors will verify the address in the DEA database prior to processing the order.
 - Approval of these types of purchases must be routed through the Department Chairperson to the Dean of the College.
 - Controlled substances must be shipped to the Registrant at the Registrant's University address.
 - The Registrant must sign for all shipments of controlled substances on a proper receiving record. The receiving record must include the date received, name and address of the supplier, type and strength or concentration of the controlled substances received, as well as the amount of each controlled substance received.

- If the Registrant is unavailable, the controlled substances order must be returned to the supplier through reverse distribution
- Registrants may only purchase controlled substances that fall within the schedules listed on their registration.
- One faculty member may not use the individual DEA Registration of another faculty member to purchase controlled substances for research or for teaching laboratory use.
- Purchases of Schedule I and II controlled substances require the DEA Form 222 in addition to other registrant information.

Controlled Substance Records

- All controlled substances records must be retained for at least two years.
- Schedule I and II records are maintained separately from Schedule III-V records.
- Records must be readily available and stored at the registration address.
- Inventories
 - The DEA requires registrants to conduct two types of inventories ([21 CFR 1304.11](#)). See Appendix A for inventory requirements and sample forms.
 - Initial Inventory: Inventory controlled substances immediately upon receipt of a new DEA registration number or a change of registrant address. If beginning with no controlled substances, indicate “zero” for the initial inventory.
 - DEA Biennial Inventory: Inventory controlled substances currently stored at the registered location every two years following the initial inventory.
- Continuing Records
 - The DEA requires registrants to maintain, on a current basis, a complete and accurate record for each controlled substance from receipt to disposal. See Appendix B for continuing records requirements and sample forms.

Disposal of Controlled Substances

- Expired, unwanted, or unusable controlled substances must be transferred to a reverse distributor for destruction under an active DEA registration.
- Clearly label the controlled substances for disposal with “to be disposed” or “expired” and segregate these substances from the remaining controlled substance inventory within the secure storage location.
- Controlled substances injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture must be disposed of using routine waste disposal procedures established by the WCU Department of Environmental Health and Safety.
- Pouring controlled substances down a lab sink drain to dispose of them is strictly forbidden.
- Contact EHS to arrange for reverse distribution of controlled substances.
- Do not dispose of controlled substances used in research or teaching in the Medication Collection Box located in the West Chester University Police Department.

Orphaned Substances

- The registrant must properly dispose of all controlled substances in their possession before the registration expires. Possessing a controlled substance without an active DEA registration

violates DEA regulations. Contact EHS immediately controlled substances remain without an active registration for assistance with disposal.

- The Department Chair is responsible for contacting the registrant if the registrant is no longer associated with the department or university. Controlled substances left by a registrant are still legally the registrant's responsibility.

Theft or Suspected Theft of Controlled Substances

- The registrant is responsible for notifying the West Chester University Police Department, the Department Chair, and EHS upon discovery of theft or suspected theft of controlled substances. WCU PD will investigate the incident.
- The registrant is responsible for notifying the nearest DEA Field Division Office of theft or suspected theft of controlled substances within one (1) business day. DEA Form 106 must be completed and may be transmitted to the DEA online. ([DEA Theft/Loss Reporting](#))
 - The nearest DEA Field Division Office is in [Philadelphia](#).

Loss of Controlled Substances

- The registrant is responsible for notifying the West Chester University Police Department, the Department Chair, and EHS upon discovery of loss (i.e. loss in transit) of controlled substances.
- The registrant is responsible for notifying the nearest DEA Field Division Office of loss of controlled substances within one (1) business day. DEA Form 106 must be completed and may be transmitted to the DEA online. ([DEA Theft/Loss Reporting](#))
 - The nearest DEA Field Division Office is in [Philadelphia](#).
- DEA requires loss to be recorded in the inventory records with an explanation of the event, two witness signatures, and the amount lost.
- Spills of controlled substances do not need to be reported to the DEA. Record the spill in the controlled substance records, with an explanation of the event, two witness signatures, and the amount lost. Recoverable substances must be disposed of via a DEA approved reverse distributor.

DEA Visits

- The Academic Department Chair, the Dean of the College, the Public Safety Director and the Director of Environmental Health and Safety must be notified of any DEA visit or inspection.
 - Whenever possible, contact EHS when the DEA arrives so that EHS may participate in the visit.

Affiliated Organizations

- Third-party organizations utilizing University facilities for proprietary research involving controlled substances must adhere to the principles outlined in this policy. Leases for University property granted to third parties must include covenants that clearly establish these obligations. Any suspected violations of DEA regulations or state or federal laws by employees of third-party organizations must be promptly reported to Public Safety and EHS. Such violations may result in the termination of the tenancy agreement.

Training

- Registrants are required to ensure that anyone authorized to access or handle controlled substances is adequately trained in the security, recordkeeping, handling, and disposal of these substances and maintain record of training records.

Definitions

- *Authorized User (AU)* – a staff member, or student authorized by the registrant to work with controlled substances under supervision of the registrant.
- *Controlled Substance* – a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of CSA, Title 21, Section 802, (6).
- *Drug Enforcement Administration (DEA)* – federal law enforcement agency under the United States Department of Justice.
- *Drug Schedule* – class assigned by regulatory body based on substance’s accepted medical use, abuse potential, and dependency potential.
- *Orphaned Substance* – Controlled substances without an active DEA registration that were purchased under an active DEA registration.
- *Registrant* – Individual that holds a DEA registration to work with controlled substances.
- *Reverse Distributor* – a person or company who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent or, where necessary, processing such substances or arranging for processing such substances for disposal by destruction.

References

- Office of Diversion Control (Page): <http://www.dea.gov/diversion-control/>
- Title 21 CFR, Part 1300-1399 (Regulation): <https://www.ecfr.gov/current/title-21/chapter-II/part-1300?toc=1>
- Title 21 United States Code (USC) Controlled Substances Act (Law): <https://www.dea.gov/drug-information/csa>

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Appendix A: Inventories

The DEA requires registrants to conduct two inventories:

- **Initial Inventory:** Inventory controlled substances immediately upon receipt of a new DEA registration number or a change of registrant address. If beginning with no controlled substances, indicate “zero” in initial inventory.
- **DEA Biennial Inventory:** Inventory controlled substances currently stored at the DEA registered location every two years following the initial inventory.

The inventories are required to record the following information:

- Inventory date and whether the inventory was conducted at the start or end of the business day
- Name of the substance
- Finished form of the substance (i.e. tablet, liquid)
- Concentration (i.e. 10 mg tablet, 10mg/ml)
- Number of units or volume in each commercial container (i.e. 100 tablet/bottle, 10 ml vial)
- Number of commercial containers (i.e. 4 bottles, 6 vials)
- For substances that have been opened:
 - If Schedule I or II, make an exact count or measure of contents
 - If Schedule III, IV, or V, make an estimated count or measure of the contents
 - Exception: Schedule III-V containers that holds more than 1,000 tablets require exact count or measure of the contents

Registrants may develop their own forms or use the following sample forms to record inventories.

Appendix B: Logs

The DEA requires registrants to maintain, on a current basis, a complete and accurate record for each controlled substance from receipt to disposal. The following sample forms may be used to

- *Receipt Record Log*: Receipt records for purchases of controlled substances from DEA registered vendors.
- *Usage Log*: Record the usage of a controlled substance from the time of acquisition to the end of use.
- *Multiple Dose Usage Log*: Documents the administration of multiple doses from one container.
- *Dilution Log*: Documents the usage details for a controlled substance that has been withdrawn from the original container and mixed with a solution to dilute the concentration.
- *Disposal Log*: Record showing when a controlled substance has expired, is no longer usable, or no longer needed and transferred to a reverse distributor for destruction.
- *Authorized Personnel Log*: List of each person allowed to handle controlled substances for research.

DRAFT

Controlled Substance Records Authorized Personnel Log

DEA Registrant Name: _____

DEA Registration Number: _____

Authorized Personnel Name (Print)	WCU ID#	Signature of Authorized Personnel	Signature of DEA Registrant	Initials of Authorized Personnel	Date of Authorization	Date of Departure