

Controlled Substance Management

Purpose and Scope

Work with controlled substances requires a federal Drug Enforcement Administration (DEA) registration. DEA registrations are issued to individual registrants, and the registrant is accountable for complying with federal DEA regulations.

The purpose of this program is to assist registrants comply with controlled substance regulations and reduce liability to the registrant and the university.

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

Responsibilities

Environmental Health and Safety

- Develop and maintain the Controlled Substances Management Program in conjunction with the Department Chair
- 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
- Maintain a record of all DEA research registrations at West Chester
- Conduct Lab Closeout Inspections when a Registrant changes locations or leaves the university

Registrant

- Comply with federal DEA regulations
- 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
- Properly dispose of all controlled substances 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 a laboratory and participate in Laboratory Closeout Inspection conducted by EHS
- Report theft, suspected theft, and loss of all controlled substances managed under registration as described in this program

Department Chair

- 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

Dean's Office

- 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 new registrants changes to registrant's status

Authorized User

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

Procurement

- Maintain procedures for controlled substance purchases

West Chester University Police Department

- 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.

Procedures

DEA Registrant Application Process

- Principal Investigators and faculty members who wish to use controlled substances in research or teaching must apply for a 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.

- Controlled substances become orphaned when the registration expires. Contact EHS as soon as possible if controlled substances remain after a registration expires for assistance with disposal.
- Notify EHS and the Department Chair if the registration status changes.

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.

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.
- Registrants may only purchase controlled substances that fall within the schedules listed on their registration.

- 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.
- 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](#).

Significant Loss of Controlled Substances

- The registrant is responsible for notifying the West Chester University Police Department, the Department Chair, and EHS upon discovery of significant loss (i.e. loss in transit) of controlled substances.
- The registrant is responsible for notifying the nearest DEA Field Division Office of significant 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 significant 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

- Department Chair and EHS 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.

Training

- Training is required for anyone using controlled substances for research at West Chester University.

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.deadiversion.usdoj.gov/>
- Title 21 CFR, Part 1300-1399 (Regulation): <https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>

- Title 21 United States Code (USC) Controlled Substances Act (Law): <https://www.deadiversion.usdoj.gov/21cfr/21usc/>

Reviewed: August, 2022

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.

**Controlled Substance Records
Receipt Log**

DEA Registrant Name: _____ DEA Registration Number: _____

Date Received	Drug Name	Concentration (mg/ml, mg/tablet, etc.)	Total Quantity per Container	Number of Containers	Lot#/Expiration Date	*Container ID#	Vendor	Received By

**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