



## **POLICY ON USE OF CONTROLLED SUBSTANCES IN RESEARCH AND IN TEACHING LABORATORY SETTINGS**

### **I. PURPOSE AND SCOPE:**

Certain research and teaching laboratory activities conducted on the University campuses by University faculty may involve the use of controlled substances. Controlled substances, by their nature, possess a high potential for abuse, and as such, require a similarly high standard of security in their acquisition, administration, storage, transfer and disposal in order to ensure that they are handled safely and are not subject to diversion. The purpose of this policy is to set forth notice of standards of expectations in this regard to those engaged in research and teaching laboratory activities involving controlled substances, and to establish accountabilities for the review and enforcement of these standards, with the goal in mind of maintaining compliance with all state and federal laws and related regulations, as well as related University policies and processes.

### **II. DEFINITIONS:**

- A. Controlled Substance: Any drug, substance, or immediate precursor listed in schedules and quantities which are published by the DEA. These are materials with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and having a tendency to promote abuse or physiological or psychological dependence. Schedules of controlled substances are listed in *Appendix A* of this policy.
- B. DEA: The Drug Enforcement Agency, a branch of the U.S. Justice Department.
- C. DEA Registrant: For the purposes of this policy, a DEA Registrant is an individual who has applied for, in accordance with Drug Enforcement Agency regulations, and received a grant of authorization by the DEA to purchase and possess controlled substances in connection with bona fide research activities. Typically the Registrant is also the Principal Investigator (PI) of a research project.
- D. Disposition Record: An accurate, continuous, current log record used to track the acquisition, use, disposal, and when necessary, the transition of custody of controlled substances.
- E. Reverse Distribution: The preferred process by which DEA Registrants can transition custody of controlled substances when they are no longer needed or are otherwise unusable for research being conducted by a DEA Registrant.

### **III. POLICY:**

The University supports research and teaching laboratory experiences as integral to its academic mission. The use of controlled substances in research and teaching laboratory settings on the University campuses is sometimes required. Effective safeguards must be in place and respected to avoid diversion and other risks associated with the use of controlled substances. In addition to adhering to the requirements of this policy, DEA Registrants are expected to conduct their research and teaching laboratory activities involving the use of controlled substances within the parameters of all applicable state and federal laws and their implementing regulations. Registrants failing to adhere to these requirements will be subject to disciplinary consequences. The University will also report any suspected violations of law to the appropriate law enforcement jurisdiction in a timely manner, and will fully cooperate with criminal investigations and prosecutions. If the University has reason to believe that a DEA Registrant has violated DEA regulations and has not self-reported the violations, the University will report those concerns to the DEA's closest field office within a timely manner. Employees other than the Registrant who share the accountabilities listed below are equally expected to fulfill those obligations consistently and competently. Internal investigations, when necessary, should not be delayed pending notice to the DEA or pending possible DEA action.

#### IV. ACCOUNTABILITIES:

- A. Primary Accountabilities: While numerous positions share responsibilities in meeting the requirements of this policy, the DEA Registrant has primary responsibility for the safe and lawful conduct of their research or teaching laboratories at all times, when using controlled substances. The Office of Environmental Health and Safety ~~and~~ has primary responsibility for monitoring the DEA Registration requirements for Registrants, as well as performing annual and ad hoc reviews of the Registrants' purchasing, inventory and disposition records, as well as for the sufficiency of security controls for controlled substances. The position also provides subject-matter guidance and support to the University's DEA Registrants, and serves as initial point of contact for the DEA in non-criminal matters involving DEA Registrants.
- B. Academic Department Chairpersons in Departments Housing Labs and/or Drug Safes Where Controlled Substances are in Use: 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. Such reports are to be made by the Academic Department Chairperson to their Dean.
- C. Dean of the College: 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.

- D. The Director of Environmental Health and Safety: The Director of Environmental Health and Safety has general responsibility for performing periodic site reviews of laboratory facilities to ensure compliance with state and federal regulations associated with environmentally safe and healthy work and learning environments; and coordinating the disposal of hazardous controlled substances, when requested. The Director may also assist the Chemical Hygiene and Compliance Officer with training and records reviews associated with controlled substances.
- E. The Director of Public Safety: 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 Public Safety Department. 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.
- F. The Chief Procurement Officer: The Chief Procurement Officer is responsible for establishing and ensuring that DEA Registrants know and comply with University procurement rules and policies, and to report any procurement-related violations to the Dean of the College.
- G. 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.

**V. DEA REGISTRATION:**

Principal Investigators are required to have current DEA Registration. DEA Registration is certified on a DEA Form 223. DEA Registrants must provide a copy of their current DEA Registration to the Director of Environmental Health and Safety, 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. The DEA Registrant also has an immediate, mandatory obligation to inform these offices of any change in the status of their DEA registration, including suspensions, lapses and renewals of current DEA Registration. DEA Registrants are responsible for renewing their Registrant status so as to avoid lapses in 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. 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 between the hours of 8:30 AM and 6:00 PM, EST; or by e-mail at [DEA.Registration.Help@usdoj.gov](mailto: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. The DEA's Philadelphia field office also has a Division Program Specialist at (215) 238-5160.

**VI. PURCHASE OF CONTROLLED SUBSTANCES:**

DEA Registrants must provide a copy of their current DEA Registration to the WCU Purchasing Department when requesting the purchase of controlled substances associated with their research or teaching laboratory activities. Orders for Schedule I and Schedule II controlled substances must be ordered using DEA Form 222. All applicable WCU Purchasing regulations must also be followed. Approval for 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.

**VII. RECORD KEEPING FOR CONTROLLED SUBSTANCES:**

Record keeping is a critical responsibility of all DEA Registrants conducting research or engaged in teaching laboratory use of controlled substances. DEA Registrants 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 must be readily available for inspection during regular work hours or at any other reasonable time. The use of codes, symbols or foreign languages in identifying controlled substances or any person in the records is prohibited. An inventory audit of all controlled substances used by the Registrant in his or her research or teaching laboratory activities must be conducted annually by the Director of Environmental Health and provided to the following offices: the Dean of the College, and the Chairperson of the Department.

Disposition records (logs) must be kept in such a manner as to facilitate quick and accurate assessment of the quantity on hand and history of use to the individual container level for all controlled substances. Standard log forms approved by the Director of Environmental Health and must be used at all times. In the event that any controlled substances are lost, stolen or otherwise missing, the kind and quantity of the controlled substance and date of discovery of the loss must be recorded in detail and immediately reported to the Chemical Hygiene Officer and the Director of Public Safety. All inventory and disposition records must be maintained on site by the DEA Registrant for a period of at least three (3) years from the date of the last recorded purchase, transfer, use or transition of custody involving the controlled substance. They must also be available for immediate inspection upon request. A sample log/disposition record is shown in *Appendix B* of this policy.

**VIII. STORAGE OF AND SECURITY CONTROLS FOR CONTROLLED SUBSTANCES:**

DEA Registrants using controlled substances in their research or teaching labs must use approved research protocols, including effective security controls and procedures to safeguard against theft or diversion of the controlled substances. These protocols must be approved by the IRB or a sub-committee of the IRB before research or lab activities involving controlled substances may begin. 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. Disposal of expired stock must follow the disposal requirements outlined in this policy.

Controlled substances must always be kept under lock and key in an approved drug safe at all times, except when the controlled substances are in use. Keys and authority to access the drug safe is strictly limited to the DEA Registrant. Drug safes should bear the approval of the DEA if they were purchased prior to January 1, 1975. Otherwise, the safe must be a Safe Manufacturer's National Association certified classes A, B or C safe; or an Underwriters Laboratories certified safe for drug storage. Door locks for the room where the drug safe is located may not be keyed to the University's master key system. Security breaches must be immediately reported to the WCU Public Safety Department.

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.

An annual inventory of all drugs stored in teaching and research laboratories must be conducted by the Chemical Hygiene and Compliance Officer to identify any substances in current inventory that may have been purchased when the substance was not considered controlled", but whose status has been changed to "controlled" due to changes in DEA regulations since their purchase.

IX. **DEA VISITS:**

DEA Registrants are required to provide timely notice to the following offices when they are involved in a DEA inspection or interview associated with their research or teaching laboratory activities relating to use of controlled substances: The Academic Department Chair, the Dean of the College, the Public Safety Director and the Director of Environmental Health and Safety must be notified.

X. **LOSS OR THEFT OF CONTROLLED SUBSTANCES:**

All DEA Registrants have an immediate, mandatory obligation to inform the Director of Environmental Health and Safety, the Director of Public Safety, the Academic Department Chairperson and the Chief Human Resources Officer of any loss or theft of a controlled substance. The DEA's Office of Diversion Control also requires that DEA Registrants notify the nearest DEA Field Division Office within one (1) business day of the discovery of any loss

or theft of any controlled substances. The Registrant must also complete a DEA Form 106, entitled "Report of Theft or Loss of Controlled Substances" and submit it to the same field office. This form can be completed and transmitted on-line using the DEA's Office of Diversion Control website. See *Appendix C* for a sample copy of Form 106.

XI. **DISPOSAL:**

Controlled substances which have expired or are unwanted or unneeded may only be disposed of using a documented return to a reverse distribution supplier or manufacturer. 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 in order to dispose of them is strictly forbidden.

XII. **AFFILIATED ORGANIZATIONS:**

Third party organizations establishing tenancies for use of University facilities to conduct proprietary research must also comport with the spirit of this policy, if controlled substances are in use. University property leases to third parties must include covenants establishing these obligations. Possible violations of DEA regulations, or state or federal law by employees of third party organizations in these instances must be promptly reported by the affiliated organization to the University's Chief Procurement Officer and could result in loss of tenancy.

XIII. **LEGAL AUTHORITIES:**

The Controlled Substances Act of 1972; The Chemical Diversion and Trafficking Act of 1988 (CDTA); The Domestic Diversion and Control Act of 1993 (DCDCA); the Commonwealth of Pennsylvania's Controlled Substances, Drugs, Devices and Cosmetics Act of 1971 (P.L. 233, No. 64).

XIV. **INTERPRETATION:**

The Director of Environmental Health and Safety is responsible for interpretation of this policy.

IX. **APPENDICIES:**

- A. DEA Drug Schedules
- B. DEA Loss or Theft Reporting Form 106
- C. Sample Disposition Log Record
- D. Dean/Department Chairperson Annual Check-Off Form (A convenience form identifying users of controlled substances in the College or Department, what schedule they controlled substances relate to, and the status of the users' DEA Registration.)
- E. Responsibilities Matrix – Quick Reference Sheet