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# Controlled Substance Policy for Research

The University of North Carolina at Greensboro

Approved 7/1/2013

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## I. Purpose

University researchers may, in the course of lawful research, teaching or testing, find it necessary to use Federally Controlled Substances. Various Federal and state statutes and regulations address this need. Due to their potential for abuse, Controlled Substances are subject to extensive licensing, storage, use, disposal, and inventorying requirements. The regulations governing Controlled Substances include the U.S. Department of Justice (DOJ), the U.S. Drug Enforcement Agency (DEA), 21 CFR Section 1300, and the North Carolina Department of Health and Human Services (NCDHHS).

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 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. Researchers acquiring these materials will be required to register with NC DHHS and obtain a DEA license. EHS will aid each Principle Investigator (PI) in obtaining his/her licenses for the purchase of controlled drugs if necessary.

In general, the regulations are designed to ensure a system of security and accountability in the procurement, use, storage, and disposal of Controlled Substances. The regulations require license holders to document the receipt of Controlled Substances once they are ordered and to continue to document use until the time of consumption or proper disposal. They also require the license holder to track the Authorized Individuals who access the substances and the places in which the Controlled Substances are stored.

**Violations of the Controlled Substance laws, even when unintentional, may lead to substantial civil and criminal liability.**

## **II. Scope**

Controlled Substances may only be used for duly authorized, legitimate medical or scientific research purposes to the extent permitted by the registrant's license and registration and in conformity with state and Federal statutes and regulations.

## **III. Policy**

### **A. Definitions**

#### Principle Investigator (PI)

The lead scientist or engineer for a particular project, such as a laboratory study or clinical trial. It is often used as a synonym for "head of the laboratory," not just for a particular study.

#### Authorized Individuals (AI)

Lab personnel who handle or manage Controlled Substances in approved research. Authorized Individuals must be trained in Controlled Substance shipping, receiving, security, inventorying, and recordkeeping procedures as outlined in this policy.

#### Reverse Distributors

Companies licensed and permitted to recycle and/or destroy Controlled Substances.

### **B. Responsibilities**

In order to ensure compliance with UNCG's obligations under the Controlled Substance regulations and licenses, it is important that authorized faculty and research staff, laboratory administrators, and affected departments understand their responsibility in connection with obtaining, preparing, handling, and using Controlled Substances.

Principle investigators (PIs) shall have the responsibility for managing the use of Controlled Substances in their labs. In the event that the PIs are on leave or are otherwise absent, they may designate another appropriate Authorized Individual to carry out the duties under the Controlled Substance program on their behalf.

PIs shall be responsible for:

- ensuring that Controlled Substances are licensed and registered for use in their lab
- ensuring that the Controlled Substances are maintained in a manner that is indicated on the license
- restricting access to Controlled Substances to only users they authorize

- maintaining usage logs, purchase orders, and inventories for Controlled Substances
- ensuring that security and access procedures are in place for any labs or facilities where Controlled Substances are located
- ensuring their licenses for Controlled Substances are regularly updated
- purchasing Controlled Substances
- maintaining records and reports relating to the Controlled Substance policy
- providing training to research staff concerning obligations for handling Controlled Substances under the license
- proper disposal of leftover Controlled Substances
- implementation of necessary corrective actions

Controlled Substance schedules periodically change to add new drugs or substances. It is the responsibility of the PI to know whether any substances currently in their possession are scheduled as a Controlled Substance, and if so to ensure compliance with this policy. Additionally, the PI must obtain a license to continue to use the substance and follow the guidelines set forth in this policy. UNCG Environmental Health and Safety (EHS) will work with departments and PIs to keep them up to date on schedule changes. EHS will maintain a link to the DEA schedules for Controlled Substances on the EHS website.

PIs should complete a Controlled Substance notification and submit it to their department head and EHS. The PI should also notify their department head and EHS if they remove or add any Controlled Substances. The Controlled Substance Notification Form may be used to submit this information as well.

At no time should a licensed PI allow other researchers to purchase Controlled Substances using their license. This practice is called “piggybacking” and is a violation of this policy and may lead to substantial civil and criminal liability. Any PI requiring the use of Controlled Substances in their research must obtain their own license and operate within the guidelines of this policy.

Persons previously convicted of a felony offense related to Controlled Substances or who had an application for registration with a state or federal agency denied or who surrendered a registration for cause may not be authorized to work with these materials.

### **C. Security**

Controlled Substances shall be stored in “securely locked, substantially constructed drug cabinets or safes” in locations where access is limited. Any PI who has concerns with security locations, please contact the NCDHHS to ensure the cabinets or safes used to store Controlled Substances conform to the Federal and state requirements. Generally, standard file cabinets are not sufficient for the storage of Controlled Substances.

All Controlled Substances must be kept locked in their storage location except when it is necessary for authorized individuals to remove, legitimately work with and replace the Controlled Substances. Controlled Substances must not be left unattended, and when they are not being used for research, they must be securely stored in the drug cabinet or safe.

Controlled access to the drug cabinet or safe is critical to establishing security for Controlled Substances. For this reason, keys and/or combinations to the cabinet or safe should be secure and under the direct control of the PI and their AIs.

#### **D. Reporting of Loss, Destruction, Theft, or Unauthorized Use**

Thefts, suspect thefts, unauthorized use, or other losses of any Controlled Substance must be reported immediately to the department administrator, EHS, and to the UNCG Police Department upon discovery. The PI or his or her staff may also have an obligation to report promptly the loss to the state or Federal authorities. DEA Form 106, available on DEA's website, is required to be used by the DEA when a formal report is made, after an initial investigation.

Link to Form 106 and instructions:

<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>

In addition, any unauthorized persons who gain access to Controlled Substances for the purpose of diversion or theft must be reported to the UNCG Police Department and may be subject to the disciplinary policies of the University and the DEA.

#### **E. Recordkeeping and Inventorying**

PIs are required to keep track of each Controlled Substance using the UNCG Controlled Substance Log or equivalent. Usage log sheets shall be numbered, bound, and if the size of the cabinet permits, maintained at all times in the locked safe or cabinet along with the Controlled Substances. Usage log sheets must be maintained for a minimum of three years after complete use and disposal of Controlled Substances and be readily available for inspection by the DEA, NCDHHS, or UNCG EHS.

All authorized users that work with Controlled Substances are to conduct self-inspections on a quarterly basis to ensure that the laboratory's Controlled Substance Usage Logs match the physical inventory. The results of those self-inspections shall be recorded.

EHS will conduct annual compliance inspections for users of Controlled Substances. The inspection will consist of reviewing recordkeeping, storage, and use.

#### **F. Controlled Substances in Field Research**

Researchers who apply for a license and plan on taking Controlled Substances off campus for research purposes should address this type of activity in their protocol to be approved by the NCDHHS. If approved, the licensed user shall follow the guidelines set forth in their license. This is an uncommon situation and usually includes activities done by licensed veterinarians and animal control personnel.

#### **G. Controlled Substances of Unknown Origin**

Possibly, laboratories or animal facilities may encounter Controlled Substances of an uncertain origin, sometimes referred to as “orphaned drugs.” For example, a licensed PI may leave the University and a researcher may encounter the Controlled Substances that a former licensed PI left behind. In these circumstances, the laboratory or other facility personnel should take the following steps:

1. make sure the Controlled Substance is secured
2. contact EHS for disposal assistance and coordination; and
3. provide EHS in writing a brief description of how the laboratory came into possession of the Controlled Substances, the location where it was found, and the type of substance and quantity.

EHS will attempt to locate the owner and coordinate the removal and destruction of the Controlled Substance with NCDHHS. EHS is not a licensed authority and may not accept or possess Controlled Substances.

#### **H. Disposal and Destruction of Controlled Substances**

Controlled Substances consumed in a reaction or converted into a hazardous waste mixture from which a Controlled Substance is not recoverable may be disposed of through routine waste disposal with EHS.

If a Controlled Substance has expired, is no longer needed, or if the PI is discontinuing research due to retirement or new employment, then the PI should contact EHS in a timely manner for disposal procedures. A PI should never abandon Controlled Substances after their employment with UNCG is complete. Abandoning Controlled Substances may affect the PI’s future ability to attain a license to work with Controlled Substances and may also carry a civil penalty. EHS will coordinate the destruction process with the PI and NCDHHS.

### **IV. Enforcement**

The U.S. Department of Justice, Drug Enforcement Administration (DEA) administers the federal law, and the North Carolina Department of Health and Human Services, Drug Control Unit (NCDU) administers the state law.

UNCG EHS through annual compliance reviews will verify compliance with the applicable regulations and report to the Vice Chancellor for Research and Economic Development and Federal and State Representatives if any items of noncompliance are identified in the annual compliance review.

## **V. Review**

UNCG Environmental Health and Safety and the Office of Research and Economic Development will periodically review this policy as necessary.

## **VI. Related Links and Additional Information**

- DEA Greensboro Field Office (336) 547-4210
- DEA Division, Atlanta, Georgia (404) 893-7000
- NCDHHS, Raleigh, North Carolina (919) 733-1765
  
- List of Controlled Substances (Alphabetical Order)  
<http://www.deaiversion.usdoj.gov/schedules/>
- NCDHHS Controlled Substance Reporting  
<http://www.ncdhhs.gov/mhddsas/controlledsubstance/index.htm>
- NC General Statutes - Controlled Substances Act – Article 5  
<http://www.ncleg.net/gascripts/statutes/StatutesTOC.pl?Chapter=0090>
  
- U.S. DEA  
<http://www.justice.gov/dea/index.htm>
- U.S. DEA Division of Diversion Control  
<http://www.deaiversion.usdoj.gov/index.html>