

# Policy- Controlled Substance Use in Animal and Laboratory Research

Version 1.0

**Office of the Vice Chancellor for Research (OVCR)  
Office of Animal Care and Institutional Biosafety (OACIB)**

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## I. Introduction

There are numerous regulations at both the state and federal level, which govern controlled substance access and use. The purpose of this policy is to ensure that all University of Illinois at Chicago (UIC) employees and other individuals covered by this policy are in compliance with all state and federal regulations pertaining to the legal purchase and use of controlled substances.

## II. Applicability

This policy and all provisions set forth in this policy are applicable to all UIC faculty, staff and students and any other individuals using UIC facilities that use controlled substances at UIC in animal or laboratory research, testing or teaching regardless of the source of funding.

The policy is not applicable to the following activities: 1) controlled substances dispensed by a practitioner to a patient in the course of professional practice or clinical research as authorized by his/her license and if applicable the Institutional Review Board and 2) teaching activities performed within the clinical environment related to patient care. However, all such activities must comply with all local, state, and federal regulations governing controlled substances.

## III. Regulatory Authority

21 CFR Part 1300-1308 Controlled Substance Act  
720 ILCS 570/ Illinois Controlled Substances Act

## IV. Institutional Responsibility

The Chancellor at the University of Illinois at Chicago has charged the Vice Chancellor for Research with the authority to implement a program governing the use of controlled substances in animal and laboratory research. The following individuals and campus units have responsibility to ensure compliance with this policy: 1) Individual Registrant, 2) Institutional Registrant, 3) the Office of Animal Care and Institutional Biosafety (OACIB), 4) the Biologic Resources Laboratory (BRL), and 5) Ambulatory Care Pharmacy Services

## V. Definitions

- A. Authorized User** – is an employee of the registrant. They must be authorized by the registrant to use controlled substances under the registrant's license if the employee is acting in the usual course of his/her employment. It is the responsibility of the registrant to ensure that all authorized users have been appropriately screened and met all state and federal regulations regarding access to controlled substances.
- B. Controlled Substances-** a drug, substance, or immediate precursor listed on DEA schedule I-V. They are drugs or other chemicals that have the potential to be addictive or habit forming and are classified according to their medical use, potential for abuse, and safety or dependence liability. For a complete list of current DEA schedules see <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>.
- C. Controlled Substances Records-** a complete log of purchasing, disposition, and disposal

records of all controlled substances procured and used under the registrant's DEA number.

- D. DEA- Drug Enforcement Agency.** Agency within the Federal Department of Justice responsible for enforcing federal regulations on controlled substances.
- E. Practitioner/Registrant-** means a physician, dentist, veterinarian, podiatrist or therapeutically certified optometrist licensed in the State of Illinois to practice his/her profession, a licensed physician assistant who issues a prescription for a Schedule III, IV, or V controlled substance, a licensed advanced practice nurse with prescriptive authority, or a hospital or other party (other than an individual) licensed, registered or otherwise permitted by the State of Illinois to dispense a controlled substance in the course of professional practice but does not include a pharmacy. Entities such as hospitals are institutional practitioners.
- F. Other Controlled Substance Profession Registrant-** is a non-practitioner who is engaged in research (with animal or in the laboratory) requiring the use of controlled substances and/or conducting chemical analysis of controlled substances.
- G. Registrant-** a person or party registered or licensed under or holding a certificate of registration or license with the State of Illinois Department of Professional Regulations and the DEA.

## VI. General Policy

### A. Required License Holders

All UIC facility or staff or any other individuals using University resources or facilities that require the use of controlled substances in their research, teaching, and testing activities that involve animals or laboratory work must be registered with the State of Illinois and the DEA. The license can be held at the level of the individual investigator or the unit level (e.g. department). **NOTE:** If use of controlled substances in animals is restricted to controlled substances that are dispensed directly to the animals by a member of the BRL staff (veterinarian, veterinary technician, or animal care), then registration is not required. For example, controlled substances that may fall into this category include anesthetic and analgesic agents that are administered by BRL staff for surgery conducted within the BRL surgical area. In general, use of controlled substances for anesthetics/analgesic purposes in small animals such as rats and mice in which the investigator administers the agent to the animal will require that the investigator hold their own state and federal licenses. BRL will not dispense controlled substances to investigators.

### B. Registration and License

#### 1. State of Illinois Registration

Registration with the State of Illinois Department of Financial and Professional Regulation (IDFPR) is a prerequisite for obtaining a DEA License. Depending on the nature of the work to be conducted, more than one registration may be required. For example, use of controlled substances for research, laboratory chemical analysis, or instructional activity are considered different activities and require separate registration, although all use the IDPR 097 registration document. Instructions and applications are available on line at <http://www.idfpr.com/dpr/WHO/cntsub.asp>. Maintenance of current license is the responsibility of the registrant. Depending on the type of license held, licenses are approved for varying periods of time. Note: Before a registration is granted, the IDFPR will conduct an inspection of the facility to ensure that safety and security measures are in place.

#### 2. Drug Enforcement Agency (DEA) License

Once IL State License is obtained, apply for DEA License. Instructions and applications are available on line at [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm). As with the state license, different

types of activities or different schedules of drugs may require different registrations. Maintenance of current license is the responsibility of the registrant.

Complete Form 224- (Practitioners, Pharmacies, Hospitals/Clinics, Teaching Institutions)

Complete Form 225- (Manufacturers, Import/Export, Distributors, Researchers, Dog Handlers, Labs)

### **C. UIC Controlled Substances User Form and Screening of Authorized Users-**

#### **1. Controlled Substance User Form**

Each UIC Individual or Institutional Registrant who will use controlled substances in animal or laboratory research must complete a UIC Controlled Substance User Form. On the form the registrant must list name, I-card number, contact information, DEA number, controlled substances required for animal or laboratory research. In addition, the names of authorized users who may receive controlled substances from the Ambulatory Care Pharmacy on the registrant's behalf, their I-card number, and phone number, as well as, other authorized users must be listed. This form must be signed and dated by the registrant. A copy of the form must be maintained in the registrant's controlled substances records and the form must be updated as additional authorized users are added. An updated form must be supplied to the Ambulatory Care Pharmacy Services at the time of the annual audit or if additional authorized users who may receive controlled substances on the registrant's behalf are added. [See Appendix A.](#)

#### **2. Screening of Authorized Users**

The DEA requires that all persons with access to controlled substances as a result of his or her status as an employee or agent of a DEA registrant complete a screening process to assess the likelihood of the person committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. The code of federal regulations governing the DEA regulations states that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry of personnel who will have access to controlled substances. Each UIC authorized user for a registrant must complete the UIC Authorized User Screening Form. [See Appendix B.](#) The registrant must maintain a copy of signed documents in a secure, confidential location that is not accessible to other employees or agents of the registrant.

The authorized user form informs the person that any false information or omission of information may jeopardize his or her position with respect to the University, that the information provided on the form in response to the questions will not necessarily preclude employment or educational status, but will be considered as part of an overall evaluation of the person's qualifications, and that responses to the form will be held in strictest confidence.

### **D. Purchasing**

#### **1. UIC Individual or Institutional Registrants- Schedule II-IV**

UIC Individual or Institutional Registrants must purchase all schedule II-IV controlled substances for use in research, testing, or teaching in animals or in the laboratory through the UIC Ambulatory Care Pharmacy Services. To obtain controlled substances, a requisition and voucher form from Pharmacy Services must be completed. In addition, DEA Form 222 must be completed in triplicate to purchase Schedule II drugs and must be signed and dated by DEA license holder or authorized user with power of attorney. This form should be requested when applying for a DEA registration for use of drugs under schedule II. Current State and DEA licenses and UIC Controlled User Form must be on file with the pharmacy to place an order. [See Appendix C and D](#) for examples of appropriately completed requisition and voucher and DEA Form 222 and additional instructions regarding these forms.

Exceptions to this purchasing requirement must be granted by the Animal Care Committee (ACC) for controlled

substances that will be used in animals or the Ambulatory Care Pharmacy Services for controlled substances that are used only in the laboratory.

Failure to comply with these purchasing requirements will result in termination of privileges to use controlled substances in animal or laboratory research, testing, or teaching at UIC.

## **2. UIC Individual or Institutional Registrants- Schedule I**

For UIC Individual or Institutional Registrants that require schedule I controlled substances in their research, these substances must be purchased through a licensed schedule I pharmacy using DEA Form 222. For those substances that are not commercially available, requests must be made to the National Institute of Drug Abuse (<http://www.nida.nih.gov>).

Failure to comply with these purchasing requirements will result in termination of privileges to use controlled substances in animal or laboratory research, testing, or teaching at UIC.

## **3. Non UIC Individuals**

Non-UIC individuals using UIC facilities to conduct animal and laboratory research involving the use of controlled substances are exempt from the requirement to purchase controlled substances through the UIC Ambulatory Care Pharmacy Services; however, all are expected to follow all applicable state and federal regulations regarding the procurement of these agents.

Failure to comply with these purchasing requirements will result in termination of privileges to use controlled substances in animal or laboratory research, testing, or teaching at UIC.

### **E. Receiving**

When receiving controlled substances from the Pharmacy, the registrant or authorized user must provide proof of identification (I-card), verify the contents and rectify any discrepancies immediately with the Pharmacy. The purchasing receipt must be signed and dated by person receiving controlled substance and a copy must be maintained with registrant's controlled substances records.

For those individual or departmental registrants that are granted an exemption to purchase controlled substances from sources other than the Ambulatory Care Pharmacy, the registrant must provide a copy of the receipt to the Ambulatory Care Pharmacy such that the controlled substances ordered, concentration/strength, and amount for each purchase is clear.

If Schedule I or II drugs are received copy 3 of the DEA Form 222 must be maintained with controlled substances records and the registrant must record on this copy the number of containers received and the dates received for each item listed on the form.

Pharmacy will maintain a database of all purchases for each registrant that is a UIC employee or staff member.

### **F. Storage**

Controlled Substances must be stored in compliance with 21 CFR Part 1300-1308 and IL 720 ILCS 570. All controlled substances must be stored in a securely locked, sturdy cabinet or safe. Only controlled substances may be stored in the cabinet. Keys to the lock must be stored in a secure location and access to keys must be limited to registrant and authorized users. In most instances, the location of storage will be within the registrant's own laboratory or department. Storage within BRL or other UIC animal facilities is prohibited unless prior approval has been granted by the Director of the BRL. The location of storage must agree with the location identified during registration with the State of Illinois and the DEA.

Unused DEA 222 Forms must also be maintained in a separate secure location. Access to these forms should

be limited to the registrant or the registrant's power of attorney.

## **G. Record Keeping**

### **1. General**

Registrant must maintain good records of purchases, disposition, and inventory. It is strongly advised that each registrant have a single designated location in which all purchasing records, disposition records, Copy 3 of Form 222s, and inventory records are kept. Access to these records should be limited to registrant and authorized users.

### **2. Purchasing Records**

Each registrant must maintain a copy of the purchasing receipt for a minimum of two years. These records must be maintained with controlled substance records. The Pharmacy or the registrant must record the lot numbers, date of expiration for all controlled substances received with the order, and the Narcotic Record Certificate of Disposition serial numbers on the disposition form(s) provided with the order by pharmacy. If more than one certificate of disposition will be required to account for use, be sure that additional forms are requested at the time of receipt from Pharmacy. Each form allows for 25 separate entries. For those approved purchases that are not made through UIC Pharmacy, a unique numbering system for disposition records should be developed such that disposition can be reconciled with purchases.

### **3. Disposition Records**

A written record of the dispensing and use of all controlled substances must be maintained by the registrant. Records must include the following information: drug dispensed, amount, reason, and who dispensed it. These records should be maintained with the controlled substance. Dispensing records must be completed at the time that controlled substance is dispensed. When dispensing liquids be sure to account for dead space in syringe and needle. For all controlled substances in schedule II-V purchased through the Ambulatory Care Pharmacy, a Narcotic Record Certificate of Disposition Form will be provided by the pharmacy regardless of whether the agent is listed as a narcotic in the DEA Schedules. This form must be used for disposition. [See Appendix E](#). For controlled substances that are not purchased via the UIC Ambulatory Care Pharmacy, an appropriate disposition record, such as the UIC Disposition Form must be maintained. [Appendix F](#) is an example of an appropriately completed disposition record. When Narcotic Record Certificate of Disposition Form is completed (e.g., balance equals zero), the form must be signed and dated by the registrant and submitted to the Ambulatory Care Pharmacy. A copy must be maintained in the registrant's controlled substance records for a period of two years. If more than one form is required to zero out an order, the serial numbers of the forms should be cross referenced on each form and the number of forms (e.g. 1 of 3 COD forms) should be indicated on each form. For non-UIC purchases, disposition forms must be signed and dated by the registrant and maintained in the registrant's controlled substance records. A copy of this completed form must also be provided to UIC Ambulatory Care Pharmacy.

### **4. Inventory Records**

#### **a. Registrant**

Inventory of all controlled substances used in animal or laboratory research must be conducted on at least a semiannual basis by each registrant. The registrant or an authorized user must reconcile purchasing records, disposition records, and disposal records with the amount of controlled substances that are on hand at the time of the inventory. A record that inventory was conducted, date it was conducted, who conducted the inventory audit, and the signature of the authorized user conducting the audit must be maintained with Registrant's controlled substance records for a period of two years. Minor discrepancies in inventory must be documented, but do not require reporting to the DEA.

**b. OACIB**

As part of the semi-annual inspection process, the Animal Care Committee (ACC) will review the use of controlled substances in animals. The ACC will determine that controlled substances are being stored appropriately, that expired drugs are not being used, that appropriate records are being maintained, and that appropriate disposal procedures are being used.

**c. Pharmacy**

An annual inventory request form will be sent to each registrant who has purchased controlled substances for use in animal or laboratory research through the UIC Ambulatory Care Pharmacy or submitted a notice of purchase for those registrants granted an exception. The request form will indicate the current pharmacy inventory record of controlled substances that the registrant has on hand. The registrant must verify that the inventory is correct, update the pharmacy on current inventory, sign and date the form, and return to the pharmacy. In addition, an updated UIC Controlled Substance User Form, and updated copies of State and DEA licenses must be submitted with inventory report. If the State and DEA Licenses are expired in between annual inventory periods, the up-to-date-versions must be submitted to the UIC Ambulatory Care Pharmacy at those times.

Failure to comply with this request will result in termination of privileges to use controlled substances in animal or laboratory research, testing, or teaching at UIC.

**H. Diversion, Loss or Theft of Controlled Substances**

The registrant has complete accountability for all controlled substances procured under the registrant DEA number. Good recordkeeping is essential to detection of diversion, loss or theft of controlled substances. Theft or misuse of controlled substances is a felony criminal act.

**1. Diversion**

The position of DEA is that any employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. This is the University Police at UIC (996-2860). Whenever possible, the UIC police will treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

**2. Theft or Loss**

If a theft or loss is detected it must be reported to the following agencies immediately.

**a. Nearest DEA Office Chicago Division-**

Kluczynski Federal Building

230 South Dearborn Street, Suite 1200

Chicago, IL 60604

Diversion Number: (312) 353-7875

Diversion Fax: (312) 353-1235

Diversion Program Manager Fax: (312) 353-1476

**b. UIC Police Department**

Emergency Number- 312- 355-5555

In addition to the immediate phone reporting to the above units, a report of Theft or Loss of Controlled Substances (DEA Form 106) must be completed and submitted. A hard copy may be printed and submitted to the nearest DEA Office or the report may be submitted online ([http://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html)). A copy of the report must be maintained with Registrant's controlled substance records. A copy of the report must also be provided to the UIC Ambulatory Care Pharmacy preferably with the Narcotic Record Certificate of Disposition Form.

Breakage and/or spills of controlled substances losses do not need to be reported as a loss. This type of loss must be documented and the registrant should sign the disposition record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (e.g. tablets), must be placed in the disposal/destruction waste stream.

**I. Disposal of Expired/Unwanted/Contaminated Controlled Substances**

To minimize waste, registrants should aim to only purchase quantities they intend to use and which can be used prior to expiration. Damaged, expired, unwanted, or contaminated controlled substances must be disposed of in accordance with state and federal regulations and records of disposal must be maintained.

When a DEA registrant has controlled substances that are expired or unwanted, the registrant must contact the Ambulatory Care Pharmacy Services. The UIC Ambulatory Care Pharmacy Services will make arrangements for transfer of ownership of the controlled substance to a DEA-approved Pharmaceutical Returns Processor for re-use, re-sale or destruction at a hazardous waste incinerator. This process may involve completion of DEA Form 222 or DEA Form 41. The UIC Ambulatory Care Pharmacy will observe all regulatory policies and procedures for this process.

**J. Training**

The registrant has the primary responsibility for ensuring that all persons authorized to use controlled substances under the registrant's DEA number have read and understand this policy. The registrant should maintain a log documenting that training on this policy has occurred. Log must be signed and dated by both the registrant and authorized user.

All personnel using animals at UIC will receive training on this policy as part of the ACC mandatory training that all principal investigators and all researchers who actively work with animals must complete prior to approval of a protocol or addition to an active protocol.