

University of Central Arkansas  
Institutional Animal Care and Use Policies

Policy/Procedure Name: Controlled Substances in Research Projects  
Submitted by: Tim Atkinson, Assistant Provost for Sponsored Programs  
Approved by: IACUC 4/29/09

**I. Purpose**

The primary purpose of this policy is to ensure safety and to prevent unlawful diversion of controlled substances used on the University of Central Arkansas (UCA) campus; and to ensure compliance with all applicable state and federal laws and institutional policies when procuring, storing, using and disposing of controlled substances.

**II. Policy**

**A. Scope of Application**

UCA requires all individuals conducting research with the Drug Enforcement Agency (DEA) controlled substances know, understand, and follow the DEA and the Arkansas Department of Health Pharmacy Services and Drug Control (ADH) rules and regulations pertaining to the acquisition, storage, use, and disposal of controlled substances, and to keep all required registrations, certificates, licenses, and records in force. Failure to comply with DEA or ADH regulations may result in forfeiture of the DEA and ADH registrations.

**B. Responsibilities**

- 1) The university address will be used as the storage facility of controlled substances in UCA IACUC approved research, all investigators at UCA who plan to use and store controlled substances on the UCA campus for approved research projects are required to register with the DEA and ADH. The registrant must maintain registration with the DEA and ADH until all controlled substances are spent, disposed of, or transferred to another registered person according to DEA guidelines.
- 2) Each investigator using DEA controlled substances for approved research shall be registered with the DEA and ADH. In accordance with State and Federal law, each registration shall bear the address of the university location where the controlled substances are procured, stored, used and disposed of.
- 3) All investigators are required to notify the UCA Office of Sponsored Programs when they apply for and obtain a DEA registration, and must indicate where the controlled substances are stored. A copy of the DEA and ADH registration will be submitted to the Office of Sponsored Programs. The registrant's number will be blacked out and the copies will be kept in a locked file cabinet.
- 4) The UCA Office of Sponsored Programs has the authority to inspect all controlled substances records to insure compliance is being maintained for IACUC protocols.

### **III. Procedures**

#### **A. Registration**

All investigators conducting research with DEA controlled substances must be registered with the DEA and ADH.

- 1) An application for ADH registration must be completed before DEA registration may be obtained. To obtain an Application for Controlled Substances Registration, contact the UCA Office of Sponsored Programs (501-450-3451) or ADH (501-661-2325).
- 2) Once a registration number is assigned by ADH, application for DEA registration may proceed. All investigators using Schedule II – V controlled substances must complete and submit DEA Form 225. This form is available at <http://www.deadiversion.usdoj.gov/> and application may be made electronically.
- 3) Re-registration is required annually and must be maintained by the registrant until all controlled substances are spent, disposed of, or transferred to another registered person.

#### **B. Procurement**

- 1) Procurement of controlled substances may be processed by a licensed pharmacy, a comprehensive account information with authorized signature, a copy of current DEA registration, and an appropriate DEA Form 222 for schedule II controlled substances.
- 2) A triplicate order form (DEA Form 222) is required for the procurement (purchasing, receiving, and transferring) of Schedule II controlled substances. Form 222s are obtained from the DEA. Form 222s should be fully completed in regards to amounts purchased and actual amounts received, and dates received.
- 3) The order form must be completed properly and bear no material alteration; if errors occur, all three copies should be marked as VOID and the three part order form filed with executed forms. Forms should be signed only by registrant or someone the registrant has granted power of attorney. Carbon copies of all order forms must be maintained and readily accessible for two years.
- 4) DEA order form 222s shall be stored securely and the range of forms documented separately to ensure accountability for all forms.
- 5) Lost or stolen order form 222s must be reported to the DEA.

United States Dept of Justice  
Drug Enforcement Administration  
Central Station  
PO BOX 28083  
Washington, D.C. 20038-8083

- 6) Schedule III-V controlled substance purchases and receipts should be documented on an internally standardized document to include all information present on the DEA order Form 222, in order to account for the total quantity received.
- 7) All receipts of controlled substances schedules II-V should be co-signed by the DEA license holder acquiring the controlled substance and then transferred immediately into inventory records upon receipt.
- 8) Limited quantities of controlled substances may be procured via transfer from another DEA registrant. Schedule II transfers require the thorough completion of DEA order Form 222, as is done for routine purchases. This should include the date of the transaction, the name, form, and quantity of the substance, and the names, addresses, and DEA registration numbers of the registrant transferring out of their stock and that of the registrant receiving the stock. Amounts to be transferred out by a registrant over a 12 month period must not exceed 5% of all controlled substances dispensed by that registrant; otherwise the registrant must be licensed as a distributor in addition to a practitioner.

**C. Dispensation Records / Recordkeeping**

- 1) All registrants storing or utilizing controlled substances are required to keep complete and accurate records of all receiving and dispensing transactions.
- 2) A continuing record use log is required for each substance and must include:
  - a. Name of substance
  - b. Date of receipt
  - c. Dosage form and unit strength of substance
  - d. Number of units or volume per container
  - e. Number of containers of substance
  - f. Date of Dispensing
  - g. Units or volume dispensed
  - h. Units or volume remaining in container
  - i. Name or initials of individual who dispensed or administered substance
  - j. Disposal record (if applicable) including date, manner or disposal, quantity of substance disposed, and signature of person performing disposal and person witnessing disposal
- 3) All records for controlled substance procurement, dispensing, inventories and all other required activities must be maintained and readily accessible for a period of two years. Records of schedule II documentation must be maintained separately from records of schedules III-V activities.

- 4) Dual signatures are recommended for each entry on dispensing records.
- 5) If an investigator terminates a study or leaves UCA, all controlled substance documentation for the study conducted at UCA should remain onsite for two years.

**D. Physical Substance Measurement/Count**

- 1) An initial inventory is required on the date when controlled substances activity is first engaged and every two years following the date of the registrant's initial inventory count, or every two years on the physical inventory date (may be specified by the UCA Office of Sponsored Programs). The inventory requires performance of an actual physical measurement/count. This is different from the expected perpetual balance recorded on paper inventory/disposition records.
- 2) Inventory records must be maintained and readily accessible for two years.
- 3) Initial inventory should include the following:
  - a. Investigator's name
  - b. Date and time inventory occurred
  - c. Signature of person(s) responsible for performing the inventory
  - d. Name of each controlled substance
  - e. Dosage and unit strength of each controlled substance
  - f. Number of units or volume of each substance per container
  - g. Number of containers of each substance
- 4) The registrant and one additional person should conduct the inventory count and both should sign the inventory records.
- 5) When taking the inventory of Schedule II-V controlled substances, an exact count or measure must be made. Unopened schedule II containers with seals intact are not required to be opened. For schedules III-V, an estimated count may be made. If the container holds more than 1,000 dosage units, an exact count must be made if the container has been opened.
- 6) When a turnover in personnel occurs, (for those who are listed by name in the UCA protocol or on UCA Diversion Form A, and thereby granted authorization to handle controlled substances) an inventory of controlled substances on hand should be conducted immediately prior to the departure of that individual.

**E. Physical Security**

- 1) Controlled substance schedules II-V must be stored under a double lock security in a substantially constructed permanently mounted cabinet, or safe (a door lock counts as one lock).

- 2) Access to keys where controlled substances are stored should be secure and limited to authorized personnel. A copy of the key should be submitted to the Office of Sponsored Programs.
- 3) The registrant is responsible for safe storage of drugs in their laboratories or offices, and for drugs that exceed the capacity of the lock boxes. In addition, it is the responsibility of the registrant to guard against theft and diversion of controlled substances, including the completion of UCA Diversion Control Form A.
- 4) Registrants are required to report any significant loss or theft of controlled substances to the local DEA office by using DEA for 106. Immediate notification also must be made to ADH by calling 501-661-2325 and faxing DEA form 106 to 501-661-2769. A copy of these forms must be sent to the Office of Sponsored Programs.

**F. Wastage and Controlled Substances Destructions**

- 1) The standard method of on-site wastage- liquids in syringes should be wasted down the sink, with the syringe placed in a sharps container, and tablets should be wasted in the sharps container. Any variance from the standard method should be documented in the dispensation/wastage records.
- 2) Unused controlled substances drawn up out of the original container (such as in a syringe) are to be wasted on-site in the presence of a witness and so documented in the dispensation/inventory records. When breakage or wastage of a controlled substance occurs, the amount given and the amount wasted shall be recorded by the authorized person who wasted the medication and verified by the signature of the person who witnessed the wastage. (As authorized in the protocol to handle controlled substances.) Documentation shall include or policy shall delineate how the medication was wasted.
- 3) If a witness is not available for wastage, or if controlled substances that are no longer usable due to expiration, deterioration, or not needed, they should be properly packaged and submitted to:

Arkansas Department of Health,  
Pharmacy Services and Drug Control  
4815 West Markham St.  
Little Rock, AR 72205-3867

This must include the proper completion of the Report of Drugs Surrendered form (available from ADH). Prior to submission to Arkansas ADH, these controlled substances should be adequately secured.

- 4) All registrants may be subject to an unannounced internal audit of their controlled substance records by the UCA Office of Sponsored Programs, which is performed

according to federal, state and local laws governing controlled substances as defined in 21 CFR 1300 to end.

- 5) The registrant must be present at each audit and he/she (or designee) retains the right to weigh the contents of any substance container in the presence of the audit team, rather than to have any member of the audit team do such. In the case of very small amounts of a substance (less than 100 mg), that would cause significant loss due to the weighing procedure, weighing will not be required.

#### **F. Graduate Students**

- 1) A registrant may at his or her discretion allow a UCA graduate student who is listed on the IACUC approved protocol to engage in the approved use of controlled substances in research projects with appropriate faculty supervision. When graduate students work under a registrant, the registrant holds complete responsibility for maintaining the appropriate drug control and diversion procedures as described in this policy.
- 2) A Diversion Control Form A will be completed when graduate students of the registrant are engaged in the approved use of controlled substances under an UCA IACUC approved research protocol. Information of the form includes:
  - a. Graduate student's name
  - b. IACUC Protocol #
  - c. Name of controlled substance
  - d. Initials of registrant under whose registrant the student works

A Diversion Control Form A will be updated each time a graduate student enters or leaves the employ of the registrant. A copy of these forms must be sent to the Office of Sponsored Programs.

- 3) Registrants are required to screen all employees prior to authorizing their involvement in research involving DEA controlled substances. As part of the screening process, a questionnaire which includes the following questions (21 CFR 1301.90) must be completed for each agent having access to DEA controlled substances:
  - Within the past five years, have you been convicted of a felony?
  - Within the past two years, have you been convicted of any misdemeanor?
  - Are you presently charged with committing a criminal offense?
  - In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
- 4) Registrants are encouraged to always supervise graduate students working under their DEA registration and to keep clear, up to date records.

