

NUMBER: 16.1.13**DATE: 12/14/2009****REVISION: 06/20/2012; 01/15/2014; 11/5/2014; 10/14/2020****PAGE: 1 of 11****SECTION: RESEARCH****AREA: RESEARCH ADMINISTRATION****SUBJECT: NON-HUMAN RESEARCH USE OF DEA CONTROLLED SUBSTANCES****PURPOSE**

To ensure compliance by the University of Arkansas for Medical Sciences (“UAMS”) with state and federal laws governing the use of Controlled Substances and to prevent diversion of those Controlled Substances when the Controlled Substances are used in biomedical animal or laboratory research not involving humans.

SCOPE

This policy covers all UAMS faculty, staff and students conducting research on the UAMS campus.

DEFINITIONS

Controlled Substance Act shall refer to Title 21 of the United States Code, which classifies certain drugs and substances as items that must be controlled and details the federal regulations to control those items.

Controlled Substance shall mean a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of Subchapter 1 of the Controlled Substance Act. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

DEA shall refer to the Drug Enforcement Administration, a division of the U.S. Department of Justice.

ADH shall refer to the Arkansas Department of Health.

POLICY

By law, all individuals conducting non-human research activities using Controlled Substances must be registered with the ADH Pharmacy Services and Drug Control and the DEA. All individuals conducting non-human research using Controlled Substances must comply with state and federal regulations regarding the acquisition, storage, use and disposal of those substances.

Each Principal Investigator or faculty member conducting non-human research using Controlled Substances will be responsible for registering with the ADH, registering with the DEA, and assuring compliance with applicable state and federal regulations. The registrant may not allow the permit to lapse until all Controlled Substances are utilized, disposed of, or transferred to another registered person.

The UAMS Office of Research Compliance will be responsible for assisting individuals in complying with applicable rules and regulations. This will include educating researchers about the requirements, assisting as necessary during implementation, providing regular oversight to ensure compliance is being maintained, and auditing biannual inventories of all Controlled Substances maintained for non-human research purposes.

PROCEDURES

I. Registration

All investigators conducting non-human research with DEA Controlled Substances must be registered with the DEA and ADH. Investigators requesting to use Controlled Substances on laboratory animals must also submit a written request and receive approval from the UAMS Institutional Animal Care and Use Committee (“IACUC”) for this use.

Controlled Substance schedules may be found at the following sites:

DEA Schedule <http://www.deadiversion.usdoj.gov/schedules/index.html>

Federal Registration Instructions – DEA

Every person conducting research activities using a Controlled Substance is required to register with the Drug Enforcement Agency, and re-registration is required annually. A separate registration is required for each principal place of business or professional practice at one general physical location where Controlled Substances are manufactured, distributed, imported, exported, or dispensed by a person.

Researchers applying to use Schedule II, Schedule III, Schedule IV and Schedule V Controlled Substances, must complete and submit DEA Form 225.

Researchers applying to use Schedule I Controlled Substances must complete and submit DEA Form 225 along with a copy of the research protocol which includes a detailed description of procedures, including number and species of research subjects, dosage to be administered, route and method of administration, and the duration of project.

Renewal of registration for researchers is required every year. If the registration lapses, the investigator must start the registration process over from the beginning. Note that that application fee will be waived for UAMS faculty as employees of a state agency. Investigators should contact the Office of Research Compliance for advice on completing the application properly in order to obtain the fee waiver.

Medical Physician “Practitioners” may also conduct research and instructional activities under their dispensing and instructing registration as long as the address of the principal place of business or practice where the applicant manufactures, dispenses, or distributes Controlled Substances is the same. DEA Form 224 should be used to register with the DEA. Renewal of registration for Practitioners is required every three (3) years. Practitioners should also register with the state

ADH if they wish to conduct research with Controlled Substances. See process for registering with ADH below.

DEA license/registration forms are available online at <http://www.deadiversion.usdoj.gov/> and registration information is available online at <http://www.deadiversion.usdoj.gov/drugreg/index.html>.

Recommendation

It is recommended that prior to acquiring Schedule I and/or II substances for use in research, registrants contact the UAMS Office of Research Compliance to discuss required security measures.

Only personnel listed in an IACUC-approved animal use protocol or an authorized veterinarian may dispense, administer, or otherwise conduct research with Controlled Substances. The Principal Investigator must provide a Power of Attorney authorizing specific personnel to act on his or her behalf when conducting animal experimentation utilizing Controlled Substances. The Power of Attorney should be maintained in the Controlled Substance lock box and be available for audit and/or DEA site visits.

It is the responsibility of the Principal Investigator to know, understand, and follow the DEA and State of Arkansas rules and regulations pertaining to all aspects of Controlled Substances and to keep all required registrations, licenses, certificates, and records in force and available for inspection. Failure to comply with DEA or ADH regulations may result in forfeiture of licensure/registration and/or fines and penalties. Failure to produce complete Controlled Substance records at the request of UAMS Office of Research Compliance or the UAMS IACUC may result in disciplinary action.

State Registration Instructions – ADH

In addition to the DEA registration, individuals in the state of Arkansas conducting research activities with Controlled Substances must register with the Arkansas Department of Health Pharmacy Services and Drug Control (ADH). The ADH has agreed to process Controlled Substance registration applications prior to the receipt of the DEA registration/license. The ADH registration application, along with the following documentation may be scanned and emailed or mailed in hard copy to the ADH:

1. A complete description of the procedure(s) utilizing the Controlled Substance(s) listed in the application
2. A statement regarding the security and accountability provisions in place in order to prevent diversion of the Controlled Substances
3. A statement of source(s) of obtaining the Controlled Substance(s) to be used in the procedure(s)
4. A letter from the UAMS Research Compliance Officer or UAMS Vice Chancellor for Research and Innovation certifying that the applicant is authorized to conduct research at UAMS.

The completed ADH registration form and above additional information should be emailed to the ADH at:

Marci Middleton-Yates
Marci.Yates@arkansas.gov

or hard copies mailed to the ADH at:

Arkansas Department of Health
Pharmacy Services and Drug Control
4815 West Markham Slot 25
Little Rock, AR 72205-3867

The ADH will contact the Principal Investigator via email to give the Arkansas State registration number. This number will be required in the DEA application process. When the Principal Investigator receives their DEA registration/license in the mail from the federal office, a copy must be forwarded to ADH. The ADH will then mail a hard copy of the Arkansas State Certificate of Registration.

ADH Registration forms are available online at
http://www.healthy.arkansas.gov/images/uploads/pdf/pacs_form_application.pdf

Instructions for completing the application can be found here:
http://www.healthy.arkansas.gov/images/uploads/pdf/pacs_application_instructions.pdf

ADH Regulations are located online at
https://www.healthy.arkansas.gov/images/uploads/rules/controlled_substancesRulesRegs.pdf

II. Employee Screening Procedure

Principal Investigators (“Registrants”) who are registered with the DEA and ADH may authorize other UAMS employees to act on their behalf or under their direction (“Agents”). The Registrant must provide a Power of Attorney authorizing the Agent to act on their behalf. Agents of the Registrant may engage in approved activities under the direction of the Registrant. The Registrant is required to screen those employees prior to authorization. As part of the screening process, a questionnaire which includes the following questions must be completed for each non-practitioner having access to DEA Controlled Substances:

- Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, 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?

A questionnaire must be completed for each employee (“non-practitioner”) who is authorized by the registrant to handle DEA Controlled Substances under his or her direction. The Registrant should maintain this documentation for the duration of the employee’s employment.

In the event an employee provides a “YES” response on the questionnaire, the Registrant (“Principal Investigator”) is advised to contact the UAMS Office of Human Resources to discuss how to proceed.

III. Investigator Responsibilities

As a DEA and ADH Registrant for research use of Controlled Substances, each investigator is responsible for managing the Controlled Substances in accordance with the requirements of the regulations including purchasing and receiving, inventory, record keeping, security, and disposal provisions.

Purchasing

Many Controlled Substances are available for purchase from the UAMS Pharmacy by a faculty researcher registered with the DEA. The Pharmacy’s hours of operation for the purchasing of Controlled Substances are Monday through Friday from 9:00 a.m. through 3:00 p.m. Schedule III through V Controlled Substances may be ordered via an Interdepartmental Transfer Form (“IDT Form”). A copy of the DEA license will be required to be presented with the IDT Form to verify the Principal Investigator’s registration for the schedule of Controlled Substances being ordered. Schedule I and II Controlled Substances must be ordered using a completed DEA Form 222. If the licensed researcher is not the one signing the DEA Form 222, then a copy of the Power of Attorney form authorizing the signee to order the Controlled Substances under that license must be presented with the Form 222.

Record Keeping and Dispensation

Each Principal Investigator registered with the DEA to use Controlled Substances in research is responsible for maintaining records related to those Controlled Substances in accordance with 21 CFR Part 1304.04. All registrants storing or utilizing Controlled Substances are required to maintain complete and accurate records of all receiving and dispensing transactions. These records should be maintained in the Controlled Substance lock box and be readily available for DEA site visits and/or audit by the Office of Research Compliance or the IACUC. Inventories and records of Controlled Substances listed in Schedules I and II shall be maintained separately from all other records of the registrant. Inventories and records of Controlled Substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. All records for Controlled Substance transactions, including procurement, dispensing and inventories, must be maintained and readily accessible at the registered location for a period of two years.

Inventories

Initial inventory date – Each registrant shall take an inventory of all stocks of Controlled Substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of Controlled Substances. Initial inventories must be performed each time a new Controlled Substance is added to the registrant’s stock of Controlled Substances.

Biennial inventory date - After the initial inventory, the registrant shall conduct a new inventory of all stocks of Controlled Substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. Each Controlled Substance inventory shall contain a complete and accurate record of all Controlled Substances on hand on the date the inventory is taken, and shall be maintained in hard copy form at the registered location. A separate inventory shall be made for each registered location and each independent activity registered.

Inventory records must be maintained and readily accessible for two years. For each controlled substance, the inventory records shall include the following:

- Name of each substance
- Each finished form of the substance (e.g., 10 mg tablet or 10 mg concentration/mL)
- Number of units or volume of each finished form in each container (e.g. 100 tablet bottle or 3 mL vial)
- Number of containers of each finished form (e.g., three 100 tablet bottles or six 3-mL vials).

Damaged, defective, expired, or impure substances awaiting disposal must also be inventoried. The inventory record should include the name of the substance, total quantity of the substance, and the reason why the substance is being maintained.

All inventory records should also include the name of the Principal Investigator/Registrant, the date and time the inventory was taken, and the signatures of the persons responsible for taking the inventory. Two authorized personnel should conduct the inventory and both should sign the inventory records.

Unopened containers with seals intact are not required to be opened when conducting controlled substance inventories. Opened commercial containers of Schedule I and II Controlled Substances must have an exact count performed. Opened commercial containers of Schedule III, IV or V controlled substances may have an estimated count or measure of the contents made, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made.

When turnover occurs in personnel (for those listed by name on the animal use protocol and granted authorization to handle Controlled Substances), an inventory of the Controlled Substances on hand should be conducted immediately prior to the departure of the personnel.

Continuing Records

To ensure accountability, a complete and accurate continuing record (e.g., real-time inventory) is required for each substance and must be maintained on a current basis. It is the investigators' or his/her designee's responsibility to audit the Controlled Substances on a day of use basis. Continuing records should be kept for 2 years after the substance is spent. The continuing records should include:

- Date of receipt
- Name of the substance

- Each finished form of the substance (e.g., 10 mg tablet or 10 mg concentration/mL)
- Number of units or volume of each finished form in each container (e.g. 100 tablet bottle or 3 mL vial)
- Number of containers of each finished form (e.g. three 100 tablet bottles or six 3-mL vials).
- Date of dispensing, units or volume dispensed, units or volume remaining in container, name or initials of the individual who dispensed or administered the substance.
- If substance is acquired from, or distributed to another person, their name, address and DEA registration number must be recorded along with date and number of units acquired or distributed.
- If substance is disposed of, include date, manner of disposal, and quantity of substance disposed. Keep disposal records for at least two years. (Note: Contact the Office of Research Compliance for assistance with the disposal of Controlled Substances.)

Note: Example Inventory Forms and Continuing Record Forms are available for use. These forms are not required forms but examples; they may be used to remain in compliance with recordkeeping requirements. See the end of this policy or contact the UAMS Office of Research Compliance for example inventory and continuing record forms.

IV. Security

Registrants shall provide effective controls to guard against the theft or diversion of Controlled Substances. Controlled Substances are required to be stored under **double-lock security in a substantially constructed permanently mounted cabinet or safe**. Only Controlled Substances are to be stored in the lock boxes. Non-controlled drugs must be maintained separately. Access to keys where Controlled Substances are stored should be secure and limited to authorized personnel only.

Registrants are required to immediately report any significant loss or theft of Controlled Substances to the local DEA office (Little Rock) by using DEA Form 106. Immediate notification must also be made to ADH by calling 501-661-2325 and faxing DEA Form 106 to 501-661-2769. Thefts must be reported whether or not the Controlled Substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

DEA Form 106 <https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>

Registrants must also be aware of the requirements of [21 CFR §1301.91 Employee responsibility to report drug diversion](#). This regulation states: “Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an 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. The employer shall 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.”

**UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES
NON-HUMAN USE OF CONTROLLED SUBSTANCES
NON-PRACTITIONER EMPLOYEE SCREENING QUESTIONNAIRE**

Instructions: A separate questionnaire must be filled out by the registrant and for each employee (non-practitioner) who is authorized by the registrant to handle DEA Controlled Substances under his or her direction.

The Drug Enforcement Agency requires that any non-practitioner who will have access to Controlled Substances under the direction of the registrant as a result of his or her status as an employee or agent of the University of Arkansas for Medical Sciences answer the following questions. Any false information or omission of information may jeopardize your position with respect to employment. Information revealed by this questionnaire will not necessarily preclude employment, but will be considered as part of an overall evaluation of your qualifications. The responses to this questionnaire will be held in strictest confidence.

1. In the past five years have you been convicted of a felony or within the past two years of any misdemeanor or are you presently charged with committing a criminal offense? (Do not include 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.

Yes _____ No _____

2. 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.

Yes _____ No _____

Signature (Employee)

Name (Print)

Signature (Registrant - Principal Investigator)

Name (Print)

Date



CONTROLLED SUBSTANCES INVENTORY

INVESTIGATOR NAME: _____

DEA LICENSE #: _____

DATE: _____ TIME: _____

BEGINNING OR END OF BUSINESS: _____

DRUG	STRENGTH	FORM	UNITS	BALANCE ON HAND	INITIALS

