

Subject to review of the Shared Governance Committee.

**ARKANSAS STATE UNIVERSITY
GOVERNING PRINCIPLES
FOR THE USE OF CONTROLLED SUBSTANCES IN RESEARCH**

1.0 INTRODUCTION

Arkansas State University (ASU) is committed to enhancing the growth of research and other sponsored activities on campus while simultaneously complying with federal and state laws and regulations concerning controlled substances.

2.0 PURPOSE

These Principles are designed to ensure security and accountability in the acquisition, use, and disposal of Controlled Substances. Substantial compliance with the regulations depends on the following factors:

1. The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, buying, possessing, and conducting research, etc.);
2. The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders, unusable powders);
3. The quantity of controlled substances handled;
4. The location of the premises and the relationship such location bears on security needs;
5. The type of building construction and the general characteristics of the building;
6. The type and adequacy of vault, safe, and secure enclosures or other storage system used;
7. The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
8. The extent of unsupervised public access to the facility;
9. Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;
10. The availability of local police protection or of the registrant's or applicant's security personnel; and
11. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

Violations of the Controlled Substances laws, even when unintended, can lead to substantial civil and criminal liability.

3.0 DEFINITIONS

Authorized Individuals are 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.

Controlled Substance is defined as a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of the Controlled Substances Act. The schedules identify materials

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containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect and promote abuse or physiological or psychological dependence. Schedules I and II are the most stringently regulated, and include many widely known street drugs, including heroin, LSD, and cocaine as well as such drugs as pentobarbital. Schedule III compounds include many stimulants and depressants, pain killers, and anesthetics, including ketamine and buprenorphine. Schedule IV substances cover the balance of lower-abuse potential stimulants and depressants, while Schedule V includes therapeutic drug mixtures containing very limited quantities of Controlled Substances. Each Controlled Substance has a specific drug code assigned to it. A general list of Controlled Substances can be found at <http://www.usdoj.gov/dea/pubs/scheduling.html>.

Drug Enforcement Administration (DEA), a unit within the Department of Justice, has responsibility for enforcing the controlled substances laws and regulations of the United States.

Principal Investigator is the individual with primary responsibility for solicitation, implementation, and administration of an externally sponsored grant or contract.

4.0 APPLICABILITY

All University employees who participate in or administer sponsored program activities, directly or indirectly, and use controlled substances in their research programs.

5.0 REGULATIONS

United States Code, Title 21

Drug Enforcement Administration Practitioner's Manual:

http://www.dea/diversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf Arkansas Code Annotated § 5-64-101¹ and § 5-64-307²

6.0 GOVERNING PRINCIPLES

A license from the DEA is required to acquire, make, possess or use a Controlled Substance and is: (i) issued to an individual, who may authorize other individuals to operate under his/her license; (ii) specific to drug schedules identified on the license, and to specific drug codes; and (iii) identified by a specific storage location. A copy of such license, whether issued to a principal investigator, department chair, or other designated official, shall be maintained in the Office of the Associate Vice Chancellor for Research.

Only licenses and authorized individuals will be permitted access to Controlled Substances.

¹ Authorized agents who conduct research on controlled substances are exempted from the provisions of this section. This section also defines a "practitioner" as a scientific investigator.

²The State code directs "Practitioners" to comply with federal law when using controlled substances. The State does not have any of its own specific provisions in these cases.

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Licensure

Application. PIs who wish to work with Controlled Substances should submit a copy of his/her Controlled Substances Application (see DEA Practitioner's Manual at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf) to departmental administrators who should, in turn, submit the form to the Dean and to the Associate Vice Chancellor for Research who will approve use of the substance on campus.

It is ultimately the individuals identified on the licenses that have responsibility for ensuring proper acquisition, use, maintenance, and accountability of Controlled Substances. The number of Authorized Individuals on the application should only include those who are essential for efficient operation. Further, persons previously convicted of a felony offense related to Controlled Substances, were denied licenses, or were asked to surrender one may not be authorized to work with these materials. License holders should take steps to ensure that they, their Chairs or equivalents, Deans or equivalents, and the Associate Vice Chancellor for Research have a record of any such changes.

Researchers who occupy ASU space but are not employed by the University must obtain the approval of the Associate Vice Chancellor for Research and from the equivalent signatory at their home institutions to use Controlled Substances on the ASU campus.

Maintenance. The DEA provides guidance at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

Renewal of Licensure. License holders must provide complete, updated information about Authorized Individuals, drug codes, schedules, and licenses when they renew their licenses with the DEA. Please see http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

Scope of Use

Controlled Substances may only be used for 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.

Synthesis of chemicals or drugs that have been deemed illegal or illicit by the DEA are prohibited unless they are consistent with the research protocol submitted to the DEA and are pre-approved by the Chair or equivalent official, Dean or equivalent, and the Associate Vice Chancellor for Research.

Purchasing

Purchasing shall be consistent with DEA rules, as specified in http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf. Orders for Controlled Substances should be kept to the smallest quantity needed for efficient operation to conduct the indicated research.

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Storage

Controlled Substances must be stored in securely locked, substantially constructed, drug cabinets or safes in locations where access is limited. (Standard file cabinets are not sufficient for their storage). Keys and/or combinations to the cabinets or safes should be secure and under the control of a limited number of Authorized Individuals. They may be removed only when they are being used for legitimate purposes.

Authorized Individuals should log out the smallest quantity of a Controlled Substance needed for efficient operation, generally no more than a single vial at a time, and must return any unused portions to the safe or vault during those times when they cannot attend to them or no longer need them.

If an Authorized Individual's laboratory is not connected to the License Holder's place of storage, the Authorized Individual must arrange to obtain his/her own license. If the license holder changes location and changes the storage location indicated on his/her license, s/he should notify the DEA in writing and make certain that the new cabinet meets Controlled Substance requirements.

Reporting of Loss, Destruction, Theft, or Unauthorized Use

Thefts, suspected thefts, unauthorized uses, or other losses of any Controlled Substance must be reported to the departmental administrator, University Police Department, and EH&S upon discovery. Additionally, the DEA requires laboratories to report losses within one business day of discovery. DEA Form 106, available on DEA's website, is required.

Any unauthorized persons who gain access to Controlled Substances for the purpose of diversion or theft must be reported to the University Police Department and may be subject to the disciplinary policies of the University.

Recordkeeping

Laboratories are required to maintain records of purchase, use, storage, and disposal of Controlled Substances in accordance with guidelines contained at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

Controlled Substances of Unknown Origin

Occasionally, laboratories or animal facilities may come across Controlled Substances of an uncertain origin, sometimes referred to as "orphaned drugs." In those circumstances, the laboratory or other facility should take the following steps: (1) make sure that the Substance is secured in a license holder's locked safe or cabinet; (2) contact the EH&S office for disposal assistance and coordination; and (3) provide the DEA with a brief written description of the material (type and quantity), how the laboratory acquired it, and a proposed method of disposal. Please see http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf for further details.

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Disposal

The DEA's Office of Diversion Control has specific requirements for disposal of Controlled Substances. These provisions can be found at http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21.htm.

Shipping

Federal law prohibits the export of Controlled Substances unless certain requirements are met, including, in most cases, export and import permits. Violators of the law risk arrest or fines both in the United States and the foreign country. Licensed brokers are available for transport of controlled substances. Contact EH&S for assistance in arranging for any necessary transport of Controlled Substances.

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