

POLICY ON CONTROLLED SUBSTANCES FOR RESEARCH, TEACHING AND VETERINARY CARE

I. REFERENCES

A. Public Law 91-513, Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to as Federal Controlled Substances Act.

B. Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970. 21 CFR, Chapter II, Drug Enforcement Administration, Department of Justice.

C. Title 20, Chapter 2, Alabama Uniform Controlled Substances Act 1407, Legislature 1971,

II. SCOPE

This policy sets forth requirements and procedures applicable to the authorization, procurement, receipt, security, storage, control, biennial inventory, and disposal of Controlled Substances, List I and Precursor Chemicals for research, teaching and veterinary care. This policy does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his/her license.

III. DEFINITIONS

A. Controlled Substance

A controlled substance is a drug or chemical substance whose possession and use are regulated under the Federal Controlled Substances Act (CFR 21 Part 1300) and the Alabama Uniform Controlled Substances Act. For purposes of this document, controlled substance policies and procedures shall also apply to control of List I and Precursor chemicals which are also contained in these documents.

B. Department of Occupational Health and Safety (OH&S)

Occupational Health and Safety is the UAB Department that provides safety guidance and legal oversight to those UAB staff using hazardous agents such as radioisotopes, chemicals and biologicals. The Department of Occupational Health and Safety is also the department where the UAB Controlled Substances Program is administered by the Controlled Substances Manager.

C. Drug Enforcement Administration (DEA) Diversion Control Division

The Drug Enforcement Administration is the Federal Agency within the Department of Justice that establishes and enforces regulations for handling and use of controlled substances.

D. Disposition Records

An accurate, continuous and current record used to track the acquisition, use and disposal of controlled substances. These records are subject to audit by internal staff and DEA officials as part of the authorization and licensing process.

E. Institutional Animal Care and Use Committee (IACUC)

The IACUC is the Committee responsible for overseeing all aspects of animal care and use at UAB in accordance with federal regulatory agencies and accrediting organization requirements. It serves under the Office of the Vice President for Research.

B. Schedules of Controlled Substances

Controlled substance schedules are classifications of narcotics and dangerous drugs, ranked according to their potential for abuse and other relevant factors, and are denoted by Roman numerals I through V. Schedules were established by Public Law 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970 (1980 Revision), in order to provide clear guidelines for the implementation of controls

on the manufacture and procurement of controlled substances. The assignment of particular substances to specific schedules depends on several factors including potential for abuse, risk to public health, its medical usefulness, its potential to produce physical or psychological addiction, etc. Drugs can change schedules as more data is available to support its move into a more restrictive or less restrictive schedule. State regulations may require a more restrictive schedule for certain drugs than federal regulations but not less restrictive.

C. Listed Chemicals

Listed chemicals are chemicals of concern that can be used to make a controlled substance and were established by Public Law 103-200, the Domestic Chemical Diversion Control Act of 1993. There are two lists, List I and List II, though for the purposes of this document only List I chemicals are referenced. These lists can be obtained at http://www.deadiversion.usdoj.gov/21cfr/cfr/1310/1310_02.htm.

D. Precursor Chemicals

Precursor Chemicals, as used in this policy, are any substance listed under the Alabama Uniform Controlled Substances Act by the Alabama State Board of Pharmacy that in addition to legitimate uses is used in the unlawful manufacture of a controlled substance or controlled substances. This list of chemicals can be obtained at <http://www.albop.com/actsprovisions/act1407%20052709.pdf>.

E. Purposes Covered by this Policy

Animal research, teaching, veterinary care, and in-vitro (non-animal) research are covered by this policy. This policy does not cover research conducted with controlled substances acquired from UAB Hospital Pharmacy such as those used in any human trials.

F. Projects

Projects shall include an actual research project or teaching or veterinary purpose.

G. Department Chair/Section Chair

A Department Chair shall include a faculty appointed Department Chair or Section Chair. He/She may serve as the signing authority for controlled substance use authorization or may appoint someone else in a position of authority that knows the faculty and staff in the department.

H. Principal Investigator

A Principal Investigator includes "In Residence," "Adjunct" and "Clinical" Professors, Associate Professors, Assistant Professors, Instructors, Professors, and Veterinarians who are assigned space for research or teaching activities. A faculty member without assigned space may be considered Principal Investigator upon approval of their Department Chair.

I. Authorized Personnel

Authorized personnel are faculty, staff, students, or visiting scholars who have a need to handle or access controlled substances for Department-approved projects at UAB. The number of Authorized Personnel shall be kept to a minimum in order to maintain security. In order to become an Authorized Personnel, the individual must sign the Controlled Substance Personnel Screening Data Sheet (PSDS), indicate no prior history with controlled substance abuse or diversion, obtain Principal Investigator signature authorization, file a copy with Occupational Health and Safety, and subsequently file for addition to the Controlled Substances Use Authorization (CSUA) of the investigator.

IV. POLICY

A. Regulatory Compliance

UAB shall comply with all applicable Federal and State Laws and regulations governing controlled substances. All controlled substance policies and procedures shall apply to control of List I and Precursor chemicals as well.

B. Registration

Authority to possess or dispense controlled substances for research, teaching, and veterinary care shall be requested through the UAB Controlled Substances Program and will require prior approval before purchase. All projects involved in the possession or use of controlled substances II-V shall be covered under an applicable University registration with the DEA following approval of a UAB Controlled Substances Use Authorization.

Registration for Controlled Substances in Schedules II-V shall be held in the name of the Institution or academic department per geographical location and activity and coordinated by the Controlled Substances Program Manager. If an operation remote from the campus requires controlled substances, a separate registration is necessary for each type of activity involved.

Registration for Controlled Substances in Schedule I shall be obtained and managed by the Principal Investigator per geographical location and activity. This registration is not transferable, requires a more detailed description of the research project and higher security for storage. Registration for a Schedule 1 controlled substance should be coordinated through the Controlled Substance Manager and may require review of the UAB Chemical Safety Committee.

C. Approval of Projects

Use of controlled substances under university registrations is restricted to projects where such use has been specifically authorized by the appropriate Department Chair as declared on the CSUA. In his/her absence, this may be delegated to one individual of a comparable level of authority. In these instances, this individual would be delegated the authority to sign as a Department Chair Alternate. The Department Chair requiring CSUA(s) for their own projects must acquire authorization from their Dean or an individual of a comparable level or the Chairman of the IACUC if applicable. Projects must be written to satisfy specific DEA requirements. An approved Institutional Animal Care and Use Program (IACUC) research protocol shall be sufficient project documentation for animal research projects. Additional approval for any project which proposes to use a Schedule I controlled substance must be reviewed by the UAB Chemical Safety Committee prior to commencement of work.

D. Orders for Controlled Substances

The Department Chair or Principal Investigator in cooperation with the IACUC, where applicable, must determine the need for and sign all requisitions for Controlled Substances, regardless of dollar value. Purchase requests shall be submitted to the Controlled Substances Program in Occupational Health and Safety (OH&S) for review.

Approved requisitions will be ordered by OH&S from the vendor following approval through the Purchasing Department system. All purchases of such materials using university-controlled funds shall be made only through the Controlled Substances Program. No orders may be placed by departmental personnel directly with vendors.

E. Penalties for Non-Compliance

Possible penalties for violating DEA regulations include rescission of the university registrations authorizing the use of controlled substances, imposition of fines, and imprisonment of those responsible. Possible penalties for violations of this policy include CSUA revocation, repossession of all controlled substances in inventory, suspension of purchase requisition authorization, and suspension or termination of Authorized Personnel privileges.

V. RESPONSIBILITY

A. The Department of Occupational, Health and Safety (OH&S)

The Controlled Substances Program Manager maintains delegated authority and responsibility for overall coordination of this policy and specific responsibility for the approval, receipt, and delivery of controlled substances to authorized personnel. OH&S is also responsible for disposal of controlled substances, biennial inventory notification to the Department Chair and/or designated Principal Investigator for

inventory of controlled substances, authorizing the storage location approval process, and for approving all storage locations. The Controlled Substances Program Manager is responsible for obtaining and maintaining any powers of attorney required for program operation within OH&S. The above information shall be available to the DEA upon request. The Controlled Substances Program Manager or a designee shall perform announced and unannounced audits to measure compliance with these policies.

OH&S is responsible for maintaining a central storage for receiving incoming shipments of controlled substances and for obtaining appropriate signatures of persons authorized to receive or have access to controlled substances. Verification of authorized personnel to receive controlled substances is required, by signature and picture ID at the time they are picked up at the OH&S office.

B. Department

1. The Department Chair is assigned responsibility for approving projects involving the use of controlled substances by departmental personnel, for authorizing faculty as Principal Investigators, for notifying OH&S if a new Principal Investigator arrives on campus with controlled substances, for notifying OH&S when a Principal Investigator authorized to experiment with controlled substances dies or intends to terminate employment, and for preparation of such reports as may be required. Department approval is granted by Chair's signature on each Principal Investigator's CSUA application for one year and may be renewed.
2. The Department Chair is responsible for assuring that a current inventory of all controlled substances under his/her control is maintained by the Principal Investigator on the Controlled Substances Log Sheet in a separate, secure book for periodic audit by OH&S and/or the DEA.
3. The Department Chair and the Principal Investigator are assigned joint responsibility for determining the need for and signing (authorizing) all requisitions for controlled substances. The Principal Investigator is assigned primary responsibility for assuring that a current inventory of all controlled substances under his/her control is maintained, that inventory forms are submitted upon notification by and at the request of OH&S, that a current CSUA is on file with OH&S, ensuring that a list is maintained of those individuals handling controlled substances in the laboratory, and that all DEA security regulations are being followed.
4. The Department Chair and/or Principal Investigator is assigned responsibility for the preparation and submission of Research Protocol and all information required for Schedule I controlled substances.
5. The Principal Investigator is assigned responsibility for assigning and authorizing laboratory personnel to handle controlled substances. Each proposed laboratory personnel to handle controlled substances must fill out a Personnel Screening Data Sheet (PSDS). The PSDS shall be sent to the Controlled Substances Program Manager for review in order to become an Authorized Personnel. If an applicant has a criminal history of mishandling controlled substances, he or she shall not be granted access to the Principal Investigator's controlled substances.

C. Purchasing

Authority to sign University Purchase Orders for controlled substances is restricted to a limited number of authorized persons in the Purchasing Department. This information shall be available to the DEA upon request.

D. Police Department

The University Police Department investigates all suspected thefts or misuse of controlled substances.

VI. REQUIREMENTS OF OTHER AGENCIES

If approval of any other federal or state agency is required for the use of any controlled substance, application for such approval shall be filed by the Principal Investigator and evidence of approval submitted to the Controlled Substances Program Manager