



## ENVIRONMENTAL HEALTH & SAFETY

The University of Alabama at Birmingham

### POLICY ON CONTROLLED SUBSTANCES AND LIST I CHEMICALS FOR RESEARCH, TEACHING AND VETERINARY CARE AT UAB

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## **Purpose**

The acquisition, use and disposal of controlled substances are subject to Drug Enforcement Agency (DEA) regulations. These regulations set specific requirements and restrictions on registration, acquisition, usage, record keeping, transfer, storage and disposal. The purpose of this policy is to establish the UAB Controlled Substances Program (UABCSP) procedures and guidelines, which meet DEA requirements. These policies and procedures limit the diversion of Controlled Substances (CS) through improved institutional control and accountability, ensure proper training for those who handle CS, and track the usage and accountability of CS.

## **Scope**

This policy sets forth requirements and procedures applicable to the authorization, procurement, receipt, security, storage, control, biennial inventory, and disposal of Controlled Substances (CS), 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 at UAB.

Research using CS in human trials is not administered through this program. For more information visit the link at <https://www.uab.edu/ohs/controlled-substances>

## **UAB Controlled Substances Program (UABCSP)**

The UABCSP is based on an Administrative Memorandum of Agreement (MOA) signed by the United States Department of Justice, Drug Enforcement Administration and The Board of Trustees of the University of Alabama for the University of Alabama at Birmingham for and on behalf of the Department of Environmental Health and Safety / UAB Controlled Substances Program. The MOA was first signed in 2011 and reviewed and revised again in 2015. Under this program, DEA issues licenses to departments and the UABCSP has the authority to issue authorizations to individual researchers under the departmental license. UABCSP also has the authority and responsibility for overall coordination of the agreement and specific responsibility for the approval, receipt, and delivery of controlled substances to authorized personnel. This controlled substance safety policy describes responsibilities and procedures for animal research, teaching, veterinary care, and in-vitro research at UAB.

## Definitions

### 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.

The link below can assist you to determine whether a chemical is a controlled substance:  
[Determining if a Chemical is a Controlled Substance](#)

### 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.

### 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.

**Schedule I** - Drugs or other substances that have a high potential for abuse; no currently accepted medical use in the United States and have a lack of accepted safety for use under medical supervision.

**Schedule II** - Drugs or other substances that have a high potential for abuse; currently have an accepted medical use in treatment in the United States, or have a currently accepted medical use with severe restrictions; abuse may lead to severe psychological or physical dependence.

**Schedule III** - Drugs or other substances that have a potential for abuse less than Schedule I or II; currently have an accepted medical use in treatment in the United States; abuse may lead to moderate or low physical and high psychological dependence.

**Schedule IV** - Drugs or other substances that have a low potential for abuse relative to those listed in Schedule III; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence those in schedule III.

**Schedule V** - Drugs or other substances that have a low potential for abuse relative to Schedule IV; currently have an accepted medical use in the United States; abuse may lead to limited physical or psychological dependence relative to those in Schedule IV.

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. A complete list of the schedules is <http://www.deadiversion.usdoj.gov/schedules/> available here.

### 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. These lists can be obtained at [https://www.deadiversion.usdoj.gov/chem\\_prog/34chems.htm](https://www.deadiversion.usdoj.gov/chem_prog/34chems.htm)

### **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 <https://law.justia.com/codes/alabama/2016/title-20/chapter-2/article-9>

### **Activities 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 a campus pharmacy such as those used in any human trials.

### **Principal Investigator (PI)**

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.

### **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 Environmental Health and Safety, and subsequently file for addition to the Controlled Substances Use Authorization (CSUA) of the investigator.

### **Regulatory Compliance**

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

- Public Law 91-513, Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to as Federal Controlled Substances Act.
- Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970. 21 CFR, Chapter II, Drug Enforcement Administration, Department of Justice.
- Title 20, Chapter 2, Alabama Uniform Controlled Substances Act 1407, Legislature 1971,

### **Responsibilities**

## **Department of Environmental Health and Safety / (UABCSP)**

- The Department of Environmental Health and Safety (EH&S), previously known as the Department of Occupational Health and Safety (OH&S), must ensure Federal and State regulations as well as UABCSP policies and procedures pertaining to the acquisition, possession, use, disposition, and disposal of the controlled substances and precursor/list chemicals.

The Controlled Substances Program Administrator (designated EH&S staff member):

- Maintains delegated authority and responsibility under the MOA for overall coordination of this policy and the authority to issue Controlled Substances Use Authorizations (CSUA) to individual researchers under their departmental licenses.
- Responsible for obtaining and maintaining any powers of attorney required for program operation
- Responsible for maintaining all required official communications with DEA, including license renewals, reporting any diversion, loss, theft etc. and Forms 222, 41, 106 etc.

The Controlled Substances Program Manager (designated EH&S staff member):

- Approval, receipt, and delivery of controlled substances to authorized personnel
- Maintaining a central storage for receiving incoming shipments of controlled substances and controlling access to CS only to persons authorized to receive or have access to controlled substances.
- Coordinating background check for the individuals trying to get authorization for CS use
- Verification of authorized personnel to receive controlled substances, by signature and picture ID at the time they are picked up at the EH&S office.
- Review of online and paper usage logs to ensure compliance
- Disposal of controlled substances, biennial inventory completion, authorizing the storage location and performing annual announced and unannounced audits to measure compliance with these policies.
- Maintaining all the records and record retention

## **UAB Academic Departments/ Department Chairs**

DEA Registration/license for Controlled Substances in Schedules II-V shall be held in the name of the UAB Academic Departments per campus geographical location and activity.

Department Chair is responsible for:

- Collaborating with UABCSP to acquire and maintain departmental licenses
- Grant approval by signing on each Principal Investigator's CSUA application for one year and renew yearly if the work continues (Department chairs cannot authorize their own CSUA application).
- Ensuring the use of controlled substances is restricted to projects where the appropriate Department Chair has specifically authorized such use as declared on the Controlled Substances Use Authorization (CSUA) application form
- The Department Chair and the PIs are assigned joint responsibility for determining the need for and signing (authorizing) all requisitions for controlled substances.
- Ensure research activities under their departmental license is in compliance with Federal and State regulations as well as UABCSP policies and procedures pertaining to the acquisition, possession, use, disposition and disposal of the controlled substances and precursor/List chemicals. This includes ensuring that a current inventory of all controlled

substances under his/her control is maintained by the Principal Investigators on the web interface and on the Controlled Substances Log Sheet in a separate, secure book for periodic audit by EH&S and/or the DEA.

- Notifying EH&S when a PI authorized to experiment with controlled substances dies, intends to terminate employment, change of location or change in research activity and preparation of such reports as may be required.

### **Principal Investigators (PI)**

- Getting Controlled Substance Use Authorization Number (CSUA Number) by filling out the online application, filling out a Personnel Screening Data Sheet (PSDS), filling out a background check consent form and obtaining approval from the Departmental Chair.
- Complete and pass the controlled substances training [CS245: Using Controlled Substances in Research, Teaching, and Veterinary Care](#)
- Ensuring the use of controlled substances is restricted to projects where the appropriate Department Chair has specifically authorized such use as declared on the Controlled Substances Use Authorization (CSUA) application form.
- Identifying and authorizing laboratory personnel to handle controlled substances under his/her CSUA number (**Manage Authorized Personnel**). PI has the authority to assign different privileges to each authorized user. Privileges may include:
  - Secondary- this user has the same rights/access as the primary CSUA holder. Only one secondary contact may be assigned on the CSUA
  - Authorized User- this user has been trained and is allowed to use controlled substances for the purposes approved in the CSUA
  - Orders- only users assigned to order controlled substances will have orders approved for purchase
  - Receives- only users assigned to receive controlled substances will be allowed to pick up ordered controlled substances from OH&S
  - Key holder- only users who possess, or have access to a key to the controlled substance storage location
  - A current inventory of all controlled substances under his/her control is maintained,
- Maintain an online inventory and submit inventory forms upon notification by and at the request of EH&S,
- Keep the online authorized user list accurate
- Ensure all DEA regulations and UABCSP guidelines are being followed
- Amend and renew CSUA annually (**Amend, Renew, or Deactivate a CSUA**)
- Deactivate the CSUA when employment comes to an end, projects/needs changes or the CS is no longer needed

Sabbatical: A CSUA remains active during a PI's sabbatical leave when an acting PI is named in writing and approved by the department chair and Controlled Substances Program Administrator. Alternatively, the department chair may serve as the acting PI.

### **Authorized Personnel**

- Complete and pass the controlled substances training [CS245: Using Controlled Substances in Research, Teaching, and Veterinary Care](#)

- Complete the consent form for the DEA-required background check (Final approval of authorized personnel rests with the CS Program administrator, following verification of DEA-required background check and on-line submission of a PSDS. 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)
- Use CS exclusively for the purpose stated in the CSUA.
- Maintain a secure storage location for CS at all times.
- Return CS to the secure storage location when not in use.
- Record dispensation of any CS in the [usage log](#).
- Properly [dispose](#) of CS through EH&S
- Involve only in those activities authorized by the PI

## **Human Resources Department**

The [UAB Human Resources Department \(UABHR\)](#) assists in the processing of the DEA required background check for anyone coming into contact with controlled substances. Designated employees of UABHR are responsible for:

- Procuring the necessary background check consent forms
- Conducts inquiries for background screening as part of the authorization process for faculty, staff and students that handle or otherwise have access to controlled substances.
- Notifies the registrant and the EHS Office of individuals cleared for authorization.

## **Police Department**

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

## **Registration**

Authority to possess or dispense controlled substances for research, teaching, and veterinary care shall be requested through the UABCSP and will require prior approval before purchase. All projects involving the possession/use of controlled substances (Schedules II-V) shall be covered under an applicable Departmental Registration with DEA following approval of a UAB Controlled Substances Use Authorization (CSUA).

Registration for Controlled Substances in Schedules II-V shall be held in the name of the Center or academic department per geographical location and activity and coordinated by the Controlled Substances Program Administrator. 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 PI per geographical location and activity. This registration is not transferable, requires a more detailed description of the research project and higher security for storage. UABCSP is not involved in the management of Schedule I licenses.

## **Eligibility to Obtain a CSUA Number**

Only PIs are eligible to apply and obtain a CSUA number under a departmental DEA license. PIs must pass a background check and complete PSDS document to get the approval. Any employee or student approved by the PI, who passes a background check, completes training and submits a PSDS is eligible to become an authorized user.

## **Approval of Projects**

Use of controlled substances is restricted to projects where the appropriate Department Chair has specifically authorized such use as declared on the Controlled Substances Use Authorization (CSUA) application form. 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. Projects must be written to satisfy specific DEA requirements. An approved IACUC research protocol shall be sufficient project documentation for animal research projects.

## **Employee Screening**

Requirement under Title 21 CFR– Employee Screening- Non-Practitioner-  
21 CFR 1301.90 (Employee Screening Procedures)  
21 CFR 1301.93 (Sources of Information for Employee Checks)

DEA recommends that registrants should not employ as an agent or employee who has access to controlled substances:

1. Any person who has been convicted of a felony offense related to controlled substances
2. Any person who has been denied a DEA license
3. Any person who has had a DEA license revoked or
4. Any person who has surrendered a DEA license for cause

To fulfill this DEA requirement UAB has adopted an employee screening program as part of the authorization process for those individuals who wish to use controlled substances for approved activities under the direction of UABCSP. The screening program has two components:

1. Background check
2. Personal Screening Data Sheet (PSDS)

Everyone (e.g., technicians, PIs, students, research employees, other staff, etc.) intending to handle or otherwise have access to a controlled substances as part of campus research activities are required to complete PSDS (Appendix-1) and undergo background screening prior to getting authorization. The PSDS must be completed annually and the background check is required once in every 5 years.

## **Background check**

As part of the screening process, each employee seeking authorization to use or otherwise access controlled substances must complete and submit a consent form to UAB Human Resources to initiate a criminal background check and an inquiry with the DEA (Appendix-2). The process goes as follows:

1. UAB HR solicits and receives the completed background check consent from PIs and individual staff members that will require access controlled substances
  - By signing this consent form, individuals are authorizing the University to obtain consumer credit reports and/or investigative consumer reports.

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2. PI will provide an account to pay for the process for students
3. UAB HR conducts the background check process
  - The University and Employment Screening Service, LLC, d/b/a Global HR Research (“GHRR”), 2700 Corporate Drive, Suite 100, Birmingham, AL 35242 or any other company authorized by the University will contact any and all corporations, companies, entities, or organizations including, but not limited to:
    - Current and former employers;
    - Consumer reporting agencies;
    - Education institutions;
    - Law enforcement agencies;
    - City, state, county, federal courts and agencies;
    - Military services;
    - Drug Enforcement Administration (“DEA”) Field Division Offices;
    - Credentialing and Licensing organizations and entities.
  - The authorization allows any and all persons and entities contacted by the University to release information about background, including, but not limited to:
    - Information about my employment;
    - Address history;
    - Professional licenses and credentials;
    - Lawsuit history;
    - Social security number validation;
    - Education;
    - Consumer credit history;
    - Driving record;
    - Criminal record;
    - General public records’ history; and
    - Any other public or private information services.
4. Upon completion of the inquiries, UAB HR will notify EH&S the names of the employees who are eligible for authorization.
5. Adverse action

## **Personal Screening Data Sheet**

DEA Requirement: §1301.90 Employee screening procedures

It is the position of DEA that the obtaining of certain information is vital to fairly assess the likelihood of an employee committing a drug security breach. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive personal screening program:

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

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Question. 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.

An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

## **Purchasing**

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

## **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 Administrator

## **Training**

PIs planning to get CSUA authorization must take and pass [CS245: Using Controlled Substances in Research, Teaching, and Veterinary Care](#)

All individuals listed on the CSUA (authorized users) are also required to take and pass [CS245: Using Controlled Substances in Research, Teaching, and Veterinary Care](#)

In addition to the on line training, the Controlled Substances website

(<https://www.uab.edu/ohs/controlled-substances>) provides training in several areas by way of specific "Job Aids", such as how to order through Oracle, etc.

### **Training links:**

Controlled Substances Program Glossary

CS245: Using Controlled Substances in Research, Teaching, and Veterinary Care

How to Order CS through the Oracle Purchasing System

How to Manage Your Online CSUA Inventory

Training records of the PI and all individuals on the CSUA are required to be kept on file. A copy of the completed training certificate must be maintained in the CSUA Binder and presented to the proper authorities upon request.  
and sentence.

## **Ordering**

Before a lab can purchase CS, the PI must have an approved Controlled Substance Use Authorization (CSUA). PI may requisition only those substances, which have been authorized and

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approved on the CSUA. 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 Environmental Health and Safety (EH&S) for review/approval.

Approved requisitions will be ordered by EH&S from the vendor. Purchase Order Requisitions will need to be generated by the PI through iProcurement system. The link [Ordering CS](#) can be used to learn more about the process. Vendor information ([Catalog Numbers by Vendors](#)) and CON Numbers ([Controlled Substances Con Item Numbers](#)) are required to complete a purchase requisition.

**Departmental personnel cannot place orders directly with vendors.** All controlled substances ordered through UABCSP will be delivered to EH&S office directly from the vendor. EH&S will record the number of individual packages or containers received and date received in CSUA web application. EH&S will hold the controlled substance in a secured storage until picked up by the PI or the designee.

### **Allow time for delivery:**

It is important to for the PI to manage their inventory carefully and plan ahead. **There is no on-site stock of any CS with EH&S.** Controlled substances are obtained from suppliers, so plan to **order quantities sufficient for a 3-6 month period** to minimize expired waste and risk of theft.

A lead time of minimum of

- 3 weeks for Schedule II
- 10 days for Schedule III
- 20 days for Listed chemicals and precursors (if their hazard class requires shipment by ground transportation) is required if the ordered materials are in-stock with the vendor.

Follow the link [Ordering CS](#) to avoid delays in your purchase and ensure your order follows the proper approval path.

### **Pickup**

CS orders will be available for pickup once the primary lab contact receives notification e-mail from EH&S regarding the arrival of the material at EH&S office. The e-mail states where to pick up the order and the times available without an appointment. The person who picks up the order must have a UAB ID, a valid driver's license, and be listed as an authorized recipient on the CSUA. For security reasons it may be desirable to have a second individual accompany the person who is carrying the controlled substance (if there are many bottles picked up at one time) to its place of storage.

After receiving your order, return directly to the approved **secure storage** location and secure the shipment until it is needed. The receipt and the Usage Log Sheet(s) sent with the order should also be placed into the EH&S provided CSUA binder and the current inventory verified. Your electronic inventory will automatically update and show the drugs transferred to the approved storage location.

### **Storage**

PIs are responsible for providing and maintaining secure storage for their controlled substances by following the below guidelines:

#### **Storage Unit Requirements**

- Steel cabinets and drawers must be able to accommodate up to two Usage Log Binders if using both Schedule II and Schedule III-V drugs. This requires a steel cabinet with

- minimum size of 11" wide x 15" high x 6" deep
- **Padlocks and hinges** must have the mounting screws or bolts of the hasp inaccessible when the door is closed and the lock is fastened.
  - **Safes and steel cabinet equivalents** must be cemented or bolted to the floor or wall, or weigh more than 750 pounds.
  - **Storage units** must be secure enough to show forced entry.
  - **Drawers** must be inaccessible from the upper or lower drawers in the stack. Assign the top drawer of the stack to use as the storage facility, if possible
  - Store controlled substances according to schedule number:
    - **Schedule II:** Store in a safe or steel cabinet equivalent
    - **Schedule III-V:** Store in a locked drawer or cabinet that is inaccessible from above or below.
    - If your lab has Schedule II-V controlled substances, you must have a steel safe and both schedules can be stored inside one safe at two different shelves.
  - EH&S may conduct an inspection of proposed controlled substance storage locations prior to issuing a CSUA Number to an applicant. The storage site is also subject to periodic inspection by EH&S.

### Storage Restrictions

- Controlled substances must be stored in their own unique storage unit together with the EH&S provided CSUA binders. No other items can be stored along with CSs
- Shelves must separate schedule II and schedule III-V CSs if stored together in one safe
- Do not share controlled substances storage facilities with another PI
- Do not transfer controlled substances from its original container for storage purposes.
- Do not store other chemicals or supplies in a controlled substances storage unit

The link [Storage and Security of Controlled Substances](#) can provide more information on safe storage of CS.

### Security

#### Access Control

Restrict access only to authorized personnel on your Controlled Substances Use Authorization (CSUA) and follow these precautions:

- Keep storage key(s) in the physical custody of authorized personnel at all times. You can make multiple key copies, but assign them only to authorized personnel with “key holder” privileges.
- Do **not** store keys in a drawer or on the wall

#### Personnel changes

When authorized personnel leave their position in the lab:

- Change combinations or retrieve the individual's keys
- Document authorized personnel security changes in your Usage Log Binder
- Remove the authorized personnel by amending your CSUA through the website

## Moving or Closing Your Lab

Changes (repairs, modifications, or moves) to your CS storage site or installation must be approved by the CS Program before the site can be used to store CS inventory. Inventory can be temporarily stored at a secure EH&S facility during storage site repairs, modifications, or during the move

Relocation of CS during lab moves or closures is strictly regulated and must be approved by EH&S.

Notify EH&S with by emailing using this link [emailing us](#)

- Email at least 3 weeks before your intended move or lab closure.
  - Moving within UAB: wait for CS Program Manager [205-934-2487] to approve your new storage location prior to moving (Moving Services must not transport CS)
  - Moving off campus or closing the lab: Follow the steps described in this policy for the termination of CSUA

## Record Keeping and Controlled Substances Binder

Each PI that is issued a CSUA number will receive EH&S issued Controlled Substances Binder appropriate for the CS Schedules being used. If a PI has Schedule II-V drugs, that individual will be receiving 2 separate binders.

- One for Schedule II Controlled Substances
- One for Schedule III-V Controlled Substances

CSUA Binder is divided into labeled sections for maintaining the required legal documents pertaining to the CSUA.

- **CSUA Summary:** CSUA approval letter, listing of all authorized personnel and privileges assigned, training records.
- **Requisitions:** documents of purchase order requisitions through iProcurement.
- **Receipts:** all signed receipts for orders delivered to and received by PI or authorized personnel with “Receiver” privileges.
- **Usage Log Sheets:** paper Usage Logs for in stock containers and containers completely used up or returned to EH&S for disposal.
- **Disposal Sheets:** Signed destruction forms according to Schedule for containers returned to EH&S for disposal.
- **Biennial Inventory:** biennial inventory forms and documents.
- **Other Reports:** any supplemented documents

The Controlled Substance Binder must be immediately available at the time of an inspection or an audit. These binders must be kept in the same storage unit as the Controlled Substances under lock and key unless being used. Records must be kept at least for three years.

## Inventory Management and Usage Log

CS inventory and usage log are managed electronically through the CSUA Web application, [CSUA Web Application](#).

Controlled substance inventory is managed through the CSUA Web Application. Both paper Usage Logs and online Usage Logs must be maintained and kept up-to-date at all times. The

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number of controlled substances in the laboratory must equal the amount recorded on both the paper Usage Logs and online Usage Logs. The original documents must be retained for three years from the date of either completely used up or returned to EH&S for disposal. Refer to **Managing Your Controlled Substances Inventory**, a job aid developed to help the users to understand how to use the web application for the management of electronic usage log.

Paper Usage Logs are:

- Given to the authorized person receiving the controlled substance at the time of receipt.
- Are pre-printed with the container ID, expiration date, substance, schedule, strength, and initial amount.
- The paper Usage Logs are required to be stored in the EH&S provided CSUA Binder inside the approved storage cabinet along with the controlled substances when not being used.
- Each container in the physical inventory must have a paper Usage Log with matching container ID.
- The date a substance is completely used up and the personnel signature who disposed of the empty container must be recorded at the bottom of the paper Usage Log.
- Mark at the bottom of the paper Usage Log Sheet, either completely used or returned to EH&S for disposal. Retain the original of the log sheet and send a copy to the Controlled Substances Manager. These forms must be retained for three years from the date of either complete use or disposal.
- A copy of the paper Usage Log must be sent to the Controlled Substance Program Manager when a container is completely used up and discarded or returned to EH&S for destruction.
- Original paper Usage Log will be retained in the CSUA binder.

Usage is tracked on a per dose or use basis. Discrepancies in Usage Logs must be explained.

The authorized user must document:

- Date of use
- Amount dispensed
- Remaining balance after deducting syringe hub loss (0.1 ml per withdrawal)
- Name of the individual dispensing. Physical signature required on paper Usage Log. BlazerID is used to document individual on online Usage Log through the CSUA Web Application.
- Reason for use/animals/protocol etc. on the paper Usage Log.

### **Stock containers of controlled substances**

- Stock containers must have the original bar code placed on by the Controlled Substance Program at the time of order receipt from EH&S. Bar codes cannot be removed from original container.
- Bar code ID must match the Usage Log ID for stock containers.

### **Dilutions of controlled substance stock containers**

Diluted vials need their own individual paper usage logs and online usage logs. Paper usage logs can be printed from CSUA web application (**Blank Controlled Substances Usage Log Sheet**). Both paper Usage Logs and online Usage Logs must be maintained and kept up-to-date at all times.

- Dilution containers must be properly labelled with the dilution ID information. Dilution ID must match the Usage Log ID for dilution containers.

- The label must have the following information: 1) CSUA number, 2) substance name (substance abbreviations are acceptable), 3) concentration, 4) expiration date, and 5) dilution ID.
- The Log Sheets are required to be stored in the EH&S provided CS Binder inside the approved storage cabinet along with the controlled substances when not being used.
- A copy of the paper usage logs should be faxed/mailed to EH&S to 205-934-7487 upon complete use/expiration of each bottle. Dilution bottles will expire in a month.

You must log the amount you are physically using at all times in the Usage Log (paper copy and online) approved by the Controlled Substances Program. This means that the quantity of Controlled Substances in the laboratory must equal the quantity that is recorded on the Usage Log (paper copy and electronic). Both the forms must be kept up-to-date at all times.

## **Expiration**

- Expired controlled substances are not allowed for use in animal research according to IACUC and UAB ARP protocols.
- Dilutions expire on the 30<sup>th</sup> day following dilution of stock.
- Stock supplies are labelled with manufacture expiration date.

Federal law strictly regulates the disposal of controlled substances. As such, all expired controlled substances are returned to EH&S for disposal

Do not loan any Controlled Substances to another PI. Investigators should keep a 3 to 6 months' supply in inventory. If for some reason a PI is in emergency need of a controlled substance for an animal then contact one of the Animal Resources Veterinarians for assistance. They cannot transfer any Controlled Substance to the PI. However, they may be able to relieve the emergency situation. The EH&S Controlled Substances Program doesn't keep any Controlled Substances on site.

Below are some reference materials/Job Aids to assist you in managing your inventory/usage log:

- [Managing Your Controlled Substances Inventory](#)
- [Web Usage Log, Web Dilution Log, and Disposal Requests](#)
- [Blank Controlled Substances Usage Log Sheet](#)
- [Sample Completed Log Sheets for Stock Bottle](#)
- [Sample Dilution Log](#)

## **Biennial Inventory**

All PIs are required by DEA regulation to submit a Controlled Substances inventory once every two years. When your biennial inventory is due, Controlled Substances Program Manager will send you an e-mail notification with a specific date, time and instructions for completing the process. The only persons authorized to conduct the inventory are Principal Investigators, secondary, and those listed on the CSUA. Other individuals are not authorized to carry out the inventory. If the biennial inventory is not completed at the specified time, the CSUA will be suspended, and any orders will be stopped. Your inventory status must be declared even if there are zero Controlled Substances in stock. As long as you have an approved CSUA on file, you must participate in the biennial inventory process.

For each substance in stock, the inventory agent must list the name and dose form of the drug, the total quantity of the substance in metric units or the total number in finished dose form, and the date the drug was purchased by the researcher or faculty member. The total amount of each substance shown as the perpetual balance on its usage log is to be listed next to the inventoried amount. If there are any discrepancies, those must be explained. A Biennial inventory can be printed from the CSUA Web application.

PIs are also required to submit an annual inventory to EH&S. This inventory is conducted to verify the perpetual balances maintained on the controlled substances usage log for individual drugs.

## **Loss or Breakage**

Any loss, breakage or misplacement of the bottle must be reported to the Controlled Substance Program immediately. The report of the breakage of a bottle or lose of the material due to a spill must be witnessed, initialed, and dated by at least two lab members and certified by the PI.

**Missing or unaccounted controlled substances: Notify EH&S immediately at 205-934-2487**

## **Discrepancies**

Any loss of drugs, theft, misuse or discrepancies in recordkeeping is to be reported to EH&S immediately upon their discovery. Based on the details and amount involved in reported losses/theft/misuse, EH&S may need to file a DEA Form 106 (loss Form) or submit an incident report. The UAB Police will investigate all suspected thefts or misuse of controlled substances and the UAB Controlled Substances Program Administrator shall notify the DEA of all thefts and misuse of controlled substances within one business day of discovery of the incident.

Discrepancies in Usage Log Forms or disposal records may trigger an internal investigation by campus authorities. The University (through police department and EH&S) also reserves the right to impound drugs and records pertinent to an investigation into inventory or recordkeeping discrepancies.

## **Disposal**

Federal law strictly regulates the disposal of controlled substances. Unwanted or expired controlled substances cannot be discarded in the regular trash. Return of all unwanted or expired controlled substances to EH&S for disposal is required. The only exception to this rule is that empty controlled substances bottles or vials can be discarded in the municipal trash. Containers must be verified completely empty and have the label defaced before discarding. You should request for a Controlled Substance disposal when:

- A project closes or is terminated and a Controlled Substance is still in supply
- A CSUA expires and a renewal has not been submitted
- The PI determines a Controlled Substance is no longer required
- The PI terminates employment
- The Controlled Substance expires (dilution samples expire on the 30<sup>th</sup> day following dilution and all unused expired dilution samples must be returned to EH&S for destruction)

Requests for disposals are made with the Controlled Substance Program Manager. Meetings are available by appointment only. The following are brought to the appointment:

- Item(s) bagged for disposal

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- Completed Destruction Forms according to controlled substance Schedule. Destruction Forms indicate the transfer of material from the CSUA holder to EH&S.
- Copies of the Usage Log(s). Scans of the Usage Log(s) can also be emailed to the Controlled Substance Program Manager.

If you are reordering the items, you may bring the expired items to EH&S when you are picking up your new orders at the EH&S office. Please bring a copy of the corresponding usage log sheet along with the CS. EH&S will provide documentation showing the transfer of material from the CSUA holder to EH&S and a copy of this document must be kept in the Controlled Substance folder inside the storage. The return of the material for disposal must be documented on the usage log too. This log must be retained for 3 years from the date you indicated its disposal return to the Controlled Substance Program Manager.

## **Audits and Inspections**

All records regarding the use of controlled substances and precursor/list chemicals under UABCSP are subject to review by the UABCSP and investigators from the U.S. Drug Enforcement Agency. Controlled Substance Program Administrator or its designee is authorized to make unannounced and announced inspections and audits on regular basis. Inspections and audit scheduled (monthly, quarterly or annually based on frequency of dispense) to ensure:

- Complete and accurate records and inventory for accountability
- Maintenance of secured storage and
- Non-pharmaceutical grade or expired drugs are not used in animal research unless conditional use has been approved by the IACUC.

All records and drugs must be immediately available for review. Representatives of state and federal agencies may also wish to inspect your operations

At the time of inspection, the following items are subject to evaluation:

- Proper storage and security arrangements
- Accuracy and completeness of online and paper usage logs
- All users are authorized by EH&S and properly trained
- Deficiencies found during previous inspections are corrected
- Disposal logs
- Online inventory matches with the amount in the storage cabinet

Departments/individual researchers are encouraged to perform periodic self-evaluation surveys.

## **Amend, Renew or Deactivate a CSUA**

### **Amending CSUA**

Amendments and renewal of a CSUA can be accomplished using the [CSUA Web Application](#).

Amendments to a CSUA

- Only the PI or the authorized user with secondary privileges can make amendments to the CSUA.
- Amendments can be made on personnel, protocols, and storage locations.
- Approval by the Controlled Substance Program Manager may be required for amendments. PI or authorized personnel are responsible for notifying the Controlled Substance Program Manager for amendment approvals.

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## Renewal of CSUA

The CSUA must be renewed annually. CSUA holders will receive an automatically generated renewal notification with instructions from the CS Program 60 days prior to the expected CSUA expiration date. Renewal reminders will be sent to both PI and the secondary contact on the CSUA, but only the PI can renew the CSUA. The renewal will extend the expiration date by one year. It is important to understand that the Federal Law prohibits you from handling controlled substances or List 1 chemicals once the CSUA authorization has expired. If the CSUA application is not renewed before the expiration date, your CSUA will be revoked and all the controlled substances in your possession will be confiscated.

In case of a PI's sabbatical, a CSUA may be extended for up to 3 months beyond the one year renewal if, due to extenuating circumstances, the PI is not available (e.g., temporarily out of the country). The renewal shall be processed at the PI's first opportunity upon returning to the project.

Yearly renewal of a CSUA consists of:

- PI logging on to [CSUA Web Application](#)
  - Review current CS needs
  - Update protocols
  - Update CSUA authorized user's information and PSDSs
  - Reconcile physical inventory on-hand with CS Usage logs (both online and paper copy) and update online inventory
  - Renew PSDS for the PI
- Department chair review and approval of the CSUA
- Approval by EH&S

A confirmation email of CSUA renewal will send to the PI once the renewal process is complete.

## Deactivate/Terminate

The deactivation and termination of a CSUA applies when a project closes, PI terminates employment at UAB or the PI no longer requires authorization to possess, purchase, or store controlled substances for research purposes at UAB.

Deactivation or termination can be initiated by contacting the Controlled Substances Program Manager. The Controlled Substance Program Manager will schedule a convenient time to meet with the CSUA account holder or authorized user with secondary privileges to return any remaining controlled substances to EH&S and to complete all required paperwork.

## Diversion control

Diversion is the act of using a Controlled Substance obtained legitimately for illegitimate purposes. It is the responsibility of all users to report any suspicious activity to the Controlled Substance Program Manager as soon as possible. You may remain anonymous if you wish. If you wish to report information anonymously, you can call EH&S at 205-934-2487 and give information without revealing your identity.

Sharing Controlled Substances within facilities or with other facilities, including nearby laboratories, is NOT allowed. You must use only the Controlled Substances bought with your Controlled Substance Authorization Number (CSUA), and only for the purpose described in your

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CSUA. If you are collaborating with another researcher, he/she is NOT allowed to use your Controlled Substances unless he/she is an authorized user under your CSUA number. The UAB Police Department will investigate all suspected thefts or misuse of controlled substances and the UAB Controlled Substances Program Administrator shall notify the DEA of all thefts and misuse of controlled substances within one business day of the discovery of the incident.

### **Penalties for Non-Compliance**

Possible penalties by DEA for violating regulations include imposition of fines, and imprisonment of those responsible.

Possible penalties by UAB for violations of this policy include notifying the Department Chair and Dean, CSUA revocation and repossession of all controlled substances in the inventory, suspension of purchase requisition authorization, and suspension or termination of Authorized Personnel privileges.

This procedure is not to be construed as a summary of all regulations that may be pertinent to handling of controlled substances and precursor/list chemicals. Individuals who bear responsibility in this area are encouraged to read for themselves the Federal and State regulations that govern use of these materials and to be aware of the fines and penalties associated with their misuse (**Title 21 Code of Federal Regulations, Part 1300-END**, [http://www.ecfr.gov/cgi-bin/textidx?SID=5aef6b5a4a42200992c0478a96fc7ee6&mc=true&tpl=/ecfrbrowse/Title21/21cfrv9\\_02.tpl#0](http://www.ecfr.gov/cgi-bin/textidx?SID=5aef6b5a4a42200992c0478a96fc7ee6&mc=true&tpl=/ecfrbrowse/Title21/21cfrv9_02.tpl#0)).

### **Purchase and management of List I chemicals**

#### **Getting approval**

Laboratories planning to use List I chemicals must get approval from EH&S before ordering the chemical.

### **Appendix-1**

#### **Personnel Screening Data Sheet – UAB Controlled Substance Program**

##### **Environmental Health & Safety, UAB**

The following is to be filled out by all proposed handlers of controlled substances (“CS”) (21CFR1301.90).

#### APPLICANT INFORMATION:

Name: \_\_\_\_\_ Date of Birth \_\_\_\_\_

\_\_\_\_\_

Al. Drivers License \_\_\_\_\_ Employee/Student/ID: \_\_\_\_\_

\_\_\_\_\_

Home Address \_\_\_\_\_

\_\_\_\_\_

Lab/Office location: \_\_\_\_\_ Phone: \_\_\_\_\_

\_\_\_\_\_

E-mail address: \_\_\_\_\_ CSUA # \_\_\_\_\_

\_\_\_\_\_

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As outlined in 21 C.F.R. 1301.90, it is the position of the Drug Enforcement Administration (“DEA”) that obtaining certain information is vital to fairly assess the likelihood of an employee committing a drug security breach. The DEA indicates that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. Please respond to the following questions:

Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any 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 on additional page.

Yes  No

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 on an additional page.

Yes  No

Have you ever surrendered a controlled substance registration for cause or had a controlled substance registration revoked, suspended, or denied? “For cause” means surrender in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of your handling of controlled substances.

Yes  No

I understand that I have an obligation to inform the Controlled Substances Program Manager if there is a change in my answers to any of the above questions. I understand that the above information may be verified with a background check, and I have signed the Background Check Acknowledgment and Authorization Form. I understand that if I have provided any false information, or omitted to provide pertinent information to UAB, or if I misuse controlled substances during my employment with UAB, my position with UAB may be jeopardized and I may be subject to disciplinary action, up to and including termination. I understand that information provided by me on this form or obtained by UAB as a result of any inquiries it makes will not necessarily preclude me from utilizing controlled substances in non-human research at UAB, but will be considered as part of the overall evaluation by UAB of my qualifications in the application. I also understand that any information provided by me on this form or obtained by UAB as a result of any inquiries will remain confidential.

I understand that as a UAB employee I will be expected to comply with UAB’s policies. UAB requires an employee who has knowledge of drug diversion from UAB by a fellow employee to report such information to the Controlled Substances Program manager who will inform the appropriate officials and initiate an investigation of the allegations. UAB 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.

Controlled Substance Handler’s Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Controlled Substances Program, EH&S •• Phone: 205-934-2487

## Appendix-2

### THE UNIVERSITY OF ALABAMA AT BIRMINGHAM BACKGROUND CHECK ACKNOWLEDGEMENT AND AUTHORIZATION

Reviewed on 4/10/23

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As a condition for my participation in the University of Alabama at Birmingham (“UAB”) Controlled Substances Program (“UAB CSP”), I understand that the University will conduct a background check about me for its use in determining whether I can utilize controlled substances in non-human research at UAB.

By signing this Authorization, I hereby authorize the University to obtain consumer credit reports and/or investigative consumer reports about me. I understand and acknowledge that this Authorization allows the University and Employment Screening Service, LLC, d/b/a Global HR Research (“GHRR”), 2700 Corporate Drive, Suite 100, Birmingham, AL 35242 or any other company authorized by the University, to contact any and all corporations, companies, entities, or organizations including, but not limited to:

- My current and former employers;
- Consumer reporting agencies;
- Education institutions;
- Law enforcement agencies;
- City, state, county, federal courts and agencies;
- Military services;
- Drug Enforcement Administration (“DEA”) Field Division Offices;
- Credentialing and Licensing organizations and entities.

I authorize any and all persons and entities contacted to release information about my background, including, but not limited to:

- Information about my employment;
- Address history;
- Professional licenses and credentials;
- Lawsuit history;
- Social security number validation;
- Education;
- Consumer credit history;
- Driving record;
- Criminal record;
- General public records’ history; and
- Any other public or private information services.

I understand that before taking any adverse action based in whole or in part on the report, the University shall provide me a copy of the report and a description in writing of my rights under the Fair Credit Reporting Act (FCRA). The Consumer Financial Protection Bureau’s “Summary of Your Rights under the Fair Credit Reporting Act” is available in [English and Spanish](#). You may also contact UAB Human Resources to request a copy of the report.

**FCRA AUTHORIZATION FORM**

Name: \_\_\_\_\_ Former/Other Names Used: \_\_\_\_\_  
SSN: \_\_\_\_\_ Driver’s License Number and State: \_\_\_\_\_  
Name As It Appears on License: \_\_\_\_\_  
Sex: \_\_\_\_\_ Race: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
Phone Number: \_\_\_\_\_ Email Address: \_\_\_\_\_  
Previous DEA license number if any: \_\_\_\_\_

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**Please Provide All Addresses Where You Have Lived for the Past Seven Years. Use the Back of this Form if You Need More Room.**

Current Address:

Full Street Address: \_\_\_\_\_ Apt. #: \_\_\_\_\_  
City/State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Date Moved In: \_\_\_\_\_

Former Address:

Full Street Address: \_\_\_\_\_ Apt. #: \_\_\_\_\_  
City/State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Date Moved In: \_\_\_\_\_

Former Address:

Full Street Address: \_\_\_\_\_ Apt. #: \_\_\_\_\_  
City/State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Date Moved In: \_\_\_\_\_

Former Address:

Full Street Address: \_\_\_\_\_ Apt. #: \_\_\_\_\_  
City/State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Date Moved In: \_\_\_\_\_

I represent to the best of my knowledge that all information provided above is accurate, true and correct, and that I fully understand the terms of this Authorization. I have read and comprehend this form and hereby authorize any person, company, or other entity contacted by the University of Alabama at Birmingham to provide the information stated above. If I am approved as a participant in the UAB CSP, this Authorization shall remain in effect for the length of my participation. I agree that a fax, photocopy or electronic copy of this authorization with my signature will be accepted with the same authority as the original.

Signature: \_\_\_\_\_ Print Name: \_\_\_\_\_

## References

- <http://www.deadiversion.usdoj.gov>
- <https://www.ecfr.gov/current/title-21/chapter-II>