

## What is a Controlled Substance?

Controlled substances are drugs or chemicals whose manufacture, and use are regulated by Federal and State Agencies. Controlled substances include illegal drugs, prescription medications, or chemicals used for manufacturing. UAB currently maintains a Memorandum of Agreement (MOA) with the [Drug Enforcement Administration \(DEA\)](#). This MOA governs the use of controlled substances for teaching purposes, veterinary care, and all non-human research. If you have questions, contact the UAB Controlled Substances Program at (205) 934-2487.

## Determining the Nature of a Substance

The following are important terms to understand and how to determine if a substance is considered a controlled substance.

- **Controlled Substances:** These are any substances considered psychotropic drugs or precursors regulated under the Federal Controlled Substances Act and the Alabama Uniform Controlled Substances Act.
- **Listed Chemicals:** These are chemicals used in the manufacturing of controlled substances.
- **Precursor Chemicals:** There are chemicals used in the illegal manufacture of narcotic drugs or psychoactive substances and also known as scheduled substances or drug precursors.

## What is a CSUA Number?

Principal Investigator (PI's is the Principal Investigator listed on the grant) must obtain a Controlled Substances Use Authorization (CSUA) Number to possess and use controlled substances for teaching, veterinary care, or non-human research at UAB. The authorization contains specific information about how your laboratory manages any controlled substances.



The UAB OH&S Controlled Substances Program is not responsible for administering controlled substances intended for research in human trials.

## CSUA Application

A CSUA Application:

- Requires approval from your Department Chair and the UAB Controlled Substances Program Manager.
- Must be renewed and approved annually.
- Can only be applied for, modified, or renewed by a PI. However, OH&S must review and approve modifications before implementation.
- Requires training to be completed before applying.

### *Applying*

As a PI applying for a CSUA, you must:

1. Describe the reasoning behind the requested controlled substance for an approved IACUC Protocol or *In-Vitro* Protocol.
2. Describe your storing and security measures for any controlled substances.
3. Have a background check on file or obtaining one with UAB Human Resources.
4. List and assign privileges to your Authorized Users. The CSUA Web Application has the following levels of access.
  - a. **Primary Contact:** The PI is the primary contact and has full privileges to the CSUA Web Application and Controlled Substance Inventory.
  - b. **Secondary Contact:** This user has the same rights, and access as the primary contact and only one secondary contact is assigned per CSUA.
  - c. **Authorized User:** This is someone who is trained and allowed to use controlled substances for the purposes approved by the CSUA.
  - d. **Order Materials:** Only approved users may place orders for controlled substances.
  - e. **Receive Materials:** Only the users assigned to receive controlled substances are allowed to pick up ordered materials from the UAB Controlled Substances Program Manager.
  - f. **Key Holder:** A key holder is a user who possesses and has access to the controlled substances storage by a key or combination number.

# UAB Controlled Substances Program Guidelines for PI's

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## *Amending*

Once logged in the CSUA Web Application, you can modify anything on a CSUA (except your inventory).

To change a CSUA:

1. Open the CSUA Web Application
2. Selecting the Protocols Tab allows you to enter a new protocol, delete an old one, or add new drugs
3. Selecting the Personnel Tab enables you to change any listed Authorized User and privileges

## *Renewing*

A PI should renew their CSUA once a year. For the annual renewal, you will be sent a reminder that your CSUA is about to expire and you should check for any changes (e.g., adding protocols, deleting personnel, etc.). If there are no changes, renew your number by selecting the renew button appearing on the CSUA dashboard. For security purposes, only the PI can renew the CSUA. If the CSUA is not renewed before the renewal date, the CSUA is suspended, and all orders are stopped.

## *Terminating*

A CSUA is terminated when a PI no longer needs authorization to possess, purchase, or store controlled substances for research purposes at UAB. If leaving UAB, a CSUA holder must terminate their CSUA.

To terminate a CSUA, contact the UAB Controlled Substances Program Manager at (205) 934-2487. Return all controlled substances and paper usage logs to OH&S for disposal. There can be no remaining controlled substances items in your inventory. Once this is complete, the UAB Controlled Substances Manager sends you additional information about terminating your CSUA.

## **Additional Authorizations and Guidelines**

### *Project-Specific DEA Registration*

If you are using [Schedule I Substances](#) or if your research requires manufacturing controlled substances, you must obtain a license directly from the DEA. The UAB Controlled Substances Program doesn't cover Schedule I Drugs. If either of these examples applies to you, contact the UAB Controlled Substances Manager at (205) 934-2487.

# UAB Controlled Substances Program Guidelines for PI's

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## *Animal Use Protocol*

If your animal research involves controlled substances, this requires an Animal Use Protocol Approval and Oversight by the [Institutional Animal Care and Use Committee \(IACUC\)](#). If you have questions, contact the IACUC office at (205) 934-7692.

## *Personnel Screening Data Sheet (PSDS)*

A PSDS is a document required by the DEA to be submitted for each person listed on a CSUA as an Authorized User. The PSDS is submitted by the CSUA Web Application and appears on the login page (the first time you log in). The PSDS must be renewed annually and if not renewed the access to the CSUA Web Application is denied. Anyone can check their approval status by logging into the CSUA Web Application.

## Responsibilities

### PI's and Authorized User's

1. Complete a Personnel Screening Data Sheet (PSDS)
2. Consent to having a background check on file with UAB
3. Pass the [Using Controlled Substances in Research, Teaching, and Veterinary Care at UAB \(AU UA\)](#) Training Course
4. Maintain an accurate inventory, on-site log binder, and online log
5. Use controlled substances exclusively for the purpose stated in the CSUA
6. Maintain a secure storage location for controlled substances at all times
7. Dispose of controlled substances through OH&S

A CSUA remains active during a PI's sabbatical leave when a Secondary is named in writing. The Secondary has to be approved by the Department Chair, and UAB Controlled Substances Manager. Final approval of an Authorized User rests with the UAB Controlled Substances Program Manager.

# UAB Controlled Substances Program Guidelines for PI's

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## Department Chair

Department Chairs should notify OH&S when a PI terminates or intends to terminate employment, if any misappropriation or diversion of controlled substances occurs, and approve or reject a PI for a CSUA.

## Ordering

Before a lab purchases controlled substances, the Principal Investigator (PI) must have an approved Controlled Substances Use Authorization (CSUA) Number. Only those substances authorized and approved on the PI's Animal Protocol or Grant may be requisitioned.

PI's generate Purchase Order Requisitions through the Oracle Purchase Order System. All orders entered for controlled substances at UAB for research, teaching, or veterinary care are routed through workflow to Occupational Health and Safety (OH&S) and placed with the vendor by OH&S.



If there is a vendor or controlled substance you need but it is not on the list, contact the UAB Controlled Substances Program Manager at (205) 934-2487.

- [How to Order Through iProcurement](#)
- [Controlled Substances Con Item Numbers](#)
- [Catalog Numbers by Vendors](#)

## Importing, Exporting, and Transferring

Importing, exporting, shipping, relocating, passing down, sharing, handing over, or removing controlled substances are not allowed at UAB. Do not loan any controlled substances to another PI. Investigators should keep a three to six month supply in their inventory. If you have to transfer your storage or inventory to another area, contact the UAB Controlled Substances Program Manager at (205) 934-2487. The Program Manager will guide you through the relocation process.



You are only approved to use or possess controlled substances for the purposes described in your CSUA at the location specified in the CSUA Application. Do not transfer controlled substances from the original container for storage purposes. Keep it in the original bottle!

## Inventory

You are required to conduct an inventory of your controlled substances every year and a biennial inventory once in two years. When your biennial inventory is due, the UAB Controlled Substances Program Manager will send you an e-mail notification with a specific date, time, and instructions for completing the form. If the inventory is not received, the CSUA is suspended, and all orders are stopped. Declare your inventory status even if there are no controlled substances in your stock. To manage your inventory:



As long as you have an approved CSUA on file, you must participate in the inventory process.

1. Log into the CSUA Web Application
2. Enter your BlazerID and strong password. Once you see the CSUA Dashboard, you can check and manage your inventory.
3. The Inventory Tab is used for verifying the number of controlled substances on hand and matching the amount on the Usage Logs.
4. The Stock Materials Tab lists both the controlled substance ordered, dilutions, and container identification numbers. Every bottle containing controlled substances is required to have a container identification number.
5. The Dispensing or Use Tab is used to generate dilutions, recording administrations, documenting and witnessing waste.

## Controlled Substance Binder

Each PI issued a CSUA, receives a binder from OH&S divided into labeled sections for maintaining the required legal documents for using controlled substances at UAB. The required labeled sections are:

1. CSUA Approval (listing all Authorized Users)
2. Usage Log Forms
3. Biennial Inventory
4. All Disposal or Return Documents
5. Training Record
6. Supplemented Documents

# UAB Controlled Substances Program Guidelines for PI's

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## Usage Logs

### *Paper and Online*

The UAB Controlled Substances Program provides a Usage Log Sheet for each controlled substance container when the item is initially picked up. The sheet is pre-printed with the:

- PI's Name and CSUA Number
- Drug Name
- Unique Container Identification Number
- Concentration
- Starting Amount
- Date

Usage Logs are required to be stored inside the binder provided by OH&S inside the approved storage cabinet with the controlled substances when not being used.

Once you finish using a controlled substance bottle, the substance expires, or you return it to OH&S. Record the date and disposition at the bottom of the paper Usage Log Sheet. Retain the original Usage Log Sheet for three years from the date of either complete use or disposal. Send OH&S a copy of the Usage Log Sheet.

Each container is labeled with a barcode for ease of inventory documentation. You must log the amount you are physically using at all times in the Usage Log approved by the UAB Controlled Substances Program. Both of the forms must be kept up-to-date at all times.

## Empty or Broken Vials

1. If a controlled substance container breaks or the substance is spilled, enter the nature and amount of loss on the log sheet. The individual responsible for the loss must initial the entry and have it witnessed by another authorized user and PI.
2. Send an electronic copy to the UAB Controlled Substance Program Manager.
3. Retain log sheets in your binder for a minimum of three years.

## Discrepancies

Discrepancies on a Usage Log Sheet or disposal record may trigger an internal investigation by campus authorities. Make sure to report any problems immediately to the UAB Controlled Substances Manager. This is especially important since the Federal Law requires that the UAB Controlled Substances Manager notify the DEA within 24 hours.

## Storage

The PI is responsible for providing and maintaining secure storage for their controlled substances meeting this criterion:

- Keeping storage key(s) in the physical custody of personnel authorized to have access to keys at all times.
- Never storing keys in a drawer or on the wall.
- Storing controlled substances according to their schedule number. Separating shelves for Schedule II and Schedule III-V (if required to be stored together in one safe).
- Storing Schedule III-V in a locked drawer or cabinet that is inaccessible from above or below.
- Storing controlled substances in a unique storage unit, together with the Controlled Substances Binder provided by OH&S.
- Providing steel cabinets and drawers accommodating up to two Controlled Substances Binders if using Schedule II and Schedule III-V. Steel cabinets and drawers must be able to accommodate up to two Controlled Substances Binders if using Schedule II and Schedule III-V. Contact OH&S at (205) 934-2487 before purchasing a storage unit to confirm it meets all DEA and OH&S requirements.
- Never use wheeled storage units are not allowed.
- Never storing anything else with your controlled substances.
- Never sharing controlled substances storage facilities. You must have your unique storage unit for your drugs. If you are in a lab with shared space, each researcher must maintain their own, separate CSUA numbers and storage units.
- Cementing or bolting safes and steel cabinets to the floor wall, that weigh more than 750 pounds.
- Storage units must be secure enough to show forced entry.

## Disposal

You should request disposal for controlled substances when:

- A project closes, terminates, or expires
- The PI determines a controlled substance is no longer required
- The PI terminates employment
- The controlled substance expires



It is unlawful for anyone to dispose of controlled substances without DEA approval and submitting of the proper form. Federal Law strictly regulates the disposal of controlled substances!

Disposal is requested through the CSUA Web Application. Return all unwanted controlled substances to Occupational Health & Safety (OH&S) for disposal. Expired and unwanted controlled substances cannot be thrown away in the regular trash. The return of the material for disposal must be documented on the Usage Log too. Retain your usage log for three years from the date you indicated upon returning the substance the UAB Controlled Substances Program manager.

The only exception to this rule is that empty controlled substance bottles or vials can be discarded at your facility. Make sure to open the container ensuring it is empty, deface the label, and discard in the regular trash.

If you have questions about controlled substances disposal, contact the UAB Controlled Substances Program Manager at (205) 934-2487.

## Lab Reviews

Lab Reviews of your work areas are conducted on a regular basis to prevent diversion, loss, and assess your security measures. You will be asked to make available all your documentation and grant access to all of your controlled substances. You are also advised to perform a self-assessment of your work area to ensure you comply.