

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

Introduction

Welcome to the Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245). This training is **required** for anyone that will be conducting research with Controlled Substances. If you are working with **ANY** Scheduled Substances in your research area, you **MUST** complete this course.

You are **required** to take this training by the:

- United States Department of Justice (DOJ)
- Drug Enforcement Administration (DEA)
- UAB's Occupational Health and Safety (OH&S) Controlled Substances Program



If you have any questions about Controlled Substances, please feel free to contact UAB's Occupational Health and Safety at 205-934-2487.

Objectives

At the conclusion, participants should be able to:

1. Define Controlled Substances and classify their respective Schedules.
2. Implement the proper procedures when it comes to documentation of Controlled Substance use.
3. Know how the DEA regulates Controlled Substances at UAB.
4. Know that the sharing and diversion of Controlled Substances are not allowed.
5. Know how to complete the usage log and proper disposal process of Controlled Substances.

Federal Drug Enforcement Administration (DEA)

The Federal Drug Enforcement Administration (DEA) is authorized to prevent, detect, and investigate the administration of legally manufactured Controlled Substances. The DEA also determines which substances are classified as Controlled Substances (CS).

DEA, UAB, and You

UAB has a Memorandum of Understanding (MOU) with the DEA that authorizes OH&S to issue Controlled Substance Use Authorization Numbers (CSUA) to individual researchers to use Controlled Substances for research, teaching, and/or veterinary care. The Department of Occupational Health and Safety (OH&S) is the administrator of the Controlled Substances Program and required by the DEA to monitor the use and management of Controlled Substances in all non-hospital (non-clinical) areas.



Authorization for Schedule I Substances is granted **directly** by the **DEA**.
Authorizations for Schedule II-V are granted from the **UAB Controlled Substances Program**.

Responsibilities & Expectations

You should:

1. Get authorization from OH&S before ordering or using Controlled Substances for research
2. Use only those Controlled Substances that are authorized and purchased through the Controlled Substances Program
3. Adhere to the proper storage, record keeping, and disposal requirements

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

Controlled Substances

UAB currently maintains Federal Drug Enforcement Administration (DEA) registrations governing the use of Controlled Substances for teaching purposes, veterinary care, and **all non-human research**. Research using Controlled Substances in human trials are not administered through this program.

Defined

The DEA defines Controlled Substances as:

- Chemicals whose manufacture, possession, and use will be regulated by the DEA
- Addictive substances that have medicinal properties
- Illegal drugs as well as prescription medicines
- Mind-altering substances

The DEA also states that Controlled Substances can be used as or in:

- Analgesics (pain control)
- Anesthetics and Sedation

Non-Controlled Substances

The DEA states that caffeine, tobacco products (any form), and alcohol (any form) are **NOT** considered Controlled Substances.

Schedules

Controlled Substances are classified into Schedules I through V. The DEA assigns substances their schedules based on a variety of factors.

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

The criteria includes the:

- Abuse potential
- Pharmacological effect
- Medical value
- Likelihood of physical or psychological dependence
- Current pattern of abuse and other risk factors

Schedules

- Schedule I: Heroin, LSD, and Ecstasy.
- Schedule II: Methamphetamine, Cocaine, Oxycodone (Percocet)
- Schedule III: Hydrocodone, Anabolic Steroid, Tylenol with Codeine
- Schedule IV: Choral Hydrate, Barbitol
- Schedule V: Donnagel with Paregoric, Robitussin with Codeine, Opium preparations.

Store the Schedule I-II Controlled Substances and the matching folder together on one shelf, and the Schedule III-V Controlled Substances with the matching folder together in a different shelf. .

Labeling

A Controlled Substance's container must be labeled with the letter "C" and the Roman numeral I through V to indicate the schedule.

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

Sharing

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 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.

Diversion

Diversion is the act of using a Controlled Substance obtained legitimately for illegitimate purposes. It is your responsibility 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 OH&S at 205-934-2487 and give information without revealing your identity.

Documentation

Record Keeping

Record keeping is an important aspect of the Controlled Substances Program. You **MUST HAVE** documentation of **activities, personnel, and equipment**. It is required that each laboratory complies with the terms of the OH&S Controlled Substance Use Authorization Program.

Biennial Inventory

A Controlled Substances inventory is managed through the CSUA Web Application. When your biennial inventory is due, Controlled Substances Program Manager will send you an e-mail notification with a specific date and instructions for completing the process. If the biennial inventory is not received after two attempts, the CSUA will be suspended, and any orders will be stopped.

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

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.

Manage your CS inventory with the CSUA Web Application

1. Log into the [Controlled Substances Use Authorization \(CSUA\) Web Application](#) Enter your Blazer ID and strong password. Once you see the **CSUA Dashboard**, you can check and manage your inventory from here.
2. The **Inventory** summary is the last tab on the right. It tracks the amount of each controlled substance on hand and the number of containers based on dilutions made, administrations recorded, waste returned, etc. The Inventory tab is used for verifying that the amount of controlled substance on hand matches the amount on the written dispensing logs. This data is also used to submit the DEA required biennial inventory.
3. The **Stock Materials** tab lists both the controlled substance ordered and any dilutions made from the Controlled Substance along with the container ID. The container ID must be on every bottle and must match the one on the dispensing log. After entering a new dilution into the system select this tab to get the new container ID. The new dilution and ID will be in **bold letters**.
4. The **Dispensing/Use** tab is used to generate new container IDs for dilution bottles, for recording administrations, for documenting and witnessing waste and for requesting a Controlled Substance waste pickup.

Controlled Substances Binder

You are required to maintain **ALL** documentation in OH&S issued Controlled Substances binders. Each PI that is issued a CSUA will receive Controlled Substance binder appropriate for the CS Schedules being used. Each binder is divided into labeled sections for maintaining the required legal documents for using Controlled Substances at UAB. If you have Schedules II-V, you are required to have separate binders:

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

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

In your Controlled Substances Binder, you should keep a variety of records:

1. CSUA approval (listing **ALL** Authorized Personnel)
2. Usage Log Forms (including copies where the Controlled Substances was used up or returned to the Controlled Substances Program Manager for Disposal)
3. Biennial Inventory
4. All disposal or return documents
5. Training records
6. Supplemented documents
7. Background check for anyone associated on a CSUA

The Controlled Substance Binder must be immediately available at the time of an inspection or an audit. Each binder must be kept with the Controlled Substances associated with it under lock and key unless being used.

These binders must be kept in the same storage unit as the Controlled Substances.

Explanation of How to do online usage log sheet

The Controlled Substance 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 Name, PI's CSUA #, Drug Name, unique Container ID number, Concentration, starting amount and date. Each container is also labeled with a barcode for ease of inventory documentation. Do not transfer a Controlled Substance from the original container for storage purposes. Keep it in the original container. The 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.

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 amount of Controlled Substances in the laboratory must equal the amount that is recorded on the Usage Log (**paper copy and online**). Both the forms must be kept up-to-date at all times.

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

Once you finish using a Controlled Substance bottle or the Controlled Substance expires, at the bottom of the paper Usage Log Sheet, you must record either the complete use, or the return of the Controlled Substances to OH&S for proper 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**.

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 OH&S, and 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 OH&S Controlled Substances Program doesn't keep any Controlled Substances on site.

Loss or Breakage

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

Discrepancies

Discrepancies in Usage Log Forms or disposal records may trigger an internal investigation by campus authorities. Make sure to report any problems immediately to the Controlled Substances Manager.

This is especially important since the Federal Law requires that the Controlled Substances Manager notify the DEA within 24 hours of a loss or theft.

Disposal

Return all unwanted Controlled Substances to Occupational Health & Safety (OH&S) for disposal. It is unlawful for anyone to dispose of Controlled Substances without DEA approval and submittal of the proper form.

Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245) Course Material

When to Request Controlled Substances Disposal

- A project closes or is terminated and a Controlled Substance is no longer in need
- 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

If you have questions about Controlled Substance disposal, contact the Controlled Substances Program Manager by phone at 934-2487.

If you have Controlled Substances that requires disposal, you can request a disposal through the web application. Once the request is submitted, the item can be brought to the OH&S office.

OH&S will provide documentation showing the transfer of material from the CSUA holder to OH&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**. Expired and unwanted Controlled Substances cannot be thrown away in the regular trash, and therefore must be returned to the Controlled Substance Program Manager and documented on the inventory as returned to OH&S.

The only exception to this rule is that empty Controlled Substances bottles or vials can be discarded at your facility.

- Make sure to open the container to ensure that it is **completely empty**.
- Deface the label and discard in regular trash.

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Conclusion

This concludes the Use of Controlled Substances in Research, Teaching, and Veterinary Care at UAB (OHS_CS245). You should now take the assessment. 90% or higher is considered passing. You have two chances to successfully complete the assessment. Failing both attempts means that you fail the course and must start over.



If you plan on applying for a Controlled Substance Authorization, you must also complete the How to Apply for an **Authorization to Use Controlled Substances in Research (OHS_CS246)**.

Want to Learn More?

OH&S has many training courses available to all UAB active employees and students. This includes topics such as in depth radiation training, biosafety, bloodborne pathogens, chemical safety, Controlled Substances, building life safety, hazardous and medical waste, universal waste, PPE, Hazard Communication, etc.

We have a [decision tree](#) to assist you in choosing the right course to match the knowledge/skills you may need at work every day as well.

If you have any questions or comments, please feel free to contact OH&S at 205-934-2487.