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## Web Capture: Use of Controlled Substances in Research

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## Controlled Substances

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## Use of Controlled Substances in Research

### Overview

Controlled substances are chemicals or drugs that can be used as analgesics, anesthetics, euthanasia solutions and/or steroids that have a tendency to promote abuse or physiological or psychological dependence. Controlled substances are chemicals that may be addictive, abused and illegal without proper licensing and registration. The U.S. Department of Justice Drug Enforcement Administration (DEA) regulates licensing, registration, storage, security, use, and disposal requirements of controlled substances.

An alphabetical list of all controlled substances can be found in the [DEA Orange Book](#).

### Regulation of Controlled Substances

The Controlled Substances Act (CSA) places all substances which are in some manner regulated under existing federal law into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. More information about the Act can be found in [Title 21 United States Code \(USC\) Controlled Substances Act](#).

Additional information about the regulations can be found on the [U.S. Department of Justice Drug Enforcement Division Diversion Control Division](#).

In accordance with [Code of Federal Regulations \(CFR\), Parts 1300 to END](#), all University employees who are conducting research or teaching activities that involve controlled substances must:

- comply with applicable federal and state laws and regulations regarding their use;
- possess any necessary US DEA registrations;
- adhere to controlled substance storage, inventory maintenance, and disposal

requirements;

- comply with reporting and record-keeping requirements.

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## Procedures and Guidance

### Prior Approval

***All research and/or teaching activities involving the use of controlled substances must have prior written approval from the appropriate campus regulatory body.***

The approving body is typically the [UMaine Institutional Animal Care and Use Committee \(IACUC\)](#). If unsure, or the use of controlled substances is not related to the use of live vertebrate animals, contact the Office of Research Compliance for guidance. Once the research/teaching activity has been approved, the DEA registrant shall purchase controlled substances from licensed vendors using his/her own registration number.

The registrant **shall not** purchase controlled substances for other personnel, or for use in other activities that have not received prior approval.

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## Licensing and Registration for Researchers

Each researcher who intends to work with DEA controlled substances in their laboratory must [obtain and maintain registration with the DEA](#). The registration allows the researcher to purchase, use, and dispose of controlled substances. The registration and licenses must be accessible upon request for inspection. Registered researchers must comply with all state and federal regulatory requirements while working with controlled substances.

*Note: Copies of all registration and licensing documents must be kept; copies must also be submitted to the Office of Research Compliance ([umric@maine.edu](mailto:umric@maine.edu)) as generated/received.*

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## Storage and Security

All controlled substances must be stored securely with limited access by authorized individuals only. Detailed information about general security requirements can be found at [21 CFR §1301.71](#). These requirements must be followed to avoid theft or diversion which may lead to a violation of federal laws. Failure to comply could lead to seizure and suspension of operations.

Below is a summary of storage and security requirements:

1. Must be stored behind a minimum of two (2) locks (i.e. locked safe in a locked room).
2. Both the room and safe must stay locked except when being used.
3. The safe must be secured to the floor or building structure.
4. Key cards and/or keys should be limited.
5. Limit time that controlled substances are out.
6. Never leave controlled substances unattended.
7. Only allow authorized users to handle them.
8. Never take controlled substances out of the secured area.

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## Disposal

All expired or unused materials must be securely locked in the same manner as described above. The PI will be responsible for disposing of any leftover drug products or products that have expired and will not be used. The PI who owns the products may not give them to another PI.

If the lab is closing or the PI is retiring, the PI must dispose of those controlled substances prior to closing the lab or before allowing the DEA registration to expire. **Abandoning them is a violation of the regulations!**

For more information about the regulations, please see [21 CFR §1307.22](#).

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## Reporting Theft or Loss

If you suspect a theft, immediately notify the UMaine Police Department (207.581.4040). In addition, Federal Law requires you report any incidents the DEA within **24 hours** of a loss (Use [DEA Form 106 Report of Theft or Loss of Controlled Substances](#)).

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## Recordkeeping

Recordkeeping is a vital part of managing controlled substances (see [21 CFR §1304.11](#)). Complete and accurate records help maintain inventories to avoid diversions and losses. Logbooks and records should be separated from other records and kept near the controlled substance work area. These records must be legible. Events of loss, destruction, or theft must be recorded in detail as well. All records and logbooks must be retained for at least two years from the last entry.

Records and logbooks should include:

Receipt of Controlled Substances: These records should indicate date received, name of supplier, substance name and description, amount received, and authorized person handling the substance. Copies of order forms (DEA Form 222) must be stored in a securely locked cabinet.

Use Log of Controlled Substance: Each controlled substance should have its own use log. Different substances shouldn't be recorded interchangeably. Information in the Use Logs should include:

1. Name of Controlled Substance
2. Date (i.e. Received, Expired, Each time used)
3. Amount (i.e. Initial, Dispensed, Remaining)
4. Purpose of use (i.e. Project or Experiment used for)
5. Authorized User Name/Initials

For administration to animals also record the following:

1. The individual animal ID of the animal(s) drug was administered to
2. A cage or group ID and total number of animals if no individual ID exists
3. At minimum, the total number of animals if no cage or group ID exists

If a volume is removed from a primary bottle to create a dilution/cocktail in a secondary bottle, the use must be recorded in both bottle logs.

Document in the log for the primary bottle:

1. The volume removed to make the secondary dilution/cocktail
2. The identification number for the secondary dilution/cocktail bottle

Document in the log for the secondary dilution/cocktail bottle:

1. The identification number for the originating primary bottle from which the substance was removed
2. The volume from the primary bottle used to make the secondary dilution/cocktail

Inventory of Controlled Substance: The complete and accurate inventory of controlled substances stocked in each registrant's lab should be conducted initially when registered and biennially (every two years). These records must be consistent with records of receipt, use, and disposal.

The inventory record must contain at a minimum:

1. The date the inventory was completed
2. The names of each controlled substance
3. The form of the substance (e.g., 20 mg tablet, 50mg/ml)
4. The number of containers of each form and the number of dosage units in each container (e.g. 15.5 mls, 60 pills)

*Note: The information provided above is not intended to cover all of the DEA regulations governing Controlled Substances. Further information on requirements for managing and handling controlled substances can be found on the [DEA website](#).*

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DEA License/Registration Number: \_\_\_\_\_

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## CONTROLLED SUBSTANCE USAGE LOG

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One log sheet must be completed for each container of Controlled Substance. If the material is converted or diluted, start a new log form to track that usage; reference the original container's lot or serial # and original bottle # assigned by lab.

PI/License Holder: \_\_\_\_\_

Drug Name: \_\_\_\_\_ Container Amount \_\_\_\_\_

**Storage (building & room #):** \_\_\_\_\_

Concentration: \_\_\_\_\_

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

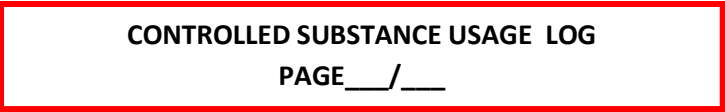
Unique bottle # assigned by lab: \_\_\_\_\_

Lot or Serial #: \_\_\_\_\_

**Form (circle one):** Tablet   Powder   Liquid   Patch   Cream

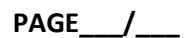
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DEA License/Registration Number: \_\_\_\_\_

Date Inventory Performed	
Time Inventory Performed	
Person Performing Inventory	

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## Resources

- [University of Wisconsin-Madison's Controlled Substances Guidance](#)
- [Stanford University Controlled Substances Program](#)
- [University of Southern California's Controlled Substances & Precursor Chemicals Program](#)



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