

THE  
UNIVERSITY  
OF RHODE ISLAND  
DIVISION OF RESEARCH  
AND ECONOMIC  
DEVELOPMENT

CONTROLLED SUBSTANCES USE  
IN RESEARCH MANUAL

Questions about the information in this manual should be  
addressed to: [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu)

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## 1.0 INTRODUCTION

This manual provides detailed information required by the University of Rhode Island (URI) Policy entitled “Use of Controlled Substances for Research.”

The URI requires Principal Investigators (PI) conducting activities with Drug Enforcement Agency (DEA) Controlled Substances in basic and applied research settings be licensed with the Rhode Island Board of Pharmacy and registered with the DEA.

All individuals shall comply with state and federal regulations regarding the acquisition, record keeping, inventory, storage, use, and disposal of those substances.

PIs using Controlled Substances in research must obtain a Rhode Island Board of Pharmacy Controlled Substance Registration and a DEA Registration prior to ordering or using Controlled Substances. For Schedule I Controlled Substances, an individual must be named and designated as providing research oversight on an approved Controlled Substance Research Protocol to serve as a DEA Registrant for that protocol. Responsibilities associated with Controlled Substances are detailed and regularly enforced by both the State and the DEA. Those individuals not comfortable with assuming the responsibility and maintaining the required records are discouraged from applying for a registration. Delegation of the administrative responsibilities is permitted; however, only the DEA Registrant should have access to their inventory of Controlled Substances and dispense substances. Responsibility is individually based. Individuals who are fined or individuals who have violated the law will not be reimbursed by URI nor defended for criminal actions.

The Vice President for Research and Economic Development (VPR) is the Institutional Official (IO) with ultimate responsibility for ensuring appropriate conduct of research at URI. The VPR is vested with the authority to suspend, revoke, or deny any researcher registration application submitted or registration issued through the state or federal processes, if necessary. In terms of Controlled Substances, the VPR acts as the Authorized Official (AO) with responsibility for reviewing and approving DEA Registration applications.

## 2.0 OFFICE OF RESEARCH INTEGRITY (ORI)

Questions about procurement, secure storage, use, disposal, required documentation, or regulatory questions regarding Controlled Substances in research should be directed to the ORI at [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu). The ORI offers Controlled Substances education sessions for faculty, staff, and students.

## 3.0 DEFINITIONS

### **Authorized Official**

The individual(s) formally authorized to be the “approver” of DEA registration applications on behalf of the institution. The Authorized Official for URI is the VP for Research and Economic Development.

### **Authorized User**

A University Member authorized to use Controlled Substances by a DEA Registrant. Appropriate training completion is required.

**Controlled Substance**

Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end) and Title 54.1, Section 3400 of the State of RI General Laws. Controlled substances are identified in the schedules contained within the "Controlled Substance Inventory List" published by the DEA.

**Controlled Substance Research Protocol**

DEA requires a research protocol as part of the registration submission. The Protocol must be consistent with [21 CFR 1301.18](#) for research utilizing Schedule I Controlled Substances. For more information, refer to Section 7.3.

**DEA Registrant**

A University Member that holds DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of controlled substances on his/her URI Controlled Substance Research or DEA protocols. Appropriate training completion is required.

**DEA Research Protocol**

A protocol to conduct research with Schedule I controlled substances in the form described in [21 CFR 1301.18](#).

**Dispense**

Prepare and distribute controlled substances to Authorized Users

**Disposal**

Relinquishment of contaminated, expired, excess, residual (or waste) and unwanted controlled substances.

**Drug Enforcement Administration (DEA)**

The agency within the United States Department of Justice that enforces the controlled substances laws and regulations.

**Expired and/or Unusable Substances**

Controlled substances for which the expiration date has passed or tablets, injections, liquid, or preparations compounded in error which contain Controlled Substances that can no longer be used for research due to contamination, etc.

**Institutional Official (IO)**

The VP for Research and Economic Development

**Location**

A room or designated area in a building where controlled substance inventory is stored.

**Office of Research Integrity (ORI)**

The department responsible for oversight of all research conducted at the University of Rhode Island.

**Principal Investigator (PI)**

The individual with final responsibility for the conduct of research or other activity described in a proposal or an award.

**Record-keeper**

An individual assigned by the DEA Registrant to assist with Registrant records. The Record-keeper is not authorized to dispense substances, enter new substances into inventory, or dispose of substances. The Record-keeper should only provide data entry services. The DEA Registrant remains responsible for all actions and records of the Record-keeper.

**Registration**

Formal grant of specific authority for controlled substances activities by the DEA and by the Rhode Island Board of Pharmacy. Often referred to as a license or certificate.

**Research**

A systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge.

**Researcher**

Any University Member that conducts research at URI.

**Teaching Activity**

Activities that include classroom demonstrations, laboratory exercises and research projects which are required for completion of a course at the undergraduate, graduate or professional level.

**Transfer**

To move a controlled substance from the inventory of one DEA Registrant to another DEA Registrant.

**University Member**

All URI full and part-time faculty, classified employees, administrative staff, paid student assistants, students (under certain conditions as described in this policy), volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by sponsored program agreement or other contractual arrangements are considered university members for purposes of this policy. Only faculty members can be DEA Registrants under this policy.

**Usage Log**

A log kept by each DEA Registrant and authorized user of Controlled Substances tracking usage that is returned to the DEA Registrant for his/her records.

**Rhode Island Board of Pharmacy**

The agency authorized by URI to implement and regulate Rhode Island Statutes and Board of Pharmacy Rules and to oversee the conduct and professional competency of Rhode Island Board of Pharmacy registrants.

**4.0 CONTROLLED SUBSTANCE DEFINITIONS**

Controlled Substances are drugs or other chemicals that have the potential to be addictive or habit forming. The DEA has divided Controlled Substances into 5 schedules based on their potential to be habit forming and usefulness in medicine as a drug. For a more comprehensive listing, see <https://www.deadiversion.usdoj.gov/schedules/>. Schedule VI substances are those identified by the State of RI General Laws. This scheduling designation is not utilized by the DEA.

- **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. Examples include: Heroin, LSD, Tetrahydrocannabinols (Delta-9-THC), Marijuana, Cathinone
- **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. Examples include: Morphine, Cocaine, Amphetamine, Oxycodone, Methadone, Pentobarbital.
- **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. Examples include: Anabolic steroids, Ketamine, Euthasol (Pentobarbital/phenytoin mix), Buprenorphine.
- **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 relative to those in schedule III. Examples include: Chloral hydrate, Phenobarbital, Benzodiazepines.
- **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. Examples include: Zolpidem, Zopiclone, Pregabalin, some Codeine cough preparations (*Robitussin*)

## 5.0 DOCUMENTATION

Using Controlled Substances requires specific documentation. Documentation must meet the requirements of all regulations. Individuals should determine a consistent documentation process to ensure best compliance practices. Documents may be maintained electronically so long as they can be printed and presented to DEA Investigators as requested.

## 6.0 WHO MUST REGISTER

University Members, who are also full-time faculty members, that store, administer or order Controlled Substances for research purposes on which they are a contributing investigator must register with both the Rhode Island Board of Pharmacy and the DEA. University Members must have oversight of the research to serve as the DEA Registrant on a protocol. Registrants may authorize a limited number of individuals (i.e., Authorized Users) to access and administer Controlled Substances from the Registrant's inventory.

### 6.1 Current Registrants Holding Clinical Practitioner Registrations

A Practitioner Registration from the DEA does allow for the following coincident activities: research and instructional activities with those substances for which registration was granted. Therefore, a

Practitioner may conduct clinical research under their Practitioner Registration. A Practitioner is not authorized to conduct animal research or chemical analysis. A separate Researcher registration is required for these activities.

## **7.0 REGISTRATION AND INSPECTION**

It is the responsibility of each DEA Registrant to obtain appropriate annual licenses and registrations, and to adhere to applicable state and federal regulatory requirements when working with Controlled Substances. DEA Registrants shall not allow the registration to lapse until all Controlled Substances are spent, disposed of, or transferred to another DEA Registrant.

### **7.1 Rhode Island Board of Pharmacy Registration**

Each individual desiring registration must complete a Rhode Island Board of Pharmacy Application for Controlled Substance Registration Certificate. The online forms are here: <http://health.ri.gov/applications/ControlledSubstances.pdf>. A copy of the application must be sent to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu).

Inspection: Prior to issuance of a Controlled Substances Registration, Rhode Island Board of Pharmacy representatives may conduct an interview and inspection to ensure that appropriate safeguards are in place to protect Controlled Substances

### **7.2 DEA Registration**

A DEA Form 225 Application for Registration is required. The VPR is responsible for approval of Schedule I applications and certification of tax-exempt status.

### **7.3 Schedule I Applications (rare)**

Information regarding registering with DEA for use of Schedule I Controlled Substances in research is found here: [https://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/225/225\\_instruct.htm](https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm). The application should be completed and forward to the ORI by ([researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu)) for review and approval prior to submission to DEA.

DEA Registrants requiring the use of Schedule I substances must also include a DEA Controlled Substances Protocol which meets the requirements described in [21 CFR 1301.18](#) and included below:

1. Investigator:
  - Name, street address, building name and room number and DEA registration number; if any.
  - Institutional affiliation.
  - Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).
2. Research Project:
  - Title of project.
  - Statement of the purpose.
  - Name of the Controlled Substances or substances involved and the amount of each needed.
  - Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

- Location where the research will be conducted.
  - Statement of the security provisions for storing the Controlled Substances (in accordance with [21 CFR 1301.75](#) and for dispensing the Controlled Substances in order to prevent diversion.
  - If the investigator desires to manufacture or import any Controlled Substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.
3. Authority:
- Institutional approval. The Authorized Official must approve your registration application.
  - Approval of the Institutional Review Board for human studies.
  - Approval of the Institutional Animal Care and Use Committee for animal studies.
  - Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number), if applicable.
  - Indication of an approved funded grant (number), if any.

#### 7.4 Schedule II-V Applications (most common)

Schedule II-V applications can be completed online. Prior to submission, forward information to ORI for review and approval. The online forms can be found here:

[https://www.dea diversion.usdoj.gov/drugreq/reg\\_apps/225/225\\_instruct.htm](https://www.dea diversion.usdoj.gov/drugreq/reg_apps/225/225_instruct.htm)

#### 7.5 Inspection

DEA Investigators may conduct a pre-registration interview with all pending DEA Registrants. Information or documentation that will be required is:

- Curriculum Vitae/Resume
- Copy of State License
- Copy of Certifications
- Summary of Controlled Substance Protocol (the URI Controlled Substances Protocol can be used, if desired)
  - List of Controlled Substances to be used
  - Quantity of Controlled Substance to keep on hand
  - List of Suppliers for Controlled Substances
  - How the Controlled Substances will be used in your research
  - Source of Funding
  - Length of Research
- List of people who will have access to the Controlled Substances
  - Full name
  - Home Address
  - Home Telephone Number
  - Date of Birth
  - Social Security Number
  - E-mail Address
- Supplier Source for the Animals (if applicable)
- Copy of the Controlled Substances Log
- Copy of the Lab's floor plan



- Specifications for Safe or Controlled Substances storage cabinet (lock information)
- Lab/Area Security Summary

Once received, a copy of each license/registration should be submitted to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) for our records.

DEA and RI Board of Pharmacy registrations remain active for a one (1) year period.

## **8.0 REGISTRATION CERTIFICATES**

As each Registration Certificate is received, a copy should be sent to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) for our Controlled Substances database.

### **8.1 Registration Amendments**

DEA Registrants may require the addition of new substances and protocols throughout the life of the registration. An amendment must be submitted in accordance with the instructions below:

For Schedule I substances, a letter with a revised Controlled Substance Research Protocol, specifically highlighting the changed information should be forwarded to ORI by email ([researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu)) for review and approval. Following approval, the application should be sent to DEA for approval.

For Schedule II-V substances, a revised Controlled Substance Research Protocol, specifically highlighting the changed information should be submitted to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) for review. Upon approval by ORI, the form will be forwarded to the DEA.

## **9.0 REGISTRATION RENEWALS**

Annual renewals for both Rhode Island Board of Pharmacy and DEA registrations can be completed online. The DEA will send a reminder notice approximately three (3) months prior to expiration. DEA renewals can be completed online at:

<https://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/renewalAppLogin.jsp>

## **10.0 VETERINARY REGISTRATION**

URI's Attending Veterinarian maintains a registration for veterinary Controlled Substances used for routine clinical care.

## **11.0 AUTHORIZED USERS**

The DEA Registrant is responsible for managing the Controlled Substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions. Authorized Users (designated employees) of the DEA Registrant may engage in approved activities under the direction of the DEA Registrant. The DEA Registrant is required to screen employees prior to authorization of work with Controlled Substances (See Section 12.0) and verify that training on Controlled Substances provided by ORI has been completed.

## 12.0 PERSONNEL SCREENING

The DEA Registrant should ensure that each potential Authorized User fulfills the screening process by completing the *Personnel Screening per [21 CFR 1301.90](#)*. The screening includes the following questions:

1. Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense?
2. In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
3. Have you ever been denied a DEA registration, had a DEA registration revoked or surrendered a DEA registration for cause?

If the answer to any of the questions is “yes”, the person should not be allowed to sign the Authorized Users Signature Log and the ORI should be contacted. Keep these questionnaires on file at the registered location

## 13.0 ROLES AND RESPONSIBILITIES

### Office of Research Integrity (ORI) Roles and Responsibilities:

- Provide guidance to faculty members for registering with state and federal agencies
- Provide guidance on storage of Controlled Substances
- Provide guidance on disposal of Controlled Substances
- Provide training on URI’s policies and procedures for use of Controlled Substances

### Units or Departments which Process Orders for Controlled Substances for DEA Registrants Roles and Responsibilities:

- Be in compliance with federal and state regulations
- Ensure only DEA Registrants order Controlled Substances using the appropriate forms
- Assure Controlled Substances ordered through the department are stored in accordance with URI, federal, and state regulations

### DEA Registrants Roles and Responsibilities:

- Comply with federal and state regulations and university policy pertaining to the possession and use of Controlled Substances. The DEA Registrant is individually responsible for adherence to URI Policy, Rhode Island Board of Pharmacy regulations and DEA regulations.
- Obtain and maintain Rhode Island Board of Pharmacy and DEA registrations
- Provide and maintain documentation on training of laboratory-specific operations involving Controlled Substances
- Maintain strict control over inventory and security and ensure proper storage of Controlled Substances
- Obtain DEA approval, via amendment, for substances not currently approved under their Registration prior to ordering, inventorying, dispensing, or disposing of such substances
- Dispense no more than weekly usage amounts to Authorized Users
- Obtain and retain usage log sheets

- Maintain separate storage areas, logs and inventory for Schedule I Controlled Substances in their possession
- Maintain separate storage areas, logs and inventory for Schedule II Controlled Substances in their possession
- Maintain separate storage areas, logs and inventory for Schedule III-V Controlled Substances in their possession
- Receive, store, use, and dispose of Controlled Substances properly and continually maintain usage log sheets.
- Maintain usage log sheets for two years after complete use or disposal of Controlled Substances
- Exercise signature authority for purchase and disposal of Controlled Substances
- Conduct an initial inventory
- Conduct a biennial inventory per DEA regulations
- Report in writing the theft or loss of any Controlled Substance to the DEA Field Division (using Form 106), Rhode Island Board of Pharmacy, URI Police and ORI within one (1) business day of discovery of such loss or theft
- Dispose of unwanted Controlled Substances in accordance with DEA regulations using DEA Form 41
- Dispose of Controlled Substances no longer supported by an active, approved protocol
- Upon receipt, send copy of registration, registration renewal or notice of lapse of registration to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu).
- Report DEA inspection and audit findings to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) within 5 business days of notice received by DEA Registrant

**Authorized Users Roles and Responsibilities:**

- Complete the “Controlled Substances Training – Authorized Users” training and provide attestation of completion to the DEA Registrant. See Training topics below.
- Complete the *Personnel Screening Form – Authorized User* before commencing use of Controlled Substances.
  - Sign the Authorized Users Signature Log (Note: separate logs are kept for I and II-V substances)
  - Complete usage log sheets
- Store Controlled Substances in an individual lockbox, marked with the individual's name, or a laboratory-level lockbox, in a locked cabinet at the Registrant's Location
- Return unused Controlled Substances and usage log sheet to the DEA Registrant
- Return usage log sheets when substance has been fully used or is no longer needed
  - Immediately report any discrepancy or suspected theft to the DEA Registrant
  - Receive laboratory-specific training on procedures before using Controlled Substances
- Immediately report to the DEA Registrant any felony violations/convictions

**14.0 TRAINING**

The DEA Registrant must supervise their employees, students and other agents who assist them in their Controlled Substances research. Supervising personnel includes: explaining what and how

Controlled Substances will be used in the Research; ensuring personnel are trained in Controlled Substances security and record-keeping procedures; and actively monitoring personnel's use of Controlled Substances in Research to ensure that this Policy and applicable laws/regulations are being followed.

## 15.0 ORDERING CONTROLLED SUBSTANCES

Registrants can only order substances appearing on approved DEA Protocols (for Schedule I), and URI Controlled Substance Research Protocols (for Schedule II-V) under their current registration.

Controlled Substances can be ordered through standard procurement processes with the following additional requirements:

- **Schedule I or II**

Any person registered to conduct research with Controlled Substances in Schedule I or II must send, in triplicate, DEA order form # 222. Instructions for ordering DEA Form #222 can be found at: <https://www.deadiversion.usdoj.gov/faq/dea222.htm>

- **Schedule I (substances that are not commercially available)**

Requests to obtain Schedule I Controlled Substances not commercially available must be made to the National Institute on Drug Abuse (301-443-1124 or <http://www.nida.nih.gov/>).

- **Schedule III-V**

Schedule III-V Controlled Substances may be ordered by a Registrant through standard procurement processes and maintenance of procurement records.

### 15.1 NIDA Drug Supply Program

The National Institute of Drug Abuse (NIDA) Drug Supply Program (NDSA) provides various controlled drugs, other chemical substances, and marijuana and nicotine research cigarettes for research purposes to research investigators working in the area of drug abuse, drug addiction, and related disciplines at academic institutions. In order to obtain these substances from NIDA, research investigators and other users are required to submit their requests along with necessary documents to the NIDA drug supply program for consideration. Complete details can be found at: <https://www.drugabuse.gov/nida-drug-supply-program-dsp-ordering-guidelines> Controlled Substances must be ordered and maintained in the smallest quantity needed.

## 16.0 RECORD KEEPING AND INVENTORY REQUIREMENTS

The following records should be maintained at the Registrant's Location (as identified on the registration):

- Results of personnel screening and training records for Authorized Users
- Executed order forms
- Receiving record that is verified, signed and dated
- Inventory records (must be kept a minimum of two years from date of last transaction)
- Controlled Substance usage records (must be kept a minimum of two years from the date of last transaction)

All Controlled Substance records must be kept separately from all other records, in or near the primary work area, and shall be available for inspection by URI representatives, DEA, or state inspectors at all times.

The DEA Registrant may assign a Record-keeper to assist with record keeping requirements. The Record-keeper cannot dispense Controlled Substances.

### 16.1 Controlled Substance Receiving

Controlled Substances must be shipped to the DEA Registrant and address as indicated on the DEA Registration. Once received, the Controlled Substances must be opened and the contents verified by the Registrant. Any discrepancies must be rectified with the supplier and/or shipper. If discrepancies cannot be rectified, the DEA Registrant must contact the ORI at [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) and the DEA to report this within five business days. The DEA Registrant must sign and date the purchase receipt and file it with the Controlled Substances records.

### 16.2 Controlled Substance Dispensing and Tracking

The DEA Registrant is the only individual that can dispense Controlled Substance from inventory. From the time a Controlled Substance is received on campus until it is fully used or disposed of, a record of the chain of custody and usage must be kept. Each point at which the Controlled Substance changes hands or is used must be documented. The documentation must be completed at each point by the Registrant dispensing the Controlled Substance and must include the substance, quantity and the signature of the authorized user or Registrant receiving it.

Every ml, mg, or tablet of a Controlled Substance should be accounted for in the dispensing records.

### 16.3 Controlled Substance Transfer

If needed, researchers with an active DEA registration can transfer small quantities to other DEA registrants at URI. The transferor must ensure that the transferee has a valid DEA registration for the category of substances to be transferred and approval, via an approved DEA protocol (if Schedule I) or URI Controlled Substances Research Protocol (if Schedule II-V), to receive the substance.

Transfers of schedule I or II Controlled Substances must be accompanied by a DEA form 222 completed by the registrant receiving the substance(s).

Transfers of schedule III-V Controlled Substances must be documented, be maintained in the appropriate records of both the recipient and supplier and include:

- Name, address, and DEA registration number of recipient
- Name, address, and DEA registration number of supplier
- Name, concentration, and quantity of Controlled Substances transferred
- Transfer date

It is a felony to transfer a Controlled Substance to a person who is not registered with the DEA.

### 16.4 Inventory Procedures

When issued a DEA registration, a registrant shall take an initial inventory, which is an actual physical count of all Controlled Substances in their possession. ***The Registrant should make a record showing a zero inventory upon initial receipt of registration.***

Each person registered to handle Controlled Substances must maintain an inventory. The inventory should be:

- Maintained at the registered location (unless a notification has been sent to DEA notifying that records will be maintained at a specified central location).
- Available for 2 years after the substance is used or is disposed.
- Completed every 2 years (biennial) to meet DEA regulations (21 CFR 1304.11). The inventory may be taken on any date which is within two years of the previous biennial inventory date and must indicate whether it was performed at the opening or closing of the day.
- Updated on the effective date of a rule (from the DEA) when a substance is added to the Schedule (list of Controlled Substances).

The inventory should have the following information:

- Name, address, and DEA registration number.
- Date the inventory was taken and whether it was at the beginning or end of the day.
- Sign and date form.

#### **For Controlled Substances in Bulk Form**

- Name of substance;
- The total quantity of the substance to the nearest metric unit weight consistent with unit size.

#### **For Controlled Substances in Finished Form**

- Name of the substance;
- Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- The number of units or volume of each finished form in each container (e.g., 100-tablet bottle or 3-milliliter vial); and
- The number of containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

**For each substance that is expired, damaged, defective or impure substances awaiting disposal, or substances held for quality control purposes, or substances maintained for extemporaneous compoundings):**

- Name of substance;
- Total quantity of the substance to the nearest metric unit weight or the total number of units of finished form (i.e. fifty 10 mg tablets or 10 ml of 50 mg/ml);
- Reason for the substance being maintained by the DEA Registrant and whether such substance is capable of use in the manufacture of any Controlled Substance in finished form;

### **16.5 Labeling Requirements**

All containers of Controlled Substances must be properly labeled. If the laboratory re-packages, compounds or dilutes Controlled Substances, appropriately label the repackaged, compounded or diluted substance and store it in the safe. The label on diluted or combined Controlled Substances that will be stored at least overnight in the safe must include the following information:

- Name of Controlled Substance
- Lot number from the supplier

- Final concentration of Controlled Substance
- Volume per container
- Expiration date

## 16.6 Storage and Security

DEA Registrants must keep Controlled Substances in a substantially constructed, securely locked cabinet (safe) that meets DEA requirements.

- **For Schedule I**  
The Controlled Substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled Controlled Substances, with the cabinet secured to a wall or otherwise not removable, as per Federal regulations
- **For Schedule II**  
The Controlled Substance must be stored in a substantially constructed, securely locked cabinet (safe), separate from other scheduled Controlled Substances, with the cabinet secured to a wall or otherwise not removable, as per Federal regulations
- **For Schedules III-V**  
The Controlled Substance must be in a locked cabinet or safe.

All Controlled Substances shall be kept locked in their storage location except for the actual time required to remove, legitimately work with, and replace them. You can find standard narcotic cabinets by searching for “narcotic cabinets” on the internet. Please be aware that DEA regulations require that the cabinet be secured so that it cannot be removed.

Access to locked rooms and locked storage cabinets containing Controlled Substances shall be restricted by the DEA Registrant.

Each DEA Registrant must determine how their Authorized Users will access substances. Authorized Users must store Controlled Substances in an individual lockbox, marked with the individual’s name, in a locked cabinet when not being legitimately worked with or at the DEA Registrant’s location for overnight storage. For Finished Form only substances, laboratory-wide lockboxes, can be established and utilized but must be stored at the DEA Registrant’s location for overnight storage. Usage logs must be completed for each lockbox and returned to the DEA Registrant upon completion.

## 17.0 TRANSPORTING CONTROLLED SUBSTANCES BETWEEN UNIVERSITY BUILDINGS

Controlled Substances cannot be transported between buildings. Example: A DEA Registrant cannot walk down the sidewalk or across the street to another building with Controlled Substances in his/her pocket.

There is one limited exception:

1. A DEA Registrant transferring a substance from their inventory to another DEA Registrant’s inventory (via a Form 222 or invoice) can transport the substance, with the proper documentation, between buildings to the new inventory location.

## **18.0 DISPOSAL**

Expired, damaged or otherwise unusable or unneeded Controlled Substances can be disposed of by transferring them to a DEA Registrant who is authorized to receive such materials. These DEA Registrants are referred to as Reverse Distributors. A pilot program with a DEA authorized reverse distributor to assist DEA Registrants with the proper disposal of Controlled Substances has been established. There is currently no cost to DEA Registrants for this service.

Schedule I and II Controlled Substances must be disposed of via DEA Form 222 with the Reverse Distributor. Schedule III-V Controlled Substances may be transferred via invoice.

Expired or unusable substances must be labeled, separated, and stored in a cabinet or safe that meets DEA requirements for the highest level Schedule, until ready for disposal. Maintaining these substances in a separate box, or container, within the same cabinet where inventory is stored is acceptable.

The Controlled Substances Inventory Record must be updated and copies of the records documenting the transfer and disposal of Controlled Substances must be maintained for a period of two years. The Controlled Substance Disposal Log can assist with this documentation.

## **19.0 THEFT OR SIGNIFICANT LOSS**

If theft is suspected, the DEA Registrant shall immediately notify ORI, URI Police, and the DEA. The DEA requires that theft or loss of Controlled Substances be reported on DEA Form-106, Report of Theft or Loss of Controlled Substances. A copy of Form-106 must be kept in the disposition records, and a copy must also be sent to the ORI.

If a container of a Controlled Substance is broken, it shall be documented in the record and a witness must sign and date it.

## **20.0 RHODE ISLAND BOARD OF PHARMACY AND DEA INSPECTIONS**

The Rhode Island Board of Pharmacy normally will call to schedule a time for their inspections. The DEA can inspect an existing DEA Registrant at any time. In preparing for their inspections, the DEA will refer to their database for the list of substances approved for the DEA Registrant, so ensuring that DEA is notified via the amendment process is extremely important. Substances in a DEA Registrant's inventory that do not match the DEA's database is cause for a finding.

If desired by a DEA Registrant, a representative from ORI will accompany DEA Registrants during Rhode Island Board of Pharmacy or DEA inspections. Send an e-mail to [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) to request a representative.

## **21.0 INSTITUTIONAL MONITORING**

The ORI, as a part of its Post-Approval Compliance Monitoring (PACM) program, will review DEA Registrant records and facilities in accordance with its standard inspection schedule. Separate reports will be issued for Controlled Substance monitoring.



## **22.0 EMPLOYEE RESPONSIBILITIES TO REPORT DRUG DIVERSION**

From 21 CFR 1301.91:

"Reports of drug diversion by fellow employees are not only a necessary part of an overall employee security program but also serve the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall 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 the information."

An employee who has knowledge of drug diversion associated with the actions of a fellow employee, student, or supervisor has an obligation to report such information to the ORI or the URI Ethics Hotline, an independently administered, toll-free hot line at 1-855-236-1845 or <https://uri.alertline.com>

### **22.1 Close Out of Registration**

Under no circumstances are Controlled Substances to be abandoned by a DEA registrant. DEA Registrants are expected to properly transfer or dispose of Controlled Substance inventory when Controlled Substances are no longer required or prior to departure from their University position. Contact [researchintegrity@etal.uri.edu](mailto:researchintegrity@etal.uri.edu) when preparing to close out.

Any person who is registered with the DEA who violates record-keeping requirements or abandons Controlled Substances will be subject to the civil penalties outlined in the United States Code (USC): [21 USC Sec. 842](#). Please note that abandoning substances is equivalent to distributing a Controlled Substance to an unauthorized person.