

Policy Type:	Administrative		
Responsible Office:	Division of Research and Economic Development, Office of Research Integrity		
Approval Date:	August 4, 2016	Revision Date:	December 27, 2018

1.0 POLICY STATEMENT AND PURPOSE

Certain research activities conducted under the auspices of University of Rhode Island (URI) require the use of Controlled Substances, where Controlled Substances are defined as any substance listed in the U.S. Controlled Substances Act and the Rhode Island Uniform Controlled Substances Act. In conducting research with Controlled Substances, authorized university members must comply with federal and state laws and regulations regarding appropriate use. These regulations cover the topics of obtaining and maintaining United States Drug Enforcement Agency (DEA) registrations, storage requirements, inventory maintenance, substance disposal, and reporting and record keeping requirements as outlined by both the DEA and the State of Rhode Island General Laws (Chapter 21-28: Uniform Controlled Substances Act). University members using URI resources, including facilities, or receiving funds administered by the University must comply with this policy and federal and state regulations relating to Controlled Substances.

Principal Investigators using Controlled Substances in research must obtain a Rhode Island Board of Pharmacy Controlled Substances Registration and a DEA registration prior to ordering or using Controlled Substances. Responsibilities associated with Controlled Substances are detailed and regularly enforced by URI, Rhode Island Board of Pharmacy, and the DEA. Those individuals not comfortable with assuming the responsibility and maintaining the required records are discouraged from applying for registration. Delegation of the administrative responsibilities is permitted; however, only the DEA Registrant and personnel named on DEA registration (Authorized User) should have access to the inventory of Controlled Substances and dispense Controlled Substances. Responsibility is individually based. Individuals who are fined or individuals suspected or found to have violated the law will not be reimbursed nor defended by URI for criminal actions.

The Vice President for Research and Economic Development (VPR) is the Institutional Official 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 with responsibility for reviewing and approving DEA Registration applications.

2.0 EXCLUSIONS

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.

This policy does not cover teaching activity performed within a clinical environment.

3.0 EMPLOYEE RESPONSIBILITY TO REPORT DRUG DIVERSION

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 Office of Research Integrity (ORI).

Noncompliance with this policy may result suspension or termination individuals or research, referral for academic misconduct proceedings and/or reporting to external licensing authorities. URI supports an environment free from retaliation. Retaliation against any employee who brings forth good faith concerns, asks clarifying questions, or participates in an investigation is prohibited.

4.0 WHO SHOULD KNOW THIS POLICY

All university members using Controlled Substances in research are responsible for knowing this policy and familiarizing themselves with its contents and provisions. University members using URI resources or facilities or receiving funds administered by the University must comply with this policy and federal and state regulations relating to Controlled Substances.

5.0 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 Vice President for Research and Economic Development.

Authorized User

A University Member authorized to use Controlled Substances by a DEA Registrant.

Controlled Substance

Any substance listed in the Controlled Substances Act, Code of Federal Regulations (21 CFR, part 1300 to end) and the Rhode Island Uniform Controlled Substances Act. Controlled substances are identified in the schedules contained within the “Controlled Substance Inventory List” published by the DEA.

DEA Registrant

A University Member that holds a DEA registration and is responsible for ordering, storing, using, recordkeeping, and disposing of Controlled Substances on his/her URI Controlled Substance Research Protocols or DEA protocols.

Dispense

Prepare and distribute Controlled Substances to Authorized Users.

Drug Enforcement Administration (DEA)

The agency within the United States Department of Justice that enforces the Controlled Substances laws and regulations.

Institutional Official (IO)

The Vice President for Research and Economic Development

Principal Investigator (PI)

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

Registration

Formal grant of specific authority for Controlled Substances activities by the DEA and by the RI Board of Pharmacy. Often referred to as a license.

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.

Teaching Institution Registration

A DEA registration awarded to a teaching institution (for Schedules II-V only) overseen by an Institutional Practitioner.

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 agreements or other contractual arrangements are considered university members for purposes of this policy.

RI Board of Pharmacy

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

6.0 CONTACTS

ORI officially interprets this policy. Please direct policy questions to ORI. Questions regarding the implementation of this policy may also be sent to researchintegrity@etal.uri.edu.

7.0 PROCEDURES

Principal Investigators using Controlled Substances in research must obtain a RI Board of Pharmacy Controlled Substances Registration and a DEA registration prior to ordering or using Controlled Substances. The VPR must be named and designated as providing research oversight on an approved DEA Research Protocol for Schedule I Controlled Substances. For Schedule II-V Controlled Substances, ORI must be notified and approve prior to obtaining Controlled Substances.

Activities associated with the use of Controlled Substances are outlined in the Use of Controlled Substances Manual, which details procedures and provides instructions and suggested forms for complying with this policy. Topics in the Use of Controlled Substances in Research Manual, include:

- Definitions
- Controlled Substance Definitions
- Registration and Inspection
- Institutional Registration
- Authorized Users
- Personnel Screening
- Roles and Responsibilities
- Training
- Ordering Controlled Substances
- Recordkeeping and Inventory Requirements
- Storage and Security
- Transporting Controlled Substances between University Buildings
- Disposal
- Theft or Significant Loss
- RI Board of Pharmacy and DEA Visits
- Diversion
- Close Out of Registration
- Forms

Please refer to this document for complete information.

Attending Veterinarian (AV)

URI's AV maintains a Controlled Substances Registration. The AV will order veterinary Controlled Substances when a veterinary license is required and appropriately transfer them to a DEA Registrant's inventory.

Oversight

The ORI will assist DEA Registrants in complying with applicable rules and regulations and provide information regarding regulatory requirements. The ORI will review DEA Registrants' Controlled Substance records and security measures as a part of post-approval monitoring. Questions regarding the implementation of this policy should be sent to researchintegrity@etal.uri.edu.

8.0 FORMS

1. DEA Form 225 – for Controlled Substances Registrations online:
https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm
2. RI Board of Pharmacy Application for a Controlled Substances Registration:
<http://health.ri.gov/applications/ControlledSubstances.pdf>
3. DEA Form-222 Books – Purchasing and Transferring Substances I and II:
<https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>
4. DEA Form 106 – Reporting Theft or Loss:
<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>
5. DEA Form 41 – Disposal of Unwanted Controlled Substances:
https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/

9.0 RELATED DOCUMENTS

1. 21 CFR 1300 – 1399: <https://www.deadiversion.usdoj.gov/21cfr/cfr/>
2. State of RI General Laws, Chapter 21-28: Uniform Controlled Substances Act:
<http://webserver.rilin.state.ri.us/Statutes/title21/21-28/index.htm>
3. DEA Storage and Security requirements:
<https://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm>
4. URI Use of Controlled Substances Manual:
<https://web.uri.edu/researchcondev/controlled-substances-in-research/>
5. DEA Disposal Requirements: https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/
6. DEA Practitioner's Manual:
<https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>

10.0 FAQ'S

1. **What are the DEA schedules or code numbers for the substances we are using?**
A list of federally Controlled Substances is located here: <https://www.deadiversion.usdoj.gov/schedules/index.html>
2. **Who do I contact if I have questions relating to this policy?**
Questions relating to this policy or implementation of Controlled Substances activities at URI should first be posed to researchintegrity@etal.uri.edu.
3. **Is there a supplier of double lock storage cabinets for Controlled Substances?**
You can find standard narcotic cabinets by searching the internet for "Narcotic Cabinets." Please be aware that DEA regulations require that the cabinet be secured. Regulatory inspection officers checking drug storage facilities will confirm that cabinets/safes are secured properly.
4. **I am retiring or leaving URI. What do I do with my Controlled Substances?**

All Controlled Substances must be transferred to another registrant who is authorized to receive such substances or disposed of in accordance with DEA regulations.

5. When do I start counting the two-year time frame required for the retention period of my records?

Records should be maintained for two years from the date of the last transaction on the record.