



## Use of Controlled Substances for Research Standard Operating Procedure

### 1. Purpose

This standard operating procedure (SOP) details the requirements for obtaining a registration and for ordering, storing, using, and disposing of Drug Enforcement Agency (DEA) Controlled Substances (CS). These will be referred to as DEA CS for the remainder of this SOP.

### 2. Scope

The use of controlled substances ([Schedule I - V drugs](#)) in research laboratory operations (including research animals) is subject to all relevant state and federal regulatory requirements. Under controlled substances regulations ([21 CFR §1308](#)), Principal Investigators(PI)/Approval Holders (AH) must obtain a **Form DEA-225 “Researcher” Registration\*** from the federal DEA. Research Laboratory & Safety Services (RLSS) has worked with local DEA agents to streamline applications and paperwork procedures, as outlined below; **you must contact RLSS prior to completing your registration application for a consultation (primer on the regulations, recordkeeping, etc.) and information to receive a fee exemption.** UA will not pay any fines or damages resulting from noncompliance with federal, state, and local regulations, or resulting from noncompliance with university policies; such fines or damages are the sole responsibility of the registered individual.

\*Medical and veterinary doctors (MD, MD/PhD, DVM) should note that these requirements are separate from and in addition to any that apply to licensing for clinical prescriptions and patient dispensing. Clinical and/or veterinary DEA registration cannot be used for research purposes.

### 3. Registration

Faculty members and limited staff members who order, store, use, and dispose of DEA CS must register with the DEA (for Schedules I-V); to be a Registrant, the individual must have oversight of the research on a protocol and be able to demonstrate the legitimacy of their research credentials (e.g. PhD or extensive research credentials).

- **State Registration:** Arizona does **not** have a state registration, unlike many other states. Contact RLSS and the local (Tucson) DEA office for assistance if you are transferring your DEA CS and registration to Arizona from another state.
- **Federal Registration:** **Contact RLSS prior to completing your federal DEA application for a consultation (primer on the regulations, recordkeeping, etc.) to receive a fee exemption.** Federal registration can be completed [online at the DEA website](#), or via mail. Researchers must use the Form DEA-225 “Researcher” registration.
  - DEA registrations must be renewed annually; the DEA will contact you the month prior to expiration for a renewal.
  - RLSS has a [Standard Operating Procedure template](#) that should be filled out at the time of registration application; once the DEA has reviewed your application,



they will request the information contained in the SOP. The applicant can simply return their current CV and a copy of the SOP to satisfy these requirements.

- For modifications\*, transfers, or terminations of a registration, contact the local (Tucson) DEA office and RLSS.

\*Modifications include a change in the use and/or storage locations (e.g. laboratory or building moves, new use spaces, etc.).

**Separate research locations, such as labs housed within different buildings, requires a separate registration;** a single registration with multiple locations on campus for use and/or storage is not compliant with DEA regulation.

#### **4. Purchasing:**

Anyone purchasing a DEA CS is required to have a registration number, which will be requested at the time of purchase. RLSS does not demand or advocate the use of one controlled substance provider over another. However, the following [controlled substance providers](#) have been commonly used by University researchers:

Sigma-Aldrich/Millipore Sigma

Henry Schein

ZooPharm (Requires a Vet Script)

Researchers should only purchase the **minimum** amount of DEA CS they will need to complete their research objectives.



## 5. Storage & Security:

- Always keep all DEA CS secured under lock and key and **behind two differently keyed locks**.
  - Only the registrant and authorized dispenser(s) should have access to the keys.
  - Only the registrant, authorized dispenser, and authorized users may use the CEA CS.
  - A DEA approved safe must be used for Schedule I and II drugs, accessible only to authorized personnel. Store Schedule I and II DEA CS separately from all other drugs and reagents.
- Return DEA CS to their approved storage location(s) immediately after use, keeping them locked at all times except when removing, replacing, or actively working with them.
- Maintain only necessary stock as required for normal efficient operation.
- Schedules I-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. RLSS recommends the use of a wall-mounted [safe](#) (Schedule 1) or a wall-mounted [narcotics cabinet](#) (Schedule II).
- For Schedules III-V, the Controlled Substance must be in a locked cabinet or safe. RLSS recommends the use of a wall-mounted [narcotics cabinet](#).
- Many drugs must remain refrigerated, and these same security requirements apply. RLSS recommends purchasing a [fridge narcotics box](#) that can be mounted or somehow locked into the fridge such that the cabinet could not be picked up and taken to a secondary location.

**Example:  
Schedule I-II**



**Examples:  
Schedule III, IV, V**



## 6. Shipping, Transport, Exporting, and/or Transferring:

- Federal law prohibits the export of DEA CS unless certain requirements are met. Special licenses, as well as export and import permits, are required to export controlled substances.
- Controlled substances cannot be transported in personal vehicles; contact [Risk Management Services \(RMS\)](#) for assistance in arranging for any necessary shipping/transport of DEA CS.
- Transferring DEA CS from one researcher to another is acceptable only if the following requirements are met:
  - **Less than 5%** of the Registrant's inventory is transferred: 5% or more constitutes the person transferring as a DEA CS distributor and is outside of the Researcher registration's scope.



- Both researchers must have valid and current registration and all necessary security and recordkeeping measures must be in place.
- Researchers must document this on their inventory and use logs and complete the [RLSS DEA CS Internal Transfer form](#). Send this to [RLSS-help@email.arizona.edu](mailto:RLSS-help@email.arizona.edu) upon completion of the transfer.
  - DEA CS Schedule I and/or II must also have a Form DEA-222 associated with the transfer.

## 7. Documentation & Recordkeeping:

Registrants, dispensers, and users have many documents and logs that must be maintained as part of a compliant registration. RLSS created [templates](#) in tandem with the DEA, which **must** be used for all recordkeeping. All DEA CS records must be kept separately from all other laboratory records, in or near the primary work area (the registered location), and must be available for inspection at any time. Documentation and records will be inspected during routine RLSS and/or DEA inspections. Schedule I and II records **must** be kept separately from Schedule III-V. RLSS recommends creating a binder, physical or digital, for consolidation of all required documentation and records:

- **Registration:** Registrants will receive both a physical and digital copy of their registration; maintain a copy of this registration that is readily available for inspection.
- **Inventories\*:** Complete the Initial and Periodic Inventories according to the RLSS templates.
  - **Initial Inventory:** Registrant should start by recording a zero inventory on the day they receive their registration. On the initial inventory, the table will be blank because the Registrant should have zero inventory. Once Controlled Substances are ordered and received, a new inventory **must** be created.
  - **Periodic Inventory:** Registrant must complete a comprehensive inventory for all DEA CS in their possession **minimally every two years**; a more frequent schedule, such as monthly, is strongly recommended.
- **Use Log(s)\*:** Complete the RLSS DEA CS Usage log every time a DEA CS is dispensed and/or used; it must be maintained for at least two years.
- **Shipping Receipts:** Maintain shipping receipts for potential inspection.
- **Form DEA-222\*:** This form applies only to Schedule I and II DEA CS. Use the RLSS log sheet to log all 222 forms and maintain them until the DEA CS has been completely used or otherwise disposed of; at that time, the Registrant must send this back to the local DEA office. Lost or stolen forms must be reported to the DEA.
- **Laboratory Specific Training\*:** This documented training must include a statement, signed by all users/dispensers, that they will report any drug-related felonies to the registrant.
- **Power of Attorney Letter:** Required if an authorized user is given the authority to sign Form DEA-222s.

\*RLSS has created [DEA-approved templates](#) (under “DEA Controlled Substances”) that must be used.

## 8. Disposal:



- Dispose of controlled substances ONLY under witness from RLSS, the DEA, or by documented return to the supplier or manufacturer.
- Expired material, unused product, and neat waste must be accumulated and stored under lock and key until ready for disposal. Contact [Risk Management Services](#) Hazardous Waste ([hazmat@email.arizona.edu](mailto: hazmat@email.arizona.edu)) to arrange a DEA CS disposal, also known as a [DEA Form 41](#), “reverse distribution.”
- Controlled substances injected into research animals, consumed in a reaction, or converted into a non-recoverable hazardous waste mixture may be disposed of through routine waste disposal procedures from Risk Management Services.

### 9. Reporting of Loss, Destruction, Theft, and/or Unauthorized Use:

Report thefts, suspected thefts, unauthorized uses, or other losses of DEA CS to the University of Arizona Police Department, RLSS, and the local DEA Office. Document the incident for submittal to the federal DEA within 72 hours, describing the kinds and quantities of materials and the specific circumstances involved.

### 10. Additional Resources:

Research Laboratory & Safety Services  
[rlss.arizona.edu](http://rlss.arizona.edu)  
(520) 626-6850

University of Arizona Police Department (UAPD)  
[uapd.arizona.edu](http://uapd.arizona.edu)  
911 (any UA phone)  
(520) 621-8273 (non-emergency line)

US Dept. of Justice, Drug Enforcement Division (DEA), Tucson Office  
[www.dea.gov](http://www.dea.gov)  
(520) 573-5500

Copies of current drug schedules and federal policies are available on the [DEA CS website](#).

### 11. Definitions

Authorized User: An individual authorized by a Registrant to use Controlled Substances under the Registrant’s direction. Completion of appropriate training is required.

Controlled Substance (CS): Any substance listed in the Controlled Substances Act (21 CFR, part 1300 to end) or Title 54.1, Section 3400 of the Code of Virginia. Lists of Scheduling Actions, Controlled Substances, and Regulated Chemicals are published by the DEA.



**Dispense:** The term "dispense" means to deliver a Controlled Substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a DEA CS and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a DEA CS to an ultimate user or research subject. (21 USC §802(10))

**Disposal:** Relinquishment of contaminated, expired, excess, residual (or waste), or unwanted Controlled Substances.

**University Animal Care (UAC):** Manages multiple centralized animal facilities at the University of Arizona and oversees the campus wide animal care and use program. UAC provides assistance to scientists, physicians, staff, and students who have received Institutional Animal Care and Use Committee (IACUC) approval to perform research, testing, or educational studies on animal subjects.

**Drug Enforcement Administration (DEA):** The agency within the United States Department of Justice that enforces the CS laws and regulations.

**Expired and/or Unusable CS:** CS for which the expiration date has passed. Or tablets, injections, liquid, or preparations compounded in error that contain Controlled Substances that can no longer be used for research due to contamination, etc.

**Registrant:** A full-time faculty member who holds a DEA Registration and who is responsible for ordering, storing, using, recordkeeping, and disposing of DEA CS research protocols.

**Registration:** Formal grant of specific authority for DEA CS activities by the DEA; often referred to as a license or certificate but registration is the proper nomenclature.

**Reverse Distribute:** To acquire DEA CS from another registrant or law enforcement for the purpose of:

- (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or
- (2) Destruction. (21 CFR 1300.01)

**Reverse Distributor** A person registered with the DEA as a Reverse Distributor.

**Transfer:** Moving a Controlled Substance from the inventory of one DEA Registrant to another DEA Registrant.

**Use Log:** A document completed by each Registrant and Authorized User tracking usage of Controlled Substances. The Registrant must keep Controlled Substances Usage Logs for a minimum of two (2) years from the date of the last transaction.