

## **RARC Guidelines for Animal Researchers Controlled Substance Registration & Security Requirements**

In order to purchase, possess, and administer controlled substances for research in Wisconsin, researchers must obtain both a federal Drug Enforcement Administration (DEA) registration and a state Controlled Substances Special Use Authorization (SUA) issued by the State of Wisconsin Department of Safety & Professional Services (WI DSPS). The registration process, along with required security measures, is outlined below.

**Note:** State of Wisconsin licensed practitioners who already hold an approved DEA registration may not be required to obtain an SUA to conduct research.

Visit: [www.rarc.wisc.edu/services/pharmacy\\_services.html?tab=2](http://www.rarc.wisc.edu/services/pharmacy_services.html?tab=2) for more information including recordkeeping and other requirements.

### **State Registration:**

- **To Begin:** Visit the WI DSPS website and obtain the relevant SUA Application Forms
  - <http://dsps.wi.gov/Default.aspx?Page=4629c414-43ce-4f3d-b1d3-7365d37e4a50>
- **New Applications:** A complete SUA application for research must include:
  1. Completed Form #2184, “Application for Controlled Substances Special Use Authorization.”
    - Read the instructions on the form carefully; Form #2275 provides additional instructions.
    - There is no fee for employees of state institutions.
  2. Completed Form #2836, “Special Use Authorization (SUA) for Controlled Substances Checklist for Research.”
  3. A detailed one page written description of IACUC-approved study that places controlled substance use in context
    - Do not send the entire IACUC protocol.
  4. A copy of the IACUC protocol approval letter.
    - This can be sent directly to WI DSPS, by the RARC IACUC Office, upon email request from the PI listed on the protocol. Visit [www.rarc.wisc.edu/protocols/forms\\_and\\_instructions.html](http://www.rarc.wisc.edu/protocols/forms_and_instructions.html) to find the appropriate contact in your school or college.
  - Print out and mail in all completed forms and materials to the address listed at the top of Form #2184.
  - **Be aware!** It can take 8 to 12 weeks or more to receive a response from the CSB regarding your application.
  - Review Form #2277, “Physical Security Requirements” and ensure there is an adequate and secure storage area in place prior to ordering controlled substances. See also: “Storage & Security Requirements” section, below.
  - Review Form #2686, “Unauthorized Possession of Excess Amounts of Controlled Substances Important Notice.”
- **Renewal Applications:** SUAs must be renewed annually!
  - No renewal notice is given by the WI DSPS but the SUA will expire if not renewed **8 – 12 weeks prior to the expiration** date of the current SUA.
  - The SUA renewal procedure is identical to that for new applications.
- **Modifications:** Registrants must amend their SUA any time there is a change in:
  - original authorization holder.
  - individuals participating in the authorized work.
  - amounts of drugs requested.
  - schedules or codes of drugs requested.
  - See the instructions on Form #2275 to begin the SUA amendment process.

## Federal Registration

- **To Begin:** Researchers can apply for DEA registration once an SUA number has been issued. Visit the DEA Office of Diversion Control website and obtain the appropriate forms
  - [www.deadiversion.usdoj.gov/drugreg/index.html#regapps](http://www.deadiversion.usdoj.gov/drugreg/index.html#regapps)
- **New Applications:**
  - Complete DEA Form 225, “Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter.”
    - DEA applications are better submitted online, but may also be submitted through the U.S. Postal Service. Do not submit both online and paper copies.
    - State employees are usually exempt from the DEA registration fee. The certifying official for fee-exemption status is typically the Associate Dean for Research in the school or college but can be anyone who can verify both employment status and authority to possess and administer controlled substances.
    - The Milwaukee DEA Office may send an additional informational questionnaire prior to issuing a DEA registration number.
- **Renewal Applications:** Registration expires after 1 year and must be renewed annually.
  - Use DEA Form 225a, “Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter.”
    - DEA typically provides a reminder to renew.
- **Modifications:** Registrants must amend their DEA registration any time there a change in:
  - Registrant name.
  - Registrant address.
  - drug schedules (i.e. a substance has been reclassified to a new schedule).
  - drug codes requested (i.e. substances needed, for which you have not been previously approved to obtain).
  - Use the DEA Update Request Form to amend your DEA registration:  
[www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp](http://www.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp)
    - The SUA must be amended and approved prior to amending DEA registration

## Storage & Security Requirements

As a DEA and SUA Registration holder, you are legally responsible for providing effective controls and procedures to prevent theft and diversion of controlled substances. Before obtaining any controlled substance, a secure storage area, that meets state and federal security requirements, must be set. Both the State of WI and the Federal DEA have physical security requirements but the requirements set by the State of WI DSPS are more stringent. Compliance with WI DSPS ensures compliance with the DEA.

WI DSPS requires a wall-mounted or floor-bolted lockbox, housed in a room that is locked during non-use hours. Please, see the full list of requirements provided by the WI DSPS on Form #2277, “Physical Security Requirements:”

<http://dsps.wi.gov/Default.aspx?Page=4629c414-43ce-4f3d-b1d3-7365d37e4a50>

An approved (small) double locking cabinet can be ordered through Health Care Logistics, 1-800-848-1633, or [www.healthcarelogistics.com](http://www.healthcarelogistics.com), item #3707-01: slim line narcotic cabinet for ~ \$150.00. Contact UW Facilities Planning & Management (FP&M) or your building manager for mounting and associated costs.