RARC Guidelines for Animal Researchers
Controlled Substance Recordkeeping Requirements

The State of WI DSPS and the Federal DEA have set separate recordkeeping and inventory requirements for researchers. The following guidance represents RARC's understanding of current state and federal regulations. This guidance is provided as an informational reference only! It is the responsibility of the Registrant to know and understand their obligations under State and Federal laws. *

Requirements At A Glance*

	State of WI ***(SUA Registrants)***	**Federal** ***(DEA Registrants)***
Records Required to be kept:	1.) Purchase Records & Receipts 2.) Disbursement, Use & Disposition of each Controlled substance 3.) Total weight in grams if solid, or volume and concentration if liquid, of each controlled substance on hand 4.) Documentation of any inventory or use discrepancies including any investigations into such discrepancies	1.) Accurate Inventory Reports 2.) Invoices, Receipts, Packing Slips with notation of a.) name, address & DEA number of Registrant AND Supplier b.) date items were received c.) drug names, strengths, forms & quantities d.) recipient's initials 3.) DEA Forms 222 - both unused forms and used forms completed in full** 4.) Administration/Dispensing Logs 5.) Loss/Theft Reports (DEA Form 106) 6.) Destruction Reports (DEA Form 41)
When to take Inventory:	Continuously	On the date work with controlled substances begins *(initial inventory)* then every 2 years *(biennial inventory)* and on the effective date a substance becomes controlled by DEA *(newly controlled substances inventory)*
What Inventory must include:	Follow federal regulations for administration logs and include substance weight in grams if solid, or volume and concentration if liquid.	1.) Name & DEA number of Registrant 2.) Date of inventory 3.) Notation of whether inventory was taken at opening or close of business 4.) List of each substance on hand including: a.) Drug Name b.) Finished Form (e.g.10 mg/mL) c.) Number of Units or Volume per Container (e.g. 100 mL vial) d.) Total number of containers (e.g. 4 vials) 5.) Two (2) signatures
What administration /dispensing log must include:	1.) Disbursement 2.) Use 3.) Disposition 4.) Total weight in grams if solid, or volume and concentration if liquid	1.) Name of Registrant 2.) Date of administration 3.) Substance Name and Finished Form (e.g. 10 mg/mL or 40 mg tab) 4.) Number of units dispensed (e.g. 1 mL or 1 tab) 5.) Animal ID & building address of animal housing 6.) Initials of person administering 7.) Notation of any waste or loss in needle hub 8.) Initials of a second person witnessing any waste
Where to keep the Records:	Registered Location	Registered Location ***NOTE:** Inventory and records of Schedule I & II substances and DEA forms 222 must be maintained separately from all other records.*
Retention:	4 years after expiration of SUA	2 years
Availability Requirements:	Copies of original records must be readily retrievable upon request	All records must be readily retrievable for inspection by the DEA upon request

*** Please Note:**

1. Inventory and administration templates, along with further details that represent RARC's understanding of current state and federal regulations can be found on the RARC's Controlled Substance webpage: https://rarc.wisc.edu/services/pharmacy_services.html?tab=2

2. For complete details of all federal requirements, see "Title 21 Code of Federal Regulations," on the Office of Diversion Control website: http://www.deadiversion.usdoj.gov/Resources.html

3. For details of state requirements, see Wisconsin Legislative Documents Chapter CSB 3, "Special Use Authorization": https://docs.legis.wisconsin.gov/code/admin_code/csb/3