**Office of the Vice President for Research**

**Standard Operating Procedure (SOP)**

 **USE OF CONTROLLED SUBSTANCES IN RESEARCH**

1. Purpose

To help ensure that all Iowa State University (ISU) researchers and staff remain compliant with current regulations, only Drug Enforcement Administration (DEA) and Iowa Board of Pharmacy registrants may procure and store controlled substances for use in research at ISU.

2. Scope

This SOP governs requirements for procurement, documentation, storage, and disposal of controlled substances used in research at ISU. This applies to all researchers who wish to use controlled substances in research, whether in the lab or with Institutional Animal Care and Used Committee (IACUC)-approved research. It does not cover the clinicians at the Lloyd Veterinary Medical Center (LVMC) and their relationship with the LVMC pharmacy.

3. Procedure

1. Guidance and Exclusions
	1. Reasons for Guidance

The State of Iowa and federal law requires that use of controlled substances for research purposes must comply with applicable regulations.

To help ensure that all ISU researchers and staff remain compliant with current regulations, only Drug Enforcement Administration (DEA) and Iowa Board of Pharmacy registrants may procure and store controlled substances.

* 1. Exclusions

This SOP does not apply to controlled substances dispensed by a practitioner to a patient in the course of professional practice as authorized by his or her license. Nor does it cover teaching activities performed within a clinical environment. This SOP does not apply to the LVMC pharmacy.

1. Responsibilities
	1. Registrant (Controlled Substance User)
		1. Ensure compliance with federal and state laws.
		2. Have employees with access to controlled substances complete the Authorized Agent Signature Log and the Employee Controlled Substance (CS) Questionnaire, and take the required training from Workday, “Use of Controlled Substances in Research".
		3. Store controlled substances properly.
		4. Maintain proper record keeping for controlled substances.
		5. Report any theft or loss of controlled substances.
		6. Properly dispose of controlled substances.
		7. Access Workday to complete controlled substance user training.
		8. Notify Iowa State University’s Vice President for Research of inspections and notifications of inspections by the DEA or Iowa Board of Pharmacy.
		9. Dispose any remaining inventory before leaving the University or canceling a license/registration.
	2. Authorized Agent
		1. Complete an Authorized Agent Signatory Log.
		2. Complete controlled substance user training.
		3. Complete the Employee CS Questionnaire.
		4. Ensure controlled substances are stored in a way that will not lead to theft or misuse.
		5. Fill out forms properly and completely according to this SOP.
2. Registration and Licensing
	1. State of Iowa
		1. Go to the Iowa Board of Pharmacy website: <https://pharmacy.iowa.gov/application-forms>
		2. Select the CSA-Individual Initial Online Application.
		3. Complete the Controlled Substance Act (CSA) Registration for Individual Practitioners or Researchers.
		4. Please leave the federal DEA number field blank.
		5. There is a $90 license fee. You may make payment on Supplier Invoice (non-PO) in Workday. Visit the ISU Procurement Services website for more information: <https://www.procurement.iastate.edu/about/policy/substances>
	2. Federal
		1. Apply for your federal DEA registration (Form DEA-225) from the Drug Enforcement Administration.
			1. The form is now available on the DEA's website: <https://www.deadiversion.usdoj.gov>
			2. Click on registration, then click on registration applications. You need form 225 Researcher. For more details on completing this form, visit the ISU Procurement Services website:

<https://www.procurement.iastate.edu/about/policy/substances>

* + - 1. Select Researcher w/Sched II – V. Note: If you feel you need to have Schedule I clearance, please contact the Office of the Vice President for Research.
			2. In the Applicant Identification Section, the Business Address must be the location where the lockbox will be kept, including the building name and room number. The mailing address should be the address at with the Registrant receives mail at Iowa State University. The second address line MUST be Iowa State University. Use your campus office phone number. *Note: If you change the location of the lockbox, you must update your Business address information with the DEA.*
			3. In the Drug Schedule section, choose the options of schedules II-V based on the substances you will be approved to use under and IACUC protocol.

Examples of common controlled substances and their schedule:

* + - * + Ketamine Schedule III
				+ Midazolam Schedule IV
				+ Fatal+ (Pentobarbital) Schedule II
				+ Buprenorphine Schedule III
			1. In section "State Licenses" of the online application process you will need to enter your state CSAR number and expiration date.
				1. The number and expiration date will be found in the email you received from iowa@igovsolution.net.
			2. In the Section 6 Exemption from Application fee section, check the box. Be sure to include your Iowa State University campus address, not your home address.
			3. Indicate the signatory as your departmental chairperson.
			4. DO NOT SUBMIT A PAYMENT TO THE DEA. You will not be reimbursed if you do.
1. Records and Inventories

Only Registrants and Authorized Agents may have access to controlled substances. Authorized Agents must fill out an Employee Questionnaire, an Authorized Agent’s signature log and take the required controlled substance training.

* 1. Inventories
		1. Use the Iowa State University Biennial & Initial Controlled Substance Inventory form for both initial and biennial controlled substance inventories.
	2. Records
		1. Use the Iowa State University Record of Inventory and Use form for individual bottles you are using or diluting for research use.
		2. Use DEA-41 form when you need to dispose of controlled substances.
1. Purchasing
	1. Information about the procurement of controlled substances is available on the ISU Procurement Services website: <https://www.procurement.iastate.edu/about/policy/substances>
	2. Orders placed for controlled substances will only be delivered to the address listed on the DEA registration certificate.
	3. The controlled substance must be used at the physical address listed on the registration.
	4. Individuals placing orders for research use will need to utilize a web requisition to process the order, but the delivery will be made to the address listed on the DEA Registration. If the order is placed via cyBUY, the distributing vendor will contact the requestor directly to obtain their DEA registration number.
2. Security
	1. All registrants/licensees must provide effective physical security controls and operating procedures to guard against theft and diversion of controlled substances. An overall evaluation of the security measures in place will be made by the DEA during the application review and physical inspection to ensure the controlled substances are stored securely.
		1. At a minimum, controlled substances in Schedule II-V must be stored in a securely locked, substantially constructed cabinet when not actively in use.
	2. Controlled substances requiring refrigeration may be stored in a locked container securely fastened within a refrigeration unit.
	3. Only authorized agents may have access to controlled substances. Access should be restricted to the minimum number of employees needed.
3. Disposal
	1. Complete the “Waste Removal Form” on the Environmental Health & Safety (EH&S) website: <https://www.ehs.iastate.edu/services/waste/wasteremoval>
	2. To dispose of controlled substances, complete a DEA-41 form.
	3. Contact EH&S (ehsinfo@iastate.edu, (515)294-5359) for controlled substances disposal.
	4. EH&S will coordinate the collection of these controlled substances by ISU Police.
4. Loss or Theft

Contact the ISU Police Department ((515)294-4428) and the Vice President for Research (515)294-1785) in the case of loss or theft of controlled substances.

1. Compliance
	1. Registrants will be subject to compliance reviews and inspections by DEA, Iowa Board of Pharmacy, or by Iowa State University officials.
	2. All registrants must submit a copy of their Biennial & Initial Controlled Substance Inventory form to vpr@iastate.edu.
	3. EH&S, the IACUC, post-approval monitors, or other governing bodies may review storage, handling, and logs during their routine inspections or visits.
	4. Compounding of controlled substances is strictly forbidden.

4. Roles and Responsibilities

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| **Roles** | **Responsibilities** |
| Registrant | Ordering and using controlled substances legally |
| Authorized Agents | Ordering and using controlled substances legally |
| ISU EH&S | Disposal of controlled substances |
| ISU Police Department | Disposal of controlled substances |
| ISU Procurement Services  | Purchasing controlled substances |

5. Definitions

Authorized Agent: a co-investigator, graduate student, post doc or member of laboratory staff authorized by the Registrant to access the secure storage cabinet, dispense, administer, and log controlled substances. Authorized Agents may request controlled substance pick up by EH&S for disposal.

Controlled substances: Drugs that are regulated by the DEA and the Iowa Board of Pharmacy because of potential for abuse.

Registrant: An individual who is named as the Registrant on a DEA registration as well as the corresponding Iowa Board of Pharmacy Registration.

Schedule I drugs, substances, or chemicals: substances that no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of Schedule I drugs are heroin, peyote, and lysergic acid diethylamide (LSD).Schedule II drugs, substances, or chemicals: drugs, substances, or chemicals with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These are also considered dangerous.

Some examples of Schedule II drugs are meperidine (Demerol), morphine, and fentanyl.

Schedule III drugs, substances, or chemicals: Drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.

Some examples of Schedule III drugs are ketamine, buprenorphine, anabolic steroids, and euthanasia solution.

Schedule IV drugs, substances, or chemicals: drugs with a low potential for abuse and low risk of dependence.

Some examples of Schedule IV drugs are diazepam (Valium), Tramadol, phenobarbital, and midazolam.

Schedule V drugs, substances, or chemicals: drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.

An example of a Schedule V drug is lomotil.

6. Appendices

Appendix 1. Iowa Board of Pharmacy registration guidance

Appendix 2. DEA registration guidance

7. Forms and Templates

DEA-225 form <https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e2s1>

DEA-41 form <https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf>

Iowa Board of Pharmacy Form

Iowa State University Record of Inventory and Use form

Iowa State University Biennial & Initial Controlled Substance Inventory form

Employee Controlled Substance (CS) Questionnaire

Authorized Agent Signature Log

8. References

1. Title 21 United States Code (USC) Controlled Substances Act.
2. DEA <https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>
3. Iowa Law Chapter 124 <https://www.legis.iowa.gov/docs/ico/chapter/124.pdf>

9. Contact Information

For questions relating to this SOP, direct questions to the Office of the Vice President for Research, (515) 294-1785, vpr@iastate.edu

For questions relating to the use of controlled substance in animal research, direct questions to the Attending Veterinarian, Dr. Mary Sauer, VMD, (515)294-0266. msauer@iastate.edu or LAR Medical, Laboratory Animal Resources, Iowa State University, (515)294-8507, larmedical@iastate.edu

For questions about the use of controlled substances in IACUC-approved protocols, direct questions to: Institutional Animal Care and Use Committee, Iowa State University, (515)294-1516, iacuc@iastate.edu

For questions about the procurement of controlled substances, direct questions to: Procurement Services, (515)294-4860, procurement@iastate.edu

For questions about the disposal of controlled substances, direct questions to: Environmental Health and Safety, (515)294-5359, ehsinfo@iastate.edu

To report the loss or theft of controlled substances, direct information to ISU Police Department, (515) 294-4428

Link to Use of Controlled Substances in Research Training: <https://go.iastate.edu/XP0IS6>