Use of Controlled Substances in Research

Effective: January 1, 2021
Contact: Vice President for Research

Introduction
The State of Iowa and federal law requires that use of controlled substances for research purposes must comply with applicable regulations. This policy governs requirements for procurement, documentation, storage, and disposal of controlled substances used in research at Iowa State University (ISU).

Definitions
- **Registrant**: A university employee who is named as the registrant on a DEA registration
- **Authorized agent**: A co-investigator, graduate student, post doc or member of laboratory staff associated with Iowa State University authorized by the registrant to access the secure storage cabinet, dispense, administer, procure, and log controlled substances.
- **Controlled substances**: Any substance listed in the Controlled Substances Act of 1970 (Code of Federal Regulations 21 CFR 1300-1399), State of Iowa Administrative Code Chapter 657; and Iowa Controlled Substances Act (Iowa Code Chapter 124).

Policy Statement
To help ensure that all ISU researchers and staff remain compliant with applicable regulations, safely handle, dispose of, and prevent diversion of controlled substances, only Drug Enforcement Administration (DEA) and Iowa Board of Pharmacy registrants may procure and store controlled substances for research purposes.

Non-registrants may possess and utilize controlled substances for research purposes only if they are an authorized agent under the supervision of a registrant.

All procurement of controlled substances shall comply with procedures set forth by ISU Procurement Services.

All storage of controlled substances shall comply with DEA storage, disposal and security requirements.

All disposal of controlled substances shall comply with ISU Environmental Health and Safety (EH&S) guidance.

ISU employees who are registered with the DEA and Iowa Board of Pharmacy for the use of controlled substances in research must provide the Vice President for Research Office with proof of registration.

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 or her license. Nor does it cover teaching activities performed within a clinical environment. This policy does not apply to the Lloyd Veterinary Medical Center Pharmacy.
Resources

Links

• Use of Controlled Substances in Research Training
• Procurement Services - Controlled Substances
• Environmental Health & Safety - Disposal of Controlled Substances
• Code of Federal Regulations, Title 21 - Food and Drugs
• U.S. Department of Justice - Drug Enforcement Administration
• Iowa Code, Chapter 124 - Controlled Substances
• Iowa Board of Pharmacy - Rules/Laws

Files

• ISU Procedures (SOP) for the Use of Controlled Substances in Research
• Appendix 1 for SOP - Iowa Board of Pharmacy guidance
• Appendix 2 for SOP - DEA guidance
• ISU Authorized Agents Signature Log
• ISU Inventory Form - Biennial & Initial Controlled Substance
• ISU Questionnaire for Employees Who Will Have Access to Substances
• ISU Record of Controlled Substance Usage
• ISU Controlled Substances Transfer Form
• Use of Controlled Substances in Research [Policy in PDF]