Use of Controlled Substances in Research

2 Effective: January 1, 2021

3 Contact: Vice President for Research

4 Introduction

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

9 **Definitions**

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- **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).

17 Policy Statement

- 18 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
- 20 Administration (DEA) and Iowa Board of Pharmacy registrants may procure and store controlled
- 21 substances for research purposes.
- 22 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
- 25 Services.
- 26 All storage of controlled substances shall comply with DEA storage, disposal and security
- 27 requirements.
- 28 All disposal of controlled substances shall comply with ISU Environmental Health and Safety (EH&S)
- 29 guidance.
- 30 ISU employees who are registered with the DEA and Iowa Board of Pharmacy for the use of
- 31 controlled substances in research must provide the Vice President for Research Office with proof of
- 32 registration.

33 Exclusions

- This policy does not apply to controlled substances dispensed by a practitioner to a patient in the
- 35 course of professional practice as authorized by his or her license. Nor does it cover teaching
- 36 activities performed within a clinical environment. This policy does not apply to the Lloyd Veterinary
- 37 Medical Center Pharmacy.

38	Resources	
39	Links	
40	•	Use of Controlled Substances in Research Training
41	•	Procurement Services - Controlled Substances
42	•	Environmental Health & Safety - Disposal of Controlled Substances
43	•	Code of Federal Regulations, Title 21 - Food and Drugs
44	•	U.S. Department of Justice - Drug Enforcement Administration
45	•	lowa Code, Chapter 124 - Controlled Substances
46	•	lowa Board of Pharmacy - Rules/Laws
47	Files	
48	•	ISU Procedures (SOP) for the Use of Controlled Substances in Research
49	•	Appendix 1 for SOP - Iowa Board of Pharmacy guidance
50	•	Appendix 2 for SOP - DEA guidance
51	•	ISU Authorized Agents Signature Log
52	•	ISU Inventory Form - Biennial & Initial Controlled Substance
53	•	ISU Questionnaire for Employees Who Will Have Access to Substances
54	•	ISU Record of Controlled Substance Usage
55	•	ISU Controlled Substances Transfer Form
56	•	Use of Controlled Substances in Research [Policy in PDF]