

Standard Operating Procedure

Individual Investigator Use of Controlled Substances in Non-Therapeutic Research

02/27/2023

1. Intent

This SOP applies to faculty and research staff in the College of Arts and Sciences who hold individual federal Drug Enforcement Administrative research or instructing registrations and State of Ohio Board of Pharmacy Terminal Distributor Licenses (to specifically use controlled substances in animal or laboratory research). The SOP also applies to faculty, staff and students acting as an authorized agent under such registrations.

2. Definitions

Controlled Substance: A drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a controlled drug. The current official schedule of controlled substances (I, II, III, IV and V) can be found at <https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfr.htm>

Controlled substances are drugs that are regulated by the Drug Enforcement Administration (DEA) and the State of Ohio Board of Pharmacy because of potential for abuse. Federal and state guidelines govern the responsible conduct of research associated with the use of controlled substances. Failure to meet DEA and Board of Pharmacy registration and licensing requirements specific to the use of controlled substances in animal and laboratory research may result in regulatory sanctions, fines, and/or drug diversion of controlled substances from their lawful purpose into illicit drug traffic. DEA regulations and Board of Pharmacy rules allow faculty and staff researchers to obtain and use controlled substances in IACUC-approved animal research or Institutional Biosafety Committee (IBC)-approved research with cell culture systems or other in vitro analyses (“laboratory research”).

DEA Research or instruction registration: A special DEA license that allows practitioner and non-practitioner investigators to obtain and use controlled substances in animal and laboratory research.

Investigator: A faculty or staff researcher, most often a principal investigator of a research study.

Authorized agent: Investigators or lab staff acting directly on behalf of a registration holder (registrant). The faculty, staff, and student laboratory members of such investigators in turn become authorized agents themselves.

3. Details

University policy on the use of controlled substances in non-therapeutic research stipulates:

- Investigators and teaching faculty who use controlled substances in the University’s non-clinical settings must obtain and keep a current DEA license/registration.
- Registrants must have ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability, and disposal of their controlled substances.
- The college is responsible for monitoring the registration, recordkeeping, inventory, security, and disposal of controlled substances used in research by their investigators.
- All registrants and their authorized agents must be audited by the college on an annual basis to assure compliance with DEA and Ohio Board of Pharmacy regulations and this policy.
- Audits must be performed by impartial and competent individuals who are not involved in either the day-to-day maintenance of the controlled substance inventory or the conduct of the research using controlled substances in the laboratory.

4. Responsibilities Under the Procedure Investigators, Registrants and Authorized Agents

- Maintain and retain appropriate records and inventories of all controlled substances used in their research or instruction at the university. Provide controlled substance documentation to the state, federal and university oversight entities listed in university policy.
- Complete training before involved in controlled substance use in research. Ensure training records related to registration are maintained. When using controlled substances in research activities, all employees in the College of Arts & Sciences must comply with federal and state regulations, as well as institutional guidelines. This module provides ASC registrants and authorized agents training on the use of controlled substances to meet the regulatory requirements. Training includes a regulatory overview, controlled substance schedules, recordkeeping requirements and form use, storage, disposal, personnel changes, and best practices. *All registrants and authorized users are required to take the training before engaging with controlled substances and must score 80% on the quiz to pass.*
- Follow requirements to purchase/order controlled substances from university-based pharmacies and non-university pharmacies or distributors and store all controlled substances in locked steel cabinet or a locked substantially constructed cabinet. Provide effective controls against theft.
- Maintain up-to-date physical inventories of all controlled substances in their laboratories and follow all inventory requirements.
- Follow requirements for administration/use documentation.
- Document spills/losses as required.
- Account for, retain, and dispose of damaged, expired, unwanted, unusable, and non-returnable controlled substances in accordance with state and federal regulations; maintain disposal records as required.
- Maintain complete accountability always of all controlled substances stored or used in their laboratory.
- Report theft/misuse of controlled substances to the college and DEA.
- Follow requirements for exempt chemical preparations, if applicable. Without a DEA registration, investigators may lawfully purchase, use in research, and store only those controlled substances in the forms described on the DEA exempt chemical preparation list pursuant to 21 CFR §1308.24. Such distribution, possession, or use must be intended for laboratory, industrial, or educational purposes and not for immediate or subsequent administration to a human being or other animal. See www.dea diversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf and Procedures Section X – Exempt Chemical Preparations.
- Investigators seeking to become registrants must follow the requirements for obtaining a license from the Ohio Board of Pharmacy and the DEA and any requirements for renewals and changes in registration. To obtain a DEA research or instructing registration, an investigator must first obtain a separate Board of Pharmacy TDDD License. https://elicense.ohio.gov/OH_HomePage. They must notify the college prior to registering with the Ohio Board of Pharmacy and/or DEA and provide copies of licenses and registrations to the college when requested.
- Investigators with DEA research or instructing registrations may not use controlled substances in research involving the use of human subjects or dispense or write prescriptions. When using controlled substances in research on animals, investigators with a DEA research or instructing registration may do so only pursuant to an IACUC-approved protocol, which defines the specific agent(s), dosage(s), and method(s) of administration of controlled substances used in the research protocol.
- Follow transfer/disposal requirements prior to leaving the university.
- Authorized agents: follow requirements to become an authorized agent.

College of the Registrants and Authorized Agents

- Monitor and oversee this SOP.
- Monitor the registration, recordkeeping, inventory, security, and disposal of controlled substances used in research by their investigators.
- Audit all registrants on an annual basis. Conduct additional audits to determine if corrective action has resolved any deficiencies found.
- Conduct off-cycle audits at college discretion.
- Provide appropriate training on the use of controlled substances in research and/or ensure that all registrants and authorized agents have undergone such training.
- Notify Office of Research Compliance of serious and/or reoccurring issues of noncompliance; review issues of noncompliance arising from those audits and determine and enact corrective action plans in consultation with Legal Affairs and applicable university units.

Required Documentation

[Controlled Substance Usage Log](#)

[Controlled Substance Dilution Log](#)

[Controlled Substance Administration Log](#)

[Individual Drug Log](#)

[Controlled Substances Authorized Agent List](#)

[Controlled Substance Program Security Release](#)

[Purchasing/Receiving Log](#)

[Record of DEA Form 222 use](#)

[DEA Form 41](#)

