1. Standard Operating Procedure

Individual Investigator Use of Controlled Substances in Non-Therapeutic Research

Applies to: Controlled Substances	Responsible Department(s): Research & Graduate Education	Date Issued: October 9, 2019
Category(ies): Research		Date for Review: December 2020

2 Intent/Background

This SOP applies to faculty and research staff in the College of Food, Agricultural and Environmental Sciences who hold individual federal Drug Enforcement Administration 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.

3 Definitions

Term	Definition
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.
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/2108cfrt.htm
Clinical setting	A setting where a controlled substance is used in a medical or veterinary application.
DEA Research or instructing registration "Registration Holder"	A special DEA license that allows practitioner and non-practitioner investigators to obtain and use controlled substances in animal or laboratory research.
Non-Clinical Setting	A setting where a controlled substance is used in research, teaching or testing, which is not a clinical usage of the controlled substance.
Investigator	A faculty or staff researcher, most often a principal investigator of a research study.
Practitioner	A physician, dentist, veterinarian or other licensed medical professional, possessing a DEA registration to prescribe, dispense, or administer a controlled substance in the course of her/his professional practice.
Non-practitioner	An investigator who conducts animal or laboratory research at OSU and does not have a practitioner's license.

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4 Standard Operating Procedure Details

University policy on the use of controlled substances in non-therapeutic research (http://orc.osu.edu/files/Individual-Investigator-Use-of-Controlled-Substances-In-Non-Therapeutic-Research.pdf) stipulates that:

- 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 have ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability, and disposal of their controlled substances.
- The college and academic unit of the registrant are 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 and/or department 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 in question.

5 Procedure

CFAES Individual Investigator Use of Controlled Substances in Non-Therapeutic Research Statement:

I) **Notification by PI:** Individual principal investigators are responsible for notifying their Department Chair/Heads and the Associate Dean for Research and Graduate Education when they obtain individual DEA/TDDD licenses, become Authorized Agents, or initiate new protocols involving controlled substances within ten days.

II) **Notification by Chair**: Department Chair/Heads and the Associate Dean for Research and Graduate Education will immediately inform one another when principal investigators obtain individual DEA/TDDD licenses, become Authorized Agents, or initiate new ORRP or IACUC protocols involving controlled substances.

III) **Purchase:** A copy of all purchase orders for all controlled substances for laboratory research shall be forwarded to the CFAES Office of Research & Graduate Education to monitor labs utilizing controlled substances. (kaser.37@osu.edu)

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IV) **Self-Audit Survey:** Annually all faculty will be surveyed to determine any new controlled substances.

V) **On-site audit:** The Associate Dean for Research and Graduate Education in cooperation with the CFAES Director -Safety, Compliance and Risk Management, will conduct annual on-site audits, and any necessary follow up meetings.

VI) **Disposal of Controlled Substances:** Principal investigators will inform the Associate Dean for Research and Graduate Education by using the Controlled Substances Waste Disposal Log. Expired substances should be disposed of within 60 days, but not more than 90 days following expiration.

VII) **Training:** Principal Investigators authorized to use controlled substances in their lab must ensure that all lab employees receiving training and maintain documentation of training.

6 Responsibilities Under the Procedure

Position or Office	Responsibilities
Investigators, registrants, and authorized agents	1. Maintain and retain appropriate records and inventories of all controlled substances used in her/his research or instruction at the university. Provide controlled substance documentation to the state, federal and university oversight entities listed in the University policy. 2. Complete training before being involved in controlled substance use in research. 3. Ensure that training records related to your registration are maintained. 4. Follow requirements to purchase/order-controlled substances from university-based pharmacies and non-university pharmacies or distributors. 5. Store all controlled substances in a locked steel cabinet or a locked substantially constructed cabinet. Provide effective controls against theft. 6. Maintain up-to-date physical inventories of all controlled substances in their laboratories and follow all inventory requirements. 7. Follow requirements for administration/use documentation. 8. Document spills/losses as required. 9. 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. 10. Maintain complete accountability always of all controlled substances stored or used in their laboratory.

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	11. Report theft/misuse of controlled substances to the college and DEA. 12. Follow requirements for exempt chemical preparations, if applicable. 13. Investigators seeking to become registrants: • Follow the requirements for registering with the university, the Board of Pharmacy, the DEA, and any requirements for renewals and changes in registration. • Notify the college and/or department prior to registering with the Board of Pharmacy and/or DEA and of any changes in registration. • Provide copies of licenses and registrations to college and department. 14. Registrants and investigators: follow transfer/disposal requirements prior to leaving the university, license termination, or making changes to the registration. 15. Authorized agents: follow requirements to become an authorized agent.
College and/or department of the registrant	1. Monitor and oversee of this SOP as it applies to registrants and their agents. 2. Monitor the registration, recordkeeping, inventory, security, and disposal of controlled substances used in research by their investigators. 3. Audit all registrants on an annual basis. Conduct additional audits to determine if corrective action has resolved any found deficiencies. 4. Conduct off-cycle audits at college/department discretion. 5. Provide appropriate training on the use of controlled substances in research and/or ensure that all registrants and authorized agents have undergone such training. 6. Notify Office of Research Compliance of serious and/or recurring 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.

7 Resources/Forms

Forms used to log the purchasing, administering, dispensing, and inventory of controlled substances possessed by university investigators:

OSU Controlled Substance Forms may be downloaded: orc.osu.edu/regulations-policies/controlled-substances/

- OSU Controlled Substances Record: Form 1.1 Usage Log
- OSU Controlled Substance Record: Form 1.2A Substance Dilution 1.2A
- OSU Controlled Substances Record: Form 1.2B: Administration Logs
  - *(Forms 1.2A and 1.2B are to be used together)*
- OSU Controlled Substance Record: Form 2 Individual Drug Log
- OSU Controlled Substance Record: Form 3 Authorized Agent List

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- OSU Controlled Substance Record: Form 4 Security Release
- OSU Controlled Substance Record: Form 5 Purchasing/Receiving Log
- DEA Controlled Substance Record: Form 6 DEA 222
- OSU Controlled Substance Record: Form 7 Record of DEA Form 222 Use
- CFAES Controlled Substance Record: Form 8 Waste Disposal Log
- DEA Controlled Substance Record: Form 9 Report of Theft or Loss of Controlled Substance
- CFAES Controlled Substance Record: Form 10 Training Record

Manuals

- DEA Practitioner's Manual deadiversion.usdoj.gov/pubs/manuals/pract/index.html

Controlled Substances Links

- Code of Federal Regulations Schedule of Controlled Substances, deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm
- DEA Security Regulation (21 CFR §§1301.71 -1301.76), deadiversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm
- U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control, deadiversion.usdoj.gov/index.html
- TTTD License Application form, pharmacy.ohio.gov/Documents/Licensing/TDDD/Apps/Limited%20License%20Application.pdf

Other University Policies, policies.osu.edu/

- Research Data policy, orc.osu.edu/files/2011/01/ResearchDataPolicy.pdf

8 Contacts for Questions

CFAES Office for Research and Graduate Education
OSU Office of Research Compliance

9 Document Change History

Version no.	Effective date	Description of change/sections revised	Reason for change	Author name
1	10/01/2019	New process	New process	L.Kaser