

## **Individual Investigator Use of Controlled Substances in Non-Therapeutic Research**

**Definition:** 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. These include both pharmaceutical and non-pharmaceutical grade substances.

**This Policy Applies to:** Faculty and research staff in the College of Arts and Sciences who hold individual, or work under a college-based program using, 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 policy also applies to faculty, staff, and students acting as an authorized agent under such registrations.

**Basis for Policy:** 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:

A: The college and department/center of the registrant are responsible for monitoring the registration, recordkeeping, inventory, security, and disposal of controlled substances used in research by their investigators.

B. 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.

C. 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.

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

- I) Individual principal investigators are responsible for notifying their unit heads and the Associate Dean for Research when they obtain individual DEA/TDDD licenses, become Authorized Agents, or initiate new ORRP or IACUC protocols involving controlled substances.
- II) Unit heads and the Associate Dean for Research 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) On a biannual basis, the Associate Dean for Research will survey unit heads for confirmation of all principal investigators who are conducting research involving controlled substances.
- IV) The Associate Dean for Research will conduct annual audits, and any necessary follow up meeting audits using the *Controlled Substance Audit Form* (Appendix 1). These will be countersigned by the principal investigator, unit head, and a college research officer.
- V) Principal investigators will inform the Associate Dean for Research using the *Controlled Substances Disposal Form* (Appendix 2) when disposing of expired substances. Expired substances should be disposed of within 60 days, but not more than 90 days following expiration.

All questions concerning this policy should be directed to Dr. Stephen Petrill, Associate Dean for Research, at [petrill.2@osu.edu](mailto:petrill.2@osu.edu).