

Augusta University

Policy Library

Research Use of Controlled Substances Policy

Policy Manager: Environmental Health and Safety Division

POLICY STATEMENT

The Research Use of Controlled Substances Policy has been established to provide guidelines, assign responsibilities and outline procedures for the management and disposal of Drug Enforcement Administration (DEA) controlled substances per 21 CFR 1300 to 1321 for used in research and educational areas at Augusta University (AU). Any AU researcher/investigator or practitioner who uses any drug or substance controlled by the DEA for research purposes at AU is responsible for compliance with all Federal and State laws, which form the basis for AU policies and procedures.

AFFECTED STAKEHOLDERS

Indicate all entities and persons within the Enterprise that are affected by this policy:

- Alumni Faculty Graduate Students Health Professional Students
 Staff Undergraduate Students Vendors/Contractors Visitors
 Other: Department Heads, Department Managers and all staff or faculty who are licensed by DEA to receive or use controlled substances in research

DEFINITIONS

- **CFR** - Code of Federal Regulations
- **Controlled Substance** – A drug or other substance, or immediate precursor, included in Schedule I, II, III, IV or V of the DEA Title 21, Chapter 13, Subchapter I.
- **DEA** – U.S. Drug Enforcement Administration
- **GDNA** – Georgia Drugs & Narcotics Agency acting as a law enforcement and regulatory division for the Georgia State Board of Pharmacy, ensuring that registrants follow the laws pertaining to dangerous drug and controlled substances.
- **IACUC** – Institutional Animal Care and Use Committee acts as oversight to ensure that all research in AU using invertebrate and vertebrate animals comply with all federal laws that govern humane care and treatment of laboratory animals.
- **List Chemical** – A chemical specified by regulation as a chemical that is used in manufacturing a controlled substance
- **Non Clinical Use** – Use of Controlled Substances by researchers/investigators at AU for research purposes not including healthcare practitioners providing patient services or veterinarians practicing animal care.
- **Practitioner** – Physician, dentist, veterinarian, scientific investigator, pharmacy, hospital or other person licensed, registered, or otherwise permitted, by the united States or the jurisdiction in which (s)he practices or does research, to distribute, dispense, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research
- **Researcher/Investigator** – An AU employee conducting research in an AU facility.

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- **Reverse Distributor** – A distributor registered with DEA to take control of the controlled substance for the purpose of returning them to the manufacturer or, if necessary, dispose of them.

PROCESS & PROCEDURES

Procedures used to support this policy are available at: Chemical Safety Guide – Appendix F: Program for Management of DEA Regulated Materials

<https://www.augusta.edu/services/ehs/chemsafe/documents/chemical-safety-guide0717.pdf>

REFERENCES & SUPPORTING DOCUMENTS

External Agencies

- 21 CFR 1300 to 1316: Drug Enforcement Administration, Department of Justice.
<http://www.deadiversion.usdoj.gov/21cfr/cfr/>
- O.C.G.A. § 43-50 Georgia Veterinary Practice Act; links to these laws and to the Veterinary Boards Rules can be found at URL:
http://www.animallaw.info/statutes/stusgast43_50_30_56.htm
- Official Code of Georgia Title 16, Crimes and Offenses, Article 1, Chapter 13, Sections 1,2,3, & 4, Controlled Substances; Article 2 Regulation of Controlled Substances, Parts 1 & 2, and: Article 5, encompass "Drug Researchers". O.C.G.A. § 16-13-1,2:
<http://statutes.laws.com/georgia/title-16>
- Official Code of Georgia, Title 26, Food, Drugs, and Cosmetics, _O.C.G.A. § 26-4-1-5:
<http://statutes.laws.com/georgia/title-26>
- Controlled Substances Security Manual, A Security Outline of the Controlled Substances Security Act of 1970: US Dept. of Justice Drug Enforcement Administration, can be found at URL: <http://www.deadiversion.usdoj.gov/pubs/manuals/sec/index.html>
- Georgia State Board of Pharmacy Controlled Substances <http://gbp.georgia.gov/>
- DEA Office of Diversion Control <http://www.deadiversion.usdoj.gov>

RELATED POLICIES

None

APPROVED BY:

Executive Vice President for Academic Affairs and Provost, Augusta University
Date: 3/22/2021

President, Augusta University

Date: 3/22/2021