

# Georgia Regents University

## Policy Library

### Research Use of Controlled Substances Policy

**Policy Owner: 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 used in research and educational areas at Georgia Regents University (GRU). Any GRU researcher/investigator or practitioner who uses any drug or substance controlled by the DEA for research purposes at GRU is responsible for compliance with all Federal and State laws, which form the basis for GRU policies and procedures.

#### **REASON FOR POLICY**

- GRU has established this policy, which applies to activities involving the acquisition, use, storage, and/or disposal of controlled substances used for research purposes, as well as required licensing and recordkeeping in connection with such activities, to ensure compliance with DEA rules and regulations.
- All GRU researchers/investigators and practitioners who use controlled substances in research, exclusive of clinical use in humans, are required to comply with this policy. It applies only to researcher use, and does not consider other independent activities as defined by the Drug Enforcement Administration (DEA) that require a separate registration, such as manufacture, distribution, or chemical analysis.
- A practitioner who is performing research activities (outside of a human clinical trial or standard of care use) must maintain the records for those controlled substances.
- All faculty, staff and students who work with controlled substances in research activities, Department Heads, Department Managers and all staff or faculty who are licensed by DEA to receive or use controlled substances in research are required to read this policy and comply with all federal state and local rules and regulations as directed.

#### **AFFECTED STAKEHOLDER AND ORGANIZATION(S)**

All faculty, staff and students who work with controlled substances in research activities, Department Heads, Department Managers and all staff or faculty who are licensed by DEA to receive or use controlled substances in research are required to read this policy and comply with all federal state and local rules and regulations as directed.

#### **DEFINITIONS**

- **CFR** - Code of Federal Regulations”

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**Office of Compliance and Enterprise Risk Management Use Only**

**Policy No.:** 607

**Policy Sponsor:** Type the title of the Executive Leader of the department.

**Originally Issued:** Not Set

**Last Revision:** 04/09/2015

**Last Review:** 04/09/2015

- **Non Clinical Use** - Use of Controlled Substances by researchers/investigators at GRU for research purposes not including healthcare practitioners providing patient services or veterinarians practicing animal care.
- **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 GRU 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.
- **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 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** - A GRU employee conducting research in a GRU facility.
- **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

<http://www.gru.edu/services/ehs/chemsafe/chemsafeguideoct2013.pdf>

## FORMS AND RELATED 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](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.dea diversion.usdoj.gov/pubs/manuals/sec/index.html>

## APPENDICES

- Georgia State Board of Pharmacy Controlled Substances  
<http://gbp.georgia.gov/>
- DEA Office of Diversion Control  
<http://www.dea diversion.usdoj.gov>

## AUTHORIZING SIGNATURE

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Ricardo Azziz, MD, MPH, MBA  
President, Georgia Regents University and CEO, Georgia Regents Health System

Date

### TO BE USED BY THE OFFICE OF COMPLIANCE & ENTERPRISE RISK MANGEMENT

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Point of Contact: Associate Vice President, Environmental Health and Safety  
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