Policy 7.29
Research Use of Dangerous Drugs, including Prescription Drugs

Responsible Official: VP for Research Administration
Administering Division/Department: Office of Research Administration
Effective Date: September 15, 2015
Last Revision: September 18, 2015

Policy Sections:

I. Overview
II. Applicability
III. Policy Details
IV. Definitions
V. Related Links
VI. Contact Information
VII. Revision History

Overview

I. Overview:

This policy sets forth requirements for using in non-human research prescription drugs that state and federal authorities have not classified as Controlled Substances. Such drugs are referred to in this policy as “Dangerous Drugs,” which is the name assigned to them by the State of Georgia. Requirements specified in this policy include record-keeping, acquisition, use, storage, and/or disposal of Dangerous Drugs. As defined below, the term “Dangerous Drugs” includes drugs that may only be dispensed via a prescription, excluding those Dangerous Drugs that also are Controlled Substances. Controlled Substances are those drugs that have been classified as such by the U.S. Drug Enforcement Agency (DEA) or the State of Georgia based on the drug’s medicinal value (or lack thereof) and potential for abuse. Emory University’s policy regarding non-human research that uses Controlled Substances is at http://policies.emory.edu/7.25.

Applicability

II. Applicability:

This policy covers any faculty, staff and/or other researchers using Emory facilities or resources for non-human research. Different rules and policies cover researchers conducting human research.

Policy Details

III. Policy Details:

A. Regulatory Control
   1. Procurement and distribution of Dangerous Drugs is restricted by federal law to those persons authorized by state authorities.
   3. The Georgia Drugs and Narcotics Agency enforces Georgia laws and rules pertaining to Dangerous Drugs.
   4. The Official Code of Georgia Annotated (OCGA) defines which practitioners are licensed to prescribe or obtain Dangerous Drugs.
   5. The State of Georgia requires researchers who are not licensed as practitioners (e.g., physicians, veterinarians) and who plan to use Dangerous Drugs in animal or bench research to register with the State of Georgia Board of Pharmacy (GBP) prior to being permitted to order and/or use Dangerous Drugs for/in their research.


B. Registration with Georgia Board of Pharmacy (GBP)

1. No Additional Registration Required for Licensed Practitioners: A licensed practitioner (e.g., physician, veterinarian) is authorized to issue prescriptions, purchase, dispense, administer or otherwise use Dangerous Drugs in clinical practice and for animal or bench research provided the practitioner has an active practitioner license in the State of Georgia.

2. Registration with GBP Required for Non-Licensed Practitioners: Non-licensed practitioners who plan to use Dangerous Drugs in animal or bench research must register with the GBP.
   
   a. The application for a Georgia researcher’s registration can be found on the GBP website at [http://gbp.georgia.gov/](http://gbp.georgia.gov/) using tab [Applications and Forms] scroll down to [Pharmacy Facility Application], complete pages 3, 6, 7, 15, 16 and 17. Application will include submission of a description of the Research protocol, proof of U.S. citizenship or qualified alien status, and the application/registration fee.

   b. Registration is required for each separate physical location at which research using Dangerous Drugs takes place. The Georgia Drugs and Narcotics Agency (GDNA) will conduct a site inspection before a registration is issued. Dangerous Drugs may be shipped only to the specific location listed on a license, for use by the named Registrant according to the permitted use.

C. Purchasing Controls

1. Researchers must purchase Dangerous Drugs through Emory Procurement/Emory Express. Emory University does not permit purchasing cards, personal credit cards, personal checks, or cash to be used to purchase Dangerous Drugs. Dangerous Drugs may be delivered only to the address specified on the researcher’s registration with the GBP. Researchers’ orders should be limited to the amount of Dangerous Drugs necessary to perform their research. The GBP Registration number is required in order to purchase Dangerous Drugs through the University Procurement System.

2. Researchers who wish to purchase Dangerous Drugs for Research must follow Procurement’s procedures outlined on the following website: [https://www.finance.emory.edu/home/Procure%20and%20Pay/how_to_buy_in_the_marketplace/index Procure_pay_mckessonfor drugs.html](https://www.finance.emory.edu/home/Procure%20and%20Pay/how_to_buy_in_the_marketplace/index Procure_pay_mckessonfor drugs.html).
at [http://www.compliance.emory.edu/](http://www.compliance.emory.edu/) may be used/modified for this purpose. [Ga. Bd. of Pharmacy R. 480-7-.04].

6. Disposal of Dangerous Drugs: A researcher must follow Emory Environmental Health and Safety (EHSO) procedures to dispose of Dangerous Drugs through chemical hazardous waste handling.

7. Records Retention: A researcher must retain separate records for Dangerous Drugs for two years after final disposition of the drugs. Records must be kept for:
   - ordering & receipt records
   - logs of current use, & disposition

Definitions

IV. Definitions:

Dangerous Drugs: Any drug, other than a Controlled Substance, that federal law prohibits dispensing of without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act. Dangerous Drug also includes any other drug, substance, or device that the Georgia General Assembly has declared to be a dangerous drug.

Controlled Substances: All drugs, substances or immediate chemical precursors listed in Schedules I to V of OCGA Sections 16-13-25 to 16-13-29; and Schedules I to V of Title 21 of the Code of Federal Regulations (CFR) Section 1308.

Related Links

- Current Version of This Policy: [http://policies.emory.edu/7.29](http://policies.emory.edu/7.29)
- [Georgia Board of Pharmacy Rules Chapter 480](http://rules.sos.ga.gov/gac/480)
- [Georgia Composite Medical Board](http://medicalboard.georgia.gov/rules)
- [Current Version of this policy](http://policies.emory.edu/)

Contact Information

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Revision History

- Version Published on: Sep 10, 2015
- Version Published on: Sep 10, 2015 *(Original Publication)*

*Emory University policies are subject to change at any time. If you are reading this policy in paper or PDF format, you are strongly encouraged to visit policies.emory.edu to ensure that you are relying on the current version.*