Policy 7.29
Research Use of Dangerous Drugs (i.e., Prescription Drugs)

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 research that uses Controlled Substances is at http://policies.emory.edu/7.25.

Applicability

This policy covers any faculty, staff and/or other researchers using Emory facilities or resources for non-human research that utilizes Dangerous Drugs. A licensed health care Practitioner is required to be involved in human research that includes the use of Dangerous Drugs and as noted below, Practitioners are permitted to use Dangerous Drugs in research under their practitioner license.
Policy Details

Regulatory Control

I. Procurement and distribution of Dangerous Drugs is restricted by federal law to those persons authorized by state authorities.

II. Penalties for unauthorized use are delineated in the Criminal Code of Georgia at O.C.G.A. Title 16. Crimes & Offenses, Chapter 13. Controlled Substances.

III. The Georgia Drugs and Narcotics Agency enforces Georgia laws and rules pertaining to Dangerous Drugs.

IV. The Official Code of Georgia Annotated (OCGA) defines which Practitioners are licensed to prescribe or obtain Dangerous Drugs.

V. 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. Note that for human research, a licensed Practitioner who is authorized to prescribe prescription drugs must be responsible for the prescribing of any Dangerous Drugs used under a research protocol.

Registration with Georgia Board of Pharmacy (GBP)

I. 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 research (animal, bench or human) provided the Practitioner has an active Practitioner license in the State of Georgia.

II. Registration with GBP Required for Non-Practitioners: Non-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/ 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 registration, for use by the named Registrant according to the permitted use.

Purchasing Controls

I. 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 used for Research 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 Practitioner’s license or GBP Registration number is required in order to purchase Dangerous Drugs through the University Procurement System.

II. 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_produce_pay_labresearchgoods.html.

Receipt, Storage, Record-Keeping and Disposition of Dangerous Drugs
I. Receipt: All supplies/inventories of Dangerous Drugs must be controlled and tracked from procurement through final disposition/disposal. [Ga. Bd. of Pharmacy R. 480-7-.04].

II. Storage and Physical Security Requirements
   a. The researcher must keep Dangerous Drugs in his/her possession secure and prevent theft, loss, unauthorized access or removal. Researchers should ensure that Dangerous Drugs are physically secure.
   b. Basic physical security requirements include:
      i) Dangerous Drug stocks must be stored at appropriate temperatures/conditions in accordance with labeled requirements or requirements published in the current edition of an official compendium (e.g., U.S. Pharmacopoeia). Storage in primary original, labeled container is recommended by GDNA. [Ga. Bd. of Pharmacy R. 480-7-.04].
      ii) Dangerous Drugs secondary storage container should be located in a place where unauthorized access is restricted; a key or combination lock on the secondary storage container is required by GDNA. [Ga. Bd. of Pharmacy R. 480-7-.04].

III. Personnel Security Requirements: A researcher should ensure that access to Dangerous Drugs used in research is limited to trustworthy personnel who have not had DEA, GBP, or Practitioner licenses/registrations revoked or restricted, and who have no prior criminal history of violations regarding Dangerous Drugs or Controlled Substances. Such individuals also should be trained in the proper use and control of Dangerous Drugs before being permitted access to such drugs. A Researcher is encouraged to keep a log of the persons whom the Researcher has authorized to work with Dangerous Drugs. The Dangerous Drugs Authorized User Signature Log – FORM_A_ (available at http://www.compliance.emory.edu/) may be used/modified for this purpose.

IV. Transfer or Distribution of Dangerous Drugs is Prohibited: A researcher must utilize any Dangerous Drugs ordered under his/her registration solely for his/her Research as described to GBP. The researcher must not transfer or provide Dangerous Drugs to any other persons for use in those persons’ research or for any other use. [O.C.G.A. § 26-4-110(a); Ga. Bd. of Pharmacy R. 480-20-.02]. An exception would be in cases where a Registrant leaves the university and is transferring the Dangerous Drugs to another person who is taking over the work, provided the transferee has appropriate registrations in place. (Note: GBP requires a new registration to reflect a change in the person primarily responsible for the research.)

V. Record-Keeping: A researcher must keep and maintain records of all transactions regarding, receipt, distribution or other disposition of Dangerous Drugs. The forms Dangerous Drugs Order/Receipt Log – Form B, and Dangerous Drugs Use and Disposition Log – FORM C (available at http://www.compliance.emory.edu/) may be used/modified for this purpose. [Ga. Bd. of Pharmacy R. 480-7-.04].

VI. 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.

VII. 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

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.

Practitioner: A Georgia licensed physician, dentist, podiatrist, pharmacist or veterinarian.
Related Links

- Current Version of this Policy: 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/7.29)

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