

Frequently Asked Questions:
State of Georgia and Federal Law Requirements to for Use of
Dangerous Drugs in Non-Human Research

DANGEROUS DRUGS (I.E., PRESCRIPTION DRUGS)

(1) What are “Dangerous Drugs”? Under Georgia law, “Dangerous Drugs” are drugs that are available only by prescription from a licensed health care professional or the purchase of which is restricted to licensed health care professionals. Dangerous Drugs do not include prescription drugs that are “Controlled Substances,” i.e., drugs that have potential for addiction/abuse and are classified as “controlled substances” under state or federal law. Dangerous Drugs also do not include over-the-counter drugs (including certain lower dose forms of drugs that would be considered prescription drugs if they were in higher dose forms). In this notice we will use the term “Dangerous Drugs” to refer to prescription drugs that are not Controlled Substances.

(2) Is there a list of what the State of Georgia considers to be Dangerous Drugs along with any exceptions? Yes. Here is the link to the list: <http://www.lexisnexis.com/hottopics/gacode/>. Click on the link. On home page click “I agree.” On page with table of contents type “16-13-71” in the search box, and then click on “search.” You will be directed to Georgia Code Section 16-13-71. Click on the link for the section and you will be taken to the page(s) that list “Dangerous Drugs.” The list is very long. At the end of the list you will see drug/dosages of drugs that are excepted from being considered Dangerous Drugs.

(3) I’ve heard that even things as benign as injectable sterile saline is a “Dangerous Drug”. Is that true? This is true. The list of “Dangerous Drugs” covers substances that many would not consider “dangerous” in the colloquial sense, such as injectable sterile saline.

(4) Why are so many drugs considered to be prescription drugs, for example sodium chloride injections? The definition of prescription or “Dangerous Drugs” in the Georgia Code stems from the federal Food Drug and Cosmetic Act. That Act has a very broad definition of prescription drugs, including: (a) any drug that because of toxicity or other potentially harmful effect, method or use, or measures necessary for use is not safe except when used under the supervision of a practitioner who is licensed to administer the drug; and (b) any drug that was approved by the FDA on the condition that they would be dispensed only pursuant to prescription. In some cases, a drug may be considered to be a prescription drug in one dose, but not another (e.g., ibuprofen is a prescription drug except when in a single dose of 200 mg. or less).

(5) Do all states have laws like this, or is this strictly a Georgia law? State laws vary regarding requirements to purchase prescription drugs that are not Controlled Substances for use in research. For example, Florida and Tennessee have laws very similar to those in Georgia, but North Carolina does not.

(6) What state or federal permits do I need to have to use Dangerous Drugs in Research (animal, bench or human subjects' research)?

Practitioners: You do not need additional permits if you are a licensed as a practitioner (e.g., MD, DO, DDS, DVM, etc.) in the State of Georgia. You may obtain Dangerous Drugs for research using your practitioner license.

Non-Practitioners: If you are a researcher who is not licensed as a practitioner (e.g., researcher who has a Ph.D. degree but does not hold an MD degree), then you must obtain a Researcher Permit from the State of Georgia in order to be able to obtain Dangerous Drugs for research.

You should provide Emory Purchasing a copy of the Georgia Board of Pharmacy (GBP) Researcher permit or practitioner license when you order the prescription drugs.

See the following charts for a summary of permit requirements:

I HAVE a Georgia practitioner license (e.g., a medical, veterinary or other practitioner license). What permits do I need from state or federal agencies to order Dangerous Drugs for use in my research?

<i>Type of Drug to be Used in the Research</i>	<i>Georgia Researcher Permit from Georgia Board of Pharmacy</i>	<i>Researcher Registration from federal Drug Enforcement Administration (DEA)</i>	<i>Practitioner Registration with DEA</i>
Dangerous Drugs (i.e., prescription drugs that are NOT Controlled Substances)	NO	NO	Not Applicable

I DO NOT HAVE a Georgia practitioner license (medical, veterinary or other practitioner license). What permits do I need from state or federal agencies to order Dangerous Drugs for use in my research?

<i>Type of Drug to be Used in the Research</i>	<i>Georgia Researcher Permit from Georgia Board of Pharmacy</i>	<i>Researcher Registration from federal Drug Enforcement Administration (DEA)</i>
Dangerous Drugs (i.e., prescription drugs that are NOT Controlled Substances)	YES	NO

(7) How do I get a Researcher Permit from the State of Georgia? Go to the webpage for the Georgia Board of Pharmacy at <http://gbp.georgia.gov/>. Click on “Applications and Forms.” Click on the form entitled “Pharmacy Facility Application.” Complete pages 3, 6, 7, 15, 16, and 17. Submission will require a brief resume and current photo (2x2 passport style), as well as proof of U.S. citizenship or qualified alien status (i.e., lawful permanent resident, granted asylum, or admitted as a refugee). The initial application needs to be sent by U.S. Postal Service with a check. Thereafter renewals can be done on-line with a credit card.

(8) How long does it take to get a Researcher Permit from the State of Georgia? The amount of time it takes to get a permit varies depending on individual circumstances and agency caseload. A wait of at least 5 weeks is not unusual. The Georgia Drugs and Narcotics Agency (GDNA) will need to inspect your facility before the permit is granted. They will check to make sure you have appropriate security, procedures and documentation set up.

(9) What are the physical and personnel security requirements for Dangerous Drugs? Generally, the GDNA requires the same security safeguards for Dangerous Drugs as they and the DEA require for Controlled Substances. The Dangerous Drugs must be stored in appropriate conditions, at temperatures that comport with their labeling requirements, and the storage area must be easy to clean and maintain. Dangerous Drugs must be stored in securely locked cabinets (or narcotics safes) in a place where access is restricted to authorized personnel. Access to the cabinet (or safe) must be limited only to persons authorized to work with Dangerous Drugs. The area in which the cabinet (or safe) is kept must be limited to a finite number of personnel. Persons with access to Dangerous Drugs must be trained on applicable laws & procedures, and cannot have been convicted of a felony related to Dangerous Drugs/Controlled Substances, or have had a Dangerous Drugs/Controlled Substances license/registration/permit revoked.

(10) What type of records do I need to maintain for Dangerous Drugs? Generally, the GDNA will require the following documentation:

- Log of persons authorized to use Dangerous Drugs;
- Log of all orders and receipts of Dangerous Drugs;
- Running use and disposition log for each container of Dangerous Drugs.

Templates for these forms can be found on the Office of Compliance website at <http://compliance.emory.edu/controlled-substances/forms.html>.

(11) How long do I need to keep records for Dangerous Drugs?

A researcher must retain separate records for Dangerous Drugs for two (2) years after final disposition of the drugs. Records must be kept for:

- ordering & receipt records
- logs of current use, & disposition

(12) Can I share my Dangerous Drugs with other researchers that need them at Emory?

No. Researcher’s permits and practitioner licenses do not allow for distribution to other researchers, even if the other researcher has the appropriate researcher’s permit or practitioner license. Furthermore, permits are geographically limited to the particular facility (i.e., room) registered.

(13) Can I get Dangerous Drugs from another researcher who has a researcher permit or practitioner license?

No. Even if you have the appropriate researcher's permit or practitioner license, you may only acquire Dangerous Drugs from an appropriately licensed supplier. Emory Finance has procedures and vendors for procurement of Dangerous Drugs on their website:

https://www.finance.emory.edu/home/Procure%20and%20Pay/how_to_buy_in_the_marketplace/index_procure_pay_labresearchgoods.html.

If you do not have the appropriate researcher's permit or practitioner license, it is illegal to possess or use Dangerous Drugs for research purposes.

(14) How do I dispose of Dangerous Drugs?

Dangerous Drugs may be disposed of through the Emory University Environmental Health and Safety Office (EHSO). Contact EHSO at <http://www.ehso.emory.edu/> and go to "Waste Collection." Complete the required information and a representative from EHSO will remove and properly dispose of the drug. Please note that EHSO cannot handle drugs that are designated as Controlled Substances, which must be disposed of via a licensed reverse distributor.

(15) To whom should I direct questions?

More detailed information and instruction regarding Dangerous Drugs can be found on the Office of Compliance website at <http://compliance.emory.edu/controlled-substances/index.html>.

The Office of Compliance also may be contacted at compliance@emory.edu or 404-727-2398 for guidance, or to accompany you during inspections.