

## **Frequently Asked Questions: State of Georgia and Federal Law Requirements to Obtain Prescription Drugs and/or Controlled Substances for Use in Animal or Bench Research**

### **A. PRESCRIPTION DRUGS (THAT ARE KNOWN AS “DANGEROUS DRUGS” IN GEORGIA LAW)**

**(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 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) What about Drugs that are Controlled Substances?** Some prescription drugs are Controlled Substances. Controlled Substances are drugs for which there is a potential for abuse/addiction. Controlled Substances are divided into Schedules I -V depending on their medicinal value and potential for abuse. Schedule I Controlled Substances are considered to have no medicinal value and high potential for abuse. Schedule II Controlled Substances have medicinal value but high potential for abuse. Schedule III – V Controlled Substances have medicinal value and lesser potential for abuse. If you use Controlled Substances in animal or bench research, then you must follow the rules for Controlled Substances (see Section B below) in order to obtain them. The rules for Dangerous Drugs only apply to prescription drugs that are not also Controlled Substances.

**(4) Is there a list of Controlled Substances?** Yes. There is a general list of controlled substances on the Drug Enforcement Administration (DEA) website at [http://www.dea.gov/divisions/office-of-division-director/controlled-substances/orangebook/c\\_cs\\_alpha.pdf](http://www.dea.gov/divisions/office-of-division-director/controlled-substances/orangebook/c_cs_alpha.pdf) . In addition, individual states can include additional substances as Controlled Substances over and above substances on the DEA list. Accordingly, here is a link to the Georgia Code list of all substances considered to be Controlled Substances in Georgia: <http://www.lexisnexis.com/hottopics/gacode/>. Follow the directions in A.(2) above to use this link, but type the following code sections individually into the search box to get information on what drugs are included in specific schedules:

- (a) For Schedule I Controlled Substances type “16-13-25.
- (b) For Schedule II Controlled Substances type “16-13-26”
- (c) For Schedule III Controlled Substances type 16-13-27
- (d) For Schedule IV Controlled Substances types “16-13-28”
- (e) For Schedule V Controlled Substances type “16-13-29”
- (f) For nonnarcotic drugs excluded from schedules of Controlled Substance type “16-13-29.1”

### **(4) What do I need to do to use Dangerous Drugs in Animal or Basic Research?**

**Practitioners:** If you are a licensed as a practitioner (e.g., MD, DO, DDS, DVM, etc.) you may obtain Dangerous Drugs (prescription drugs that are not also Controlled Substances) 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. You should provide Emory Purchasing a copy of this permit when you order the prescription drugs. See the following charts:

**I HAVE a Georgia medical license or a Georgia veterinary license. What else do I need from state or federal agencies to order Dangerous Drugs or Controlled Substances for use in my animal research?**

<i>Type of Drug to be Used in the Animal 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
Controlled Substances	YES	YES	DEA will ask if you have other registration numbers

**I DO NOT HAVE a Georgia medical license or a Georgia veterinary license. What else do I need from state or federal agencies to order Dangerous Drugs or Controlled Substances for use in my animal research?**

<i>Type of Drug to be Used in the Animal 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)	YES	NO	NO
Controlled Substances	YES	YES	NO

**(5) 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 - Updated 07/17/15](#). 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.

**(6) 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.

**(7) What type of facilities and security do I need for a Researcher Permit for Dangerous Drugs?** The Dangerous Drugs must be stored in appropriate conditions and at temperatures that comport with

their labeling requirements. Additionally, the area/container in which the Dangerous Drugs are stored must be locked or otherwise provide security from unauthorized entry, and it must be of a size and design that facilitates cleaning, maintenance and proper operations. 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.

**(8) What type of records to I need to maintain for Dangerous Drugs?** Researchers need to maintain records of the receipt of Dangerous Drugs and any use, distribution, disposal or other disposition of Dangerous Drugs. Records must be kept for two (2) years following the final disposition of any drug received. There are forms that you can use for record keeping on the Office of Compliance webpage. Go to <http://compliance.emory.edu/> and click on the Controlled Substances & Dangerous Drugs link. Then click on the tab for the “Forms.”

**(7) 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.

**(8) 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).

## **B. CONTROLLED SUBSTANCES**

**1. What are Controlled Substances?** Controlled Substances are drugs for which there is a potential for abuse. Controlled Substances are divided into Schedules I -V depending on their medicinal use and potential for abuse. Schedule I Controlled Substances are considered to have no medicinal value and high potential for abuse. Schedule II Controlled Substances have medicinal value but high potential for abuse. Schedule III – V Controlled Substances have medicinal value and lesser potential for abuse. If you use Controlled Substances in animal or bench research you have to follow the rules for Controlled Substances in order to obtain them.

**2. Is there a list of Controlled Substances?** Yes. There is a general list of controlled substances on the DEA website at [http://www.deadiversion.usdoj.gov/schedules/orangebook/c\\_cs\\_alpha.pdf](http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf) . In addition, individual states can include additional substances as Controlled Substances over and above substances on the DEA list. Accordingly, here is a link to the Georgia Code list of all substances considered to be Controlled Substances in Georgia: <http://www.lexisnexis.com/hottopics/gacode/>. Follow the directions in A.(2) above to use this link, but type the following code sections individually into the search box to get information on what drugs are included in specific schedules:

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- (e) For Schedule V Controlled Substances type “16-13-29”
- (f) For nonnarcotic drugs excluded from scheduled of Controlled Substance type “16-13-29.1”

### **3. What do I need to do to use Controlled Substances in Animal or Basic Research?**

Practitioners: If you are a licensed as a practitioner (e.g., MD, DO, DDS, DVM, etc.) you must also obtain a Researcher Permit from the State of Georgia and a Researcher Registration from the DEA to obtain Controlled Substance for use in animal or basic research.

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 and a Researcher Registration from the DEA. You should provide a copy of this permit when you order the prescription drugs. See the charts above under Section A.4.

### **4. How do I get a Researcher Permit from the State of Georgia and a Registration from the DEA?**

(a) First, apply for the State of Georgia Researcher Permit. Follow the directions above in Section A.5. You will need to have the Georgia Researcher Permit in order to apply for the DEA Researcher Registration. The Georgia Drugs and Narcotics Agency will come to inspect your site before they issue the Georgia Researcher Permit. To pass the inspection, you will need the specific process for Security; Record-keeping; Procurement and Disposal. To find out what you need, go to this link: <http://compliance.emory.edu/controlled-substances/index.html> . Click on the “Training” button and carefully read the slide presentation. Next, go back to the above link and click on the “Forms” button. There you will find that forms that you need to put in place to keep track of Controlled Substances in your lab. Use these forms and keep them up to date. Finally, go back to the link above and click on the “Policy” button. Read and familiarize yourself with Emory Policy 7.25, *Research Use of Controlled Substances*.

(b) Second, apply for the DEA Researcher Registration. To apply, go to this link: [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/225/225\\_instruct.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm) . If you are a researcher applying to use Schedule I controlled substances, you will need to print out DEA Form 225 available at this link (click “Download DEA Form 225 (PDF)”) and send it in by mail. If you are not using Schedule I Controlled Substances, you can apply on-line by clicking on “Complete DEA Form 225 Online.” Before completing Form 225 on-line or in hardcopy, read the instructions posted under the aforementioned links to the Form 225. The DEA may rely on an inspection of your site by the Georgia Drugs and Narcotics Agency, or it may perform an additional inspection of your site.

### **6. How long does it take to get the Georgia Researcher Permit and DEA Researcher Registration?**

The amount of time it takes to get a permit varies depending on individual circumstances and agency caseload. A wait of at least two to three months is not unusual.

### **7. Are the laws regarding the use of Controlled Substances in research the same in all states?**

The laws for the use of Controlled Substances in research are not exactly the same in all states, but they are very similar. This similarity stems from the fact that there are substantial and comprehensive federal regulations governing the use of Controlled Substances that influence state laws.

### **Questions on this FAQ?**

Contact the Emory University Office of Research Compliance at [orc@emory.edu](mailto:orc@emory.edu) or

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