Frequently Asked Questions: State of Georgia and Federal Law Requirements to Obtain Dangerous Drugs and/or Controlled Substances for Use in Research

A. 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.

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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?

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

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?

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<th>Type of Drug to be Used in the Research</th>
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<tbody>
<tr>
<td>Dangerous Drugs (i.e., prescription drugs that are NOT Controlled Substances)</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

(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/](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

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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. Records must be kept for two (2) years following the final disposition of any drug received.

(11) 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.

(12) 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_procur_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.

(13) 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.

(14) 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.

B. CONTROLLED SUBSTANCES

(1) What 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. Some prescription drugs are Controlled Substances. If you use Controlled Substances in research, then you must follow the rules for Controlled Substances in order to obtain them. The rules for Dangerous Drugs only apply to prescription drugs that are not also Controlled Substances.

(2) 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.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 Section 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”

(3) What state and federal permits do I need to do to use Controlled Substances in research (animal, bench or human subjects)?

Registration requirements depend on whether or not you are a practitioner, the Schedule of the drug to be used in the research and the type of research.

See the following charts for a summary of permit/registration requirements:

I HAVE a Georgia practitioner license (medical, veterinary or other practitioner license). What else do I need from state or federal agencies to order Controlled Substances for use in my research?

<table>
<thead>
<tr>
<th>Type of Drug to be Used in the Research</th>
<th>Georgia Researcher Permit from Georgia Board of Pharmacy</th>
<th>Researcher Registration from federal Drug Enforcement Administration (DEA)</th>
<th>Practitioner Registration with DEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Substances</td>
<td>YES(^1)</td>
<td>NO for human subject research Schedule II-V YES for animal &amp; bench research Schedule I-V &amp; human subject research Schedule I</td>
<td>YES [DEA will ask if you have other registration numbers]</td>
</tr>
</tbody>
</table>

\(^1\) DEA allows practitioners to dispense, or conduct research with controlled substances in schedule II, III, IV, or V for human research if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he/she practices. Georgia, however, requires a separate researcher permit for use of controlled substances in research.

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I DO NOT HAVE a Georgia practitioner license (e.g., medical, veterinary or other practitioner license). What else do I need from state or federal agencies to order Controlled Substances for use in my research?

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<th>Researcher Registration from federal Drug Enforcement Administration (DEA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Substances</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

The registration process can be summarized as follows:

a. You must apply for the Georgia permit first. This can be done by completing the GBP’s “Pharmacy Facility Application.” See specific directions below. (Note: If during the course of your research you change to a different schedule of Controlled Substance, you will need to file a new Georgia registration application. [See Pharmacy Facility Application, pg. 3, “Purpose of Applications” section, “Change in Schedule”].

b. 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 in place.

c. Once you have the Georgia permit, you can apply for the DEA registration. This can be done by completing the DEA Form 225 and submitting with other needed documentation online or by mail (research that involves Schedule I Controlled Substances must be done by mail). See specific directions below.

d. The DEA may rely on the GDNA inspection, or may come to inspect at its discretion.

e. DEA Registration is site specific. If you conduct your research at more than one location, you will need a separate registration for each separate address. DEA Registration for Schedule I Controlled Substances is also protocol specific, so if you change your research protocol you will need to file a supplemental protocol with DEA and permission is also required to increase the amount of Schedule I Controlled Substance used under the protocol. [See 21 CFR Section 1301.18].

(4) How do I apply for a Researcher Permit from the State of Georgia?

Go to the webpage for the Georgia Board of Pharmacy (GBP) 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.

The GDNA will come to inspect your site before the GBP will issue the Georgia Researcher Permit. To pass the inspection, you will need to ensure that you have appropriate processes and documentation in place 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 the forms that you need to put in place to keep track of Controlled Substances. 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.

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(5) How do I apply for a Researcher Permit from the DEA?
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 Substance, 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.

(8) What are the physical and personnel security requirements to have Controlled Substances?
Generally, the GDNA and DEA will look for the following security safeguards:
- Locks on rooms where Controlled Substances are stored
- Controlled Substances must be stored in securely locked cabinets or safes that cannot be easily moved, and constructed so that forced entry is easily detected. Schedule I Controlled Substances must be kept in narcotics safe or similar container.
- There should be controlled access to the room in which the Controlled Substances are stored; a list must be maintained of persons with keys/codes to enter the room. Access to storage cabinet must be limited to only those authorized to work with Controlled Substances.
- Persons with access to Controlled Substances must be trained on applicable laws & procedures, and they cannot have been convicted of a felony related to controlled substances, or have had a DEA registration revoked.
- Schedule I and Schedule II Controlled Substances must be kept separately from Schedule III to V Controlled Substances.

(9) What documentation do I need to maintain for Controlled Substances?
Generally, the GDNA and DEA will look for the following documentation:
- Log of persons with access to room where Controlled Substances are stored;
- Log of persons authorized to use Controlled Substances;
- Log of all orders and receipts of Controlled Substances;
- Initial and biennial inventory log;
- Running use and disposition log for each container of Controlled Substances;
Templates for these forms can be found on the Office of Compliance website at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html).
Records for Schedule I and II Controlled Substances must be kept separately from records for Schedule III to V Controlled Substances.
(10) Can I provide Controlled Substances to other researchers under my registration or obtain Controlled Substances for research from another researcher?
No. Emory University Policy generally prohibits registrants from transferring controlled substances to another registrant. See Emory Policy 7.25, Research Use of Controlled Substances, Section C.ii, Personnel Security Requirements, Section (2).

*If you do not have the appropriate researcher’s permits and registration, it is illegal to possess or use Controlled Substances for research purposes.*

(11) How do I dispose of Controlled Substances?
You must engage an appropriately licensed reverse distributor to dispose of extra or expired Controlled Substances.

(12) I recall there being annual “Days of Destruction” for onsite disposal. Is that an option?
No, DEA no longer permits these events. At present, the only available disposal option is through a reverse distributor.

(13) What if I discover a theft of any amount of a Controlled Substance or a significant loss of a Controlled Substance?
Promptly on discovery, notify EPD; EHSO and OC. EHSO and OC can provide assistance to Researchers in completing reports to DEA and GDNA and researchers are advised to contact either of these units before submitting reports to DEA/GDNA. Reports to Emory units should be made using the Controlled Substances Discrepancy Report Form – FORM 5 (available at [http://compliance.emory.edu/](http://compliance.emory.edu/)). Contact information for Emory units to which reports should be made is listed on Form 5.

(14) To whom should I direct questions?
More detailed information and resources regarding Controlled Substances can be found on the Office of Compliance website at [http://compliance.emory.edu/controlled-substances/index.html](http://compliance.emory.edu/controlled-substances/index.html). The Office of Compliance may also be contacted at compliance@emory.edu or 404-727-2398 for guidance, or to accompany you during inspections.