

# **Frequently Asked Questions: State of Georgia and Federal Law Requirements for Use of Controlled Substances in Research**

## **Background Information**

### **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 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](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. 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/>. On the home page click “I agree.” In the table of contents type the following code sections individually into the search box to get information on what drugs are included in specific schedules:

- For Schedule I Controlled Substances type “16-13-25”
- For Schedule II Controlled Substances type “16-13-26”
- For Schedule III Controlled Substances type “16-13-27”
- For Schedule IV Controlled Substances types “16-13-28”
- For Schedule V Controlled Substances type “16-13-29”
- For nonnarcotic drugs excluded from schedules of Controlled Substance type “16-13-29.1”

### **3. 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.

## **Research Use**

### **4. If I want to use a controlled substance for research, what steps do I need to take?**

If you do not have a Georgia practitioner license (medical, veterinary or other practitioner license), you will be required to obtain a Georgia Researcher Permit and DEA Researcher Registration. If you do have a Georgia practitioner license (medical, veterinary or other practitioner license), you may have other requirements depending on the research you are conducting and the controlled substance schedule.

### **5. 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.

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

Registration requirements depend on if 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?

<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>
Controlled Substances	YES <sup>1</sup>	NO for human subject research Schedule II-V YES for animal & bench research Schedule I-V & human subject research Schedule I	YES [DEA will ask if you have other registration numbers]

<sup>1</sup> 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.

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?

<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>
Controlled Substances	YES	YES

**7. What is involved in the Registration process?**

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].

**8. 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*.

#### **9. How do I apply for a Researcher Registration from the DEA?**

To apply, go to this link:

[http://www.dea diversion.usdoj.gov/drugreg/reg\\_apps/225/225\\_instruct.htm](http://www.dea diversion.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.

#### **10. How do I renew?**

The renewal periods for the GBP and the DEA permits do not synchronize. DEA usually will send a reminder about 45 days before expiration; the GBP will never send a reminder.

GBP: The GBP Researcher permit will always expire on June 30 of the even numbered years. The application for a Georgia researcher’s permit can be found on the GBP website at <http://gbp.georgia.gov/> using: (a) Online Services; (b) Renew Online.

DEA: The DEA registration must be renewed every year, with the renewal date a year from the original issue month. Researchers must submit renewal Form 225a and Practitioners renewal Form 224a. DEA will send only one renewal notification to the registrant. Additionally, renewal applications must be received no later than the current license expiration date. If you allow your license to expire, a new application must be submitted. Late renewal applications will not be accepted by the DEA.

#### **11. What steps are required to get approval to use Schedule 1 Controlled Substances in Human Subjects research?**

Use of Schedule 1 Controlled Substances in a clinical trial with human subjects requires obtaining a researcher permit from the GBP and registration with the DEA in addition to IRB approval. If an Emory investigator will hold the Investigational New Drug application (IND), the investigator must first obtain this from the FDA. Click [here](#) for IND information including IND submission forms and templates.

Investigators should consult with the Office of Compliance (OC) to look at any potential issues with state law and FDA research regulations. The Emory IRB will direct investigators to submit a completed [Investigator Checklist for Use of Schedule 1 Controlled Substances](#) to OC at [compliance@emory.edu](mailto:compliance@emory.edu) for review of any research study using a Schedule 1 Controlled Substance. OC will perform a compliance review to ensure that processes are in place to meet state and federal requirements.

## **Ordering**

### **12. How do I obtain Controlled Substances for non-human research?**

Registrants must order Controlled Substances for research through Emory's Procurement Department [https://www.finance.emory.edu/home/Procure%20and%20Pay/how\\_to\\_buy\\_in\\_the\\_marketplace/index\\_procure\\_pay\\_labresearchgoods.html](https://www.finance.emory.edu/home/Procure%20and%20Pay/how_to_buy_in_the_marketplace/index_procure_pay_labresearchgoods.html). You will need to provide a copy of the Georgia Board of Pharmacy (GBP) Researcher permit or practitioner license and DEA registrations when you order the controlled substances.

A Registrant must order Schedule I and II Controlled Substances himself/herself, or alternatively, delegate a responsible person to perform ordering by signing a Power of Attorney form. Orders for Schedule I and II Controlled Substances must be made using hardcopy DEA Form 222 or the DEA's electronic Controlled Substances Ordering System (CSOS) process. To establish a CSOS account, the Registrant must contact McKesson, an Emory vendor of Controlled Substances, and complete the necessary registration form with DEA.

## **Documentation**

### **13. 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>.

**14. How long do I need to keep records for Controlled Substances?**

Registrant must keep all records relating to Controlled Substance ordering, procurement, use and inventory for three (3) years from final disposition of drug. Records for Schedule I and II Controlled Substances must be kept separately from records for Schedule III to V Controlled Substances. Completed inspection forms/materials provided to the Researcher by the GDNA and/or the DEA for application approval must be perpetually retained with the respective active Registration.

**Security**

**15. 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.

**16. 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.*

**17. 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 (See <http://compliance.emory.edu/controlled-substances/Report%20A%20Loss.html>). 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/>). Contact information for Emory units to which reports should be made is listed on Form 5.

## **Disposal**

### **18. How do I dispose of Controlled Substances?**

You must engage an appropriately licensed reverse distributor to dispose of extra or expired Controlled Substances. Researchers are required to ensure that all Controlled Substances are properly disposed when the substances expire; or the Registrant's DEA registration is not renewed; or when the Registrant no longer conducts research at Emory University using Controlled Substances or leaves Emory University. This may require establishing an account with an approved Reverse Distributor vendor, e.g. The Rx Exchange (<http://therxe.com/>)

### **19. 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.

## **Additional 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>.

The Office of Compliance may also be contacted at [compliance@emory.edu](mailto:compliance@emory.edu) or 404-727-2398 for guidance, or to accompany you during inspection