News from ORIC on Controlled Substances and Dangerous Drugs

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IRB
Review of submissions using Schedule 1 Controlled Substances in clinical trials with human subjects
Schedule 1 Controlled Substances in a clinical trial with human subjects

The Emory IRB directs investigators to submit a completed Investigator Checklist for Use of Schedule 1 Controlled Substances to ORIC for review of any research study using a Schedule 1 Controlled Substance.

ORIC performs a compliance review to ensure that processes are in place to meet state and federal requirements.

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.

Investigators are advised to create an SOP for managing the Schedule 1 drug. We have an SOP Template on the ORIC website.
We are updating our current Dangerous Drugs and Controlled Substance training and we are adding it in ELMS!

The new format has a better layout and streamlined information so you can receive more effective training.

Find our training offerings here at https://rcra.emory.edu/oric/controlled-substances/training.html
Policy Revisions

Combining current 7.25 and 7.29

Clarifying information, streamlining processes

ORIC/RCRA will be Administering Office

Created Working Group of stakeholders

Includes recommendations that registrants submit registration information to ORIC and that registrants take training offered by ORIC
The ORIC Team is currently working on the following initiatives:

- Merging Policy 7.25 (Controlled Substances) and 7.29 (Dangerous Drugs) into one Policy.
- Updating our Controlled Substance and Dangerous Drug Training and making them available in eLMS.
- Pre-Inspection Program
- QA/QI Program
- Updated and New Forms available on the ORIC website
- Updating the ORIC website
Pre-Inspection Program

For those who intend to conduct research with Dangerous Drugs and/or Controlled Substances, you are required to have a GA Board of Pharmacy license and/or D.E.A. license. A Licensee is called a Registrant and the process to obtain a license can be laborious. The ORIC Team is here to help you get you through it with our Pre-Inspection Program.

Our office can help:

• Walk you through the procedures required to obtain a license
• Assist you with your application submission documents for each regulating agency
• Make sure everyone has proper training, clearance to handle the drugs, and review Emory forms
• Pre-inspection readiness checks (including security requirements, DEA/GDNA Ready Binder)

Please notify us if you intend to acquire a license or modify an existing one.
Dangerous Drug Registration Process Overview

1. Contact ORIC to help with your pre-inspection, process and document submission
2. Look for adequate storage location for dangerous drugs
3. Complete application with Georgia Board of Pharmacy (GBP), and await approval
4. Call Georgia Drug and Narcotics Agency (GDNA) at 404-656-5100 to schedule your pre-inspection

Wait time of
60 days or more

Wait time of
30 days or more

After pre-inspection is completed, you will receive your Georgia researcher permit.

You are done!
Controlled Substance Registration

Process Overview

1. Contact ORIC to help with your pre-inspection, process and document submission
2. Look for adequate location and purchase and install locked cabinets for storage of drugs
3. Complete application with Georgia Board of Pharmacy (GBP), and await approval
4. Call Georgia Drug and Narcotics Agency (GDNA) at 404-655-5100 to schedule your pre-inspection
5. After pre-inspection is completed, and you received your Georgia researcher permit, submit your application with DEA online
6. DEA will review your application and do an inspection
7. You are done!

Wait time of 60 days or more

Wait time of 30 days or more

Wait time of 30 days or more
Modifications to a Registration

A simple change of address initiates the Same Process
Same Wait Times

And you can't move the drugs until you have been fully approved!!!
Let Us Help

We can alleviate some of the burden by guiding you through this tedious process with our Pre-Inspection Program. Let's get it right the first time!

You can find a roadmap on our website Registration Process | Emory University | Atlanta GA

After receiving your GA Board of Pharmacy and/or DEA License then you're eligible for our QA/QI Program.
Quality Assurance/Quality Improvement (QA/QI) Program

- In Mid-March our office is launching the QA/QI Program.

- The goal of the program is to ensure that every Emory Registrant is compliant with the state/federal regulations, Emory Policy, and to prepare Researchers for Agency Audits.

- DEA/GDNA *does not* announce when they are going to audit a Registrant!

- The ORIC Team will be randomly selecting Emory Registrants and begin reviewing records and conducting drug accountability checks for controlled substance users to help ensure a successful Regulating Agency audit.
What can I expect?

- You will be notified one week prior to the onsite visit to set up a time to inspect your lab.
- We ask that you conduct the Controlled Substance (Form 1) and/or Dangerous Drug Self-Assessment Forms which can be found on our website prior to our visit [Forms | Emory University | Atlanta GA](https://www.emory.edu/)
- Once we are onsite, we will review your records and security processes. If you have controlled substances, we will conduct a drug accountability check (just like DEA does).
- After we have completed the QA/QI assessment you will be provided with a report that will help you make improvements should any deficiencies be found.
Don't wait for us to call you.

You can be your own QA/QIP Superhero by contacting us to schedule your Assessment today!
We also have new and updated forms for your use:

- **Form 1**: Controlled Substances Self-Inspection (DOCX)-updated
- **Form 5**: Controlled Substances Discrepancy Report Form (DOCX)-updated
- **Form 13a**: Use and Disposition Log Prescription (EXCEL)
- **Form 13b**: Disposal Log Prescription (EXCEL)
- **Dangerous Drugs Self-Inspection (DOCX)**-updated
- **Form E**: Dangerous Drugs Discrepancy Form (DOCX)
Recent Website Updates

Our website has been revamped to offer more organized information at your fingertips

We have added the following pages for easier information access:

- Registration
- After Approval Information
- We Can Help!

We also have created this infographic to help you with your controlled substances questions: https://rcra.emory.edu/_includes/documents/sections/oric/tips-cs-infographic.pdf
Our contact info

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Thank you! Any Questions?