News from ORIC on Controlled Substances and Dangerous Drugs

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ORIC Ongoing Programs

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IACUC

Review of Controlled Substances and/or Dangerous Drugs findings from Post Approval Monitoring

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

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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.

Updated Training

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

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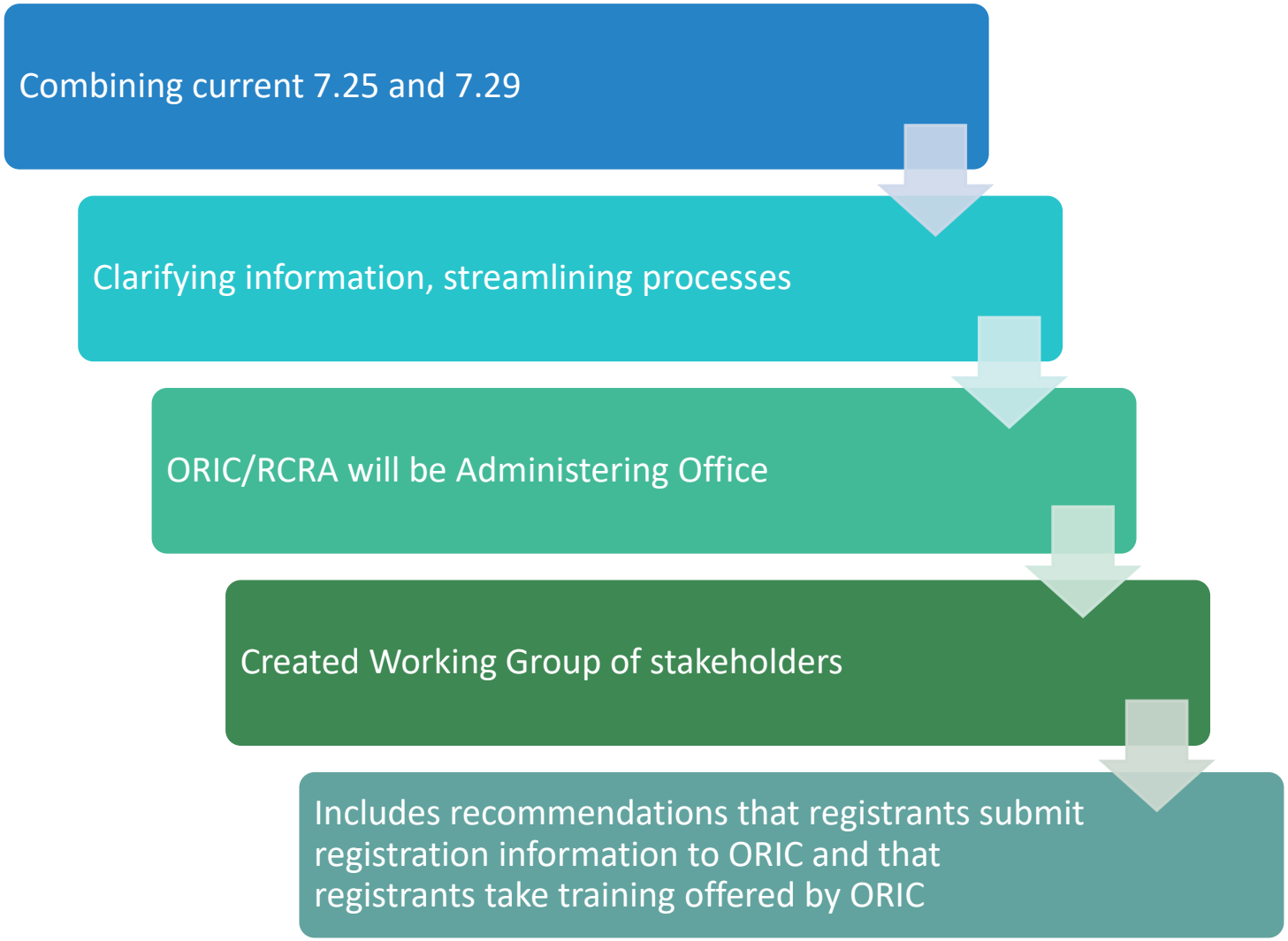

Policy Revisions

Initiatives

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

Contact ORIC to help with your pre-inspection, process and document submission

Look for adequate storage location for dangerous drugs

Complete application with Georgia Board of Pharmacy (GBP), and await approval

Wait time of 60 days or more

Call Georgia Drug and Narcotics Agency (GDNA) at 404-656-5100 to schedule your pre-inspection

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

Contact ORIC to help with your pre-inspection, process and document submission

Look for adequate location and purchase and install locked cabinets for storage of drugs

Complete application with Georgia Board of Pharmacy (GBP), and await approval

Wait time of 60 days or more

Call Georgia Drug and Narcotics Agency (GDNA) at 404-656-5100 to schedule your pre-inspection

Wait time of 30 days or more

After pre-inspection is completed, and you received your Georgia researcher permit, submit your application with DEA online

DEA will review your application and do an inspection

Wait time of 30 days or more

You are done!

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
- 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!

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Updated and New Forms

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?

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