



CONTROLLED SUBSTANCES AND DANGEROUS DRUGS QUALITY ASSURANCE (QA)/QUALITY IMPROVEMENT (QI) PROGRAM



WHAT WOULD THE QA/QI REVIEW ENTAIL?

We will review documents (logs, permits/licenses) and processes for using Controlled Substances and Dangerous Drugs for compliance with Georgia law, federal regulations, and institutional policies. We provide subject matter expertise on regulatory requirements, institutional policies, and best practices based on the specific needs of your research.

WHY IS ORIC CONDUCTING QA/QI REVIEWS?

To help Emory researchers using Controlled Substances and Dangerous Drugs follow regulatory and institutional requirements at each step in the process--from license application to disposal. Thus, investigators are always ready for announced or unannounced inspections by the DEA and GDNA offices.

WHAT CAN I EXPECT?

- We will schedule a time to visit. The visit will begin with an inventory of the drugs on hand.
- We will review the records associated with the drugs and note anything missing or unavailable.
- We summarize our findings and recommendations in a report to the Registrant.
- If issues need corrections (e.g., missing a biannual review, lapse licenses, incorrect accountability), we will work with the Registrant to create an effective Corrective and Preventive Action (CAPA) plan as needed.
- The ORIC team will follow up with the Registrant to ensure the completion of the CAPA plan, if applicable.
- If a finding negatively affects the safety and welfare of human or animal subjects, we will work with the PI to report it to the IRB or IACUC, as appropriate.

How Can I Prepare?

Visit our website at <https://rcra.emory.edu/oric/controlled-substances/contact-us-cs-dd.html> for more information,