

Considerations for Studies Using Controlled Substances and Dangerous Drugs

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Definitions

Controlled Substances: All drugs, substances or immediate chemical precursors listed in **Schedules I to V** of OCGA Sections 16-13-25 to 16-13-29; and Title 21 of the Code of Federal Regulations (CFR) Section 1308.

Dangerous Drugs: Any drug, other than a Controlled Substance, that federal law prohibits dispensing of without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act. Dangerous Drug also includes any other drug that the Georgia General Assembly has declared to be a dangerous drug.

Note: This presentation does not cover the use of controlled substances or dangerous drugs by a licensed physician, pharmacist, dentist, podiatrist, or veterinarian (a Practitioner) **in providing health/veterinary care** for his/her patients or clients.

Emory Policy 7.25- Research Use of Controlled Substances

Emory Policy 7.29- Research Use of Dangerous Drugs



EMORY
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Office of Research Integrity and Compliance
Research Administration

Who can use Controlled Substances or Dangerous Drugs in Research?

Dangerous Drugs

- Licensed practitioners are permitted to use Dangerous Drugs under their license
- Unlicensed researchers must obtain a permit

Controlled Substances

- A licensed practitioner
 - Require a permit to use the controlled substance for research purposes, if using a schedule, I drug (not needed for schedules II to V)
 - DEA registration: needed for animal or bench research, or if using a Schedule I controlled substance
- Unlicensed researcher
 - You will be required to obtain a Georgia Researcher Permit and DEA Researcher Registration



How do I verify if the drug I want to use is Controlled or Dangerous?

Go to the [Department of Justice](#), drug enforcement division and check.

Then [go to our website](#), and check on the process to obtain a permit and DEA registrations as applicable

Learn about your responsibilities!

Required Actions and Activities

Register

Implement Physical Security Measures

- DEA will do an inspection before issuing a registration (unique per location)
- Ensure drugs are properly secured in a locked, safe place (cabinet) and in their original packaging

Implement Personnel Security Measures

- Cabinets need to be bolted to the wall
- Ensure proper key handlings and security measures
- Promptly report loss or theft



Required Actions and Activities

Follow Proper Ordering & Procurement Process

- Authorized User log (form 4) and signed Emory University Employee and Agent Screening Statement (form 5)
- Cannot transfer CS or DD
- Use Emory procurement to order your drugs
- Keep logs of the drug use and storage location

Follow Proper Disposal Process

- Dispose before expiration using appropriate means (reverse distribution for CS; EHSO procedures for DD)

Adhere to Record Keeping Requirements

- Initial, biennial inventory
- Log use
- Documentation (purchase, receipt) and records per schedule



Consequences of not following Emory Policy/GA DEA requirements

Immediate loss of the ability to conduct the Emory-supported Research using Controlled Substances

Immediate loss of the ability to use Emory University facilities to conduct Research using Controlled Substances

Disciplinary action being taken against that person, up to and including termination of employment or dismissal from academic programs; and/or referral for prosecution by law enforcement officials



Question 1

A faculty member wants to buy a Schedule I drug for a research with human subjects. He is a physician, licensed in Georgia. **What would he need to start his project?**

1. The physician does not need anything. As a physician licensed in Georgia, he can prescribe any drug
2. The physician needs a DEA license besides his current license
3. The physician needs both a DEA license and a research permit for this use

Answer:

The physician needs both a DEA license and a research permit for this use

Because the physician is using a Controlled substance under Schedule I, he also needs a permit to conduct this research.



Question 2

A faculty member ordered too much of a dangerous drug for animal research. Another investigator in his department, with an approved IACUC study, needs the same drug for her research.

Is it OK to share the drug, documenting the transfer in the log?

Option 1: Yes, as long as it is well documented, this would be acceptable

Option 2: No, dangerous drugs cannot be shared

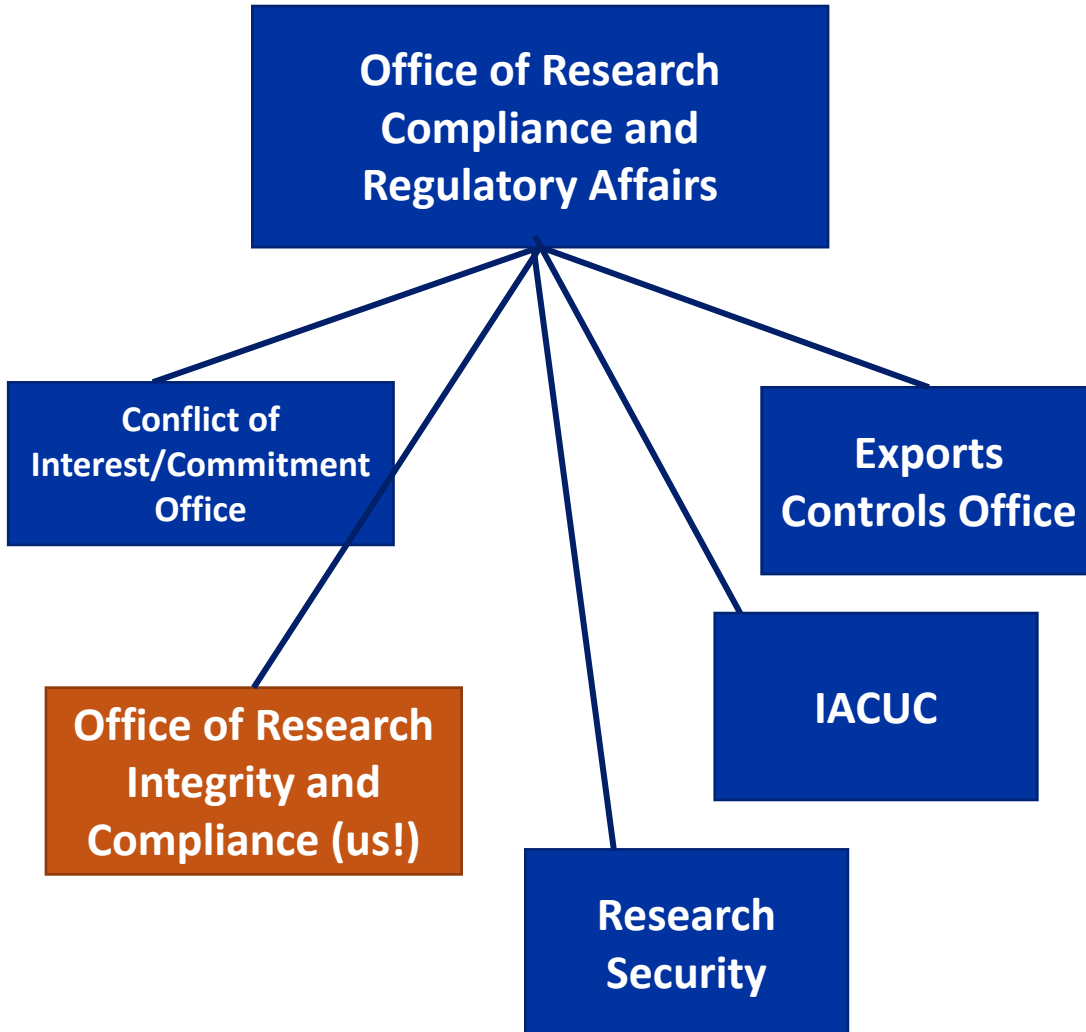
Option 3: Yes, if ORIC approves it

Answer

No, dangerous drugs cannot be shared.

Also, the drugs need to be disposed using EHSO current guidance.

Office of Research Integrity and Compliance



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Latest Efforts

- Policy modifications to improve accessibility
- Taskforce group
- Common issues: Reverse Distribution, improper use of forms, and removal of Buprenorphine SR