Considerations for Studies Using Controlled Substances and Dangerous Drugs

Julian A. Hinds, JD
Office of Research Integrity and Compliance
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
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
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.
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Because the physician is using a Controlled substance under Schedule I, he also needs a permit to conduct this research.
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
No, dangerous drugs cannot be shared.

Also, the drugs need to be disposed using EHSO current guidance.
Office of Research Integrity and Compliance

Maria Davila
Director, Office of Research Integrity and Compliance
Deputy Research Integrity Officer
maria.davila@emory.edu
404-712-8676

Margaret Huber
Compliance Manager (FDA, HSR)
mhuber@emory.edu
404-727-2233

Julian Hinds
Compliance Officer (IACUC, Controlled Substances)
 julian.a.hinds@emory.edu
404-727-2516

https://rcra.emory.edu/about/ask_rcra.html
Latest Efforts

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