

IACUC Inspection Controlled Substances and Dangerous Drugs FAQs

All controlled substances and dangerous drugs must be approved in the IACUC protocol before these are used in animal subjects. Similarly, all personnel handling controlled substances and dangerous drugs must be included in the IACUC protocol. Contact iacuc@emory.edu if you have any questions.

IACUC policies must be followed when using controlled substances and dangerous drugs on animal subjects.

What are Controlled Substances?

Controlled Substances are drugs for which there is potential abuse/addiction. Controlled Substances are divided into Schedules I -V depending on their medicinal value and potential for abuse. The Drug Enforcement Administration (DEA) website lists a [general list of controlled substances](#).

In addition, individual states can include additional substances as Controlled Substances over and above substances on the DEA list. Here is a link to the [Georgia Code](#) list of all substances considered Controlled Substances in Georgia (under Title 16, Chapter 13, Art, 2, Pt.1).

If the drug bottle contains a mark that reads "C1," it is a Schedule 1.

What are Dangerous Drugs?

"Dangerous Drugs" refer to prescription drugs that are not Controlled Substances. There is a list of Dangerous Drugs and exceptions in the [Georgia Code](#) (under Title 16, Chapter 13, Art. 3, Pt 71).

At the end of the list, you will see drugs/dosages excluded from being considered Dangerous Drugs.

Common examples of Dangerous Drugs are Isoflurane and Meloxicam. If the drug has RX in the box or the registrant used their license for purchase, it is considered a Dangerous Drug.

Getting Started

How do new researchers get started if using Controlled Substances and/or Dangerous Drugs in research?

[Review this registration information](#) to get started with Controlled Substances and/or Dangerous Drugs. If there are additional questions, contact the Office of Research Integrity and Compliance at oric@emory.edu.

Forms

Are the ORIC forms required for using Controlled Substances and Dangerous Drugs?

No, ORIC forms are not required. Despite that, we strongly encourage our researchers to use them because they are updated according to DEA and GDNA advice. Find the forms [in this link](#). If a researcher chooses to use their own forms, they should ensure that they are maintaining a current, running use and disposition log that shows the type and amount of drug dispensed/administered; name and initials of the person who dispensed/administered them; date dispensed/administered; and purpose of use. For controlled substances, keeping a biennial inventory and records of drug receipt and disposition is required. If there are doubts about the form used for documentation, send us a copy to oric@emory.edu.

Should researchers weigh the bottle or the amount of drug in a bottle?

It depends. For Isoflurane, the bottle should be weighed and the difference should be recorded after each use. The user should record the amount used for other drugs in powder or liquid, and not weigh the bottle. For special circumstances, please contact ORIC at oric@emory.edu.

If a drug is not a controlled substance or dangerous drug (for example, Xylazine), should it be logged?

Drugs that are not controlled substances or dangerous drugs are not required to be logged for regulatory purposes. The IACUC may have other requirements, and the logs can be used if needed, but the [ORIC forms](#) are not required.

During a site inspection, a registrant had forms that needed to be completed. What is required?

Registrants should follow the forms' directions and complete them fully (if using [ORIC forms](#)). If you note an incomplete form, ask them to complete it if it is not part of the drug use and disposition record. If the drug use and disposition is not completed or completed partially, please refer it to ORIC and let us know the form that was not completed as required.

Usage and Storage of Controlled Substances and Dangerous Drugs

Can drugs be transported for use at a different building than the approved storage location?

Controlled substances should not be moved from the building approved by the GDNA/DEA for use. If the Controlled Substances are being used on a different floor at the same address, the drug must be stored back in the DEA/GDNA-approved location at the end of the day.

Dangerous Drugs can be transported for use anywhere but must be stored back in the GDNA-approved location at the end of the day.

Where should researchers keep their Controlled Substances and Dangerous Drugs?

They should be kept in the storage location approved by the DEA and GDNA at the time of registration. Controlled Substances must be kept in a securely locked, substantially constructed cabinet or safe that is securely fastened to the floor or wall so that it can't easily be removed. Dangerous Drugs should be kept in the same manner as Controlled Substances.

During an inspection, I noticed that a drug had expired. What should we do?

The drug bottle should be marked as expired and saved in the DEA/GDNA-approved cabinet (if used in animals, these drugs need to be separated from those used in animals and marked "not for use in animals"). The researchers should contact a reverse distributor (controlled substances) or EHSO (for dangerous drugs) to dispose of the drug when possible or as mandated by the IACUC. The registrants should update their logs with the drug disposition.

Sharing Controlled Substances and Dangerous Drugs

Can registrants share Controlled Substances or Dangerous Drugs with other researchers?

Emory policy does not permit the Registrant to provide drugs to any other persons for use in those persons' Research or for any other use. For research collaborators to use these drugs, they should be included in the registrants' research protocol; the registrant has authorized the user to use that Controlled Substance by completing the authorized user logs, and the registrant is actively collaborating with the user on the research and not in name only.

Can registrants store drugs at another location other than the DEA or GDNA-approved location?

The drug can only be stored in the DEA/GDNA-approved container at the address listed on the license. If the registrant needs to relocate the drug to another cabinet or move it to a different location, they must request approval from the GDNA and DEA before moving it. This ensures that the drug is stored safely and securely and that all necessary regulations are followed.

Drug Disposal

How do registrants should remove unwanted or expired Controlled Substances?

Expired or unwanted Controlled Substances must be disposed of using a reverse distributor. Registrants at Emory have used [Rx Exchange](#) or [Maximum Rx Credit](#) for reverse distribution. Find more information on the [ORIC webpage](#).

How do registrants remove unwanted or expired Dangerous Drugs?

To dispose of Dangerous Drugs, registrants should go to the [EHSO website](#) and select the waste collection icon on the left side of the page. This will allow the registrant to schedule a time for pickup. Find more information on the [ORIC webpage](#).

Additional Resources

[Policy 7.25 Research Use of Controlled Substances](#)

[Policy 7.29 Research Use of Dangerous Drugs](#)

[Controlled Substance and Dangerous Drugs information](#), including [after-approval information](#).