



#### In This Presentation

- What is a controlled substance?
- What is a dangerous drug?
- How to identify if a drug is a controlled substance or dangerous?
- I plan to use a CS/DD for research; what must I do?
- Cases
- Questions

# What is a Controlled Substance (CS)?

- Controlled Substances (CS) are drugs for which there is a potential for abuse/addiction. CS are divided into Schedules I -V depending on their medicinal value and potential for abuse.
  - Schedule I are considered to have no medicinal value and a high potential for abuse.
  - Schedule II has medicinal value but a high potential for abuse.
  - Schedule III V have medicinal value and lesser potential for abuse.

### **Drug Classification Chart**

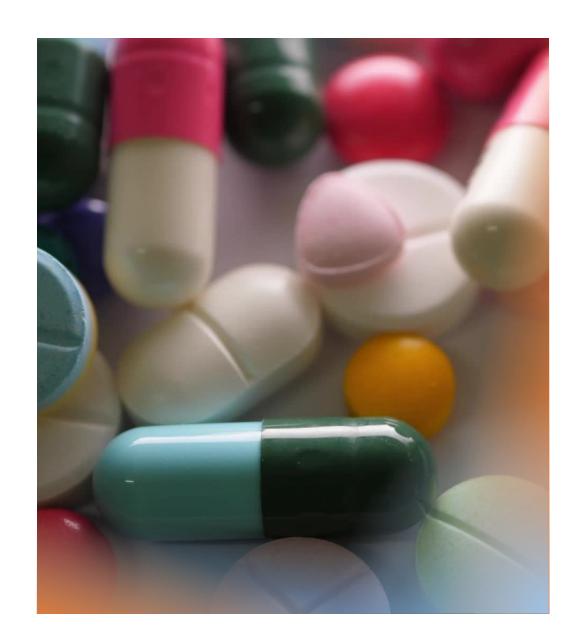
How Drugs Are Classified In The U.S.

Classification	Examples	Description
Schedule I	- Marijuana - LSD - Ecstasy (MDMA) - Heroin	Schedule I drugs as classified as substances that have a high potential for abuse and no accepted medical use and are not safe to use under medical supervision.
Schedule II	<ul> <li>Cocaine</li> <li>Opium</li> <li>High Grade Morphine</li> <li>Oxycodone</li> <li>Methamphetamines</li> <li>(i.e. Adderall)</li> </ul>	Schedule II drugs are classified as substances that have a high potential for abuse, despite having an accepted medicinal use in the U.S.
Schedule III	- Low-Grade Morphine - Anabolic Steroids - Ketamine - Certain Codeine Mixtures	Schedule III drugs are classified as substances that have less potential for abuse than Schedule I or II but abuse can lead to moderate physical dependence or high psychological dependence.
Schedule IV	- Ambien - Soma - Valium - Darvon - Xanax - Darvocet - Rohypnol - Ativan - Zolpidem - Talwin	Schedule IV drugs are classified as substances that have less potential for abuse than Schedule III and has accepted medical use in the U.S. but abuse of the drug may lead to limited physical or psychological dependence compared to those of Schedule III
Schedule V	- Cough Syrup (less than 200 mg) - Lomotil - Motofen - Lyrica - Parepectolin	Schedule V drugs are classified as substances with limited quantities of certain narcotics that have less potential for abuse than Schedule IV and have accepted medical use in the U.S. with limited risk of physical/psychological dependency.
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### What is a Controlled Substance (CS)?

Some prescription drugs are CS. If you use CS in research, you must follow the rules for them to obtain them.

Please refer to the <u>DEA Researcher</u> <u>Manual</u> for additional information.



Containers for CS are required by law to have the schedule classification on them so when in doubt check the container



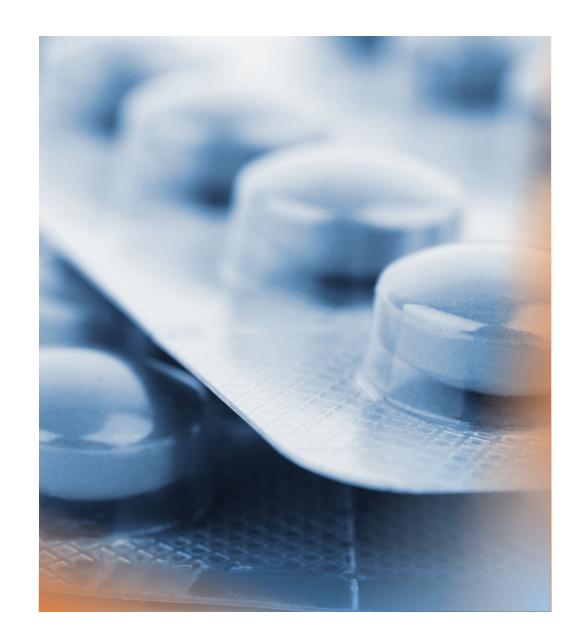






### What is a Dangerous Drug?

- Under Georgia law, "Dangerous Drugs" are drugs that are available only by prescription from a licensed healthcare professional or the purchase of which is restricted to licensed healthcare professionals.
- Dangerous Drugs do not include overthe-counter drugs (including certain lower-dose forms of drugs that would be considered prescription drugs if they were in higher-dose forms). Georgia Drugs and Narcotics Agency has a list of the drugs.
- A good rule of thumb is if the drug <u>can</u>
   <u>be issued</u> via a prescription/order, it is a dangerous drug.



## How to identify if a drug is controlled or dangerous?



The Drug Enforcement Administration has a list on their website. Access the list There is a general list of controlled substances <u>here</u>.



For dangerous drugs, see the list in the GA code at <a href="http://www.lexisnexis.com/hottopics/gacode.">http://www.lexisnexis.com/hottopics/gacode.</a> On the page with a table of contents type "16-13-71. You can access the same list in Excel on the ORIC website. Find the list here.

## I plan to use a CS/DD for animal/bench research; what must I do?

To use one of these drugs, you need to follow a process that would last up to 3 (DD) to 6 months (CS). Having all the documents completed correctly is critical before submission to the regulatory agencies, as any error causes additional delays.

ORIC provides help with the submission of these documents to the agencies- find more here.

In the following slides we will see the roadmap from submission to approval

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



Look for adequate storage location for dangerous drugs





You are done!



After preinspection is completed, you will receive your Georgia researcher permit.



Call Georgia
Drug and
Narcotics
Agency (GDNA)
at 404-6565100 to
schedule your
pre-inspection



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



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



DEA will review your application and do an inspection

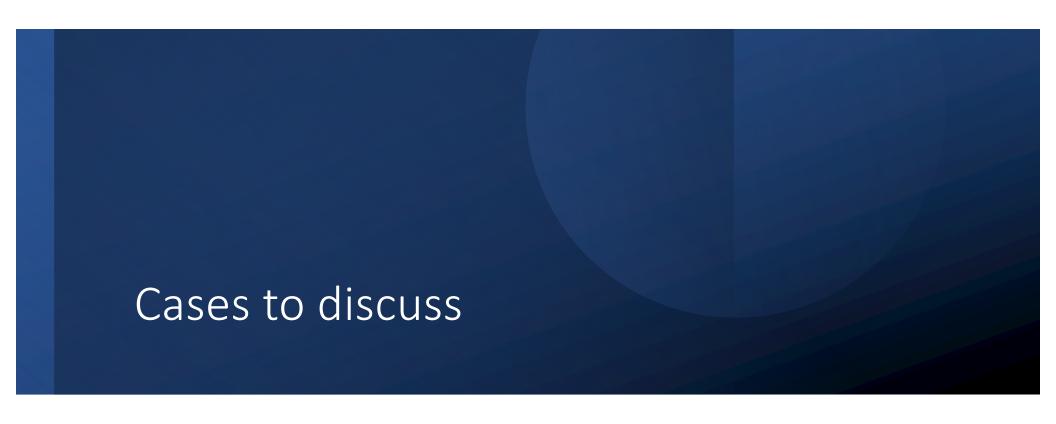


After completing pre-inspection and receiving your Georgia researcher permit, submit your application with DEA online.



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

You are done!



Register for
Training Session
s here: Meeting
Registration Zoom



#### MANAGING CONTROLLED SUBSTANCES & DANGEROUS DRUGS IN RESEARCH

Come learn how to manage your drugs and ask your pressing questions!

Presented by the Office of Research Integrity and Compliance (ORIC) part of Research Compliance and Regulatory Affairs (RCRA)

### Managing Controlled Substances & Dangerous Drugs in Research

Date & Time

You can choose to attend one or more of the following sessions.



Nov 8, 2023 12:00 PM

Recording available on our website

Dec 13, 2023 12:00 PM

Jan 10, 2024 12:00 PM

