



# Tutorial on Use of “Dangerous Drugs” in Research

Emory University  
Office of Compliance

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# Who Should View this Presentation?

- Researchers using in bench/animal research prescription drugs that are not Controlled Substances, i.e., Dangerous Drugs.
- The rules and policies that are discussed in this presentation apply to persons using Dangerous Drugs in the conduct of animal or bench research.
- Different rules and policies apply to persons using Dangerous Drugs in human subjects research. These rules/policies aren't covered here.
- Different rules and policies apply to the use of Controlled Substances in bench/animal research. See Emory Policy 7.25, Research Use of Controlled Substances at <https://policies.emory.edu/7.25>.



# Overview of Presentation

- What Are Dangerous Drugs?
- How Are Dangerous Drugs Regulated?
- What do Researchers Need to do to Use Dangerous Drugs in Bench or Animal Research?
  - Registration
  - Ordering/Purchasing
  - Security
  - Records
  - Disposal
- Penalties for Non-Compliance



# What are Dangerous Drugs?

- The laws of the State of Georgia define “Dangerous Drugs.”
- In general, the term “Dangerous Drugs” includes prescription drugs that are not also “Controlled Substances.”
- “Controlled Substances” are drugs classified as such by the federal Drug Enforcement Administration (DEA) or the State of Georgia because of their potential for abuse and, in some cases, lack of medicinal value.



## Is there a List of Dangerous Drugs?

- The State of Georgia maintains a list of all chemicals that it considers to be “Dangerous Drugs.”
- This list can be found at the following link: <http://www.lexisnexis.com/hottopics/gacode/layout.htm>. Go to the link. Click “I agree.” Enter “16-13-71” in the search box. Click on link for “16-13-71 ‘Dangerous Drug’ defined.”



# How Are Dangerous Drugs Regulated?

- The State of Georgia has laws and regulations that govern how Dangerous Drugs may be used.
- The laws are in the Official Code of Georgia Annotated (OCGA) Title 16, Chapt. 13 at <https://gpb.georgia.gov/documents/georgia-law>.
- The regulations are in the State Board of Pharmacy Rules, Chapt. 480 at <http://rules.sos.ga.gov/gac/480>.



# Emory Policy on Dangerous Drugs

- Emory University has a policy on Dangerous Drugs that follows the laws and regulations of the State of Georgia.
- The Emory Policy is “Policy 7.29, Research Use of Dangerous Drugs, Including Prescription Drugs” at <http://policies.emory.edu/7.29>.
- Forms for use to comply with Policy 7.29 can be found at <http://www.compliance.emory.edu>.



# What do Researchers Need to do to Use Dangerous Drugs in Bench & Animal Research?

- The State of Georgia has certain requirements that researchers must meet before they can use Dangerous Drugs in animal or bench research.
- The requirements fall into 4 categories:
  - Registration
  - Ordering/Purchasing
  - Security
  - Records





## Registration – Who Needs to Register?

- Practitioners – If the researcher is a practitioner (e.g., physician, dentist, veterinarian, etc.), then separate registration with the State of Georgia is not required to use Dangerous Drugs in bench/animal research.
- Practitioners may order and use Dangerous Drugs for bench/animal research under their practitioner licenses.



## Registration – Who Needs to Register?

- Non-Practitioners – If the researcher does not have a practitioner’s license (e.g., is a Ph.D. research who is not also a M.D.), then he/she must register with the Georgia Board of Pharmacy (GBP) before he/she can obtain and use Dangerous Drugs in bench/animal research.
- The registration from the GBP is called a “Researcher Pharmacy facility” registration.
- The person holding the registration is the “Registrant.”



# Georgia Researcher's Registration

- The application for a Georgia Researcher's registration can be found at <http://gbp.georgia.gov>.
- Click on the tab “[Applications and Forms]”
- Scroll down to “[Pharmacy Facility Application].”
- Complete pages 3, 6, 7, 15, 16 and 17.
- Applications require a description of the research protocol, proof of U.S. citizenship or qualified alien status, and the application/registration fee.
- A separate registration is required for each physical location at which research using Dangerous Drugs is conducted.



# Registration – Inspection

- After receipt/review of the application, the Georgia Drugs and Narcotics Agency (GDNA) will contact the researcher to arrange a time to inspect the facility at which the research using Dangerous Drugs is conducted.
- Dangerous Drugs may be used only by the Registrant (or persons working for him/her) on the Registrant's research.
- It can take 5 or more weeks to receive a registration, depending on GBP's and GDNA's backlog.



## Ordering/Purchasing Dangerous Drugs for Research

- Researchers must purchase Dangerous Drugs through Emory Procurement/Emory Express.
- Vendors will require the researcher's Georgia registration number to process the purchase.
- Emory does not permit purchasing cards, personal credit cards, personal checks or cash to be used to purchase Dangerous Drugs for Emory research.



# Ordering/Purchasing Dangerous Drugs for Research

- Procurement's process for purchasing Dangerous Drugs can be found at [https://www.finance.emory.edu/home/Procure%20and%20Pay/how\\_to\\_buy\\_in\\_the\\_marketplace/index\\_procure\\_pay\\_mckessonfordrugs.html](https://www.finance.emory.edu/home/Procure%20and%20Pay/how_to_buy_in_the_marketplace/index_procure_pay_mckessonfordrugs.html).
- Dangerous Drugs will only be delivered to the address on the Georgia researcher registration.



# Security

- The Registrant must keep the Dangerous Drugs he/she orders secure and prevent theft, loss, unauthorized access, use or removal.
- Dangerous Drugs must be stored according to label requirements. Storage in original, labeled containers is recommended.
- GDNA requires that Dangerous Drugs be kept in a key/combination lock secondary container that is located in a place where unauthorized access is restricted.



# Security

- Registrants must limit access to Dangerous Drugs to trustworthy personnel who are assisting in the Registrant's research.
- Personnel should be trained in the proper use and control of Dangerous Drugs before being permitted access.
- Access should not be permitted for personnel who have had DEA, GBP or practitioner licenses/registrations revoked or restricted or who have a prior criminal history of violations regarding Dangerous Drugs or Controlled Substances.
- Registrants should keep a log of persons to whom they have permitted access. See *Dangerous Drugs Authorized User Signature Log – FORM A* at <http://www.compliance.emory.edu>. Click on “Controlled Substances & Dangerous Drugs” Tab, and then click on “Forms” Tab.





# Records

- Registrants must keep records that track receipt, use, distribution, and disposal or other disposition of Dangerous Drugs.
- GDNA expects that the Registrant will have records that document every use/disposition of a Dangerous Drug.
- Registrants may use the *Dangerous Drugs Order/Receipt Log – Form B*, and *Dangerous Drugs Use and Disposition Log – Form C* at <http://www.compliance.emory.edu>. Click on “Controlled Substances & Dangerous Drugs” Tab, and then click on “Forms” Tab.
- Records must be kept for two years after the final disposition of the drugs.



# Disposal of Dangerous Drugs

- Unused Dangerous Drugs must be disposed of following Emory Environmental Health and Safety Office procedures re. chemical hazardous waste handling.
- Transfer or distribution of Dangerous Drugs for use by other persons outside of the Registrant's research is not permitted.



# Penalties for Non-Compliance

- Penalties for unauthorized use, distribution and/or possession of Dangerous Drugs are set forth in OCGA Title 16, Chapt. 13. Sections 16-13-72 to 16-13-79. Penalties differ depending on violation and drug involved.
- Failure to follow security or other registration requirements may result in revocation of Georgia researcher registration.



## Additional Resources

- Emory University Office of Compliance web page at <http://www.compliance.emory.edu>. Click on “Controlled Substances & Dangerous Drugs” Tab.



# Questions?

Contact the Office of Compliance  
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