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# Use of Controlled Substances in Research

A Tutorial on Regulatory  
Requirements



# Tutorial Outline

- Overview
- Applicable laws, regulations and policies
- What Investigators Must Do to Use Controlled Substances in Research at Emory:
  - Register
  - Implement Physical Security Measures
  - Implement Personnel Security Measures
  - Follow the Proper Ordering & Procurement Process
  - Follow a Proper Disposal Process
  - Adhere to Record Keeping Requirements



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# Overview



## Overview

This tutorial provides an overview of Emory University policy and the basic legal requirements that investigators must follow in order to use Controlled Substances in research conducted at Emory University.

**Scope:** Designed for investigators who are performing bench research or animal research using Controlled Substances.

- NOT for health care practitioners or veterinarians who provide care for their patients/clients,
- NOT designed for investigators conducting clinical trials with human participants.
- Practitioners are subject to different laws, regulations and University policies.



## Overview

Expectation: Investigators are expected to be knowledgeable of and adhere to the requirements of federal and state laws/regulations regarding the use of controlled substances in research.

- Emory University’s Policy for Research Use of Controlled Substances (“Policy”) is based on these laws/regulations, and investigators must be aware of and adhere to this Policy.
- Failure to follow the laws, regulations or Policy can result in loss of privilege to use Controlled Substances in Research; civil action or license revocation by licensing agencies; and/or criminal prosecution by law enforcement agencies.



## Overview – Defined Terms

- The following terms and acronyms are used throughout this tutorial:
  - DEA = Drug Enforcement Administration
  - GBP = Georgia Board of Pharmacy
  - GDNA = Georgia Drugs & Narcotics Agency
  - Practitioner = a licensed healthcare provider or veterinarian authorized to prescribe Controlled Substances.
  - Registrant = an investigator who registers with the DEA and GBP to use Controlled Substances.



## Overview

The applicable laws, regulations and Emory Policy set forth requirements within the following broad categories: (a) registering with state and federal agencies; (b) establishing certain physical security measures; (c) establishing personnel screening measures; (d) procuring Controlled Substances; (e) disposing of Controlled Substances; and (f) record keeping. Each category is covered in this tutorial.



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# Applicable Laws, Regulations & Policy





## Applicable Laws, Regulations & Policy

- Federal and state laws and regulations define drugs that are considered to be Controlled Substances and prescribe the rules that must be followed to use those drugs in research.
- If there is a difference between the federal and state laws, Registrants should follow the stricter of the two laws. Similarly, if there is a difference between the Emory Policy and an applicable law, Registrants should follow the strictest provision.
- Controlled Substances are regulated by the Drug Enforcement Administration (DEA) on the federal level, and by the Georgia Board of Pharmacy (GBP) and the Georgia Drug & Narcotics Agency (GDNA) on the state level.



## Applicable Laws, Regulations & Policy

- Controlled Substances are divided by the DEA into Schedules I to V, depending on a drug's medicinal use and addictive potential/potential for abuse. Schedule I drugs have no legally-recognized medicinal use.
- A drug's potential for abuse and public health hazards increases as the schedule number decreases. For example, a Schedule II drug is considered to have greater abuse potential than a Schedule III drug. Drugs may be placed in different Schedules under federal and state laws; in this event, the strictest schedule requirements must be followed.



## Applicable Laws, Regulations & Policies

The main federal laws and regulations that regulate Controlled Substances and their use in research are found in:

- Federal Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) at <http://www.deaiverison.usdoj.gov/21cfr/21usc/index.html>.
- Federal Regulations at Title 21 Code of Federal Regulations (CFR) Parts 1300 – 1321 at <http://www.deaiverison.usdoj.gov/21cfr/cfr/index.html>.



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## Applicable Laws, Regulations & Policies

The list of Controlled Substances under federal law can be found at the site below:

- Scheduled drugs in Schedules I to V of Title 21 of the Code of Federal Regulations (*CFR*) Section 1308 are listed at <http://www.deadiversion.usdoj.gov/schedules/index.html>.



## Applicable Laws, Regulations & Policy

The main State of Georgia laws and regulations that regulate Controlled Substances and their use in research are found in:

- Georgia Controlled Substances Act, Official Code of Georgia Annotated (*OCGA*), Sections 16-13-1 to 16-13-43 at <http://www.lexisnexis.com/hottopics/gacode/>.
- Applicable provisions of the Rules and Regulations of the Georgia Board of Pharmacy, Chapter 480 at [http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=GEORGIA\\_STATE\\_BOARD\\_OF\\_PHARMACY](http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=GEORGIA_STATE_BOARD_OF_PHARMACY)



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## Applicable Laws, Regulations & Policy

The list of Controlled Substances under State of Georgia law can be found at the site below. Each Controlled Substance is listed under its assigned Schedule.

Schedules I to V of *Official Code of Georgia Annotated (OCGA)* Sections 16-13-25 to 16-13-29 at <http://www.lexisnexis.com/hottopics/gacode/>



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## Applicable Laws, Regulations & Policy

Emory University's Policy for Research Use of Controlled Substances can be found at the following link under the tab labeled "Controlled Substances": Office of Research Compliance website: <http://www.orc.emory.edu/>

Forms for use with this Policy also can be found at the tab labeled "Controlled Substances".



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What Must Investigators Do  
to Use Controlled Substances  
in Research at Emory ?





## Summary of Steps that Must Taken to Use Controlled Substances in Research at Emory

- Outline of requirements for Investigators to conduct Research with Controlled Substances:
  1. Register
  2. Implement Physical Security Measures
  3. Implement Personnel Security Measures
  4. Follow Proper Ordering & Procurement Processes
  5. Follow Proper Disposal Process
  6. Adhere to Record Keeping Requirements
- Each step is discussed in the slides that follow.



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# 1. Register



## 1.a. Register – State Requirements

- Per guidance received from the Georgia Board of Pharmacy (GBP): All Investigators must obtain a researcher's permit from the GBP in order to use Controlled Substances for non-clinical research.
  - This includes Investigators who are already authorized to prescribe Controlled Substances as healthcare providers or veterinarians (“Practitioners”).
  - GBP research registration must be renewed each even numbered year. (Expires June 30 of even numbered year.)



## Register – State Requirements

- The application for a Georgia researcher's permit can be found on the *GBP* website at <http://gbp.georgia.gov/> under the following tabs: (a) Download Forms; (b) Pharmacy Facility Application. Investigators need to complete pages 3, 6, 7, 15-17 of this Application.
- A Georgia researcher permit is a prerequisite for DEA researcher registration.



## Register – State Requirements

- As part of the registration process, Investigators must provide the GBP with:
  - (a) a description of the research protocol; and
  - (b) proof of US citizenship or qualified alien status.
- A separate registration is required for each separate geographical research location.



## Register – State Requirements

- Inspections: The GDNA must inspect the site where Controlled Substances will be used. The inspector looks at facilities, security measures and record-keeping processes.
  - Once the GBP notifies an investigator that his/her application has been processed, the investigator should contact the GDNA to schedule an inspection.
  - Contact information for the GDNA is on its website at <http://gdna.georgia.gov/>



## 1.b. Register – Federal Requirements

- Investigators using Controlled Substances outside of human subject research must obtain a Researcher registration from the DEA.
  - The DEA has advised that if an Investigator-Practitioner plans to perform basic or animal research with Controlled Substances, then he/she must apply for a Researcher registration from the DEA.
- Outside the scope of this policy: Investigators who are Practitioners (licensed healthcare providers or veterinarians) planning to use Controlled Substances in a clinical or clinical trial setting register with the DEA as a Practitioner.



## Registration – Federal

- DEA registration information and application forms can be found on *DEA's* website at <http://www.dea.gov/diversion/usdoj.gov/drugreg/index.html#1>.
- Use DEA Form 225 for the initial researcher application and Form 225a for renewals.
- Researcher registration must be renewed annually (every year).





## Registration – Federal

- If an investigator wants to do research using Schedule I Controlled Substances, then as part of the registration packet, he/she must provide the DEA with:
  - (a) a copy of the research protocol; and
  - (b) copies of any required committee approvals for the research protocol (e.g., IACUC, IHBC).



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## 2. Implement Physical Security Measures



## 2. Physical Security

- The DEA may perform its own inspection of a site before issuing a registration, or it may rely on the GDNA inspection.
- **A separate DEA registration is required for each separate geographical location at which research with Controlled Substances is conducted.**
- Persons who hold DEA and State of Georgia registrations to use Controlled Substances in research are called “Registrants.”



## Physical Security Measures

- The Registrant must make sure that the Controlled Substances are secure from theft, loss, unauthorized access or removal.
- Physical security measures must take into account the container in which Controlled Substances are kept and the rooms in which they are stored.



## Physical Security Measures

- Drug Containers: Controlled Substances should be kept in their original, labeled containers and stored apart from general chemicals.



# Physical Security Measures

## Locked Cabinet or Safe:

- Schedule I 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.
- Schedule II-V Controlled Substances must be stored in a securely locked cabinet. A well-anchored narcotics cabinet is recommended. *More* secure storage, such as that for Schedule I Controlled Substances, is acceptable.
- Cabinets/safes should be of a size and weight that makes transport or concealment difficult; have a key or combination lock; and be constructed so that forced entry is easily detected.



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# Physical Security Measures

Locked narcotics cabinets that can be securely mounted can be ordered via Emory University procurement through Fisher Scientific. Some available cabinets are shown below.





## Physical Security Measures

- Locked cabinets or safes should be located in rooms or areas in which unauthorized access is easily noticed.
- When possible, rooms or areas in which Controlled Substances are stored should be kept locked when authorized personnel are not present.
- The Registrant should keep a log of all persons who have a key, combination or access code to the locked cabinet/safe and/or to the area in which Controlled Substances are stored. A form that can be used for this purpose is at <http://www.orc.emory.edu/> under the Controlled Substances Tab, Forms tab, Form 2.
- The Registrant should immediately terminate access for persons who no longer need access to Controlled Substances for their work; leave employ; or present security concerns.





# Physical Security Measures

## Compromise of Security –

### Reporting **Loss** or **Theft** of Access Control Devices/Measures

- The Registrant must immediately report to the Emory Police Department and the Emory Environmental Health & Safety Office any loss, theft or compromise of combinations, keys, locks, access codes or other access controls devices of measures.
- The Registrant must train all persons whose work for him/her involves Controlled Substances to immediately report to Registrant any access device/measure compromise.
- The Registrant must immediately replace any compromised access device or measure.



# Physical Security Measures

## Compromise of Security –

### Reporting **Loss** or **Diversion** of Controlled Substances

- The Registrant must immediately report any theft or significant loss of Controlled Substances to the Emory Police Department, Environmental Health & Safety Office and Office of Research Compliance. The loss/theft may be reported using the form at <http://www.orc.emory.edu/> under the Controlled Substances tab, Forms heading, Form 5.
- Contact information for the above offices is at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Policy heading, Section VI, Contact Information.
- The Registrant must train all employees and agents whose work for him/her involves Controlled Substances to immediately notify Registrant of any theft or significant loss of Controlled Substances.



# Physical Security Measures

## Reporting Theft/Loss of Controlled Substances, continued

- The Registrant also must report theft or significant loss of Controlled Substances to DEA and GDNA.
- The Environmental Health & Safety Office and the Office of Research Compliance can assist the Registrant in preparing the appropriate report forms.
- Links to government reporting forms and contact information for the referenced government agencies can be found in the Emory Policy at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Policy, Section III, C, Subsection (ii), Reporting Loss or Diversion of Controlled Substances.



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### 3. Implement Personnel Security Measures



## 3. Personnel Security Measures

- Individuals whose work involves Controlled Substances can't have been convicted of a felony related to Controlled Substances or have had a DEA registration revoked.
- To ensure compliance with this requirement, Registrant should maintain a user signature log (Form 4), and must obtain a signed Emory University Employee and Agent Screening Statement (Form 3) from those users, to include each employee and agent whose work for Registrant involves use of Controlled Substances.
- These forms can be found at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Form 3 & Form 4.



## Personnel Security Measures

### Prohibition Against Transferring Controlled Substances:

- Emory's Policy requires that each Registrant use Controlled Substances ordered under his/her registration only for Registrant's research.
- The Registrant cannot transfer Controlled Substances ordered under his/her Registration to another researcher for use in a different research project.



# Personnel Security Measures

## Training:

- Registrants should train any employees and agents whose work for them involves Controlled Substances on the requirements of the Emory Policy and applicable laws and regulations.
- Training regarding physical security; reporting of loss or theft of Controlled Substances or compromise of access controls; and appropriate record-keeping is especially important.



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## Security Measures Checklist

- A checklist of appropriate physical and personnel security measures that Registrants should take can be found at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Form 1.





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## 4. Follow Proper Ordering & Procurement Process



## 4. Ordering & Procurement Process

- Registrants must order Controlled Substances for use in research through Emory's Procurement Department using the process outlined at the following website:
- [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%20to%20buy%20in%20the%20marketplace/index%20procure%20pay%20mckessonfordrugs.html)
- Registrants may not use purchasing cards, personal credit cards, personal checks or cash to purchase Controlled Substances for use at Emory.



## Ordering/Procurement

- Orders are limited to the amount of Controlled Substances necessary to perform the research or a 6-month supply, whichever is less.
- Orders will only be delivered to the physical address that is specified on the Registrant's registration form.



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## Ordering/Procurement

### Orders for Schedule I or II Controlled Substances:

Orders for Schedules I or II Controlled Substances must be made using hardcopy DEA Form 222 or using the DEA's electronic Controlled Substances Ordering System (CSOS) process.

To establish a CSOS account, the Registrant must contact McKesson, Emory's vendor for Controlled Substances, and complete the necessary registration form with the DEA.



## Ordering/Procurement

- The Registrant must keep accurate records of all Controlled Substance orders placed and received.
- Forms for tracking orders placed and received can be found at: <http://www.orc.emory.edu/>  
-- Controlled Substances Tab, Forms,  
Form 8 (C - I & II), Form 9 ( C - III, IV & V).



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## 5. Follow Proper Disposal Process



## 5. Disposal

- The Registrant must properly dispose of all Controlled Substances when:
  - (a) the Substance's use-by date expires
  - (b) the Registrant's DEA registration expires and is not renewed;
  - (c) the Registrant no longer conducts research using Controlled Substances; or
  - (d) the Registrant leaves Emory.



# Disposal

- Proper disposal of Controlled Substances can be achieved through one of the following methods:
  - (a) The Registrant arranging for a DEA - registered reverse distributor to accept and dispose of the Substances.
  - (b) The Registrant bringing the Substances to a University-sponsored on-campus destruction event that is supervised by appropriate state law enforcement agents.
- The Registrant must maintain disposal records.





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## 6. Adhere to Record-Keeping Requirements



## 6. Record-Keeping Requirements

- Registrant's must keep the following records, each of which is discussed in more detail in the following slides:
  - Initial Inventory
  - Biennial Inventory
  - Use Log
  - Purchase and Receipt Documentation
  - Discrepancy Reporting Documentation



## Record-Keeping

- Separate Records for Schedules I and II: Records pertaining to Schedule I and Schedule II Controlled Substances must be kept separately from all other Controlled Substance records and from normal business records.
- Records for Schedules III to V: Records pertaining to Schedules III to V Controlled Substances must be kept separately from all other normal business records.



# Record-Keeping

## Initial Inventory:

- Registrants are responsible for performing and documenting an initial inventory of all Controlled Substances on hand at the beginning of work with Controlled Substances.
- A separate inventory is required for each registered site.
- The initial inventory for Schedules I and II substances must be kept separately from the inventory for Schedules III-V.
- A form that can be used to conduct this inventory can be found at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Form 6. The “initial inventory” box should be marked on this form.



## Record-Keeping

### Biennial Inventory:

- The Registrant must perform a physical inventory of all Controlled Substances on hand every 24 months following the date of the initial inventory.
- A form that can be used for the biennial inventory is at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Form 6. The box for “biennial inventory” should be marked and the date and time of the inventory (start or close of business) must be noted on the form.
- A separate inventory must be kept for Schedule I & II Controlled Substances.



# Record-Keeping

## Use Log

- The Registrant must keep a running log of his/her use and disposition of Controlled Substances. The log must be kept in a secured place.
- The log must show the type and amount of Controlled Substances dispensed/administered; name and initials of the person responsible for the use; date of use; and purpose of use.
- Each entry on the log must be initialed by the person who dispensed/administered the substance.



## Record-Keeping

### Use Log:

- A separate log must be kept for each container of a Controlled Substances.
- A form that can be used for this log is at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Form 7.



## Record-Keeping

### Purchase and Receipt Documentation:

- The Registrant must keep all documents relating to his/her order, purchase and receipt of all Controlled Substances.
- The Registrant's copy of the DEA Form 222 used for orders of Schedule I and II Controlled Substances must be maintained as a part of this documentation.
  - The Registrant must also maintain control of unused DEA 222 forms.





## Record-Keeping

- Forms for tracking the ordering and receipt of Controlled Substances are found at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Forms 8 and 9.
- Separate forms must be kept for Schedule I & II Controlled Substances (Form 8) and Schedule III to V Controlled Substances (Form 9).



## Record-Keeping

### Discrepancy Report Documentation

- The Registrant must report any discrepancies that are noted in the amount of Controlled Substances during an inventory or audit.
- The report should be made using the form at <http://www.orc.emory.edu/> -- Controlled Substances Tab, Forms, Form 5.



## Record-Keeping

### Record Retention Schedule:

- Registrant must keep all records relating to the ordering, procurement, inventory and use of Controlled Substances in Research for 3 years: the current year in which the document is generated, plus an additional two years.



## Summary

This module has covered the overview, applicable laws, regulations and policies relating to what Investigators must do to use Controlled Substances in Research at Emory.

Also, this module has provided you with information on registration, implementing Physical Security and Personnel Security Measures; it has introduced forms for the proper ways of ordering & procuring substances and how to properly dispose of them. In addition, this module has explained how to adhere to the proper Record Keeping Requirements.



## Note

You have completed the reading materials and are ready to take the assessment. Once you pass the assessment, do not re-enter the course. To print your score go to ELMS, My Learning tab, then All Learning tab and you will see a printer icon next to the course, select the printer icon and wait a few minutes for it to print.

If you have questions regarding this training module, the Policy for Research Use of Controlled Substances at Emory University, or the assessment, please contact Emory's Office of Research Compliance at (404) 727-2398 or [orc@emory.edu](mailto:orc@emory.edu).