Use of Controlled Substances in Research

A Tutorial on Regulatory Requirements and the Emory University Policy 7.25 “Research Use of Controlled Substances”
Tutorial Outline

• Overview
• Applicable laws, regulations and Emory policies
• Required actions: What Researchers 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 the Proper Disposal Process
  – Adhere to Record Keeping Requirements
This tutorial provides an overview of Emory University Policy 7.25 and the basic legal requirements that researchers must follow in order to use Controlled Substances in research conducted at Emory University.

**Scope:** Designed for researchers who are performing research using Controlled Substances.

Scope of Policy 7.25 *Research Use of Controlled Substances* does **not** include:

- medical practitioners or veterinarians providing care for their patients/clients (medical practice, healthcare, veterinary care).

**NOTE:** Even though Policy 7.25 covers only research use of Controlled Substances, practitioners who use Controlled Substances in clinical practice must follow all pertinent federal and state laws and regulations concerning Controlled Substances, and, in general, the security and record-keeping requirements are the same for Controlled Substances used in Research or in clinical practice.
The applicable laws and regulations 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.
Overview

• A researcher is required to follow all laws and regulations pertaining to the control and use of his/her scheduled drugs.

• A researcher must maintain registration with both state and federal agencies as long as he/she possesses any Controlled Substances.

• A researchers must maintain accurate records of Controlled Substances usage and inventory.
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, the stricter of the two laws should be followed. Similarly, if there is a difference between Emory policy and an applicable law, the strictest provision should be followed.

- Controlled Substances are regulated by the:
  - **DEA**: Drug Enforcement Administration (federal),
  - **GBP**: Georgia Board of Pharmacy (state), and
  - **GDNA**: Georgia Drug & Narcotics Agency (state).
Emory University’s Policy for Research Use of Controlled Substances can be found at the Office of Compliance (OC) website: [http://www.compliance.emory.edu/](http://www.compliance.emory.edu/) under the resource link labeled “Controlled Substances & Dangerous Drugs”; or at [http://policies.emory.edu/7.25](http://policies.emory.edu/7.25).

Related forms on the OC website should be used: [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html).
Applicable Laws, Regulations & Policies

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


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

http://www.deadiversion.usdoj.gov/schedules/index.html

listing Scheduled drugs, in Schedules I to V, of Title 21 of the Code of Federal Regulations (CFR) Section 1308
Applicable Laws, Regulations & Policy

The main **State of Georgia** laws and regulations that regulate Controlled Substances, including listed drugs’ classifications, are found in:


- 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)
Required Actions and Activities

Outline of requirements for Researchers:

1. Register
2. Implement Physical Security Measures
3. Implement Personnel Security Measures
4. Follow Proper Ordering & Procurement Process
5. Follow Proper Disposal Process
6. Adhere to Record Keeping Requirements

These 6 steps are discussed in the following slides.
What Emory Researchers Must Do to Use Controlled Substances in Research

1. Register
1.a. Register – State Requirements

• In order to use Controlled Substances for research, all Researchers must obtain a researcher permit (as a “RESEARCHER PHARMACY”) from the GBP.
  – Researchers who are Practitioners authorized by Georgia to prescribe/administer Controlled Substances as healthcare providers or veterinarians must register separately with the GBP as a “Researcher Pharmacy” to conduct research.
Register – State Requirements

• The application for a Georgia *RESEARCHER PHARMACY* can be found on the *GBP* website at [http://gbp.georgia.gov/](http://gbp.georgia.gov/) under the following tabs: (a) Download Forms; (b) Pharmacy Facility Application. Investigators need to complete pages 3, 6, 7, 15, 16 & 17 of this Application.

• GBP research registration must be renewed biennially; registration always expires June 30 on even numbered years.
As part of the registration process, Researchers must provide the GBP with:

- 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.

A separate registration is required for protocols using Schedule 1 drugs.
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 a researcher that his/her application has been processed, the researcher should contact the GDNA to schedule an inspection.
  - Contact information for the GDNA is on its website at http://gdna.georgia.gov/

- Georgia researcher registration is a prerequisite for DEA researcher registration.
1.b. Register — Federal Requirements

- Researchers who do not have practitioner licenses (e.g., MD, DVM) and who are using Controlled Substances in research must register with the DEA.

- The DEA has advised that if a researcher who is a practitioner must apply for a researcher registration from the DEA for:
  - Human, animal or bench research with Schedule I substances.
  - Animal or bench research with Schedule 1 – V substances.
Registration – Federal

- DEA registration information and application forms can be found on DEA’s website at http://www.deadiversion.usdoj.gov/drugreg/index.html#1.

- Use DEA Form 225 for the initial researcher application and Form 225a for renewals.

- Georgia researcher registration is a prerequisite for DEA researcher registration.
Registration – Federal

- DEA researcher registration must be renewed annually (every year).
- A separate registration is required for each separate geographical research location.
- A separate registration is required for protocols using Schedule 1 drugs.
- Disposal of controlled substances requires that the Investigator holds a current DEA registration certificate.
What Emory Investigators Must Do to Use Controlled Substances in Research

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.”
The Registrant must make sure that the Controlled Substances are secure from theft, loss, unauthorized access or removal.

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

Physical security measures must take into account the container(s) in which Controlled Substances are kept and the rooms in which they are stored.

Security self-assessment should be conducted; use Form 1 found at http://compliance.emory.edu/controlled-substances/forms.html.
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.
Locked narcotics cabinets that can be securely mounted can be ordered via Emory University procurement. Some sample cabinets are shown below.
Locked refrigerators or narcotics cabinets that can be bolted to refrigerator shelving should be used for Controlled Substances requiring refrigeration. For Schedule I substances, the refrigerator should be anchored to wall or floor.

Fisher Scientific

http://www.medicus-health.com/Medication-Storage.aspx
Physical Security Measures

- Locked cabinets or safes should be located in rooms or areas in which unauthorized access is easily noticed.
- Rooms or areas in which Controlled Substances are stored should be kept secured (locked) when not in use.
- 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. Use Form 2 for this purpose found at http://compliance.emory.edu/controlled-substances/forms.html.
- 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.
Compromise of Security – Reporting Loss or Theft of Access Control Devices/Measures:

• The Registrant must immediately report to the Emory Police Dept. and the Emory Environmental Health & Safety Office (EHSO) any loss, theft or other compromise of keys, locks, combinations, 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 compromise of an access device/measure.

• The Registrant must immediately replace any compromised access device or measure.
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 Dept., EHSO and Office of Compliance. The loss/theft may be reported using the Form 5 at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html).

• Contact information for the aforesaid offices is at [www.compliance.emory.edu](http://www.compliance.emory.edu) -- Controlled Substances link, Policy, Section VII, 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 - Reporting

Theft/Loss of Controlled Substances, continued

• The Registrant also must report theft or significant loss of Controlled Substances to DEA and GDNA.

• The EHSO and the Office of 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 [www.compliance.emory.edu](http://www.compliance.emory.edu) -- Controlled Substances link, Policy, Section III, C, Subsection (ii), Reporting Loss or Diversion of Controlled Substances.
What Emory Researchers Must Do to Use Controlled Substances in Research

3. Implement Personnel Security Measures
3. Personnel Security Measures

- Individuals who have been convicted of a felony related to Controlled Substances or have had a DEA registration revoked cannot work with Controlled Substances.

- 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 all users, including each employee and agent whose work for Registrant involves use of Controlled Substances.

- These forms can be found at http://compliance.emory.edu/controlled-substances/forms.html: Form 3 & Form 4.
Personnel Security Measures

Prohibition Against Transferring CS

• 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 all employees and agents whose work for them involves Controlled Substances on the requirements of the Emory Policy, and applicable laws and regulations.

• Especially important is training regarding physical security, reporting of loss or theft of Controlled Substances or compromise of access controls, and appropriate record-keeping.

• Security self-assessment should be completed using Form 1 found at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html).
What Emory Researchers Must Do to Use Controlled Substances in Research

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:


- Registrants may not use purchasing cards, personal credit cards, personal checks or cash to purchase Controlled Substances for use at Emory.
Ordering/Procurement

- Orders should be 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 DEA researcher certificate.
- Emory’s Policy requires that Registrants order Controlled Substances only for Registrant’s own research; these drugs are non-transferable.
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://compliance.emory.edu/controlled-substances/forms.html,
Form 8 (C-I & II), Form 9 (C-III, IV & V).

Procurement for Class I or II drugs is more complicated than for Class III, IV or V.
Orders for Class I or II Controlled Substances:

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

To establish a CSOS account, the Registrant must contact McKesson, an Emory vendor for Controlled Substances, and complete the necessary registration form with the DEA.
DEA Power of Attorney Form for Orders of Class I or II Controlled Substances:

- A Registrant may authorize one or more individuals to issue orders for Schedule I and II controlled substances on his/her behalf by executing a power of attorney for each such individual. Use the Power of Attorney form (Form 10 at http://compliance.emory.edu/controlled-substances/forms.html).

- The Power of Attorney Form must be kept in the same file with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

- A Registrant may revoke any power of attorney at any time by executing a notice of revocation.
5. Follow Proper Disposal Process
5. Disposal Process

The Registrant must properly dispose of all Controlled Substances:

a) **before expiration** of his/her DEA registration 
   *and*

b) when the substances’ expiration date is passed;

c) when the Registrant no longer conducts research using Controlled Substances at Emory.
Disposal

- Proper disposal of Controlled Substances is done through “reverse distribution”.
- The Registrant must arrange with a DEA-registered reverse distributor to accept and dispose of the Substances using an approved vendor through the Emory procurement process.
- The Registrant must maintain disposal records.
- Disposal for Class I or II drugs is more complicated than for Class III, IV or V.
Disposal of Class I or II Controlled Substances:

• Registrant must arrange to have the Reverse Distributor request shipment of Class I or II drugs from the Registrant. Registrant is the “supplier”.

• Registrant will ship Class I or II drugs to the Reverse Distributor only upon receipt of accurately completed DEA Form 222 order from the Reverse Distributor.

• Registrant fulfills the order and completes the DEA Form 222 as the “supplier” to the Reverse Distributor, retaining the supplier copy in his/her records.
6. Adhere to Record-Keeping Requirements

What Emory Researchers Must Do to Use Controlled Substances in Research
6. Record-Keeping Requirements

- Registrants 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.
- Initial inventory should be “zero”.
- 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.
- Form 6 should be used to conduct this inventory, found at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html). Mark the “initial inventory” box.
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.

• Form 6 should be used for the biennial inventory, found at http://compliance.emory.edu/controlled-substances/forms.html. Mark the box for “biennial inventory” noting the date and time of the inventory (start or close of business) on the form.

• A separate inventory must be kept for Schedule I & II Controlled Substances.
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.
Use Log:

- A separate log should be kept for each container used or each experimental use of a Controlled Substance.
- Form 7 should be used for this log, found at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html).
- If Controlled Substances are diluted, use Form 11, the dilution use log, at link above.
- The use log should reference the experimental record.
Record-Keeping

- Forms for tracking the ordering and receipt of Controlled Substances are found at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html), 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) (see link above).
Record-Keeping

Purchase and Receipt Documentation:

• The Registrant must keep all documents relating to the order, purchase and receipt of Controlled Substances.

• The Registrant’s copy of the DEA Form 222 used for orders of Schedule I or II Controlled Substances must be maintained as a part of purchasing/receipt documentation.
  – The Registrant must maintain control of unused order forms, DEA Form 222.
  – Form 8 serves as a DEA Form 222 tracking log.
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 Form 5 at [http://compliance.emory.edu/controlled-substances/forms.html](http://compliance.emory.edu/controlled-substances/forms.html).
Inspections

Record Retention Schedule:

Registrant must keep all records relating to the ordering, procurement, inventory and use of a Controlled Substance for 3 years past the final use.
Record-Keeping

Inspections:

Registrants and their staff must permit the following units officials to inspect their controlled substance storage and records on request: DEA; GDNA, IACUC, EHSO, IBC or Compliance Office.

Failure to permit inspection by DEA or GDNA is a crime.

Failure to permit inspection by Emory units may result in loss of the privilege to conduct research using Controlled Substances at Emory.
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.

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.

This module has explained how to adhere to the proper Record Keeping Requirements.
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 compliance@emory.edu.