



Policy 7.25 Research Use of Controlled Substances

Responsible Official: VP for Research Administration
Administering Division/Department: Research Compliance
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Overview

Overview

Emory's Controlled Substances Policy covers all persons at Emory who conduct *Research* that uses *Controlled Substances*.

Both the State of Georgia and the United States federal government regulate *Controlled Substances* used in *Research*

The drugs that are considered to be *Controlled Substances* are listed in the following laws/regulations: (i) 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/>; and (ii) Schedules I to V of Title 21 of the Code of Federal Regulations (CFR) Section 1308. Scheduled drugs are listed at <http://www.deadiversion.usdoj.gov/schedules/index.html>.

To use *Controlled Substances* for *Research*, a researcher must register with the State of Georgia Board of Pharmacy (GBP) and the federal Drug Enforcement Administration (DEA).

Registration is required for each separate physical location at which *Controlled Substances Research* takes place. The Georgia Drugs and Narcotics Agency (GDNA) will conduct a site inspection before a GBP *Registration* is issued; the DEA may also conduct a site inspection in response to application.

Registration has to be maintained at all times while *Controlled Substances* are being used in *Research* or in the user's possession.

Researchers must use the *Controlled Substances* they order exclusively for their own *Research*. These drugs can't be shared or transferred to others not supervised directly by the researcher.

Researchers have to supervise their employees, students and other agents who assist them in their *Controlled*

Substances Research. Supervising personnel includes: explaining what and how *Controlled Substances* will be used in the *Research*; ensuring personnel are trained in *Controlled Substances* security and record-keeping procedures; and actively monitoring personnel's use of *Controlled Substances* in *Research* to ensure that this Policy and applicable laws/regulations are being followed.

Researchers conducting animal or bench research must order *Controlled Substances* through Emory's Procurement and Payment Services. The researcher who has registered with the GBP and the DEA to use *Controlled Substances* in *Research* ("*Registrant*") is responsible for keeping the *Controlled Substances* in a secure locked cabinet or safe and controlling access to the *Controlled Substances*. *Controlled Substances* used in human subject research may be managed by the Investigational Drug Service (IDS) or the *Registrant*, depending on the location and circumstances of the *Research*, including the Schedule of the *Controlled Substances* to be used in the *Research*.

Researchers must keep accurate records on the receipt and use of *Controlled Substances*. Researchers also must keep an initial and biennial inventory of their *Controlled Substances*. Records for Schedule I and II *Controlled Substances* must be kept separately. Researchers must only dispose of *Controlled Substances* through a reverse distributor.

Researchers must immediately report any theft or significant loss of *Controlled Substances* to DEA and the GDNA government regulatory agencies and the Emory Office of Compliance (OC), Emory Police Department (EPD), and Emory Environmental Health and Safety Office (EHSO).

Forms: This Policy has a number of forms associated with it that can be found at <http://www.compliance.emory.edu> under the "Controlled Substances and Dangerous Drugs" tab. The best way a *Registrant* can ensure compliance with the Policy and laws/regulation is to correctly use these forms.

Failure to follow this Policy can result in loss of ability to conduct *Research* using *Controlled Substances* at Emory, disciplinary sanctions, or referral for prosecution.

Applicability

Applicability

What is Covered by this Policy?

This Policy covers researchers who use *Controlled Substances* in *Research* activities at Emory. For purposes of this Policy, the term *Research* is defined as follows: "Any type of scientific investigation."

This Policy applies to the acquisition, use, storage, disposal and/or related activities, including record-keeping, that involve the acquisition, use, storage, and/or disposal of *Controlled Substances* in *Research* that takes place at Emory University facilities. Research using *Controlled Substances* in animal subjects also is governed by the policies of the Emory University Institutional Animal Care and Use Committee (IACUC). Research using *Controlled Substances* in human subjects also is governed by the policies of the Emory University Institutional Review Board (IRB), or other IRB with jurisdiction over the *Research*.

This Policy does not cover activities such as drug manufacture, distribution or analysis. The federal Drug Enforcement Agency (DEA) has separate rules and *Registration* requirements for these activities.

Purpose of this Policy:

This Policy is designed to set forth the major requirements of the applicable laws and regulations that apply to *Research* involving *Controlled Substances* and to assist Emory researchers in complying with those laws/regulations and this

Policy. It does not set forth every detail of every law and regulation with which persons who use *Controlled Substances* in *Research* must comply. Instead, this Policy attempts to reflect accurately the major requirements of applicable laws and regulations. In the event of a conflict between this Policy and applicable laws and regulations, the more restrictive will govern.

Who is Covered by this Policy?

All Emory University employees, students, as well as any other persons (e.g., visiting scholars) who are conducting *Research* using *Controlled Substances* that utilizes Emory resources or facilities. NOTE: Emory University employees and students who are conducting *Research* using *Controlled Substances* at Emory Healthcare facilities also are subject to any applicable Emory Healthcare policies, and in the event of any conflict between these policies, the stricter policy shall control.

Who is Not Covered by this Policy?

This Policy does not cover the use of *Controlled Substances* by a physician, pharmacist, dentist, podiatrist, or veterinarian (a *Practitioner*) **in providing health/veterinary care for his/her patients or clients.**

Summary of Responsibility under this Policy:

Any person who uses *Controlled Substances* in his/her *Research* at Emory is responsible for knowing and following all applicable federal, state and local laws/regulations and Emory policies, including the applicable laws and regulations noted below. Supervisors are responsible for making sure that any person who works for them also follows these laws/regulations and Emory policies.

Consequences for Failure to Follow this Policy:

If a person subject to this Policy does not follow this Policy and/or the applicable laws and regulations, such failure may result in any or all of the following consequences: (a) immediate loss of the ability to conduct the Emory-supported *Research* using *Controlled Substances*; (b) immediate loss of the ability to use Emory University facilities to conduct *Research* using *Controlled Substances*; (c) disciplinary action being taken against that person, up to and including termination of employment or dismissal from academic programs; and/or (d) referral for prosecution by law enforcement officials.

Updates to Policy:

This Policy shall be reviewed periodically and updated to ensure accuracy and conformity with the laws in this area.

Policy Details

Policy Details

The Policy Details Section is divided into the following subject matter areas: (A) Applicable Laws and Regulations; (B) Scope; and (C) Requirements for Use of *Controlled Substances* in *Research*. Defined words and acronyms in the Policy are shown as capitalized, italicized terms and listed in the Definitions Section.

Forms referenced in this Policy are available at the Office of Compliance website under at <http://compliance.emory.edu/> under the "Controlled Substances & Dangerous Drugs" tab.

Researchers should use these forms to ensure Policy compliance.

A. Applicable Laws and Regulations

Researchers who use drugs that are classified as *Controlled Substances* in their *Research* must follow applicable laws and regulations including those set forth below, which can be found at the listed websites:

- Federal Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) at <http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html>.
- Federal Regulations at Title 21 Code of Federal Regulations (*CFR*) Parts 1300 - 1321 at <http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>.
- 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, Chapt. 480 at http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=GEORGIA_STATE_BOARD_OF_P_HARMACY%2Findex.html&d=1.

B. Scope

Drugs to which this Policy Applies. This Policy applies to the following drugs, which are referred to as *Controlled Substances* in this Policy:

- (a) All drugs, substances or immediate chemical precursors listed in:
 - (i) Schedules I to V of *OCGA* Sections 16-13-25 to 16-13-29 at <http://www.lexisnexis.com/hottopics/gacode/>; and
 - (ii) Schedules I to V of Title 21 of the Code of Federal Regulations (*CFR*) Section 1308. Scheduled drugs are listed at <http://www.deadiversion.usdoj.gov/schedules/index.html>.

Drug Schedules. The “Schedules” noted above refer to the categories into which *Controlled Substances* are divided under federal and state law. Specifically, drugs with addictive potential are divided into categories called “schedules” or “classes” based on potential for abuse and existence of medicinal use. There are five Schedules (I-V), as well as separate groupings for pre-cursor chemicals. Each *Controlled Substance* is specifically listed by name within the Schedule to which it has been assigned by regulators. Classification at the state level may differ from classification at the federal level. Schedule I *Controlled Substances* are not considered to have any medicinal use, and therefore, regulations for these substances are more restrictive than for substances falling under other Schedules. Drugs in Schedules II through V have medicinal use, but the potential for abuse and public health hazards decreases as the Schedule number increases (i.e., a Schedule II drug is considered to have greater abuse potential than a Schedule III drug). Each *DEA Registration* will specifically describe the Schedules that the *Registration* holder (*Registrant*) is permitted to use. A *Practitioner Registration* does not include authorization to possess, prescribe or administer Schedule I *Controlled Substances* because they are not considered to have any medicinal use.

References: Controlled Substances Act, 21 USC Chapt. 13, §801, *et. seq.*; 21 CFR Part 1308; OCGA §16-13-1 to 16-13-43; Rules and Regulations of the Georgia Board of Pharmacy, Chapt. 480. NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations.

C. Requirements for Use of Controlled Substances in Research

This Policy area covers the basic requirements that a researcher must fulfill in order to use *Controlled Substances* in *Research* at Emory. It is divided into the following five subsections: (i) Registration; (ii) Security and Storage; (iii) Ordering and Procurement; (iv) Disposal; and (v) Records.

Subsection (i): Registration

Overview: All persons at Emory who want to do *Research* using *Controlled Substances* must register with the appropriate agencies. Registration requirements differ depending on whether *Registrant* is a *Practitioner* and type of *Research* to be conducted. See chart below for summary of permit/*Registration* requirements.

Researcher with a Georgia practitioner license (medical, veterinary or other practitioner license): Permit/*Registration* requirements from state or federal agencies to order Controlled Substances for use in research

Type of Drug to be Used in the Research	Georgia Researcher Permit from Georgia Board of Pharmacy	Researcher Registration from federal Drug Enforcement Administration (DEA)	Practitioner Registration with DEA
Controlled Substances	YES	NO for human subject <i>Research</i> Schedule II- V YES for animal & bench <i>Research</i> Schedule I- V & human subject <i>Research</i> Schedule I	YES [DEA will ask if you have other registration numbers]

Researcher DOES NOT HAVE a Georgia practitioner license (e.g., medical, veterinary or other practitioner license): Permit/*Registration* requirements from state or federal agencies to order Controlled Substances for use in research

Type of Drug to be Used in the Research	Georgia Researcher Permit from Georgia Board of Pharmacy	Researcher Registration from federal Drug Enforcement Administration (DEA)
Controlled Substances	YES	YES

Process for Registration with the GBP: The application for a Georgia researcher’s permit can be found on the *GBP* website at <http://gbp.georgia.gov> using: (a) Online Services; (b) Apply Online; (c) Embedded "forms" link; (d) Pharmacy Facility Application (see pages 3, 6, 7, 15, 16 and 17).

Researchers must first apply for a researcher’s permit from the *GBP*. A description of the *Research* protocol must be

submitted to the *GBP*. Proof of U.S. citizenship or qualified alien status also must be submitted. The *GBP* permit number is required for the *DEA* application.

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Process for Registration with the DEA: *DEA Registration* information and application forms can be found on *DEA's* website at <http://www.deadiversion.usdoj.gov/drugreg/index.html#1>. Researchers should use *DEA Form 225* for their initial application and *Form 225a* for renewals. A *Practitioners' Registration* (using *DEA Form 224*) only permits use of *Controlled Substances* in clinical practice and use of *Schedule II - V* drugs in human clinical research.

All State of Georgia requirements must first be satisfied in order to obtain a *DEA Registration*. All *Researchers* must obtain a Georgia researcher permit before applying for a *DEA Researcher* permit. For *Research* using *Schedule I Controlled Substances*, a copy of the *Research* protocol containing the information set forth in 21 CFR §1301.18 must be provided to *DEA*. If the protocol requires approval from an Emory University committee such as the *IRB, IACUC, IBC* or *RHSC*, then this approval must be obtained before the *Registration* application is submitted to the *DEA*. A copy of the committee's approval for the protocol must be submitted to *DEA* along with the protocol and *Registration* application.

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Location of Registration: ALL *REGISTRATIONS* ARE LOCATION SPECIFIC, i.e., a researcher must obtain a separate *Registration* for each site at which *Research* using *Controlled Substances* is performed. *Controlled Substances* only may be shipped to the specific location listed on a registration, for use by the *Registrant* according to the permitted use.

Pre-Registration Inspections: The Georgia Drugs and Narcotics Agency (*GDNA*) must inspect a site before the *GBP* issues a *Registration*. The *Registrant* is responsible for contacting the *GDNA* to arrange for an inspection *only after* the *GBP* has notified the *Registrant* that his/her application has been processed. The inspection is performed to insure that facilities and processes are in place to satisfy all regulatory requirements, such as security and record-keeping requirements. Contact information for the *GDNA* can be found at the agency's website: <http://gdna.georgia.gov/contact-us-0>. The *GDNA* agent will leave a copy of the completed inspection form with the applicant, which must be retained by the *Registrant*.

The *DEA* also may conduct an inspection of an applicant (21 CFR §§1301.31, 1316) but may rely on the *GDNA* inspection.

Registration for Employees/Agents who Assist in Controlled Substances Research:

Employees or students working for the *Registrant* may be authorized to work with the *Controlled Substances* in carrying out their usual course of employment/course of study, provided they are under the supervision and control of the *Registrant*. Supervision includes explaining to personnel: what *Controlled Substances* will be used in the *Research*; how the *Controlled Substances* will be used in the *Research*; security measures that must be taken with regard to the *Controlled Substances*; record-keeping activities, such as inventories and use logs, that must be followed with respect to the *Controlled Substances*; and procedures for reporting any suspected loss or diversion of *Controlled Substances*. Supervision also requires the *Registrant* actively monitor personnel's use of *Controlled Substances* in *Research* to ensure that this Policy and applicable laws/regulations are being followed.

References: 21 USC §823; 21 CFR Part 1301; OCGA §§16-13-35 to -38; 26-4-49; Rules and Regulations of the State of Georgia §480-20-.01. NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations.

Subsection (ii):

Security and Storage Of Controlled Substances

The *Registrant* is responsible for making sure that the *Controlled Substances* used in his/her *Research* are kept secure

to prevent theft, loss, unauthorized access or removal. The *Registrant* must follow all applicable security requirements specified in the applicable laws and regulations listed above. Particular attention should be paid to the requirements set forth in 21 CFR §§1301.71, 1301.75-.76 at <http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>.

A form for **Self-Inspection of Controlled Substances -- FORM 1** is available at <http://compliance.emory.edu/>; use of this self-inspection form will assist *Registrant's* compliance with physical and personnel security requirements.

Physical Security.

Under the applicable laws and regulations, *Practitioners* and non-*Practitioners* who use *Controlled Substances* in *Research* follow the same security requirements. The *DEA* and *GDNA* evaluate physical security measures based on the type and amount of *Controlled Substances* on hand; the *Registrant's* location in a high or low crime area; the number of persons who have access to the *Controlled Substance* storage area; the presence and use of an alarm system; and any prior history of drug diversion.

Basic physical security requirements include the following:

- (1) **Containers:** *Controlled Substances* should be stored in their original, labeled containers, and they should be stored separate from general chemicals.
- (2) **Schedule I Substances:** Schedule I *Controlled Substances* must be kept in a securely locked, substantially constructed cabinet. A strong metal cabinet or safe securely fastened to the floor or wall in a manner that prevents it from being readily removed is generally acceptable.
- (3) **Schedule II - V Substances:** Except as noted below, Schedule II, III, IV and V *Controlled Substances* must be stored in a securely locked, substantially constructed cabinet. [NOTE: Although the pertinent regulations specify a securely locked, substantially constructed cabinet, State inspectors in pre-*Registration* inspections have permitted small amounts of these substances to be kept in a securely locked drawer of substantial construction. Use of a drug lock box is encouraged.]
 - (a) **Carfentanil, etorphine hydrochloride and/or diprenorphine:** These Schedule II *Controlled Substances* must be kept in a safe or a steel cabinet equivalent to a U.S. Government Class V security container. These containers are a type of safe or locked cabinet that is able to withstand forced entry. Class V containers must provide the following security protection: (a) 30 man minutes against surreptitious entry; (b) 10 man minutes against forced entry; (c) 20 man hours against lock manipulation; and (d) 20 man hours against radiological attack. Class V containers are available for purchase through Emory Procurement.
 - (b) **Cabinets and Drawers:** The cabinet (or for small amounts, drawer) used to store *Controlled Substances* must have a key or combination lock. In addition, it is preferable for it to: (a) be constructed so that forced entry is easily detectable; (b) be of a size and weight that makes it difficult to transport or conceal and limit the chances of removal; and

(c) be located in a place in which unauthorized access would be noticed. Cabinets and lock boxes are available for purchase through Emory Procurement.
- (4) **Rooms in Which Controlled Substances are Stored:** Rooms in which *Controlled Substances* are stored must be kept locked when not in use. *Registrant* must control access to the room and keep a list of all persons to whom the *Registrant* has issued a key, key card, or key code for room access. An **Access Log -- FORM 2** is available at <http://compliance.emory.edu/> and should be used for this purpose. *Registrant* must immediately disable access for persons who no longer require access to perform job duties; persons who no longer work for *Registrant* and/or Emory; and persons whose access to *Controlled Substances* must be terminated because of security concerns.

(5) **Compromise of Security:** *Registrant* must immediately report loss or theft of access control devices/measures (e.g., keys, combinations, codes) to the Emory Police Department (EPD) and (EHSO). Contact information for these units is set forth below in "Contact Information." *Registrant* must instruct all those who work for him/her and whose work involves *Controlled Substances* to immediately report to *Registrant* any loss, theft or compromise of access control devices/measures. *Registrant* is responsible for ensuring that compromised access control devices/measures are replaced (e.g., re-key lock; change authorization code, etc.). Reporting of loss or diversion of *Controlled Substances* is discussed below under the heading **Reporting Loss or Diversion of Controlled Substances.**

Personnel Security Requirements.

(1) **Employees and Agents:** The *Registrant* cannot hire or utilize any employee or agent whose work requires them to have access to *Controlled Substances* if that person has been convicted of a felony relating to *Controlled Substances*, or has had a *DEA Registration* denied, revoked or surrendered for cause. The *Registrant* must require all employees and students or other agents who will be working with *Controlled Substances* to complete and sign the **Emory University Employee and Agent Screening Statement -- FORM 3** (available at <http://compliance.emory.edu/>) prior to beginning their work. In addition, employees will be expected to undergo any criminal background or any other checks routinely required of employees by Emory University's Division of Human Resources.

Employees and agents who work with *Controlled Substances* in *Research* and who are convicted of a felony relating to *Controlled Substances* or have a *DEA Registration* denied, revoked or surrendered for cause while working for *Registrant*, must immediately report such events to *Registrant*, and *Registrant* immediately must terminate their access to *Controlled Substances* at Emory. Each *Registrant* needs to keep a log of the persons working for him/her to whom *Registrant* has granted authorization to work with *Controlled Substances*. The **Controlled Substances Authorized User Signature Log -- FORM 4** (available at <http://compliance.emory.edu/>) should be used for this purpose.

(2) **Transfer or Distribution of Controlled Substances is Prohibited:** Emory University requires that the *Registrant* utilize any *Controlled Substance* ordered under his/her *Registration* solely for his/her *Research* as described to *DEA* and/or *GBP*. Emory does not permit the *Registrant* to transfer or provide *Controlled Substances* to any other persons for use in those persons' *Research*, or for any other use; provided, however, that:

(a) Yerkes animal resources units may transfer certain anesthetic and/or euthanasia agents to a *Registrant* provided that his/her *Registration* is on file with Yerkes; and

(b) In cases where a *Registrant* leaves the university and is transferring substances to another person who is taking over the work, provided the transferee has appropriate *Registrations* in place (Note: *GBP* requires a new application when there is a change in the primary person in charge of research).

Reporting Loss or Diversion of Controlled Substances

Emory employees and students have a duty to report any suspected loss or theft of *Controlled Substances* to their supervisors, who in turn must immediately notify the *Registrant*. Reports also may be made directly to the *Registrant*, Emory's Office of Compliance (OC) or EHSO. The *Registrant* must promptly report any theft or significant loss of any *Controlled Substance* to the following entities:

- **Emory Entities:** Promptly on discovery, notify EPD; EHSO and OC. EHSO and OC can provide assistance to *Researchers* in completing reports to *DEA* and *GDNA*, and researchers are advised to contact either of these units before submitting reports to *DEA/GDNA*. Reports to Emory units should be made using the **Controlled Substances Discrepancy Report Form - FORM 5** (available at <http://compliance.emory.edu/>). Contact information for Emory units to which reports should be made is listed on Form 5.

- **DEA:** Within one business day of discovery, complete *DEA* Form 106, found on-line at http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

- **GDNA:** Within 48 hours of discovery, fax copy of completed *DEA* Form 106 to

GDNA at (404) 651-8210.

Inspections

By law, inspection of registered sites may be conducted by agents of the *DEA*, *GBP*, *GDNA* or other authorized licensing, police or law enforcement agencies. A pre-*Registration* site inspection will be conducted by the *GDNA* and, potentially, the *DEA*. The *Registrant* should request appropriate identification from government inspectors, if they do not initially provide it. The *Registrant* should promptly notify *OC* via email to compliance@emory.edu or phone call to (404)727-2398 of any inspection or pending inspection, and subsequently provide *OC* with a copy of any inspection report received.

Site inspections of programs conducted under the auspices of Emory University also may be conducted by *EHSO*; the *IACUC* (for *Research* involving animals); the *IRB*, *IBC*; *RHSC*; *OC*; or *EPD*. Emory University requires that the *Research* use of *Controlled Substances* that occurs on Emory University property is in compliance with federal and state requirements, therefore *Registrants* and their employees and agents must fully cooperate with all inspections and provide copies of any requested documentation pertaining to *Controlled Substances Research* or *Registration* upon request.

Emory requires that employees consult with the Office of the General Counsel before signing any affidavits or providing any other written statements to governmental agencies concerning activities at Emory. If any inspectors from governmental agencies ask the *Registrant* or his/her employees or agents to sign/provide a written statement or affidavit, the *Registrant* should refrain from signing/providing the statement; advise the inspectors that Emory policy requires the *Registrant* to first contact the Office of General Counsel; and immediately contact the Office of the General Counsel at (404) 727-6011.

Training

Training regarding use of *Controlled Substances* for *Research* at Emory is provided via *OC*. The Emory University *IACUC* may require this training for all *Registrants* and their employees and agents who work for them on *Controlled Substances Research* involving animals. The training is highly recommended for all *Registrants* and their employees and agents.

Training materials can be accessed at <http://compliance.emory.edu/controlled-substances/index.html> or contact *OC* at (404) 727-2398 or compliance@emory.edu.

References

21 CFR §§1301.71, .75-.76; 21 USC §823; OCGA §§ 16-13-44, -46 & 26-4-49;

Theft or Loss of Controlled Substances at http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html;

DEA Questions & Answers - Registration at <http://www.deadiversion.usdoj.gov/drugreg/faq.htm>;

DEA Controlled Substances Security Manual at <https://www.deadiversion.usdoj.gov/pubs/manuals/sec/index.html>

DEA Practitioners Manual at <https://www.deadiversion.usdoj.gov/pubs/manuals/pract/>. *Security Outline of the Controlled Substances Act of 1970* at http://www.deadiversion.usdoj.gov/pubs/manuals/sec/sec_non_prac.htm. NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations.

Subsection (iii)

Ordering & Procurement

Emory University administers and facilitates the ordering and purchase of *Controlled Substances* for use in *Research*

through its Procurement Department. *Registrants* who wish to purchase *Controlled Substances* for animal or bench *Research* must follow Procurement's procedures outlined on the following website:
https://www.finance.emory.edu/home/Procure%20and%20Pay/how_to_buy_in_the_marketplace/index_procure_pay_labresearchgoods.html.

For Schedule I or II *Controlled Substances*, a *Registrant* must order drugs himself/herself, or alternatively, delegate a **responsible** person to perform ordering by signing a Power of Attorney form (**FORM 10** -- available at <http://compliance.emory.edu/>). For Schedule III to V *Controlled Substances*, a power of attorney is not required, but *Registrant* is encouraged to document persons to whom authority for ordering Schedule III to V *Controlled Substances* has been delegated. In all cases, *Registrant* is responsible for supervising any person to whom he/she delegates the authority to procure *Controlled Substances* and for periodically reviewing orders and inventory/usage.

A *Registrant* may use the Power of Attorney Form to authorize a responsible individual to obtain and execute DEA Forms 222 or to use the DEA-approved electronic Controlled Substances Ordering System (CSOS). To order Schedule I and II *Controlled Substances*, the *Registrant* or his/her delegate specified on the Power of Attorney Form must complete DEA Form 222 or obtain a CSOS certificate.

The Power of Attorney Form must be signed by the *Registrant*, the individual to whom the Power of Attorney is delegating authorization, and two witnesses. The Power of Attorney Form should be filed with executed DEA Form 222 or provided in conjunction with a CSOS certificate application. A copy of the Power of Attorney Form should be provided to the purchasing department. The Power of Attorney Form must be available for inspection by DEA upon request.

A person to whom authority to order *Controlled Substances* has been granted by a Power of Attorney must be a full-time Emory employee. The *Registrant* shall advise the delegate named in the Power of Attorney of the following information:

The scope of power of attorney

Pertinent state and federal regulations regarding DEA 222 forms

Effective date of power of attorney

The *Registrant* may revoke the power of attorney at any time by executing a Notice of Revocation, which is included at the bottom of **FORM 10**. A copy of the Notice of Revocation shall be provided to purchasing department at the time that it is signed. The *Registrant* must immediately inform the delegate named in the Power of Attorney Form that revocation of the Power of Attorney has occurred.

Emory University does not permit purchasing cards, personal credit cards, personal checks, or cash to be used to purchase *Controlled Substances*. *Controlled Substances* only may be delivered to the address specified on the *Registrant's Registration*. For security reasons, *Registrants'* orders should be limited to the amount of *Controlled Substances* necessary to perform their *Research*, or a 6-month supply, whichever is less.

Subsection References: 21 CFR Part 1205; *DEA Questions & Answers -- Form 222* at <http://www.deadiversion.usdoj.gov/faq/dea222.htm>. NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations; CSOS information at <https://www.deaecom.gov/>.

Subsection (iv)

Disposal

The *Registrant* is responsible for making sure that all *Controlled Substances* are properly disposed when the substances expire; or the *Registrant's DEA Registration* is not renewed; or when the *Registrant* no longer conducts *Research* at

Emory University using *Controlled Substances* or leaves Emory University. The *Registrant* can establish an account with an approved Reverse Distributor vendor, e.g. The Rx Exchange, and arrange with the *DEA* registered reverse-distributor to accept and dispose of *Controlled Substances*.

The *Registrant* should keep a biennial inventory of *Controlled Substances* in his/her possession, and the order, receipt and shipping records for materials in inventory, as well as any records evidencing disposition of the substances for 3 years from date of final disposition of drug.

Subsection References: 21 CFR § 1307.21; *DEA Practitioner's Manual* at <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section4.htm>.

NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations.

Subsection (v) Records

General Requirements for All Records

Separate Records: *Registrant* must keep records pertaining to Schedule I and Schedule II *Controlled Substances* separately from all other *Controlled Substance* and ordinary business records. *Registrant* must keep all records pertaining to Schedule III to V *Controlled Substances* separately from all other ordinary business records.

Retention Period: Per Emory University's records retention schedule, *Registrant* must keep all records relating to *Controlled Substance* ordering, procurement, and inventory for 3 years from final disposition of drug. The record retention schedule is at

<http://records.emory.edu/retention-schedules/entries/d-h/drug-inventory-controlled.html>

Inspection Records: Completed inspection forms/materials provided to the Researcher by the GDNA and/or the *DEA* for application approval must be perpetually retained with the respective active *Registration*.

Inventory: *Registrant* must perform a baseline written initial inventory of all *Controlled Substances* on hand when a *Registrant* begins work with *Controlled Substances*. The inventory must be maintained at the registered site, and a separate inventory is required for each registered site. After the initial inventory is taken, *Registrant* must perform a biennial inventory thereafter, on or before 24 months following the date of the initial inventory. The time (either "beginning of business" or "close of business") and the date of the inventory must be noted on each inventory sheet. Inventory criteria that must be included are set forth in 21 CFR §1304.11(e)(3) and discussed at http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm. The template **Controlled Substances Inventory -- FORM 6** (available at <http://compliance.emory.edu/>) contains all elements required to be included in the inventory.

Use Logs: *Registrant* must maintain a current, running use and disposition log that shows type and amount of *Controlled Substances* dispensed/administered; name and initials of person who dispensed/administered them; date dispensed/administered; and purpose of use. Each entry on the log must be initialed by the person who dispensed/administered the *Controlled Substance*. A template **Controlled Substance Current Use & Disposition Log - FORM 7** (available at <http://www.compliance.emory.edu/>) contains the required elements. A separate log must be kept for each container of a *Controlled Substance*.

Purchasing and Receipt Documentation: *Registrant* must maintain all documents relating to the ordering, purchasing and delivery of all *Controlled Substances*. *DEA* Form 222 must be used to place hard-copy orders of Schedule I and II *Controlled Substances*, and *Registrant* must keep a copy of this form. *Registrant* should keep a log showing each *Controlled Substances* order and receipt thereof. A template log entitled **Order/Receipt Log for Controlled Substances Schedules I & II -- FORM 8**, and a template log entitled **Order/Receipt Log for Controlled Substances Schedules III-V -- FORM 9** are available at <http://www.compliance.emory.edu/>.

Disposal: *Registrant* must maintain all documentation relating to the transfer and disposal of all *Controlled Substances* for 3 years after disposal/transfer to a DEA registered Reverse Distributor or authorized agent.

Inspection: All records pertaining to the acquisition, use and disposition of *Controlled Substances* must be made available to appropriate governmental and university officials for inspection.

Subsection References: 21 CFR Part 1304; OCGA §§ 16-13-39 & 21-4-49. NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations.

Registration for Employees/Agents who Assist in Controlled Substances Research:

Employees or students working for the *Registrant* may be authorized to work with the *Controlled Substances* in carrying out their usual course of employment/course of study, provided they are under the supervision and control of the *Registrant*. Supervision includes explaining to personnel: what *Controlled Substances* will be used in the *Research*; how the *Controlled Substances* will be used in the *Research*; security measures that must be taken with regard to the *Controlled Substances*; record-keeping activities, such as inventories and use logs, that must be followed with respect to the *Controlled Substances*; and procedures for reporting any suspected loss or diversion of *Controlled Substances*. Supervision also requires the *Registrant* actively monitor personnel's use of *Controlled Substances* in *Research* to ensure that this Policy and applicable laws/regulations are being followed.

References: 21 CFR Part 1301; OCGA §§16-13-35 to -38; 26-4-49;

Rules and Regulations of the State of Georgia §480-20-.01.

NOTE: Section III, Subject Matter Area A contains links to websites for state and federal laws/regulations.

Definitions

Definitions

Defined Terms & Acronyms Used in this Policy

CFR: Code of Federal Regulations

Controlled Substances: All drugs, substances or immediate chemical precursors listed in Schedules I to V of OCGA Sections 16-13-25 to 16-13-29; and Schedules I to V of Title 21 of the Code of Federal Regulations (CFR) Section 1308.

DEA: United States Drug Enforcement Agency.

EHSO: Emory Environmental Health and Safety Office

EPD: Emory Police Department

GBP: Georgia Board of Pharmacy

GDNA: Georgia Drugs and Narcotics Agency

Human Clinical Research or HCR: Clinical research involving human subjects.

IACUC: Emory Institutional Animal Care and Use Committee

IBC: Emory Institutional Biosafety Committee

IDS: Investigational Drug Service

IRB: Institutional Review Board

OCGA: Official Code of Georgia Annotated

OC: Office of Compliance

Practitioner: A Georgia licensed physician, dentist, podiatrist, pharmacist or veterinarian.

Registrant: A person who registers with the DEA and Georgia Board of Pharmacy to use *Controlled Substances*.

Registration: The permit obtained from the DEA and/or the Georgia Board of Pharmacy to use *Controlled Substances*.

Research: Any type of scientific investigation.

RHSC: Research Health and Safety Committee

Related Links

- Current Version of This Policy: <http://policies.emory.edu/7.25>
- [Current Version of This Policy](http://policies.emory.edu/7.25) (<http://policies.emory.edu/7.25>)
- [Current Version of Policy 7.29: Research Use of Dangerous Drugs, Including Prescription Drugs](http://policies.emory.edu/7.29) (<http://policies.emory.edu/7.29>)

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- Version Published on: Sep 04, 2014 (*Update website links.*)
- Version Published on: Nov 07, 2013 (*additional drug destruction/disposition update*)
- Version Published on: Nov 05, 2013 (*drug destruction/disposition update*)
- Version Published on: Jul 10, 2013 (*Corrected inconsistencies*)
- Version Published on: Jul 03, 2013 (*Updated website links in Section C in Policy Details*)
- Version Published on: Apr 19, 2013 (*Edited "Subsection (i): Registration" to reflect current practices.*)
- Version Published on: Oct 22, 2012 (*Addition regarding Power of Attorney in Subsection iii*)
- Version Published on: Feb 21, 2012 (*Original Publication*)

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