Policy Summary

This Policy sets forth the primary requirements for the use of Controlled Substances in Research at Georgia State University (Georgia State).

Full Policy Text

Research Use of Controlled Substances

· This policy applies to all individuals including faculty, staff, students, and visiting faculty and researchers who conduct research using controlled substances at Georgia State.

· 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 Georgia State facilities.

· 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; and

  (ii) Schedules I to V of Title 21 of the Code of Federal Regulations (CFR) Section 1308.

· This Policy does not apply to use of Controlled Substances by a licensed physician, pharmacist, dentist, podiatrist or veterinarian in providing health/veterinary care for his/her patients or clients.

· This Policy does not cover the use of Controlled Substances in human clinical research, or drug manufacture, distribution or analysis.

Policy Administration

Mandating Authority:

State law or regulation: Georgia Controlled Substances Act, OCGA, Sections 16-13-25 to 16-13-29; and Rules and Regulations of the Georgia Board of Pharmacy Chapter 480.

**Responsible Office:**
Office of Research Integrity, Dahlberg Hall, Suite 217, 404-413-3500

**Responsible Executive:**
Vice President for Research and Economic Development

**Forms**
Controlled Substance Authorized User Signature Log
Access Log
Security Checklist
Georgia State University Employee and Agent Screening Statement
Controlled Substances Discrepancy Report Form
Power of Attorney
Order/Receipt Log for Schedules I & II Controlled Substances
Order/Receipt Log for Schedules III-V Controlled Substances
Controlled Substances Inventory
Controlled Substance Current Use & Disposition Log

**Rationale or Purpose**

This Policy sets forth the major requirements of the applicable laws and regulations that apply to research involving Controlled Substances. It does not set forth every detail of every law and regulation. 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.

**Policy**

It is the Policy of Georgia State for all individuals who use Controlled Substances in research at Georgia State to adhere to all federal and state laws and regulations governing the use of Controlled Substances in research as well as all Georgia State policies and procedures. Any person who uses Controlled Substances in his/her research at Georgia State is responsible for knowing and following all applicable federal, state and local laws/regulations, and Georgia State policies and procedures.
Supervisors, including principal investigators, are responsible for making sure any person working for him/her also follows the laws, regulations, and policies and procedures.

The following five requirements must be fulfilled to use Controlled Substances at Georgia State.

I. Registration

A. All persons at Georgia State who conduct research using Controlled Substances must register with both the GBP and the DEA as a researcher.

1. Registration with the GBP: Researchers must first apply for a researcher’s permit from the GBP. The application for a Georgia researcher’s permit can be found on the GBP website.
   a. A description of the research must be submitted to the GBP.
   b. Proof of U.S. citizenship or qualified alien status must be submitted.

2. Registration with the DEA: All State of Georgia requirements must be satisfied in order to obtain a DEA registration. DEA registration information can be found on the Drug Enforcement Administration Office of Diversion website.
   a. Researchers should use DEA Form 225 for their initial application and Form 225a for renewals.
   b. For research using Schedule1 Controlled Substances, a copy of the research protocol containing the information set forth in 21 CFR 1301.18 must be provided to DEA.
   c. The GBP permit number is required for the DEA online application. (NOTE: The DEA’s electronic system no longer permits concurrent registration with GBP registration.)

B. All registrations are location specific.

1. A researcher must obtain a separate registration for each separate physical location (building) at which research using Controlled Substances is performed.

2. Controlled Substances may be shipped only to the specific location listed on a registration, for use by the researcher according to the permitted use.

C. GDNA must inspect a site before the GBP issues a registration. The inspection is performed to ensure the facilities and processes satisfy all regulatory requirements, such as security and record keeping requirements.

1. The researcher is responsible for contacting the GDNA to arrange for an inspection only after the GBP has notified the researcher that his/her application has been processed.

2. The DEA may conduct an inspection of an applicant, but generally relies on the GDNA inspection.

3. Agents of DEA, GBP, GDNA or other authorized licensing, police or law enforcement agencies may conduct inspections of registered sights at any time. Researchers should promptly notify the ORI at 404-413-3500 of any inspection or pending inspection and subsequently provide ORI
with a copy of any inspection report received.

4. Researchers should request identification from the government inspectors, if they do not initially provide it. Researchers and their employees and agents should fully cooperate with all inspectors and provide copies of any requested documentation pertaining to Controlled Substances research or registration.

5. Georgia State employees should consult with the Office of Legal Affairs at 404-413-0500 before signing any affidavits or providing any other written statements to governmental agencies concerning activities at Georgia State.

D. Researchers must use the Controlled Substances they order exclusively for their own research. The Controlled Substances cannot be shared or transferred to others not supervised directly by the researcher.

1. Employees or students working for the researcher 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 researcher with the registration for the Controlled Substance. See the Controlled Substance Authorized User Signature Log Form. Supervision includes appropriate training and explaining to personnel the following:

   a. What Controlled Substances will be used in the research;
   b. How the Controlled Substances will be used in the research;
   c. Security measures that must be taken with regard to the Controlled Substances;
   d. Record-keeping activities, such as inventories and use logs, that must be followed with respect to the Controlled Substances; and
   e. Procedures for reporting any suspected loss or diversion of Controlled Substances.

2. The researcher must actively monitor personnel’s use of Controlled Substances in research to ensure this Policy and applicable laws and regulations are followed. See the Access Log Form.

E. Registration must be maintained at all times while Controlled Substances are being used in research or are in the user’s (researcher’s) possession.

II. Security and Storage of Controlled Substances

A. The registrant is responsible for ensuring the Controlled Substances used in his/her research are kept secure to prevent theft, loss, unauthorized access or removal. See the Security Checklist Form.

B. Physical Security and Storage: The DEA and GDNA evaluate physical security measures based on the type and amount of Controlled Substances, 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.

1. Controlled Substances should be stored in their original, labeled containers, and they should be stored separate from general chemicals.

2. Schedule I Controlled Substances must be kept in a securely locked, substantially constructed cabinet. A strong metal cabinet or safe that is securely fastened to the floor or wall in a manner that prevents it from being readily removed is generally acceptable.
3. Schedule II – V Controlled Substances, except as noted below, must be stored in a securely locked, substantially constructed cabinet.

4. Carfentanil Etorphine Hydrochloride and Diprenorphine Controlled Substances must be kept in a safe or steel cabinet equivalent to a U.S. Government Class V security container. 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.

5. Cabinets or drawers used to store Controlled Substances must have a key or combination lock.

6. Rooms where Controlled Substances are stored must be locked when authorized personnel are not present in the room. The 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. The 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 Georgia State, and persons whose access to Controlled Substances must be terminated because of security concerns.

7. The registrant must immediately report loss or theft of access control devices/measures (keys, combinations, etc.) to the Georgia State Police Department and the ORI.

C. Personnel Security

1. Registrants may not 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 had a DEA registration denied, revoked or surrendered for cause.

2. Registrants must require all employees, students and other agents who work with Controlled Substances to complete and sign the Georgia State Employee and Agent Screening Statement Form prior to beginning work with Controlled Substances. Employees will be expected to undergo any criminal background or any other checks routinely required of employees by Georgia State’s Department of Human Resources.

3. 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 suspended for cause while working for the registrant, must immediately report such events to the registrant and the registrant must immediately terminate their access to Controlled Substances at Georgia State.

4. Registrants must keep a log of the persons working for them who the registrant has authorized to work with Controlled Substances. (See the Access Log Form.)

5. Georgia State requires the registrant use any Controlled Substance ordered under his/her registration solely for his/her research as described to DEA and/or GBP.

6. Georgia State does not permit the registrant to transfer or provide Controlled Substances to any other persons for use in those person’s research or for any other use. However, Georgia State’s Department of Animal Resources (DAR) may transfer certain anesthetic and/or euthanasia agents to a researcher provided his/her registration is on file with DAR and there is appropriate IACUC and or IBC approval.

D. Reporting Loss or Diversion of Controlled Substances
1. Georgia State 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 may be made directly to the registrant or ORI at 404-413-3500.

2. The registrant must promptly on discovery of any theft or significant loss, notify the Georgia State Police Department at 404-413-3333 and ORI at 404-413-3500. Reports to the Georgia State Police Department or ORI should be made using the Controlled Substances Discrepancy Report Form.

3. A report must be made to the DEA within one business day of discovery of any loss or theft. ORI may assist the registrant with completing the DEA Form 106.

4. Within 48 hours of discovery of any loss or theft, a copy of the completed DEA Form 106 must be faxed to GDNA at 404-651-8210.

III. Ordering and Procurement

A. General Ordering Requirements

1. Georgia State personnel must follow all Georgia State purchasing rules when purchasing Controlled Substances.

2. Georgia State does not permit personal credit cards, personal checks, or cash to be used to purchase Controlled Substances.

3. Ordering Controlled Substances must be processed in Panther Mart as a non-catalog item.

4. When processing the non-catalog item, the Controlled Substance box must be selected prior to adding the item to the cart.

5. Controlled Substances may only be delivered to the address specified on the registrant’s registration.

6. For security reasons, registrants’ orders should be limited to the amount of Controlled Substances necessary to perform their Research, or a six-month supply, whichever is less.

B. Ordering Schedule I or II Controlled Substances

1. 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. Schedule I or II Controlled Substances may be tracked on the Order/Receipt Log for Schedules I & II Controlled Substances Form.

2. 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.

3. A registrant may use the Power of Attorney Form to authorize a responsible individual to obtain and execute DEA Form 222.

4. 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.

5. The Power of Attorney Form must be signed by the registrant, the individual to who the Power of Attorney is delegating authorization, and two witnesses.

6. The Power of Attorney Form should be filed with the executed DEA Form 222.

7. A copy of the Power of Attorney Form should be maintained by the registrant.
8. The Power of Attorney Form is not submitted to DEA, but it must be available for inspection upon request.

9. A person to whom authority to order Controlled Substances has been granted by a Power of Attorney must be a full-time Georgia State employee.

10. The registrant shall advise the delegate of the following information:

   a. The scope of the Power of Attorney

   b. Pertinent state and federal regulations regarding DEA 222 forms;

   and

   c. The effective date of the Power of Attorney.

   d. The registrant may revoke the Power of Attorney at any time by executing a Notice of Revocation, which is included at the bottom of the Power of Attorney Form.

   e. The registrant must immediately inform the delegate named in the Power of Attorney Form that revocation of the Power of Attorney has occurred.

   f. The registrant should maintain a copy of the Notice of Revocation.

C. Ordering Schedule III, IV or V Controlled Substances

1. For Schedule III-V Controlled Substances, a Power of Attorney is not required by the registrant to delegate ordering, but the registrant should document persons to whom authority for ordering Schedule III-V Controlled Substances has been delegated.

2. Schedule III-V Controlled Substances may be tracked on the Order/Receipt Log for Schedule III-V Controlled Substances Form.

3. A person to whom authority to order Schedule III-V Controlled Substances has been granted must be a full-time Georgia State employee.

IV. Disposal

A. The registrant is responsible for making sure all Controlled Substances are properly disposed when: the substances expire; the Registrant’s DEA registration is not renewed; the Registrant no longer conducts research at Georgia State using Controlled Substances; or the Registrant leaves Georgia State.

B. The registrant should arrange for a DEA registered reverse-distributor to accept and dispose of Controlled Substances. The registrant may dispose of Controlled Substances by bringing them to a University-sponsored opportunity for on-campus destruction. Research and Environmental Safety arranges for an authorized agent of the State to come to campus for this purpose on an annual basis. There is no charge for this on-campus destruction.

C. The registrant should keep a biennial inventory of Controlled Substances in his/her possession, including any records of disposition of the substances for three (3) years (current year plus two (2) years) from the date the record was created.
V. Records

A. Separate Records

1. Registrant must keep records pertaining to Schedule I and II Controlled Substances separately from all other Controlled Substances and ordinary business records.

2. Registrant must keep all records pertaining to Schedule III to V Controlled Substances separately from all other ordinary business records.

B. Retention Period

1. Registrant must keep all records related to Controlled Substance ordering, procurement and inventory for three (3) years: the current year in which the document is generated, plus an additional two (2) years.

C. Inventory

1. Registrant must perform a baseline written initial inventory of all Controlled Substances on hand when a registrant begins work with Controlled Substances.

2. The inventory must be maintained at the registered site, and a separate inventory is required for each registered site.

3. 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.

4. The time and date of the inventory must be noted on each inventory sheet.

5. Inventory criteria that must be included are set forth in 21 CFR Section 1304.11(e)(3). See the Controlled Substances Inventory Form.

D. Use Logs

1. Registrant must maintain a current, running use and disposition log that shows type and amount of Controlled Substances dispensed/administered; name and initial of person who dispensed/administered them; date dispensed/administered; and purpose of use.

2. Each entry on the log must be initialed by the person who dispensed/administered the Controlled Substance.

3. A separate log must be kept for each container of a Controlled Substance.

See the Controlled Substance Current Use & Disposition Log Form.

E. Purchasing and Receipt Documentation

1. Registrant must maintain all documents relating to the ordering, purchasing and delivery of all Controlled Substances.

2. DEA Form 222 must be used to place hard-copy orders of Schedule I and II Controlled Substances. Registrant must keep a copy of this form.

3. Registrant should keep a log showing each Controlled Substances order and receipt thereof. See the Order/Receipt Log for Controlled Substances Schedules I & II Form and Order/Receipt Log for Controlled Substances III- V Form.

F. Disposal
1. Registrant must maintain all documentation relating to the transfer and disposal of all Controlled Substances for three (3) years (current year plus two (2) years) after disposal or transfer.

G. 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.

http://ursa.research.gsu.edu/ursa/resources/formsandpolicies/

Administration of Policy

**Mandating Authority:**
Fed. Controlled Substances Act and Title 21 CFR Part 1300; GA Controlled Substances Act

**Responsible Office(s):**
Office of Research Integrity, 2nd floor Dalberg Hall, 3-3500

**Responsible Executive(s):**

Policy History

**Approving Body:** Administrative Council

Rationale or Purpose

This Policy sets forth the major requirements of the applicable laws and regulations that apply to research involving Controlled Substances. It does not set forth every detail of every law and regulation. 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.

Appendix

View Appendix

Additional Information

Approved by Senate Research Committee 9/16/2013

Additional Helpful Resources