Georgia State University

Application for Authorization of Minor (16 or 17 years of age) to Work or Volunteer in a Laboratory or Other Hazardous Area

Return this form to the Director of Safety and Risk Management a minimum of five working days BEFORE the Minor begins to work or volunteer at Georgia State University.

**Proposed Project/Program Information**

Project/Program Title:

Expected duration of Temporary Employment, Volunteering or Other Activity (Start Date and End Date):

Is the Project sponsored or funded by an outside organization? (Y/N) If yes, please provide the name of the sponsor:

**FACULTY INFORMATION**

Supervising Faculty Member Name:

Principal Investigator (if different from Supervising Faculty Member):

Department:

Email: Telephone: Campus PO Box:

Building where work will be done: Room(s):

What faculty member is responsible for this/these room(s):

**Materials and Equipment to be Used – Check all that apply and List each specific item under the category checked:**

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>Biological Material</th>
<th>Equipment</th>
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</thead>
<tbody>
<tr>
<td>Flammable:</td>
<td>Recombinant DNA:</td>
<td>Fume Hood:</td>
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<tr>
<td>Reactive:</td>
<td>Bacteria:</td>
<td>Biosafety Cabinet:</td>
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<tr>
<td>Carcinogenic:</td>
<td>Viruses:</td>
<td>Laminar Clean Bench:</td>
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<tr>
<td>Toxic:</td>
<td>Fungi:</td>
<td>Autoclave:</td>
</tr>
</tbody>
</table>
Describe the Minor’s activities. Include a detailed list of techniques and equipment to be used. (To be completed by Supervising Faculty Member):

Indicate measures to be taken to ensure that the Supervising Faculty Member will have constant line-of-sight supervision of the Minor at all times while in the laboratory. Detail what measures will be taken when the Supervising Faculty Member indicated is absent or has to leave the laboratory for any reason.

Indicate measures to be taken to ensure the Minor is not exposed to radioactivity or radiation producing devices.

Indicate measures to be taken to ensure the Minor is not exposed to explosive chemicals.

Indicate measures present within the laboratory to mitigate the risks of exposure of chemical and biological agents to the Minor.

**Health and Emergency**

Will the Minor be working with live animals?

If yes, the Minor must be enrolled in the medical monitoring program. The IACUC must approve the Minor working on the project prior to the Minor working on the project. Please include the IACUC project number below.

Will the Minor require any vaccinations prior to initiation of the project/program?

**Please note that Minors are not allowed in the non-human primate facility.**

**Training**

Prior to the Minor beginning work in the laboratory, the Supervising Faculty Member must certify and retain documentation of the following training:
• Completion of Online Laboratory Safety training to include Chemical Right To Know Awareness Training, Blood Borne Pathogen Training, Portable Fire Extinguisher Training, and Hazardous Waste Generator Training.

If the Minor(s) will have contact with live animals, the Supervising Faculty Member is responsible for certifying completion of AALAS Learning Library Training (online) and retaining documentation of such training prior to the individuals entering the laboratory.

The Supervising Faculty Member is responsible for certifying completion of any additional training that is required, i.e. Species Specific Training, CITI training for human subjects, etc., and maintaining documentation of such training prior to the individuals entering the laboratory or participating in the project.

**Personal Protective Equipment (PPE)**

Please check which PPE the minor(s) will be required to wear (all are required to wear a lab coat)

X-Lab Coat (required) __ Gloves __ Protective Eyewear __ Aprons __ Mask __ Shoe Covers __ Hair Cover __ Other (Specify): ______________________

**MINOR INFORMATION**

How many Minors will participate in the program? ________

Check one:

__ Temporary Employment  __ Volunteering  __ Other (explain):

Please provide the following information for each Minor participating in the program:

Minor’s Name: 

Minor’s Age: 

Minor’s Email Address: 

Parent/Guardian Name: 

Parent/Guardian Contact Telephone Numbers:  Daytime:  __Evening:__

**Committee Approvals:**

Will the minor(s) be working on a project involving biohazardous materials? (Please note that Minors may not work with or be exposed to rDNA.)
If Yes, has the Institutional Biosafety Committee approved the minor to work on the project?

Provide the IBC protocol number: __________

Will the minor(s) be working on a project involving animals?

If yes, has the IACUC approved the minor to work on the project?

Provide the IACUC protocol number: __________

Will the minor(s) be working on a project involving human subjects?

If yes, has the IRB approved the minor to work on the project?

Provide the IRB protocol number: __________

Supervising Faculty Member Approval

I AGREE TO SUPERVISE THE ABOVE NAMED MINOR(S) AND BY MY SIGNATURE BELOW, CERTIFY AND AGREE THAT:

- I have read, understand and will adhere to all applicable GSU policies, including those addressing Minors in laboratories.
- The above named Minor(s) has/have completed or will complete prior to entering the Right to Know, Laboratory Hazard and Laboratory Specific Safety Training and all required IRB, IACUC, IBC and RPC training and approvals.
- Personal protective equipment appropriate for, and specific to, laboratory hazards will be provided and the Minor(s) instructed on proper use and disposal.
- The minor(s) will receive constant line-of-sight supervision at all times while in the laboratory and never left alone.
- The hours of work or volunteering for the Minor(s) will comply with Federal Regulation 29 CFR 570.35.
- My laboratory is in full compliance with all applicable Georgia State University safety programs and regulations.

Printed Name of Supervising Faculty Member:

____________________________________  ________________
Supervising Faculty Member Signature                Date
Georgia State University
CONSENT AND RELEASE FOR MINOR’S PRESENCE IN LABORATORY

I, the undersigned parent/legal guardian of _______________ (the “Participant”) who was born on ____________, understand and consent to the following:

I understand that my child has been offered the opportunity to participate in a project entitled ________________ in a laboratory at Georgia State University (“GSU”) for the period from _______ to __________, under the supervision of _________________________________ [name(s) of Supervising Faculty Member and Principal Investigator].

I understand that some laboratory facilities or related locations at GSU are potentially hazardous environments. Even under ideal conditions, including the proper use of materials and adherence to safety procedures, a risk of personal injury exists. The list of Possible Risks from Exposure provided below provides the most common potential risks, but it is not intended to be an exhaustive list. Failure to adhere to established procedures may result in greater risk. The Participant will receive appropriate training concerning how to identify hazards and how to work safely with materials and equipment and will be supervised in the handling of instrumentation and materials that may pose a risk.

The hazardous materials that may be in this laboratory and to which the Participant may be exposed include (__ check here if additional sheet is attached):

<table>
<thead>
<tr>
<th>Hazardous Materials</th>
<th>Possible Risks From Exposure</th>
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</table>

I understand that the Participant may be removed from the project on a temporary or permanent basis if he or she refuses, or is unable, to follow the safety rules, to wear assigned personal protective equipment, or to perform activities as directed.

I hereby warrant that to the best of my knowledge, the Participant is in good health and, except as specified below, has no allergies or other physical, mental, or emotional condition that might limit his or her ability to safely participate in activities in the laboratory. I assume all responsibility for the health of the Participant.

<table>
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<tr>
<th>Allergies</th>
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<tr>
<td>Physical Conditions</td>
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<tr>
<td>Mental or Emotional Conditions</td>
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<tr>
<td>Other</td>
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In the event of an emergency, I hereby give permission to transport the Participant to a hospital for emergency medical or surgical treatment. I assume the responsibility for the payment of all such emergency care and treatment. I also assume responsibility for the payment of all subsequent treatment and care that the Participant may require. I have listed emergency contact and medical insurance information below:

**Emergency Contact Information**

*Primary*
Name(s) ___________________________
Relation to Participant: ______________
Daytime phone: _______________
Evening phone _______________

*Secondary*
Name(s) ___________________________
Relation to Participant: ______________
Daytime Phone _____________________
Evening Phone _____________________

**Medical Insurance Information:**

Insurance Carrier __________________
Carrier Group Number ________________
Policy Holder's Name _______________
Policy Holder's ID# __________________
If applicable, Insurance Carrier pre-certification telephone number _______________
Address for claim submission ______________________________________________

In consideration of GSU permitting the Participant to participate in a project in a laboratory, I hereby release, indemnify and hold harmless the Board of Regents of the University System of Georgia, GSU, and their officers, directors, faculty, staff, agents and authorized representatives from all claims, demands, rights, causes of action, suits, liabilities, losses, damages, costs and expenses (including attorney’s fees and court costs) arising out of or resulting from the presence of the Participant in the above referenced laboratory.

I further understand that GSU facilities are being made available to the Participant as an educational opportunity and that he or she is not a student, employee, or affiliate of GSU. Knowing and understanding the circumstances and the risks described above, I consent to allow the Participant to be present and participate in a project in the above-referenced GSU laboratory.

Signed: ____________________________  Printed name: ____________________________
(Parent/Legal Guardian) (Date)

Witness Signature: ___________________  Printed name: ________________________
(Date)

*Copy of completed form must be submitted prior to start of Participant activities to the Georgia State University Department of Safety and Risk Management, 75 Piedmont Avenue, Suite 506, Atlanta GA 30302; Fax: 404-413-9550; Email: jsanders26@gsu.edu. Original copy should be maintained by the Super*
Research Use of Controlled Substances

Brief Policy Summary

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

<table>
<thead>
<tr>
<th>Applicability/Eligibility</th>
<th>Exceptions</th>
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<tr>
<td>• This policy applies to all individuals including faculty, staff, students, and visiting faculty and researchers who conduct research using controlled substances at Georgia State.</td>
<td>• 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.</td>
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<tr>
<td>• 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.</td>
<td>• This Policy does not cover the use of Controlled Substances in human clinical research, or drug manufacture, distribution or analysis.</td>
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<tr>
<td>• 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.</td>
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</tbody>
</table>

Policy Administration

Mandating Authority: Federal law: Federal Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970); and Title 21 CFR Part 1300. 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
<table>
<thead>
<tr>
<th>Policy Management</th>
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<tr>
<td><strong>Policy History</strong> (dates of approval)</td>
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</tbody>
</table>

### 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.

Definitions


Controlled Substance(s) means 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 CFR Section 1308.

DEA means the United States Drug Enforcement Agency.

GBP means the Georgia Board of Pharmacy.

GDNA means the Georgia Drugs and Narcotics Agency.

Georgia State means Georgia State University.

OCGA means Official Code of Georgia Annotated.

ORI means Georgia State Office of Research Integrity.

Registrant means a person who registers with the DEA and GBP to use Controlled Substances.

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 Schedule 1 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.
Form 1

Controlled Substance Authorized User Signature Log

List the names, titles and signatures of all persons (employees and agents) designated by the Registrant as persons Registrant has authorized to assist in conducting Research using Controlled Substance at this Location.

Note: For security, the number of individuals who have access to controlled substances should be limited to the minimum number necessary.

Registrant Name: ___________________________ Registration Location: ___________________________

(Print Name Legibly)

Department: ________________________________________________________________

<table>
<thead>
<tr>
<th>Employee/Agent Name (Print or Type)</th>
<th>Job Title</th>
<th>Signature</th>
<th>Name and Schedule of Controlled Substances to be Used</th>
<th>Registrant's Initials</th>
<th>Date</th>
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</tbody>
</table>
Form 2
Access Log

Registrant Name: ____________________________________________________

Department: _________________________________________________________

Registrant Location: ________________________________________________

Instructions:
List below all persons to whom Registrant has issued a key, key code or other access device to have access to the controlled substances.

<table>
<thead>
<tr>
<th>Recipient's Name</th>
<th>Recipient's Title</th>
<th>Date Access Device Issued</th>
<th>Recipient's Initial</th>
<th>Registrant's Initials</th>
<th>Date Access Device Returned or Terminated</th>
<th>Registrant's Initials</th>
<th>Recipient's Initials</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Form 3
SECURITY CHECKLIST

Registrant: ________________________________________________________________

Registration Location: ______________________________________________________

Registrant Checklist:

- Yes  No
  - Has a State of Georgia researcher permit been obtained from the Georgia Board of Pharmacy and is it current?

- Yes  No
  - Has DEA registration been obtained and is it current?

Type & Form of Controlled Substances in Use

<table>
<thead>
<tr>
<th>Type</th>
<th>Form(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bulk Liquid</td>
</tr>
<tr>
<td></td>
<td>Bulk Powder</td>
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<tr>
<td></td>
<td>Dosage Form</td>
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<tr>
<td>Schedule II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bulk Liquid</td>
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<tr>
<td></td>
<td>Bulk Powder</td>
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<tr>
<td></td>
<td>Dosage Form</td>
</tr>
<tr>
<td>Schedule III</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bulk Liquid</td>
</tr>
<tr>
<td></td>
<td>Bulk Powder</td>
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<tr>
<td></td>
<td>Dosage Form</td>
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<tr>
<td>Schedule IV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bulk Liquid</td>
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<tr>
<td></td>
<td>Bulk Powder</td>
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<tr>
<td></td>
<td>Dosage Form</td>
</tr>
<tr>
<td>Schedule V</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bulk Liquid</td>
</tr>
<tr>
<td></td>
<td>Bulk Powder</td>
</tr>
<tr>
<td></td>
<td>Dosage Form</td>
</tr>
<tr>
<td>Room where Controlled Substances are Stored</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td>Is room access limited to researcher and authorized personnel?</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td>Are room access devices (keys, key-cards, combinations, etc.) available only to the Registrant and authorized personnel?</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td>Is there a log that shows to whom room access devices have been assigned and when they are returned?</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td>Is the room kept locked when not in use?</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td>Is the room located in an area where access can easily be monitored?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage of Controlled Substances (CS)</th>
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<tbody>
<tr>
<td>☐ Yes ☐ No</td>
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<tr>
<td>☐ Yes ☐ No</td>
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<td>☐ Yes ☐ No</td>
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<td>☐ Yes ☐ No</td>
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<td>☐ Yes ☐ No</td>
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</table>

<table>
<thead>
<tr>
<th>Initial/Baseline and Biennial Inventory</th>
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</thead>
<tbody>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
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<tr>
<td>☐ Yes ☐ No</td>
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<tr>
<td>☐ Yes ☐ No</td>
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</table>
### Continuing Use Log

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Does the site have a continuing use log for each container of a Controlled Substance?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Does the continuing use log show type and amount of Controlled Substance dispensed/administered, along with name and initials of person who dispensed/administered, and date/purpose of dispensing/administration?</td>
</tr>
</tbody>
</table>

### Records

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<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Are Controlled Substance records kept secured and separate for general business records?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Are records for Schedule I &amp; II substances kept separately from records for Schedule III -V substances?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Are logs kept showing ordering and receipt of Controlled Substances?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Are copies of DEA Form 222 kept for orders of Schedule I &amp; II substances?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
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<tr>
<td></td>
<td>Are back-up documents such as invoices and receipts maintained for ordering/receipt of Controlled Substances?</td>
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<tr>
<td>Yes</td>
<td>No</td>
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<td></td>
<td>Are records maintained to document transfer or disposal of Controlled Substances?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Are documents maintained showing proper reporting of any lost or diverted Controlled Substances?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
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<tr>
<td></td>
<td>Are Controlled Substance records maintained for 3 years from date of creation?</td>
</tr>
</tbody>
</table>

### Personnel Security Checklist

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Does Registrant have a log of all persons authorized by him/her to use Controlled Substances for carrying out Registrant’s research?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Has Registrant trained persons authorized to work with Controlled Substances on necessity of and procedure for reporting loss or diversion of Controlled Substances?</td>
</tr>
</tbody>
</table>
Form 4

Georgia State University Employee and Agent Screening Statement
(based on 21 CFR 1301.90)

Georgia State University requires that all employees who have access to controlled substances used in research as a part of their work duties complete the following questionnaire in order to ensure compliance with the federal regulations governing controlled substances found at 21 CFR Section 1301.90. The U.S. Drug Enforcement Agency requires the collection of this information in order to “fairly assess the likelihood of an employee committing a drug security breach.” The information collected on this form will only be used by Georgia State University to assess an employee’s security risk with respect to working with controlled substances.

(1) Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.)

☐ Yes  ☐ No

If the answer is yes, furnish details of conviction, offense, location, date and sentence.

(2) Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician?

☐ Yes  ☐ No

If the answer is yes, furnish details.

Statement of Employee:

If I have knowledge of drug diversion from Georgia State University (e.g., by a colleague, student, fellow employee, etc.), I agree that it is my obligation to report such information to a responsible security official of Georgia State University. This information will be treated as confidential and Georgia State University shall take all reasonable steps to protect the confidentiality of the information and my identity, as the employee furnishing information. I understand that failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area.

Signature ___________________________ Date ___________________________

Print Name ___________________________
CONTROlLED SUBSTANCES DISCREPANCY REPORT FORM

Instructions: This form should be completed in the event that a discrepancy in the amount of Controlled Substances is discovered during an audit or inventory or as the result of loss or theft. See the following page for CHECKLIST OF STEPS TO BE TAKEN IN CASES OF SUSPECTED LOSS OR THEFT OF CONTROLLED SUBSTANCES.

Type of Discrepancy:
Include discrepancies noted during audits or inventories that are potentially indicative of a significant loss or theft of Controlled Substances.

☐ Significant Loss of Controlled Substances
☐ Theft of Controlled Substances

Date and Time of Discovery: _____________________________________________________

Location where Discrepancy was Discovered: _______________________________________

Name/Phone Number/Email of Person who Made Discovery: __________________________

______________________________________________________________________________

Description of Discrepancy:
Include name(s). Schedule(s), and form(s) of Controlled Substances involved; name of registrant responsible for affected Controlled Substances; description of circumstances of discrepancy (e.g., evidence of attempted break-in; broken safety tab on container; evidence of missing containers or substances; discrepancy in inventory/audit; names and titles of any persons involved in discrepancy and/or discovery or reporting of discrepancy).

Name/Title of Person Completing this Report: ______________________________________

Signature: ______________________________ Date: ______________________

Copies: Fax or email copies of this form to the following units:

Georgia State University Police Department

Georgia State University Office of Research Integrity
CHECKLIST OF STEPS TO BE TAKEN IN CASES OF SUSPECTED LOSS OR THEFT OF
CONTROLLED SUBSTANCES

(1) If a registrant has a reasonable belief or suspicion that there has been (a) theft of any amount of a
Controlled Substance; or (b) significant loss of a Controlled Substance, then the even must be promptly
reported to the following units:
   • Georgia State University Office of Research Integrity
   • Georgia State University Police Department
   • U.S. Drug Enforcement Agency (DEA)
   • Georgia Drug and Narcotics Agency (GDNA).

If there is doubt about whether a report should be made, err on the side of reporting.

(2) To determine if a loss is "significant," the registrant should consider the following factors:
   (a) The actual quantity of controlled substance lost in relation to the type of activities performed by
   registrant.
   (b) The specific controlled substance that was lost and whether it is a likely candidate for diversion.
   (c) Whether the loss can be associated with access to the controlled substances by specific
   individuals.
   (d) Whether the loss can be attributed to unique activities that take place involving the controlled
   substances.
   (e) Whether there has been a pattern of losses of a specific period or alternatively, whether the loss
   appears to be random.
   (f) The results of any efforts to resolve the loss.
   (g) Any local trends or other indicators that the lost controlled substance has been diverted.

Registrants with questions about how to apply the foregoing factors in determining if a loss is significant
contact Research Health and Safety or the Office of Legal Affairs for advice.

(3) The contacts, correct forms and timetable for reporting are listed below:

<table>
<thead>
<tr>
<th>Unit Receiving Report</th>
<th>Contact Information</th>
<th>Timetable</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA</td>
<td>Complete and submit DEA Form 106 on-line</td>
<td>Within one business day of discovery of theft or significant loss</td>
</tr>
<tr>
<td>GDNA</td>
<td>FAX copy of completed DEA Form 106 to GDNA</td>
<td>Within 48 hours of discovery</td>
</tr>
<tr>
<td>Georgia State University Police</td>
<td>Complete and submit Controlled Substances Discrepancy Report indicating loss or theft</td>
<td>Promptly upon discovery.</td>
</tr>
<tr>
<td>Office of Research Integrity</td>
<td>Complete and submit Controlled Substances Discrepancy Report indicating loss or theft</td>
<td>Promptly upon discovery.</td>
</tr>
</tbody>
</table>
FORM 6
POWER OF ATTORNEY for DEA Forms 222 and Electronic Orders

Name of Registrant: ____________________________________________________________
Address or Registrant: _________________________________________________________
DEA Registration Number: _____________________________________________________

I, ______________________________________, (printed name of person granting power), the undersigned, who am
authorized to sign the current application for registration of the above-named registrant under the Controlled
Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by
these presents, do make, constitute and appoint ___________________________ (printed name of attorney-in-fact),
my true and lawful attorney for me in my name, place, and stead to execute applications for Forms 222 and to sign
orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in
accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and
confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

______________________________ (Signature of person granting power) Date: _________________

I, _____________________________ (printed name of attorney-in-fact), hereby affirm that I am the person
named herein as attorney-in-fact and that the signature affixed hereto is my signature.

______________________________ (Signature of attorney-in-fact) Date: _________________

Witnesses:
1. _______________________________ (Signature of witness) Date: _________________
2. _______________________________ (Signature of witness) Date: _________________

NOTICE OF REVOCATION (to be completed only when Power of Attorney is revoked)
The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current
application for registration of the above-named registrant under the Controlled Substances Act or the Controlled
Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact,
______________________________ (printed name of attorney-in-fact), this same day.

______________________________ (Signature of person revoking power) Date: _________________

Witnesses:
1. _______________________________ (Signature of witness) Date: _________________
2. _______________________________ (Signature of witness) Date: _________________
FORM 7
ORDER/RECEIPT LOG FOR SCHEDULES I & II CONTROLLED SUBSTANCES

Registrant Name: ___________________________ Registration Location: ___________________________

Date DEA Forms 222 Received ________________ DEA Order Form 222 Numbers (inclusive) ________________
to ____________________________

This form is to be used for orders made with paper DEA Form 222.

DEA Form 222 Order Number: Take this information from the block titled “No. of this Order Form” on lower left quadrant of the Form 222. This number is preprinted by the DEA.

Name of Supplier: Name of Company or Person to whom the form was submitted.

Date Form Submitted: Date entered on DEA 222 Form.

Amount Ordered: Enter amount ordered (number and dosage form).

Date Received: Enter each shipment’s Date Received.

Name of Person who received shipment.

Amount Received: Enter amount received. Note and explain discrepancies in comments (e.g., note if order filled by multiple shipments).

In addition, annotate copy of DEA Form 222 to show quantity of controlled substances received/date of receipt.

Void or Rejected Forms: Retain void and rejected/returned forms.

• If form is rejected by the supplier, write date the form is returned from the supplier in the date received column and an explanation in the comments column.

Retain all backup documentation for orders placed and received .

<table>
<thead>
<tr>
<th>DEA Form 222 Order Number</th>
<th>Name of Supplier</th>
<th>Date Form 222 Submitted</th>
<th>Amount Ordered</th>
<th>Date Shipment Received</th>
<th>Name of Person who Received Shipment</th>
<th>Amount Received</th>
<th>Comments</th>
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Form 8
ORDER/RECEIPT LOG FOR SCHEDULES III - V CONTROLLED SUBSTANCES

Registrant Name: ___________________________________  Registration Location: ___________________________________

**Purchase Order No.**: Number given to the order for tracking purposes.
**Name of Supplier**: Name of entity to which the form was submitted.
**Date Order Placed**: Date Order was submitted to Supplier.
**Amount Ordered**: Enter amount ordered (number and dosage form).
**Date Shipment Received**: Enter each shipment’s Date Received.
**Name of Person who received shipment**: Insert name of person who received shipment. This person should check to make sure order is completed.
**Amount Received**: Enter amount received. Note and explain discrepancies in comments (e.g., note if order filled by multiple shipments).

_Retain all backup documentation (e.g., packing list, shipment documentation, etc.) for orders placed and received._

<table>
<thead>
<tr>
<th>Purchase Order Number</th>
<th>Name of Supplier</th>
<th>Date Order Placed</th>
<th>Amount Ordered</th>
<th>Date Shipment Received</th>
<th>Name of Person who Received Shipment</th>
<th>Amount Received</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Form 9
Controlled Substances Inventory

Initial Inventory: ☐ Yes ☐ No    OR    Biennial Inventory: ☐ Yes ☐ No

Instructions: A separate copy of this form should be used for baseline controlled substances inventory and for subsequent biennial inventories. A complete physical inventory should be completed for all controlled substances at the beginning or close of business. Separate inventory sheets must be maintained for Schedule I & II Controlled Substances and Schedule III & V Controlled Substances.

Registrant’s Name: ___________________________    Department: ___________________________

Registration Number: ___________________________    Registration Location: ___________________________

Complete Physical Inventory? ☐ Yes ☐ No    Date: ___________________________

Time: ________________    Beginning of Business: ________________    Close of Business: ________________

<table>
<thead>
<tr>
<th>Line No.</th>
<th>Name of substance</th>
<th>Identification Number or Manufacturer’s Lot Number</th>
<th>Product Form / Concentration</th>
<th>Schedule</th>
<th>Volume or Quantity per Container</th>
<th>Number of containers</th>
</tr>
</thead>
<tbody>
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*List opened/partially used containers individually.

Make an exact count of C-I or C-II contents. Make an exact count if a C-III, -IV or -V container held more than 1,000 tablets or capsules. Count or measure the contents if the container holds less than 1,000 tablets or capsules.

At least two (2) people must together perform, sign and date this inventory:

1) ___________________________    2) ___________________________

Reviewed by Registrant: ___________________________    Date: ___________________________

(Signature)
Form 10  
CONTROLLED SUBSTANCE CURRENT USE & DISPOSITION LOG

One log sheet should be completed for each container of a Controlled Substance. Controlled Substance usage must be tracked on a per dose (use) basis. Record the total quantity of the substance to the nearest metric unit weight or the total number of units finished form.

Drug Name: ______________________  Schedule # (I-V): _______  Lot #: ____________________________

Concentration: _______  Amount Received (e.g. 10 ml vial): _____________  Drug Expiration Date: ______________

Registrant's Name: ___________________________________________  Date Added to Inventory: _______________________

Container ID # (individual containers should be assigned unique numbers upon receipt to assist in tracking): _______

Registrant's Address (as it appears on Form 223): ____________________________________________________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Amount Used</th>
<th>Balance (unit)</th>
<th>Printed Name of Authorized User Who Dispensed Drug</th>
<th>Authorized User Initials</th>
<th>Reason for Use/Protocol #</th>
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</table>

*The log balance must match the physical balance of CS at all times.

*Any log discrepancies, or other circumstances that indicate significant loss or theft of controlled substance must promptly be reported to Georgia State University Police, ORI, DEA/GDNA; see Form 5 for reporting instructions.

*When this controlled substance is no longer needed, use a reverse distributor for disposal.

*When this controlled substance is completely used up, retain this log in your records for three years, deface empty container label and throw in regular trash.