**Background:** Controlled Substances, drugs for which there is a potential for abuse, are divided into Schedules I -V depending on their medicinal use and potential for abuse. Schedule I Controlled Substances (or Class I, abbreviated as C-I) have no medicinal value and high potential for abuse Schedule II Controlled Substances have medicinal value but high potential for abuse. Schedule III – V Controlled Substances have therapeutic value and lesser potential for abuse. Both federal and state law applies to investigators who are performing research using Controlled Substances. Click [here](http://or.emory.edu/research-compliance/controlled-substances/index.html) for more information on Controlled Substances (CS).

Use of Schedule 1 Controlled Substances (CS) in research requires obtaining a researcher permit from the Georgia Board of Pharmacy (GBP) and registration with the Drug Enforcement Administration (DEA) in addition to institutional approval.

For human subject research, a [Certificate of Confidentiality](https://irb.emory.edu/guidance/faqs/certificate.html) is recommended if the research includes questions about the use of illegal substances.

**Investigator:** *Please submit the completed form to the Office of Research Integrity and Compliance (ORIC)* *oric@emory.edu* *for any research using a Schedule 1 controlled substance. ORIC will perform a compliance review to ensure that processes are in place to meet state and federal requirements.*

Researcher Name:

Protocol Title:

IRB or IACUC number if applicable:

1. **Provide the following information**

**Controlled Substance drug name** Click or tap here to enter text.

**Researcher who will hold GBP researcher pemit & DEA license:**  Click or tap here to enter text.

**Site where drug will be stored:** Click or tap here to enter text.

**Site where drug will be dispensed:** Click or tap here to enter text.

 **Research Type: Animal \_\_\_ Bench \_\_\_ Human \_\_\_\_**

1. **Registering with state agency:** Apply to GBP for a State of Georgia Research Permit

Researchers must first apply to the GBP as a “Pharmacy Facility”. The GBP researcher application process, which on average takes 6 weeks, requires submission of the research protocol and proof of U.S. citizenship or qualified alien status. Registration information can be found here: [Registration Process | Emory University | Atlanta GA](https://rcra.emory.edu/oric/controlled-substances/registration.html)

The application for a Georgia researcher’s permit can be found [online](https://gbp.georgia.gov/sites/gbp.georgia.gov/files/related_files/document/Pharmacy%20Facility%20Application%20Updated%2011-16-2017.pdf).

**Date submitted to GBP** Click or tap here to enter text.

**When received, provide a copy of the Researcher permit to the Office of Research Integrity and Compliance at** oric@emory.edu.

1. **Registering with federal agency:** Apply to DEA for DEA Researcher Registration

After obtaining the GBP permit, researchers must submit a DEA application. The DEA application process, which usually takes another 2-3 months, requires submission of a DEA Form 225 (Researcher) application electronically. **For Class-I the entire protocol must be submitted with the application.** DEA registration information and application forms can be found on [DEA’s website](https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm). Institutional approval along with approval from any Emory University committee (e.g., radiation safety, biosafety) must be obtained before the registration application is submitted to the DEA. Institutional approval will be provided by the IRB for human subject research, the IACUC for animal research, and ORIC for bench researc. All registrations are location specific, i.e. a researcher must obtain a separate registration for each site at which research using the controlled substance is performed. Controlled Substances may only be shipped to the specific location listed on a registration for use by the Registrant according to the permitted use.

**Date submitted to DEA** Click or tap here to enter text.

**When received, provide a copy of DEA Registration Certificate to the Office of Research Integrity and Compliance at** oric@emory.edu

1. **Procurement:** Describe process for obtaining drug or cite protocol reference

**Specify**: Click or tap here to enter text.

1. **Physical Security**: C-1 drugs must be in a locked room limited to research personnel and kept in a securely locked and substantially constructed cabinet or safe. The cabinet/safe must be securely fastened to the floor or wall to avoid being readily removed or weighing more than 750 pounds. The cabinet/safe must have a key or combination lock and be constructed so that forced entry is easily detected. The cabinet/safe must be located where the drug will be dispensed to subjects and may be ordered through Emory Procurement or provided by sponsor. Researchers must maintain an Access Log listing all persons with access to the room or area housing-controlled substances.

**I acknowledge that I am responsible for securely storing Controlled Substances and maintaining documentation of those with access to the area where the CS are stored**:Click or tap here to enter initials

**Specify source of cabinet or safe, description & location:** Click or tap here to enter text.

1. **Personnel Security: Researchers are required to undergo a criminal background check and complete and sign the Emory University Employee and Agent Screening Statement prior to working with Controlled Substances.**

**I acknowledge that I am responsible to ensure completion of a criminal background check**

**For each person working with CS:** Click or tap here to enter initials

**Date Criminal background checked completed for each person:** Click or tap here to enter text.

 **Date Emory University Employee and Agent Screening Statement signed by each person:**

 **:** Click or tap here to enter text.

1. **Records and inventory: Researchers** must keep accurate records on the shipment, delivery, receipt and disposition of Controlled Substances. This includes an initial and biennial Inventory Form, an Order/Receipt log, and Current Use & Disposition log. Records for Schedule I and II Controlled Substances must be kept separately.

**I acknowledge that I am responsible to conduct:**

**An Initial Inventory (balance will always be zero)** Click or tap here to enter initials

**A Biennial Inventory:** Click or tap here to enter initials

1. **Disposal Plan:** Researchers are required to ensure 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. This may require establishing an account with an approved Reverse Distributor vendor, e.g. The Rx Exchange (<http://therxe.com/>)

**I acknowledge that I am responsible for ensuring that all Controlled Substances are properly disposed using an approved reverse distributor:** Click or tap here to enter initials

**Specify disposal plan**: Click or tap here to enter text.

1. **Renewal:** The renewal periods for the GBP and the DEA permits do not synchronize. The GBP Researcher permit will always expire on June 30 of the even numbered years. The DEA registration must be renewed every year, with the renewal date a year from the original issue month. DEA usually will send a reminder about 45 days before expiration; the GBP will never send a reminder.

**I acknowledge that I am responsible to renew my GBP Researcher Permit June 30 of even numbered years:** Click or tap here to enter initials

**I acknowledge that I am responsible to renew my DEA license every year prior to the expiration date listed:** Click or tap here to enter initials

**GBP Researcher permit expiration date:** Click or tap here to enter text.

**DEA registration expiration date:­­­** Click or tap here to enter text.

**When received, provide copies of renewals to the Office of Research Integrity and Compliance.**

1. **I acknowledge that I am responsible to complete online training and ensure that all those authorized to assist in conducting research with the CS 1 have also completed online training** [Training | Emory University | Atlanta GA](https://rcra.emory.edu/oric/controlled-substances/training.html)**:** Click or tap here to enter initials

**Date online training completed for each person:** Click or tap here to enter text.