DEA Schedule I Researcher Pre-application Checklist

This information is based on the DEA website requirements to obtain a license to use a Controlled Substance Schedule I drug for research purposes. This information is for a researcher, not a drug manufacturer, so please be aware that if your application involves manufacturing activities not permitted under a researcher registration, your application may be denied. Some examples of manufacturing activities include the following:

* Activities to satisfy regulatory requirements such as FDA submissions or good manufacturing practice
* Activities related to production of material used for pilot, scale-up, and reformulation studies
* Activities related to product development including bioavailability, dosage formulation, stability, and validation studies

**Please, be aware of the following before starting this process:**

* Registering as a researcher requires a non-refundable fee of $296. There is no prorated application fee, and the subsequent withdrawal of an application does not qualify for a return of the application fee.
* The applying researcher must be the only individual completing and certifying by E-signature that the information provided is accurate for the purposes of this DEA application. There is an exception if the applying researcher files a power of attorney with DEA ([Title 21 CFR § 1301.13(j)](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR0f5a129834f0129/section-1301.13)).
* You must currently possess a Georgia State Research License to handle controlled substances. See more information at <https://rcra.emory.edu/oric/controlled-substances/registration.html>. A lack of state authorization does not entitle you to a return of the application fee.
* You must currently possess the appropriate institutional authority to conduct research with Schedule I controlled substances (see below for more information).

You must separately identify each of the studies/projects, by project name, that are covered by this application. If your research involves one or multiple studies/projects, you will need to provide information specific for each of these studies/projects.

* If you are conducting research with human subjects, you must submit the IRB approval letter for your study.
	+ If the research is a clinical investigation, you must submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as proscribed in [paragraph (a)(2)(vi)](https://www.ecfr.gov/current/title-21/section-1301.18#p-1301.18(a)(2)(vi))), and have such submission approved by the Food and Drug Administration as required in [21 U.S.C. 355(i)](https://www.govinfo.gov/link/uscode/21/355) and [§ 130.3 of this title](https://www.ecfr.gov/current/title-21/section-130.3). Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in [paragraph (a)](https://www.ecfr.gov/current/title-21/section-1301.18#p-1301.18(a)) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on \_\_\_\_\_\_\_\_\_\_ (Date), pursuant to [21 U.S.C. 355(i)](https://www.govinfo.gov/link/uscode/21/355) and [21 CFR 130.3](https://www.ecfr.gov/current/title-21/section-130.3), I, \_\_\_\_\_\_\_\_\_\_ (Name and Address of IND Sponsor) submitted a Notice of Claimed Investigational Exemption for a New Drug (IND) to the Food and Drug Administration for:

(Name of Investigational Drug).

(Date)

(Signature of Applicant).

* If you are conducting animal research, you must submit the Emory IACUC approval letter for your study.
* If you are conducting research that does not involve animals or human subjects, contact ORIC at oric@emory.edu for institutional approval.
* You must have a protocol, see [Title 21 CFR § 1301.18](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR0f5a129834f0129/section-1301.18) and [21 CFR § 1301.32](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR3b1489fb21ea6df/section-1301.32) for the protocol requirements

## **Checklist**

[ ]  Curriculum Vitae for each investigator(s) working on each of the studies/projects as part of the application process.

[ ]  If obtaining the Schedule I controlled substances mentioned in the research protocol from external sources, you must provide the DEA registration number(s) of the source(s) and validate their name and address.

[ ]  Protocol created that includes the above information plus:

[ ]  Name, address, DEA registration number (if any); institutional affiliation and qualifications (detailed in the CV with bibliography)

[ ]  Title of project.

[ ]  Statement of the purpose.

[ ]  Name of the controlled substances or substances involved and the amount of each needed.

[ ]  Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

[ ]  Location where the research will be conducted.

[ ]  Statement of the security provisions for storing the controlled substances (in accordance with [§ 1301.75](https://www.ecfr.gov/current/title-21/section-1301.75)) and for dispensing the controlled substances in order to prevent diversion.

[ ]  If the investigator desires to manufacture or import any controlled substance, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.