Emory Sponsor Name: IND status:

Principal Investigator Name: IRB #:

Study Title:

*Please submit completed checklist to Margaret Huber at* [*mhuber@emory.edu*](mailto:mhuber@emory.edu) *in the Office of Research Integrity and Compliance for review of any research study where an IND will be held by an Emory Investigator*.

1. Are there written SOPs in place to ensure that the trial is conducted and data are generated, documented, and reported in compliance with the IRB approved protocol?

No Yes

* ***Note: Best Practice is to implement written SOPs for the conduct of a clinical trial.*** See[Sample CT SOPs](https://rcra.emory.edu/_includes/documents/sections/oric/gcpguidesamplesops.docx) which should be customized.

1. Will the Sponsor-Investigator delegate any or all of sponsor’s trial-related duties and functions to a Contract Research Organization (CRO)?

No Yes *If “Yes”, please provide a copy of the FDA required delegation agreement with this submission. If the delegation includes the responsibility to monitor the trial, please include a copy of the monitoring plan.*

1. Is this a multi-site trial?

No Yes: if “Yes”, list sites \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

complete [S-I IND Responsibilities Checklist Multi-site Trials](https://rcra.emory.edu/_includes/documents/sections/oric/s-i_ind_responsibilities_form_multi-site_trials.docx)

1. Specify the criteria (e.g. licensure, subject matter expertise, & other qualifications) the Sponsor-Investigator will use to select qualified investigators at any/all sites, including Emory, for which the Sponsor-Investigator will have oversight responsibilities.

1. Provide name(s) and contact information for the appropriately qualified medical personnel who will be readily available to assess adverse events and advise on trial-related medical questions or problems.

1. Provide the reference (protocol citation or separate document attachment) for the Data Safety Monitoring Plan (DSMP). The DSMP must include a plan for site monitoring to ensure that the investigation is conducted according to the investigational plan & protocol?

1. Provide the name of the individual (or CRO) who will perform site monitoring to review data quality & ensure that the investigation is conducted according to the investigational plan.

***Note: Sponsor-Investigators are required to ensure proper monitoring; per FDA inspection experience, onsite monitoring is highly recommended at least once per year***

1. Describe plans or attach written SOPs that outline how each participating Investigator will be informed of new observations regarding the study drug, e.g. adverse events.

***Note: Important safety information is required to be relayed to investigators in accordance with 21 CFR §312.32.***

1. As a Sponsor-Investigator, I understand that it is my responsibility to assure the following in accordance with 21CFR§312.53:
   1. Control of drug – ensure investigational drugs are only shipped to investigators participating in the trial; (312.53)
   2. Ensure labeling of immediate packaging of investigational drug includes: “Caution: New Drug—Limited by Federal law to investigational use.” (312.6)
   3. Obtain and maintain the following critical information from each Investigator:
      1. A signed 1572;
      2. Name and address of Investigator;
      3. Name and address of any facility where clinical investigation will be conducted;
      4. Name and address of any clinical laboratory facilities to be used;
      5. Name and address of the IRB that is responsible for review and approval;
      6. Commitments/agreements in writing with each investigator to outline specific criteria outlined in 21CFR§312.53(c)(1)(vi)(a-g) and 21CFR§56.
   4. Maintain a file for each Investigator, including a curriculum vitae, current license information and training record (312.53)
   5. Obtain and maintain on file financial disclosures from each Investigator. (312.53)
   6. Register applicable clinical trials with clinicaltrials.gov <http://prsinfo.clinicaltrials.gov/> (42 U.S.C. § 282(j))

I understand \_\_\_\_**initials**

1. As a Sponsor-Investigator, I understand that I am responsible for ensuring proper monitoring of the investigation(s) in accordance with 21CFR§312.50. I understand that I must either bring into compliance or terminate participation in the trial for any participating investigator who is not complying with the signed 1572 agreement, federal regulations, and other applicable laws, policies, and guidance. Termination includes stopping shipment of the investigational drug and verifying proper disposal or return of the non-complying investigator’s current supply in accordance with the requirements in 21CFR§312.59.

I understand \_\_\_\_**initials**

1. As the Sponsor-Investigator, I understand that I am responsible for reviewing and evaluating the evidence relating to the safety and effectiveness of the drug *as it is obtained*, and for providing reports to the FDA and all participating investigators regarding information relevant to the safety of the drug as required under 21CFR§312.32.

I understand \_\_\_\_**initials**

1. As the Sponsor-Investigator, I understand that I am responsible for ensuring that required annual reports as outlined in 21CFR§312.33 be submitted to the FDA within 60 days of the anniversary date that the IND went into effect. See [IND Annual Report Template](https://rcra.emory.edu/_includes/documents/sections/oric/ind_annual_report_template.docx)

I understand \_\_\_\_**initials**

1. As the Sponsor-Investigator, I understand that I am responsible for assuring recordkeeping and record retention in accordance with 21CFR§312.57, which responsibilities include the following:
   1. Maintaining adequate records for receipt, disposition, etc. of the investigational drug;
   2. Maintaining complete and accurate records regarding financial interests; See [financial disclosure certification form.](https://rcra.emory.edu/_includes/documents/sections/oric/fda_financial_disclosure_certification.docx)
   3. Retaining records and reports for 2 years after a marketing application is approved for the drug; or if an application is not approved for the drug , until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified;
   4. Maintaining any samples or data associated with bioequivalence or bioavailability studies described in 21CFR§320.38 and §320.63.

I understand \_\_\_\_**initials**

1. As the Sponsor-Investigator I understand that any properly authorized officer or employee of the FDA has a right of access to, and may copy and verify any records and reports relating to this clinical investigation and can request the submission of records or reports (or copies) to the appropriate parties at the FDA.

I understand \_\_\_\_**initials**

**The sponsor-investigator is responsible for compliance with applicable regulations, which may include:**

* + - 21 CFR 11 (Electronic records and electronic signature)
    - 21 CFR 54 (Financial Disclosure by Clinical Investigators)
    - 21 CFR 210 (Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding of Drugs; General)
    - 21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)
    - 21 CFR 312 (Investigational New Drug Application)
    - 21 CFR 314 (Drugs for Human Use)
    - 21 CFR 320 (Bioavailability and Bioequivalence Requirements)
    - 21 CFR 330 (Over-The-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded)
    - 21 CFR 601 (Biologics Licensing)

Emory Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_

Name Signature Date

The Office of Research Integrity and Compliance (ORIC) is committed to providing education and consultation regarding regulatory requirements, compliance obligations, and best practices with particular support for Sponsor-Investigators. This form and other tools to assist Sponsor-Investigators can be found [here](http://www.or.emory.edu/research-compliance/FDA-regulated-studies/drug-studies.html).