Emory Sponsor Name: IND #:

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 continuing review of any research study where an IND is held by an Emory Investigator. This form and other tools to assist Emory Sponsors and/or Emory Sponsor-Investigators can be found* [here](http://www.or.emory.edu/research-compliance/FDA-regulated-studies/drug-studies.html)*.*

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? ***Note: Best Practice is to implement written SOPs for the conduct of a clinical trial.*** See[Sample CT SOPs](http://www.or.emory.edu/research-compliance/oric/documents1/GCPGuideSampleSOPs.docx) which should be customized.

No Yes

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

No Yes *If “Yes”, provide a copy of the FDA required delegation agreement if not previously submitted. If the delegation includes the responsibility to monitor the trial, please include a copy of the monitoring plan.*

1. Is a [Financial Disclosure certification Form](http://www.or.emory.edu/research-compliance/oric/documents1/fda_financial_disclosure_certification.docx) (FDF) on file for each individual listed on Form 1572?

*Sponsor must obtain FDF from each individual prior to allowing participation in trial.*

No Yes

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

1. Who is performing site monitoring to review data quality & ensure that the investigation is conducted according to the investigational plan (may include self-monitoring, independent monitor and/or CRO)?

Provide monitoring type & schedule: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Provide dates of completed site monitoring: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Were site monitoring reports submitted to CTAC (ctcompliance@emory.edu)?  No Yes

1. Who reviews the data for safety (e.g., investigator, DSMB, Medical Monitor)?

If DSMB, provide date of last review: ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Provide date most recent IND Annual report was submitted to FDA: \_\_\_\_\_\_\_\_\_\_\_\_\_.

Was most recent IND Annual report submitted to the IRB at Continuing Review?  No Yes

If registration with clinicaltrials.gov is required, provide date of last update: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Provide the protocol reference(s), written SOPs or a description of how each participating Investigator is 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. Is this a multi-site trial?

No Yes: if “Yes”, complete multi-site information on next page

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

Name Signature Date

**Multi-site trials**

Complete this page for each site:

Site­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Co-investigator[[1]](#footnote-1)\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Responsible IRB\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Currently enrolling  No Yes

Site initiation date \_\_\_\_\_\_\_\_\_\_\_ Current number enrolled at this site \_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How is drug supplied to this site (i.e., directly from manufacturer, Emory IDS)?

1. What is agreed disposition of unused drug (e.g., agreement regarding collection of unused drug for return to Emory Sponsor or destruction and related record-keeping)?

1. Has the co-investigator at the additional site provided the Emory Sponsor with a signed Form FDA 1572?

No Yes

1. Has the co-investigator provided the Emory Sponsor with [Financial Disclosure certification Form](http://www.or.emory.edu/research-compliance/oric/documents1/fda_financial_disclosure_certification.docx) (FDF)and current CV and licensing information, and is he/she maintaining copies of such information at the co-investigator’s site?

No Yes

1. Was this co-investigator listed in initial IND submission?  No Yes

If no, has an IND amendment been submitted to FDA to add this investigator?  No Yes

1. How is information (e.g., enrollment, protocol changes, information updates) communicated between Emory Sponsor and the co-investigator at the additional site?

1. How are adverse events communicated to Emory Sponsor?

1. What process does the Emory Sponsor follow for evaluating adverse events and notifying co-investigators, IRBs and the FDA of safety reports?

1. Who reviews the site’s IRB correspondence and status of site’s IRB approval?
2. Who reviews proposed changes to protocol and/or consent forms for accuracy and sponsor requirements?

1. Who conducts data quality and protocol compliance monitoring at this site?

Provide monitoring schedule and dates & type of completed site monitoring (e.g. on-site, remote data review):

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***Note: per FDA inspection experience, onsite monitoring is highly recommended at least once per year.***

1. The FDA considers a “co-investigator” to be the equivalent of an investigator and to have all of the responsibilities of an investigator. Although FDA regulations do not use the term “principal investigator,” individuals who are “investigators” or “co-investigators” have the responsibilities of a principal investigator. [↑](#footnote-ref-1)