Emory Sponsor Name: IRB #: IND #:

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 any multi-site research study where an IND is held by an Emory Investigator. 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)

Complete this page for each site:

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

Responsible IRB\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Current IRB status \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Site initiation date \_\_\_\_\_\_\_\_\_\_\_

1. How is drug supplied to site (e.g., 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 local destruction) and related record-keeping?

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

Has the co-investigator provided the Emory Sponsor with FDA required financial disclosure information and current CV and licensing information, and is he/she maintaining copies of such information at the co-investigator’s site?

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

If no, has an IND amendment been submitted to FDA to add a new investigator?

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

1. How are adverse events communicated to Emory Sponsor?
2. 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 data for safety (e.g., investigator, DSMB, Medical Monitor) and how often is it reviewed?

1. Who reviews proposed changes to protocol and/or consent forms for accuracy and sponsor requirements?

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

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

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

Name Signature Date

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)