Emory Sponsor Name: IRB #: IDE #:

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 IDE 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/device-studies.html)

Complete this page for each site:

Site­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Co-investigator[[1]](#footnote-2)\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

1. How is the study device supplied to the site and who is responsible for labeling and record keeping?

1. What is agreed disposition of used/unused devices and who is responsible for related record-keeping?

1. Has the co-investigator at the additional site provided the Emory sponsor with a signed Investigator Agreement?

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 site listed in initial IDE submission?  No Yes

If no, has an IDE supplement been submitted to FDA to add a new site?

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

1. What process does the Emory Sponsor follow for evaluating adverse effects 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 monitoring at this site?

***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-2)