Emory Sponsor Name: IRB #: IDE status/risk:

Principal Investigator Name:

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 a significant risk IDE 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 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”, number of sites\_\_\_\_, number of subjects\_\_\_\_\_ approved by FDA.

Complete [S-I IDE Responsibilities Checklist Multi-Site Trials](https://rcra.emory.edu/_includes/documents/sections/oric/s-i_ide_multi_site_trials_form.docx)

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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 effects 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 ensure data quality and that the investigation is conducted according to the investigational plan. Include this information along with written procedures for monitoring the investigation contained in 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 device?

***Note: Important safety information is required to be relayed to investigators in accordance with 21 CFR §812.46(b).***

1. As a Sponsor-Investigator, I understand that it is my responsibility to assure the following in accordance with 21CFR§812.40:
   1. Control of device – ensure investigational device is only shipped to investigators participating in the trial; (812.43)
   2. Ensure labeling of investigational device or immediate packaging includes: “Caution—Investigational Device. Limited by Federal law to investigational use.” (812.5)
   3. Obtain and maintain the following critical information from each Investigator:
      1. A signed investigator agreement
      2. Name and address of Investigator
      3. Curriculum vitae for each Investigator
      4. Financial disclosures from each Investigator
      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§812.43(c)(4)(i-iii) and 21CFR§56
   4. Select monitors qualified by training & experience to monitor the investigational study
   5. 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§812.40. As a Sponsor-Investigator, 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 investigator agreement, federal regulations, and other applicable laws, policies, and guidance. Termination includes stopping shipment of the investigational device and verifying proper disposal or return of the non-complying investigator’s current supply in accordance with the requirements in 21CFR§812.46.

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 device *as it is obtained*, and for providing reports to the FDA regarding information relevant to the safety of the device as required under 21CFR§812.46(b).

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

1. As the Sponsor-Investigator, I understand that I am responsible for ensuring that required current investigator list and progress reports as outlined in 21CFR§812.150(b) be submitted to the FDA for significant risk devices. Current investigator list is required to be submitted at 6 month intervals and progress reports are required at regular intervals and at least yearly

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

1. As the Sponsor-Investigator, I understand that I am responsible for assuring recordkeeping and record retention in accordance with 21CFR§812.140, which responsibilities include the following:
   1. Maintaining adequate records for receipt, use or disposition of the investigational device;
   2. Maintaining complete and accurate records regarding financial interests; [Financial disclosure certification form.](https://rcra.emory.edu/_includes/documents/sections/oric/fda_financial_disclosure_certification.docx" \t "_blank)
   3. Retaining records and reports for 2 years after the latter of: the date the investigation is completed or terminated, or the date the records are no longer required in support of a premarket approval application or a notice of completion of product development protocol;

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§56 (Institutional Review Boards)
    - 21 CFR§801 (Labeling)
    - 21 CFR§812 (Investigational Device Exemptions)
    - 21 CFR§820 (Quality System Regulation)

Sponsor-Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_

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).