



## **ICECAP Investigator Agreement Form - pursuant to 21 CFR 812.43(c)**

Submission of this form to the sponsor from a participating investigator represents the participating investigator's assurance of the following:

1. That the investigator's curriculum vitae has been provided by uploading to WebDCU, and that the version provided is accurate and current.
2. That the investigator's relevant experience to serving as an investigator in this trial is accurately described in the provided curriculum vitae and/or is reported in "Investigator Experience and Qualifications" form in WebDCU.
3. That if the investigator was involved in an investigation or other research that was terminated, that an explanation of the circumstances that led to termination of a study have been submitted in WebDCU.
4. That the investigator commits to:
  - a. conducting the investigation in accordance with the agreement, the investigational plan, the IDE and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA,
  - b. supervising all testing of the device involving human subjects. And
  - c. ensuring that the requirements for obtaining informed consent are met.
5. That the investigator has provided the sponsor sufficient accurate financial disclosure information to allow the sponsor to submit a complete and accurate certification or disclosure statement as required under 21 CFR 54, Financial Disclosure by Clinical Investigators. The investigator confirms that the presence or absence of these financial conflicts of interest have been reported to the sponsor in WebDCU on 'Initial Site Submission Review' Form, and commits to promptly updating any conflicts of interest in WebDCU as directed during the study and through one year after completion of the study.

Investigator Signature:

Investigator Name:

Date: