***Please use UA letterhead issued by your own department.***

**IDE INVESTIGATOR AGREEMENT**

**FOR THE CLINICAL INVESTIGATION OF THE**

*(Specify Investigational Device)*

IDE #: *[insert IDE #]*

Sponsor: *[insert Sponsor name]*

Protocol title: *[insert protocol title]*

Investigator Name: *[insert name of investigator]*

Location(s) of study activities: *[insert each address]*

I agree and/or certify that:

1. I have the appropriate, relevant qualifications to conduct and oversee the conduct of the clinical investigation, as documented by the following:
2. The most recent curriculum vitae (CV) is attached to this Agreement.
3. The CV includes information about my relevant experience, including dates, locations, extent, and type of experience. *If the CV does not reflect my relevant qualifications,* a summary of my relevant experience is attached.
4. I have not participated in an investigation or had other research activity that was terminated by the FDA, the reviewing IRB or sponsor due to a non-compliance issue. *If applicable,* an explanation of the circumstances that led to the investigation or termination is attached.
5. As an investigator, I will commit to:
6. Conduct the clinical investigation in accordance with this agreement, all requirements of the investigational plan, IDE regulations, other applicable regulations of the FDA, and conditions of approval by the reviewing IRB,
7. Supervise all testing of the device involving human subjects, and
8. Ensure that the requirements for obtaining informed consent are met.
9. I will disclose sufficient and accurate financial information to the sponsor (sponsor-investigator) by completing the Certification of Financial Interest form (attached) and if applicable, the Disclosure of Financial Interest form (attached). I will also notify the sponsor (sponsor-investigator) if my disclosed financial information changes at any time during the clinical investigation or up to one year following the closure of the study.

**PRINCIPAL INVESTIGATOR**

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Name of Principal Investigator (please print or type)

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Office (Mailing Address)

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City/State/Zip E-mail

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Telephone Fax

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Signature of Principal Investigator Date

**PHYSICIAN CO-INVESTIGATORS** (i.e., physicians participating as co- or sub-investigators on this clinical investigation under supervision of the Principal Investigator): A **current CV** or statement of relevant experience and a completed **Certification of Financial Interest** form and, if applicable, **Financial Interest Disclosure** form **is required** to be submitted to the sponsor (sponsor-investigator) **for each physician co-investigator listed below.**

As a physician co-investigator for this investigation, I have read the foregoing and agree to be bound by its terms.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Physician Co-Investigator (please print or type)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**NON-PHYSICIAN CO-INVESTIGATORS** (i.e., non-physicians participating as co- or sub-investigators on this clinical investigation under supervision of the Principal Investigator): A **current CV** or statement of relevant experience and a completed **Certification of Financial Interest** form and, if applicable, a **Financial Interest Disclosure** form is required to be submitted to the sponsor (sponsor-investigator) for **each non-physician co-investigator** listed below.

As a non-physician co-investigator for this investigation, I have read the foregoing and agree to be bound by its applicable terms.

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Name of Co-Investigator (please print or type)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature Date