INVESTIGATOR AGREEMENT FOR THE CLINICAL INVESTIGATION OF

THE (\_\_\_\_\_\_\_)

 I, (\_\_\_\_\_\_\_), agree to participate as the IDE Sponsor and Principal- Investigator in the clinical investigation: (\_\_\_\_\_\_\_).

All investigators have signed this agreement and no additional investigator will be added until the agreement is signed.

I agree and/or certify that:

1. I will conduct the clinical investigation in accordance with this agreement, all requirements of the investigational plan, IDE regulations, other applicable regulations of the FDA, and any conditions of approval imposed by my reviewing Institutional Review Board (IRB) or FDA. I agree to abide by all of the responsibilities of Investigators addressed under 21 CFR Part 812, Subpart E and Subpart G, including but not limited to the following:

a. I will obtain written approval from the authorized IRB for the institution at which this investigation will be conducted. If I am not also the sponsor-investigator of the corresponding IDE application, I will submit the certification of IRB approval and any conditions of this approval to the sponsor (sponsor-investigator).

b. I will ensure that Informed Consent is obtained from each subject participating in this clinical investigation in accordance with the informed consent regulation found in 21 CFR Part 50, and that a signed copy of the informed consent is available to the sponsor (sponsor- investigator) and the sponsor’s (sponsor-investigator’s) designated monitor.

c. I will supervise all testing of the (specify investigational device) on human subjects and will allow only those physician sub-investigators listed on the last page of this agreement to administer this devices and/or perform follow-up medical evaluations on the device.

d. I will be responsible for accountability of the (specify investigational device) at the study site and, if I am not also the sponsor-investigator of the corresponding IDE application, I will return all unused (specify investigational device) to the sponsor (sponsor-investigator) or otherwise follow the instructions of the sponsor (sponsor-investigator) for disposal of the unused devices.

e. I will ensure the accurate completion of protocol case report forms and, if I am not also the sponsor-investigator of the corresponding IDE application, I will submit completed protocol case report forms, progress reports, and a final report to the sponsor (sponsor-investigator) at the time frames specified in the Protocol and/or FDA regulations.

f. I will direct the retention of required records and documents related to the investigation.

2. I have the appropriate, relevant qualifications to conduct and to oversee the conduct of the clinical investigation as documented by the following:

\_\_\_\_\_My relevant qualifications, including dates, location, extent, and type of experience, are listed in my most recent curriculum vitae (CV), which is attached to this Agreement and which will be maintained by the sponsor (sponsor-investigator) of the corresponding IDE application.

3. There are no reasons to question my ability to oversee the appropriate conduct of this clinical investigation. (Check applicable statement.)

\_\_\_\_\_\_ I have never participated in an investigation or other research activity which was terminated (disqualified) by FDA, the IRB (or equivalent), or sponsor of a study due to a non- compliance issue.

4. I further certify that I have not been debarred under the Generic Drug Enforcement Act of 1992, 21 USC §§ 335a and 335b. In the event that I become debarred or receive notice of an action or threat of an action with respect to my debarment during the term of this Agreement, I agree to immediately notify the sponsor (sponsor-investigator) and the authorized IRB for my study site. If I am the sponsor-investigator of the corresponding IDE application I will notify the authorized IRB for my study site and the FDA.

5. As required by 21 CFR Part 54, I will obtain sufficient accurate financial disclosure information from all investigators that participate in this clinical investigation in order to submit a complete and accurate certification or disclosure statement.

PRINCIPAL INVESTIGATOR

(\_\_\_\_\_\_\_) Name of Principal Investigator (please print or type)

(\_\_\_\_\_\_\_) (Mailing Address) City/State/Zip E-mail FAX

Signature of Principal Investigator Date

Sub-INVESTIGATORS: (i.e., research fellows, residents, associate) who will be assisting the investigator in the conduct of the investigations.)

Name of the Sub -Investigator (please print or type)

Signature of Sub- Investigator Date