GEORGIA INSTITUTE OF TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

INVESTIGATOR AGREEMENT

**FOR A CLINICAL INVESTIGATION OF THE**

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

*(Specify Investigational Device)*

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*(Protocol Number and Study Title)*

Relevant Definitions:

* **Clinical investigation** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.
* **Investigation** is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device.
* **Investigator** is an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed to, or used involving a subject. In the event of an investigation being conducted by a team of individuals, "investigator" refers to the responsible leader of that team.
* **Sponsor-investigator** is an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed, or used. The term does not, for example, include a corporation or agency. The obligations of a sponsor-investigator include those of an investigator *and* those of a sponsor.
* **Subject** is a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or who participates as a control. A subject may be in normal health or may have a medical condition or disease.

I AGREE AND/OR CERTIFY THAT:

1. I agree to participate as the Principal Investigator in *a clinical investigation of the* *investigational device specified above.* I have been provided links to the following Food and Drug Administration (FDA) regulations: [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1), Investigational Device Exemptions; [21 CFR Part 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1), Protection of Human Subjects; and [21 CFR Part 54](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=54&showFR=1), Financial Disclosure by Clinical Investigators.
2. I will conduct the clinical investigation in accordance with this agreement; with all requirements of the investigational plan (protocol), Investigational Device Exemption (IDE) regulations, other applicable regulations of the FDA; with adherence to the principles of good clinical practices; and any conditions of approval imposed by the Georgia Institute of Technology Institutional Review Board (IRB), by any other IRB or Ethics Committee that reviews and approves this study, or by the FDA. I agree to abide by all of the investigator responsibilities enumerated at [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1), Subpart E and Subpart G, including but not limited to the following:

a. I will obtain written approval from the Georgia Institute of Technology Institutional Review Board in advance of undertaking any activities with human subjects. 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).

c. I will supervise all testing of the *investigational device specified above* on human subjects and will allow only those individuals who are qualified by education, licensure, and/or the governance of the local medical board to perform these tests.

d. 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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1), and that a signed copy of the informed consent shall be available to the sponsor (sponsor-investigator) and the sponsor’s (sponsor-investigator’s) designated monitor.

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

f. 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.

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

3. I have the appropriate, relevant qualifications to conduct and to oversee the conduct of the investigation as documented by the following: (*Check applicable statement)*

\_\_\_\_ 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.

\_\_\_\_ My curriculum vitae (CV) does not reflect my relevant qualifications, therefore attached to this Agreement is a statement of my relevant experience (including dates, location(s), extent, and type of experience) which will be maintained by the sponsor (sponsor-investigator) of the corresponding IDE application.

4. 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.

\_\_\_\_ I have 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. The specific circumstances leading to this termination and my role in the respective problems or issues and the resolution of these problems or issues are summarized in an attachment to this Agreement.

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 Georgia Tech IRB. If I am the sponsor-investigator of the corresponding IDE application, I will also notify the FDA, should I become debarred or receive such notice.

5. Listed below are the names and addresses of all facilities where the study will be conducted, if other than my Georgia Institute of Technology laboratory:

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6. Listed below are the names and addresses of all clinical laboratories, if any, to be used in the study:

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7. Listed below are the names and addresses of all Institutional Review Boards or Ethics Committees, other than the Georgia Institute of Technology IRB, responsible for review of this study. *(If this is a multi-site clinical trial, I have listed only those IRBs or Committees that will review my proposed work).*

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8. As required by [21 CFR Part 54](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=54&showFR=1), Financial Disclosure by Clinical Investigators, I will disclose sufficient and accurate financial information to the sponsor (sponsor-investigator) and to the Georgia Tech Institutional Review Board by completing the Certification of Financial Interest form (attached). If applicable, I will also submit to the Georgia Tech IRB the determination letter and/or management plan from the Georgia Tech Research Corporation (GTRC) Office of Conflict of Interest Management. I will also notify the sponsor (sponsor-investigator) and the Georgia Tech IRB if my disclosed financial information changes at any time during the investigation or up to one year following the closure of the study.

PRINCIPAL INVESTIGATOR:

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

*Name of Principal Investigator (please print or type)*

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

Signature of Principal Investigator Date

CO-PRINCIPAL INVESTIGATORS AND INVESTIGATORS : A current CV or statement of relevant experience and a completed Certification of Financial Interest form and, if applicable, letter of determination and copy of your COI management plan is required to be submitted to the sponsor (sponsor-investigator) for each Co-Principal Investigator or Investigator listed below.

**As a Co-Principal Investigator or Investigator for this investigation, I have read the foregoing and agree to be bound by its terms.**

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

Name (please print or type)

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**Certification of Financial Interest of Investigators**

Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Investigational Drug/Device: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

As an investigator who will be participating in the above-specified clinical study being conducted under a University-based (i.e., investigator-sponsored) or University-sponsored IND or IDE application, I certify that *(check the appropriate box for each statement):*

[ ] I do [ ] I do not Have an ownership interest, stock options, or other financial interest (i.e., *equity interest*) in the company (public or non-public) that owns the investigational drug or device being evaluated in the clinical study.

[ ] I do [ ] do not Have property or other financial interest (i.e., *proprietary interest*) in the investigational drug or device being evaluated in this clinical study; including, but not limited to, a patent or patent interest, trademark, copyright, licensing agreement, or any arrangement tied to a current or future right to receive royalties associated with the development or eventual commercialization of the drug or device.

[ ] I will [ ] I will not Receive payments from the company (i.e., other than the University) that owns the respective investigational drug or device during the term of the conduct of the clinical study; nor do I anticipate receiving payments from the company during a 1 year period following completion of the study. Applicable payments (i.e., *financial interest*) include, but are not limited to, grants to fund projects or research or compensation in the form of monetary payments, equipment, or retainers for consultation or honoraria.

**If the response to any of the above statements is affirmative, submission of your approved Conflict of Interest Management Plan is required.**

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Name of Investigator (Printed or Typed)

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Signature of Investigator Date