IDE INVESTIGATOR AGREEMENT FOR THE CLINICAL INVESTIGATION OF

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

*[Specify Investigational Device]*

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agree to participate as the Principal Investigator in the clinical investigation of [*specify investigational device].*

I have been provided links to the following Food and Drug Administration (FDA) regulations listed below:

* **21 CFR Part 812** Investigational Device Exemptions - <https://ecfr.federalregister.gov/current/title-21/chapter-I/subchapter-H/part-812>
* **21 CFR Part 50** Protection of Human Subjects - <https://ecfr.federalregister.gov/current/title-21/chapter-I/subchapter-A/part-50>

* **21 CFR Part 54** Financial Disclosure by Clinical Investigators at - <https://ecfr.federalregister.gov/current/title-21/chapter-I/subchapter-A/part-54>

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 co-investigators listed on the last page of this agreement to administer this device 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:

(*Check the 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.

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.

\_\_\_\_ 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.

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, Financial Disclosure by Clinical Investigators, 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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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.

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

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Signature Date

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

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

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 Signature Date

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

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 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)

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Signature Date

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 Name of Co-Investigator (please print or type)

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Signature Date

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 Name of Co-Investigator (please print or type)

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 Signature Date

**Template Revision History**

Version1: July 13, 2014

Version2: October 27, 2017

Version3: February 9, 2021
Version4: April 14, 2025