**Principal Investigator Agreement for Investigational Device Study**

In accordance with Good Clinical Practice (GCP) and 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 (IDE), and [21 CFR Part 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1), Protection of Human Subjects, this document serves as an Investigator Agreement for:

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| **IRB Number:** |  |  |
| **Protocol Title:** |  |

By signing this form, I commit to the following:

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](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:
* I will ensure that informed consent is obtained from each subject participating in this clinical trial 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 is available to the sponsor/sponsor-investigator and the sponsor/sponsor-investigator’s designated monitor.
* I will supervise testing of the investigational device on human subjects and will only allow qualified investigators to administer the device(s) and/or perform follow-up medical evaluations on the device(s).
* I will be responsible for accountability of the investigational device(s) at the study site and, if I am not also the sponsor-investigator of the corresponding IDE, I will return all investigational device(s) to the sponsor/sponsor-investigator or follow the instructions of the sponsor/sponsor-investigator for disposal of the device(s).
* 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 (as applicable) to the sponsor/sponsor-investigator at the time frames specified in the protocol and/or FDA regulations.
* I will direct the retention of required records and documents related to the clinical trial.
* I agree to comply with all other requirements regarding the obligations of investigators and all other pertinent requirements in [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1).
1. I have the appropriate, relevant qualifications to conduct and to oversee the conduct of the clinical trial. I have provided my most recent curriculum vitae (CV), which details my relevant qualifications, including dates, location, extent, and type of experience.
2. I certify there are no reasons to question my ability to oversee the appropriate conduct of this clinical trial.
* I *have never* participated in a clinical trial 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;

 **- *OR -***

* I *have* participated in a clinical trial 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 provided documentation with further details describing the specific circumstances leading to this termination and my role in the respective problems or issues and the resolution of these problems or issues.
1. I certify that I have not been disqualified under 21 CFR Part 812, Subpart E. In the event I become disqualified or receive notice of an action or threat of an action with respect to my disqualification during the term of this Agreement, I agree to immediately notify the sponsor/sponsor-investigator and the reviewing IRB. If I am the sponsor-investigator of the corresponding IDE application, I will notify the Office of Research, reviewing IRB, and the FDA.
2. As required by [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1) and 21 CFR 54.4, I have disclosed complete and accurate financial information by completing an Outside Activities Report (OAR) in compliance with the Medical College of Wisconsin Conflict of Interest (COI) Policies and Procedures. I will update my disclosed financial information with changes at any time during the clinical trial following the completion of the study, per applicable regulations.
3. I agree to remain compliant with conditions of approval imposed by my reviewing Institutional Review Board (IRB) for conduct of this clinical trial as under 21 CFR Part 56 and 45 CFR Part 46.

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| **Printed Name:** |   |  |  |
| **Signature:** |  | **Date:** |  |