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| **Investigator Agreement** |
| **1. Name and Address of the Investigator** |
| **2. Relevant education, training, and experience that qualifies the investigator to participate in this study. One of the following is attached:**** Curriculum Vitae  Other Statement of Qualifications** |
| **3. Were you ever involved in any research or clinical studies that were terminated early?  Yes  No****If yes, please explain the circumstances that led to study termination** |
| **4. Name and Address of any medical school, hospital, or other research facility where the clinical investigation(s) will be conducted.** |
| **5. Name and Address of any clinical laboratories to be used in the study.**  |
| **6. Name and Address of the Institutional Review Board (IRB) that is responsible for review and approval of the study** |
| **7. Name (and number if applicable) of the protocol(s) in the IDE for the study(ies) to be conducted by the investigator.**  |

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| **Commitments:** By signing this Investigator Agreement, you commit to do the following: * Conduct the investigation in accordance with the agreement, the investigational plan, 21 CFR Part 812 and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB and FDA;
* Only supply investigational devices to persons authorized to receive them;
* Supervise all testing of the device involving human subjects;
* Ensure that the requirements found in 21 CFR Part 50 for obtaining informed consent are met;
* Ensure approval by FDA and the IRB before requesting informed consent;
* Complete and maintain the records as described in 21 CFR 812.140;
* Complete and submit reports as directed in 21 CFR 812.150 including unanticipated adverse device effects reports, withdrawal of IRB approval, progress and final reports, and deviations from the protocol or consenting processes;
* Return or otherwise dispose of remaining investigational devices upon study completion or termination as the sponsor directs, and,
* Provide sufficient and accurate financial disclosure information and update this information if any relevant changes occur during the investigation and for one year following the completion of the study.
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| **Signature of Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **mm/dd/yyyy** |