NIH NATIONAL CANCER INSTITUTE Center for Cancer Research	Office of Sponsor and Regulatory Oversight	Document #: F01-406-S02
	Investigator Agreement for Investigational Device Exemption	Revision #: 1
		Effective Date: 06MAY2020

INSTRUCTIONS

1. Complete all sections.
2. Provide a copy of your curriculum vitae or other statement of qualifications as described in Section 2.
3. Sign the form digitally.
4. Email the completed form and supporting document to OSROMonitoring@mail.NIH.gov by clicking on the Submit Form button at the bottom of page 4.

1. NAME AND ADDRESS OF INVESTIGATOR			
Name of Clinical Investigator			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DEVICE FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

Provide CV or Statement of Qualifications with form submission.
Provide statement of relevant experience, including dates, location, extent, and type of experience on page 2.

Box 2 Continuation Page

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED			Box 3 Continuation Space
Name of Medical School, Hospital, or Other Research Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY			Box 4 Continuation Space
Name of Clinical Laboratory Facility			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

Box 2. Statement of relevant experience, including dates, location, extent and type of experience.

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)			
Name of IRB			
Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IDE FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. WERE YOU INVOLVED IN ANY INVESTIGATION OR OTHER RESEARCH THAT WAS TERMINATED? ☐ YES ☐ NO
IF YES, EXPLAIN THE CIRCUMSTANCES THAT LED TO THE TERMINATION.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the device is being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s). I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the device.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 812.140 and to make those records available for inspection.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to 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. This information shall not be submitted in an investigational device exemption application, but shall submitted in any marketing application involving the device.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 812.

10. SIGNATURE OF INVESTIGATOR

Box 3 Continuation Space

Box 4 Continuation Space