To participate in a Division of Microbiology and Infectious Diseases (DMID) IDE study; an investigator must complete this agreement and submit it to the Clinical Research Operations and Management Support Contractor at Technical Resources International, Inc. (TRI) as part of a complete Protocol Registration Package including required Essential Documents.

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| Study name and protocol number:  **1.** |
| Name and address of Investigator of Record (IoR):  **2.** |
| Education, training, and experience that qualifies the investigator to conduct this study. Please indicate which of the following is attached.  **3.**  Curriculum Vitae  Other Statement of Qualifications |
| Name and address of all facilities where the study will be conducted:  **4.** |
| Name and address of any clinical laboratories to be used in the study (Mark *none* if no lab will be utilized for this study.):  None  **5.** |
| Name(s) and address(es) of the institutional review board(s) or ethics committee(s), and the names, and contact information for the IRB chairperson(s) responsible for review of this study:  **6.** |
| Name(s) of sub-investigators(s) who will assist the IoR in the conduct of this study (Mark *none* if no sub-investigators will be involved in this study.):       None  **7.** |
| Commitments:  **8.**  I agree to conduct the investigation in accordance with this agreement, the investigational plan, 21 CFR Part 812, the clinical protocol and other applicable FDA regulations, such as 21 CFR Parts 50 and 56, and conditions of approval imposed by the reviewing IRB or FDA.  I agree to supervise all testing of the device involving human subjects.  I will ensure that the requirements for obtaining informed consent are met. |
| Investigator of Record signature and date:  Date: |