# MATRIX INVESTIGATOR OF RECORD FORM

Any Investigator of Record participating in a Non-IND clinical trial supported and/or sponsored by USAID through MATRIX should complete this form and submit a copy to the MATRIX Clinical Trials Hub and, as needed, their respective IRBs/IECs.

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.**
   - [ ] Curriculum Vitae
   - [ ] Other Statement of Qualifications (e.g., biosketch)

3. **Name and address of Clinical Research Site(s) where the study will be conducted:**

4. **Name and address of any clinical laboratories to be used in the study (Specify none if no lab will be utilized for this study) [ ] None**

5. **Name(s) and address(es) of the institutional review board(s) (IRB), independent ethics committee(s) (IEC) or other regulatory entities responsible for review of this study:**
6. **Name(s) of sub-investigator(s) who will assist the IoR in the conduct of this study:**

7. **Protocol title and protocol designation:**

8. **Commitments:**

   I agree to conduct the study in accordance with the relevant, current protocol(s) and will not make changes in the protocol without permission of MATRIX and/or USAID, except when necessary to protect the safety, rights, or welfare of study participants.

   I agree to personally conduct or supervise this study.

   I will ensure that the requirements relating to obtaining informed consent and IRB or IEC review and approval are met per ICH/GCP and the applicable national regulatory authorities.

   I agree to report to MATRIX, USAID and/or their authorized representatives all adverse experiences that occur during the course of this study. I have read and understand the information in the investigator’s brochure, package insert, and/or product label, including the potential risks and side effects of the study product (if applicable).

   I agree to maintain adequate and accurate study records and to make those records available for inspection by MATRIX, USAID and/or their authorized representatives.

   I will ensure that an IRB or IEC that complies with the requirements of the applicable national regulatory authorities will complete initial and continuing review and approval of the study. I also agree to promptly report to the IRB/IEC all changes in the study and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the study without MATRIX and/or USAID and IRB/IEC approval, except where necessary to eliminate apparent immediate hazards to study participants.

   I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

9. **Signature of Investigator of Record**

10. **Date (mm/dd/yyyy)**