



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:

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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)