DAIDS INVESTIGATOR OF RECORD FORM

Any Investigator participating in a Non-IND, clinical trial supported and/or sponsored by DAIDS should complete this form and submit a copy to the DAIDS Protocol Registration Office (DAIDS PRO).

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
3. Name, address, and DAIDS site ID number of all 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), ethics committee(s) 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 ID number:

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 the DAIDS, 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 Ethics Committee (EC) review and approval (*insert relevant terms of assurance here, e.g. 45 CFR 46, ICH/GCP, etc.*) are met.

I agree to report to the sponsor adverse experiences that occur during the course of this study. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to maintain adequate and accurate study records and to make those records available for inspection by DAIDS and/or DAIDS' authorized representatives.

I will ensure that an IRB or EC that complies with the requirements of 45 CFR Part 46 will complete initial and continuing review and approval of the study. I also agree to promptly report to the IRB/EC 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 DAIDS and IRB/EC 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**