US City, State or Non-US City, Country:

Site(s) name/ DAIDS ES number:

CTU PI:

Name and location of CRS where study will take place:

CRS PI/Proposed Investigator of Record:

Person filling out this questionnaire:

1. **General Site Information (Research Experience/ Network Affiliation/ Recruitment/Retention/ Regulatory)**
2. Current or past Experience recruiting and retaining in related research trials. List detailed results for recruitment and retention including length of time for recruitment and time points for retention. How many participants can you recruit within X months?
3. List staffing available to work with HPTN XXX. Indicate the approximate amount of time they would be available for this research study.
4. Is there other research planned or ongoing that will compete with HPTN XXX for either study participants or research staff and space? What is the relative timing of those activities?
5. Timeline and detailed description of Regulatory Approval process. For US sites: How many Institutional Review Boards (IRBs) are required to approve research studies at your site? Based on your experience, what do you believe would be the approximate timeline for approval of this study through those committees? Summarize the relevant steps and time line (in days, weeks or months) for approval. For non-US sites: Outline the required approvals and estimated timeline for each (including MOH and EC, and any drug-related importation approvals), and include whether these are “staged” in chronological order or can be reviewed simultaneously. Be as specific as possible about the timeline for each required approval. In addition, indicate the frequency of each review step, e.g., how often do EC review meetings occur, etc.
6. **Risk/ Incidence/Prevalence**
7. HIV infection risk; proportion of HIV-infected population in the target community who may be HIV infected.
8. Evidence of high risk behaviors among population.
9. **Laboratory**
10. Where will blood be drawn and processed? Assuming the processing lab has the LDMS program, provide the affiliated LDMS number.
11. Is your site able to collect and process the laboratory samples outlined in the draft Schedule of Evaluations and Procedures, and where will specimen processing take place, and within what timeframe? Please be specific as related to items listed in the draft Schedule of Evaluations and Procedures.
12. Does the laboratory participate in DAIDS-sponsored EQA programs such as the IQA, PQA or VQA and/or other EQA programs? If so, indicate the lab used and the tests included in these programs at your site.
13. Do the facilities have experience running HIV rapid antibody tests on site? List the HIV tests (Ab or other) which you currently use.
14. Are any of the staff currently trained and IATA-certified to ship specimens? What are the requirements for exporting laboratory samples to the US? Is a MTA or STA required to ship samples to the US? Describe the process.
15. Do you have a sufficient number of freezers to store samples for enrollment, follow up and at least one year post follow up? What is your freezer space capacity in terms of new vials or -80oC storage?
16. It is possible that we will conduct a small sub-study in the US only to collect cervical, vaginal and rectal fluids and tissue biopsies. Please indicate your experience with this type of study.
17. **Data**
18. Please list your DataFax potential/IT infrastructure/Quality of Data Management (cite previous experience including queries per 100 CRF pages and days to fax in to SCHARP).
19. **Other**
20. Does the current political landscape allow for such a trial to be conducted?
21. Describe your pharmacy, pharmacists’ credentials, and control of supply including import and export if applicable.