

**SUBJECT: OLE Qualitative Sub-study Data Collection Services for CDC Botswana**

Dear Prospective Bidder:

The Embassy of the United States of America in Gaborone, Botswana has a requirement for a contractor to provide **OLE Qualitative Sub-study Data Collection Services for CDC Botswana**. The HIV Prevention Research (HPR) unit of the Centers for Disease Control and Prevention in Botswana is conducting the last phase of a clinical trial research study which will conclude in 2014. The Open Label Extension (OLE) of the TDF2 study is designed to provide active drug for prevention of HIV infection to former participants of the TDF2 randomized controlled trial and to gather data about adherence to the study drug outside of the clinical trial setting. Enrollment into OLE concluded in May 2013, and participants will be followed for up to 12 months.

Please submit all questions by phone or emailed to the below e-mail address. All responses should be submitted not later than November 28, 2013, 4:30pm. For more specification please refer to the attached documents.

Direct any questions regarding this request for quotations to the Embassy Contracting Office telephone #: **3953982** or email: **malabolat@state.gov** during regular business hours.

# Scope of Work for OLE Qualitative Sub-study Data Collection Services

## Background

The HIV Prevention Research (HPR) unit of the Centers for Disease Control and Prevention in Botswana is conducting the last phase of a clinical trial research study which will conclude in 2014. The Open Label Extension (OLE) of the TDF2 study is designed to provide active drug for prevention of HIV infection to former participants of the TDF2 randomized controlled trial and to gather data about adherence to the study drug outside of the clinical trial setting. Enrollment into OLE concluded in May 2013, and participants will be followed for up to 12 months. The study includes a brief exit interview for those who formally exit the study to explore the reasons for taking (or not taking) the study drug. HPR has identified the need for a qualitative sub-study to collect in-depth data regarding experiences in the OLE study, barriers and facilitators to adhering to Truvada and remaining in the study, and reasons for leaving the study.

## Purpose of this procurement

To procure data collection services from an organization that can provide expertise in conducting focus groups and in-depth interviews of research study subjects. Using government-provided data-collection instruments, the focus groups and interviews are needed to identify the motivating reasons for continuing in the study or leaving the study early, as well as the barriers and facilitators to study drug adherence.

**Tasks/Requirements** (Please see Appendix A for a more detailed description of the study protocol.)

- **Recruitment tasks to be conducted by CDC Botswana staff:**
  - Potential participants for each group will be contacted after exit from the study (or loss to follow-up) at their last known contact number. Recruitment will continue until all focus group sessions have filled. (to be conducted by CDC staff)
  - Voluntary informed consent will be documented for each participant for this qualitative sub-study. (to be conducted by contractor/interviewer)
  - Participants will be offered a small incentive of BWP 50 (~USD\$5.75) for participation in this qualitative sub-study, to be paid at the focus group or interview **by the contractor.**
  
- **Focus Group Interviews to be conducted by contractor:**
  - To investigate facilitators and barriers to (1) ongoing study participation and (2) daily pill-taking adherence. Focus group interviews will focus on two groups:
    - Group 1: Individuals who completed fewer than 10 monthly OLE visits (approx. 5 per group)
    - Group 2: Individuals who completed at least 10 monthly OLE visits (approx. 5 per group)
  - One FGI will be conducted at each site per group for males and another for females, for 8 FG interviews in all
  - **Focus group questions/instruments will be provided by CDC investigators after IRB approval.**

- In-depth Interviews
  - One to three participants from the focus groups (total of 12 interviews) will be recruited to participate in in-depth individual interviews to gain further detail on key themes identified during the FG sessions.
  - **Interview questions/instruments will be provided by CDC investigators after IRB approval**
  
- Transcription, Translation and Analysis
  - All FG and individual interviews will be recorded with audio recorders and transcribed into Setswana by individuals fluent in both English and Setswana, with verification by a second native speaker. **Recording equipment will be provided by CDC.**
  - Transcripts will then be translated into English for analysis, with verification of translational accuracy by back-translation by at least 2 individuals fluent in both English and Setswana. English translations will be analyzed using appropriate qualitative analysis software and methodology.
  - **Data analysis will be conducted by CDC staff.**

### **Period of Performance**

Initiation of these services is dependent on IRB/HRDC approvals. Work will begin immediately after approval of the study protocol is received, expected to be early February 2014. Work is expected to conclude by August 2014, per the estimated timeline below.

### **Projected Timeline**

- Sep-Dec 2013 Protocol approvals (CDC IRB, HRDC)
- Jan-Feb 2014 Identify contractor and award
- Mar-Apr 2014 Training and recruitment
- May-June 2014 Data collection (interviews and FG)
- July-Aug 2014 Transcription and translation
- Sep-Nov 2014 Data analysis

### **Schedule of Deliverables** to be submitted to Contracting Officer Representative

- Proposed work plan for entire project to be delivered 7 working days after award
- Monthly progress report to be delivered by the 5<sup>th</sup> working day of the following month.
- Monthly invoice to be delivered by the 10<sup>th</sup> working day of the following month.
- Final translations and other data to be delivered no later than August 22, 2014.

## **Appendix A: OLE Qualitative Substudy Protocol**

### *Background*

In the first 3 months of the OLE we observed a high loss to follow-up despite efforts to increase retention. Given the importance of adherence, it will be critical to understand the reasons for this high attrition including barriers and facilitators to adherence and visit attendance. We will conduct a small sub-study to better understand the reasons participants stopped attending their visits.

### *Objectives*

- 1) Determine differences in knowledge, attitudes and beliefs between persons who stopped attending visits and those who completed at least 10 months of the OLE.
- 2) Identify barriers and facilitators to remaining in the TDF2 OLE study
- 3) Describe reasons for not completing the study

### *Population*

A selection of approximately 52 TDF2 OLE participants and a random sample of 20 persons who said they would participate in the OLE but did not attend a screening appointment.

### *Methods*

#### *General methods*

Eight Focus Group Discussions (FGDs) and 12 In-depth Interviews (IDIs) will be convened, half in Gaborone and half in Francistown. TDF2 OLE trial staff will contact participants for potential participation in the substudy. If funding and available time permit, in order to reduce possible social desirability bias related to participants' familiarity with study staff, a local (Botswana) external organization with experience in structured interviews may be engaged to conduct all interviews under the supervision of a behavioral scientist.

All discussions and interviews will be conducted in the local language, Setswana, or in English, per participant preference. Written guides and surveys, as well as consent forms, will be translated accordingly by the organization implementing the sub-study.

Implementation of each substudy activity (focus group and interviews) may depend upon availability of sufficient funding, staff and time.

#### *Focus group discussions (FGD)*

FGDs will be used to hear from participants in the TDF2 OLE about reasons they may have stopped attending visits and thus stopped taking PrEP.

Participant inclusion and exclusion criteria:

- Group 1: OLE participants who attended fewer than 10 monthly visits in the OLE.
- Group 2: OLE participants who completed at least 10 monthly visits in the OLE.

Estimated number of participants: 40 persons for 8 focus groups (approximately 5 persons per group). We will over-recruit at least 10 additional persons to allow for those who fail to attend convened in Gaborone and 4 in Francistown. FGDs will be stratified by sex and Group (see table below).

Type	Gaborone FGDs	Francistown FGDs	Total
1. Individuals who did not complete the OLE	1Male 1Female	1Male 1Female	2 Male 2 Female
2. Individuals who completed at least 10 monthly visits.	1Male 1Female	1Male 1Female	2 Male 2 Female
	2Male 2Female	2Male 2Female	4 Male 4 Female

Potential participants for each group will be contacted after exit from the study (or loss to follow-up) or as they are nearing study completion at their last known contact number.

FGDs will focus on several domains, as outlined in Appendix E3 OLE Qualitative Substudy Focus group discussion and in-depth interviews moderators guide:

1. Motivation for participation/completion of study (including HIV risk perception, reasons for joining and/or participating in the study, concerns, social supports, priorities, etc.)
2. Perceptions of study logistics and staff treatment of participants
3. Suggestions for future prevention work and study.

The moderator will have the following characteristics:

- Knowledge of English, local Setswana language and communication skills;
- Familiarity and comfort with discussing health topics;
- Ability to respect dignity and confidentiality of participants;
- Good listening skills, non-judgmental and non-biased approach;
- Previous experience with interviews or other qualitative data collection methods.

All discussions will be conducted in appropriate locations. Qualifying criteria include:

- Located in a safe neighborhood;
- Spacious and comfortable, well-lit, good climate control, quiet to allow all to be heard, non-cluttered to allow easy eye contact with each other;
- Providing sufficient privacy for the discussion.

FGDs will be audio- (not video) recorded and discussions will be transcribed in a text format. Participants will not be identified in the FGD transcripts. Participants will not be identified by name during the interview and in transcripts.

#### *In-depth interviews*

We are conducting IDIs in addition to FGDs in order to capture any sensitive information that the participants may not feel comfortable sharing in front of other people.

Participant inclusion criteria:

Group 1: OLE participants who attended fewer than 10 monthly visits in the OLE.

Group 2: OLE participants who completed at least 10 monthly visits in the OLE their scheduled discussion, for a total of approximately 50 persons. 4 focus groups will be

Estimated number of participants: A total of approximately 12 IDIs will be carried out, stratified by site, gender, and Group (see table below).

Type	Gaborone IDI	Francistown IDI	Total
1. Individuals who did not complete the OLE	2 Male 2 Female	2 Male 2 Female	4 Male 4 Female
2. Individuals who completed at least 10 monthly visits.	1 Male 1 Female	1 Male 1 Female	2 Male 2 Female
	3 Male 3 Female	3 Male 3 Female	6 Male 6 Female

Interviews will be pre-arranged and conducted in any private location or over the phone and last approximately 20-30 minutes. Interview topics will be similar to those outlined above for the FGDs and are presented Appendix E3 OLE Qualitative Substudy Focus group discussion and in-depth interviews moderators guide.

IDIs will be audio recorded and transcribed into a text format. Participants will not be identified in the IDI transcripts.

The use of different interview types in this study aims to increase data credibility as well as facilitate interpretation of the results [5-7].

#### *Brief telephone interviews*

We may conduct a short interview with approximately 20-30 individuals who scheduled an OLE screening visit but failed to attend in order to learn more about this group's reasons for not attending screening visits. This interview will be brief (approximately 10 minutes) and will be conducted over the telephone. We will attempt to contact only TDF2 participants who previously provided consent to be recontacted and who scheduled an OLE screening visit. The interview instrument is found in Appendix E4: OLE Telephone Interview and may be modified slightly on the basis of FGD and IDI.

#### Study time line

The estimated time frame for the study stages are as follows: Qualitative interviews-six weeks; telephone interview- four to six weeks. Transcription and translation of the FGDs, IDIs and data entry for the telephone interview will require an additional 8 weeks for a total of approximately 20 weeks.

#### Training

A staff Behavioral Scientist will conduct a training session with the local implementation staff (FGD moderators, IDI interviewers, telephone interviewers, etc). The training will encompass review of the sub-study objectives and procedures and aspects of qualitative interview methodology as appropriate.

#### *Data handling*

##### FGD and IDI data storage

FGD and IDI data will be stored by the local supervisor. Audiotapes will be kept in a locked file cabinet or equivalent password protected electronic file and only study personnel will have access. Staff will transcribe and translate the FGD and IDI data and give the electronic versions as well as the audio tapes to the principal investigator within one month following the last interview. The principal investigator will keep audiotapes in a locked file cabinet and only study personnel will have access. They will be responsible for the security of the data throughout the

life of the project. Audio tapes will be destroyed after completion of all study-related analyses and publications. Transcript data will be retained in accordance with CDC and Botswana MOH data retention guidelines for clinical trials. Only first names will be associated with the tapes, and no names will be associated with the transcripts.

#### Phone interview data storage

Staff will be responsible for maintaining secure storage of the telephone interview data while it is in their possession. All of the data from the interviews will be entered into a database in English, cleaned and edited by at least two bilingual (English- and Setswana speaking) data managers to ensure accuracy. Study ID numbers will be used on all materials, and personal identifiers will be securely stored separate from these data. The principal investigator will keep these materials for one year following termination of data collection. They will keep responses in a locked cabinet or equivalent password-protected digital files and only study personnel will have access to the hard copies and the computer files. The principal investigator will be responsible for the security of the data throughout the life of the project. Hard copies of the interview instrument and the electronic version of the database will be sent to the principal investigator. Data will be retained in accordance with CDC and Botswana MOH data retention guidelines for clinical trials.

#### Data entry, editing and management

FGD and IDI transcription and telephone interview data entry will be done in-country by at least 2 trained bilingual (English- and Setswana speaking) personnel. Upon completion of data entry, the electronic data files will be sent to the principal investigator. The data file will be converted to SAS analytic data file. Hard copies or electronic files of telephone interview data collection forms will be delivered to the principal investigator.

#### Quality control/assurance

Completed telephone interview questionnaires will be checked by study supervisors to assure completeness. The data will be entered and checked by two bilingual (English- and Setswana speaking) staff. A sample of IDs (10%) with their corresponding data will be extracted from the database. The data entered into the electronic database will be compared with the information written on the hard copy questionnaire.

#### *Analysis*

##### FGD and IDI

Qualitative analysis will allow us to carefully examine what participants have said about various topics. As new themes and issues emerge, all of the relevant information will be retrieved and examined for further coding designations using Nvivo, a qualitative data analysis software. Only study investigators will have access to study materials.

##### Telephone interviews

Data entry will be conducted on-site by at least two experienced bi-lingual data managers. The principal investigator will be responsible for the security of these data. No names will be associated with the data. SAS statistical software will be used for analysis. We will use chi-square tests, exact methods, and multivariable techniques as appropriate to explore associations among participant characteristics and reasons for not participating in an OLE screening visit. Descriptive analyses will be used to outline barriers and motivations for joining the OLE. Only aggregate data will be analyzed and presented in the report and future publications.

##### Expected outcomes

Identification of differences between persons enrolled in the TDF2 OLE study who stopped attending monthly visits and persons enrolled in the TDF2 OLE study who have continued to

attend monthly visits, barriers and facilitators to remaining in the OLE study, reasons for leaving the study, and what can be done to improve PrEP adherence and retention.

### *Human subjects protection and consent forms*

Risk to the participant is minimal, and consists mainly in the possibility of emotional discomfort when answering questions about their personal reasons for dropping out of the study. The anonymous format of the FGD and IDI helps to minimize this risk. It will also be made clear to participants both by the interviewer and in the informed consent documents that participation is voluntary and they may refuse to answer individual questions or discontinue participation completely at any time without penalty or loss of benefits.

### Request for waiver of documentation of informed consent

Because the sub-study procedures represent no more than minimal risk to participants, and because the sub-study involves no procedures for which written consent is normally required outside of the research context, we request a waiver of documentation of informed consent for the FGDs, IDIs, and telephone interviews. Participants in the formative and telephone interview portions of the sub-study will receive a standardized verbal explanation of informed consent (see Additional Documents A14 and A15), and those participating in in-person interviews will also receive the consent form to take home which includes the contact information for the study principal investigator and the Chief Research Officer, Health Research Unit at the Botswana Ministry of Health. Potential participants will read the consent form, or the text will be read to them, followed by adequate time allowing participants to ask questions before verbally consenting to be in the study.

Participants in FGD or IDI interviews will be reimbursed for transportation expenses and time (BWP 50 (~USD\$6.00) or equivalent). For the brief telephone interviews, reimbursement of approximately BWP 20 (~USD\$2.40) or equivalent will be provided either via bank transfer or in the form of mobile airtime to cover the cost of the call.

### *Dissemination and reporting the results*

Results will be used to increase the understanding of reasons why participants were lost to follow up and will provide important information on the potential barriers of using PrEP in a non study setting. Results will be reported as part of publications describing the Open Label Extension phase of TDF2 in peer-reviewed journals and to study participants.

### *References*

1. Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med* 2012;367(5):411–22.
2. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363(27):2587–99.
3. Baeten J, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012; 367(5):399–410.
4. Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med* 2012;367(5):423–34.
5. Patton, M. *Qualitative research & evaluation methods*. 3rd ed. 2002. Thousand Oaks: Sage Publications.
6. Patton, M. Q. *(Qualitative evaluation and research methods (2nd ed.))*. 1990. Newbury Park, CA: Sage Publications.
7. Teddlie A, *Handbook of Mixed Methods in Social and Behavioral Research*. 2003. Thousand Oaks: Sage.
8. Willis, GB. *Cognitive Interviewing: A “How To” Guide*. Short Course presented at the 1999 Meeting of the American Statistical Association. Rachel A. Caspar, Judith T. Lessler, and Gordon B. Willis—Research Triangle Institute.

## **Appendix A1 TDF2 Open Label Extension Formative Interview Informed Consent Form**

You have participated in the extension phase of the TDF2 Study called the TDF2 Open Label Extension (TDF2 OLE). This study was done by BOTUSA (CDC/Botswana), a project with the Ministry of Health here in Botswana and the Centers for Disease Control and Prevention in the United States.

### **PURPOSE**

This study is being done to identify the reasons why some people stopped attending visits and why some people did attend their study visits. We are inviting you to do an interview. The interview time may be between 30 and 90 minutes. You will be asked questions that do not have right or wrong answers. You may be asked to take part in a group discussion to talk about issues, for example, self-perception of risk for HIV infection and social support. During the interview, you are free to answer or not to answer any question. You can stop taking part in the interview at any time.

### **POSSIBLE RISKS & BENEFITS**

There are only mild risks of doing the interview. Some of the interview questions may ask you about personal issues like your sexual behavior. These things might be mildly embarrassing to you. You will not receive direct benefit from taking part in this study. You may enjoy sharing your thoughts and experiences. The results may help people who might participate in future studies.

### **COSTS TO YOU**

It will not cost you anything to be in this study. You will receive BWP 50 for your time and travel expenses.

### **ALTERNATIVES TO BEING IN THE STUDY**

You are free to agree to the interview or not. Your decision will not affect your participation in future studies.

### **HOW YOUR RECORDS WILL BE KEPT PRIVATE**

The interview may be audio recorded and a staff person will take notes. People's names will not be kept in the notes or used in reports. Only the people doing the study will be able to listen to recordings and read the notes. The audio recordings and notes will be destroyed at the end of the study.

### **YOUR RIGHTS TO REFUSE OR WITHDRAW**

You can take part in this study or not. You can choose not to answer any question. You can stop at any time.

### **IF YOU HAVE QUESTIONS OR CONCERNS**

If you have questions or concerns, please call and speak to Dr. Ian Chirwa (office: 241 5222; mobile: 7190 2837) or Ms. Onkabetse Matlhaba (office: 390 1696; mobile: 7190 2856). If you have any questions about your rights, complaints about how we treated you, or feel that you have been harmed, please call and speak to Mr. Pilate Khulumani, Chief Research Officer at the Health Research Unit, Botswana Ministry of Health (office: 391 4467).

**Appendix A2 TDF2 Open Label Extension  
Phone Interview Informed Consent Form**

You have participated in the TDF2 study to see if taking a drug may help prevent HIV. You were invited to participate in the extension phase of the TDF2 Study called the TDF2 Open Label Extension (TDF2 OLE). The studies were done by BOTUSA, a project with the Ministry of Health here in Botswana and the Centers for Disease Control and Prevention in the United States.

**PURPOSE**

This phone interview is being done to identify the reasons why some people did not participate in TDF2 OLE. This interview may take up to 10 minutes.

**POSSIBLE RISKS & BENEFITS**

There are no risks associated with this interview. You will not receive direct benefits. The results may help people who might participate in future studies.

**COSTS TO YOU**

There are no costs to you with this interview. You may receive up to BWP 20 or equivalent in phone airtime for your time.

**ALTERNATIVES TO BEING IN THE STUDY**

You are free to agree to the interview or not. Your decision will not affect your participation in future studies.

**HOW YOUR RECORDS WILL BE KEPT PRIVATE**

We will use a code number, not your name, on the interview. Only restricted study staff has access to a list with both names and code numbers.

**YOUR RIGHTS TO REFUSE OR WITHDRAW**

You can take part in this interview or not. You can choose not to answer any question. You can stop at any time.

**IF YOU HAVE QUESTIONS OR CONCERNS**

If you have questions or concerns, please call and speak to Dr. Ian Chirwa (office: 241 5222; mobile: 7190 2837) or Ms. Onkabetse Matlhaba (office: 390 1696; mobile: 7190 2856). If you have any questions about your rights, complaints about how we treated you, or feel that you have been harmed, please call and speak to Mr. Pilate Khulumani, Chief Research Officer, Health Research Unit at the Botswana Ministry of Health (office: 391 4467).

## Appendix A3 OLE Qualitative Substudy Focus group discussion and in-depth interviews moderators guide

### Introduction talking points

- Thank you for helping us today. My name is \_\_\_\_\_ and I am working on behalf of the Centers for Disease Control and Prevention Botswana or CDC Botswana. CDC Botswana is interested in understanding what TDF2 participants thought about the OLE study. We are here to learn from you. Your name or study ID will not be connected with anything that you say here today. The information collected in these discussions will be used to help us learn how we can improve upon the work that we do as well as how we can better support participant's needs while in a research study.
- This is not a test of your knowledge on the subject. There are no right or wrong answers. Instead this is an opportunity for us to learn from you.
- Are there any questions now, before we get started?

### Domains and talking points *(unless specified, domains should be asked to all participants)*

#### Domain 1: Motivation for study participation

Q1: Why did you decide to join the TDF2 OLE study?

- Explore the different motivations for joining the study
- Compare/contrast costs/benefits of the study
- Explore HIV risk perception and the participants' perceptions of the impact of that risk
- Explore perceived efficacy of PrEP and the perceived value of PrEP and HIV prevention

Q2: What concerns did you have about joining the study?

- Probe for how concerns were dealt with, who was consulted, what kind of advice was received
- Explore if information given about the OLE answered all questions
- Explore if there was information the participant would like to have known but didn't before joining the study and how did this may have impacted their interest in participating.

Q3: What was liked and disliked about being in the study?

- Explore satisfaction and dissatisfaction with the procedures and/or events identified

Q4 (*Study completers only*): You have now been in the study several months, how have you managed to keep up participation in the study?

- Explore motivations, challenges, and strategies to overcome any difficulties faced
- Explore advice participant could give to researchers to assist in retention in future studies
- Explore social support (family, friends, partners, community, church, media, employer) received or not received to participate in the study
- Explore how they balanced work/life commitments and study participation/visits.

Q5 (*Loss to follow-up only*): We are interested in understanding the reasons why you stopped attending the study visits?

- Explore challenges/barriers experienced
- Explore if there would have been ways the study could have helped overcome these challenges/barriers so they could continue with study visits

- Explore social support (family, friends, partners, community, church, media, employer) received or not received to participate in the study
- Explore life priorities (work, children, food and necessities, etc.) and how study participation interacted with those priorities (e.g., cost-benefit of participation)

#### Domain 2: Staff treatment

Q6: How do you feel about the quality of health care provided during OLE? Can you give examples?

- Explore if this impacted their interest in participating in the study
- Explore if this impacted how they answered study questions

Q7: How do you feel you were treated by the study staff during OLE? Can you give examples?

- Explore if this impacted their interest in participating in the study
- Explore if this impacted how they answered study questions

#### Domain 3: Suggestions for improvements

Q8: Do you have anything else that you think would be important for the people conducting the study to know about how they could have made participation in the study better?

Q9: Explore what kinds of activities or prevention strategies participants think might help Botswana to protect themselves and others from becoming infected with HIV.

We do appreciate the time that you took to help us today. Do you have any questions that we have not answered?

Thank you very much!

## Appendix A4 TELEPHONE INTERVIEW

Participant ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Site ID: <input type="checkbox"/> (1) Gaborone <input type="checkbox"/> (2) Francistown
Staff ID: <input type="text"/> <input type="text"/> <input type="text"/>	Interview Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> dd mm yy

*CRF Instructions: This phone interview is administered to former TDF2 participants who did not attend their first OLE screening visit and are part of the qualitative substudy.*

**[Read to Participant] THANK YOU FOR PARTICIPATING IN THIS PHONE INTERVIEW. WE UNDERSTAND THAT YOU CHOSE NOT TO PARTICIPATE IN THE OLE STUDY AND THIS IS OKAY. WE WOULD LIKE TO UNDERSTAND THE REASONS WHY YOU DID NOT COME SO THAT WE CAN BETTER UNDERSTAND HOW TO SUPPORT PARTICIPANTS IN FUTURE STUDIES. PLEASE REMEMBER THAT THERE ARE NO RIGHT OR WRONG ANSWERS. FIRST, I AM GOING TO FIRST ASK YOU QUESTIONS ABOUT YOUR BACKGROUND.**

1. What is your current age?

years

2. Participant gender:

(1) Female

(2) Male

3. What is the highest level of schooling you completed?

(1) None

(2) Primary - Grades 1-7

(3) Junior Secondary – Forms 1-3

(4) Senior Secondary – Forms 4-5/O-Levels

(5) Tertiary – Brigade/Vocational

(6) Advanced University/College

4. Thinking about the past 3 months, that is since [*Day, Month, Year*], what was your average monthly income from any source?

Pula

5. Thinking about the past 3 months, that is since [*Day, Month, Year*], what was your average monthly income from any source?

Pula

6. Thinking about the past 3 months, that is since [Day, Month, Year], what was your average monthly income from any source?

Pula

7. We would like to understand the reasons that initially made you interested in the OLE study and agreeing to attend a screening visit. For each reason I read, please respond with a 'yes' 'no'.

**[Read to Participant before each option]** Did you agree to a screening visit because ...

Y  N  (a) of the access to the medical care provided by the study?

Y  N  (b) of the access to frequent HIV testing?

Y  N  (c) you wanted to use condoms less and still be protected from HIV by taking Truvada?

Y  N  (d) you have a positive partner and wanted to become pregnant?

Y  N  (e) you felt at risk for getting HIV and wanted to take Truvada to protect yourself?

Y  N  (f) of any other reasons? **[If yes]** Specify:

---

8. Thank you for those responses. I am now going to read back the reasons that you said yes to.  
**[Read all reasons that were marked 'yes' from Q1(a) – Q1(f) back to the participant]**

**[If 1 or 2 reasons, read to participant]** Was this/these your main reasons for participating?

(1) Yes

(2) No **[Ask about additional reasons. Update Q5(f). Update Q6 to 'yes'.]**

**[If 3 or more reasons, read to participant]** Of these, which were the **two** main reasons you decided to enroll in OLE?

#1 Main Enroll Reason:

**[Indicate letter option in text box. If participant says none of these, ask about additional reasons. Update Q5(f). Update main reason letter response to 'f' if main reason]**

#2 Main Enroll Reason:

9. We would like to understand the reasons why you did not to attend the screening visit. For each reason I read, please respond with a 'yes' 'no'.

**[Read to Participant before each option]** Did you not attend the visit because ...

Y  N  (a) of problems getting to the clinic, such as lack of available transport, clinic hours, or lack of money?

**[If yes]** What were the problems? \_\_\_\_\_

Y  N  (b) of the study visits, such as how long it took, clinic location, testing and blood draws, being asked personal questions, counseling, staff behaviors?

**[If yes]** What did you not like about the study visits?

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Y  N  (c) you did not feel at risk for HIV or your risk was not great enough to want to take a pill every day?

Y  N  (d) of lack of support from others? This can include sex partners, friends, family members, community, media, religious leaders, and health care workers?

[If yes] Who?

---

Y  N  (e) of side effects from taking Truvada?

Y  N  (f) of no reimbursement (transport money) provided?

Y  N  (g) of any other reasons?

[If yes] Specify:

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10. Thank you for those responses. I am now going to read back the reasons that you said yes to. **[Read all reasons that were marked 'yes' from Q7(a) – Q7(g) back to the participant.]**

[If 1 or 2 reasons, read to participant] Was/were this/these the main reason(s) you did not attend your visit?

(1) Yes

(2) No [Ask about additional reasons. Update Q7(g). Update Q8 to 'yes'.]

[If 3 or more reasons, read to participant] Of these, which were the **two** main reasons for why you did not attend?

#1 Main Stop Reason:

[Indicate letter option in text box. If participant says none of these, ask about additional reasons. Update Q7(g). Update main reason letter response to 'g' if main reason]

#2 Main Stop Reason:

**Read to Participant]** THANK YOU FOR TAKING THE TIME TO ANSWER THESE QUESTIONS AND THANK YOU AGAIN FOR PARTICIPATING IN THIS PHONE INTERVIEW.

**General Comments:**

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Staff ID and Signature

dd

mm

yy

QC ID:  QC Initials: \_\_\_\_\_

Data Entry Stamp: