

APPENDIX NUMBER 6: Eligibility Screening Interview
(administered via handheld computer)

**Form
Approved**
OMB NO. _____
Exp. Date _____

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXX)

Flesch-Kincaid Reading Level 4.8

Recruiter instructions: "Read questions to respondent and enter **all** responses unless instructed otherwise."

DATE Date: __/__/__ (auto entered by HAPI program, format: mm/dd/yyyy)

TIME Time ____:____ (auto entered by HAPI program, format: hh:mm 24 hour format)

RECNUM Record # ____ (auto entered by HAPI program; site code and computer number assigned during installation should be a component of the RECNUM; format to be designated later)

SITE

- University of North Carolina
- University of Miami
- Health Services Center

RECRUITID Recruiter's ID: ____

VENUE At what venue location is this interview being conducted?
_____ (enter venue code from drop down menu)

TYPCON What is the form of contact established with the respondent?

- In person
- By telephone

- SOURCE** How did respondent find out about study?
- Approached at venue _____ (enter venue location)
 - RDS coupon _____ (enter RDS coupon tracking number)
 - Flyer or Brochure
 - Word-of-mouth
 - Unknown

- PRVSCR** Has respondent previously been screened for this study?
- Yes _____ (enter previously assigned screener record number(s) if known)
 - Yes, but previously assigned screener record number is unknown
 - No

*If PRVSCR = no, ask SCR1
If PRVSCR = yes, ask PRVNUM*

PRVNUM How many times has this respondent previously been screened for this study?
_____ (insert number; range 1-99)

- PRVENRL** Has this potential respondent previously enrolled in this study?
- Yes
 - No

*If PRVENRL = no, ask SCR1
If PRVENRL = yes, **Recruiter instructions:** "Please inform the respondent that she may only enroll in this study one time", then end interview*

SCR1. Can you read or understand (English if site = UNC or site = HSC; English or Spanish if site = UM)?

- Yes
- No

*If SCR1= yes, ask SCR2
If SCR1 = no, **Recruiter instructions:** "Please thank the respondent".
Auto-fill SCR2 response –select "Approached but does not read/understand English/Spanish"
Then end interview*

SCR2. Are you willing to answer a few questions to see if you are eligible to take part in a study about women's health risk behaviors?

- Yes
- No
- Approached but refused contact
- Approached but does not read/understand English/Spanish

If SCR2= yes, ask SCR3

If SCR2 = no, skip to SCR18

*If SCR2 =approached but refused contact, **Recruiter instructions:** "Please thank the respondent", then end interview*

*If SCR2= approached but does not read/understand English/Spanish, **Recruiter instructions:** "Please thank the respondent, then end interview*

SCR3. What is your age?

_____ age in years (range 15-75 years)

SCR4. Do you consider yourself to be Hispanic or Latina?

- Yes
- No

SCR5. What is your race? You can choose more than one race.

- White
- Black or African-American
- American-Indian or Alaska-Native
- Asian
- Native Hawaiian or Pacific-Islander

SCR6. Were you born a female?

- Yes
- No

Recruiter instructions: "Please read this question to the respondent but allow her to enter her response privately. Instruct her to say "I'm finished" after she has entered her response."

SCR7. Have you had either vaginal or anal sex with a man in the past 12 months or since (HAPI inserts 12 month date)?

- Yes
- No

Recruiter instructions: "Please read this question to the respondent but allow her to enter her response privately. Instruct her to say "I'm finished" after she has entered her response."

SCR8. Have you ever had a test that showed you have HIV?

- Yes
- No

Recruiter instructions: "Please read this question to the respondent but allow her to enter her response privately. Instruct her to say "I'm finished" after she has entered her response."

SCR9 Are you willing to be tested for HIV using a rapid oral test?

- Yes
 No

Read: "Let's find out if you are eligible for this study."

SCR10. Does respondent meet all core eligibility criteria?

NOTE: (HAPI will calculate this but not display this question)

Validation: If SCR1= yes, AND SCR3 = age 18-59, AND SCR4=yes if site= UM OR SCR5= Black or African American if site = UNC or HSC, AND SCR6=yes AND SCR7 = yes AND SRC8= no, and SCR9=yes, then eligibility =yes. Else eligibility =no

NOTE: Computer to display the following read statements according to the preceding validation.

*If SCR10= Yes AND TYPCON= in person, **Recruiter instructions:** "Please read ... You are eligible for this study." Then ask SCR11*

*If SCR10= No, **Recruiter instructions:** "Please read.... I am sorry. According to one of more of your answers, you are not eligible for this study. Thank you for your interest and for taking time to answer our questions" and end interview.*

SCR11. Would you like more information about this study to see if you might be interested in taking part in it?

- Yes
 No

*If SCR11= Yes, **Read:** Recruiter will initiate site specific consenting procedure. After consenting procedure is completed, resume interview with question SCR12*

If SCR11=No, skip to SCR16

SCR12. Did the potential participant consent to being in the study and sign the informed consent form?

- Yes
 No

If SCR12 = Yes, go to SCR13

If SCR12 = No, skip to SCR14

SCR13. Assign Participant Study ID Number _____ (HAPI to generate and display Participant ID Number)

*Validation: IF SCR12 = Yes and SCR13 contains Participant Study ID number, **Recruiter instructions:** Please write down the Participant ID Number on listed below and begin ACASI interview now.*

SCR14. Did you schedule an appointment for this potential participant for to return for the study visit at a later time?

- Yes, she has an appointment
 No, she wants to enroll but can't schedule her appointment right now.
 No, she does not want to enroll in the study

If SCR14 = Yes, **or** SCR14 = No, she wants to enroll but can't schedule her appointment right now, HAPI should display RECNUM and expiration date.

Read: Recruiter, please write this screening number and expiration date* on a study card and give it to the respondent with the instruction to bring it with her when she comes in for her appointment", then end interview.

If SCR14= No, she does not want to enroll in the study, skip to SCR16

*Note: An expiration date of 14 days will be calculated for the RECNUM based on the date this screening ended. If the expiration date falls on a Saturday or Sunday, shift expiration date to the first Monday following the initially calculated expiration date.

SCR15. Based on the information I just gave you, would you like to set up an appointment to find out more about taking part in this study?

- Yes
- No

If SCR15=yes, **Read:**" Recruiter will schedule appointment and document per telephone encounter script. HAPI should display RECNUM and expiration date* and read: Recruiter, please write this screening number and expiration date on a study card and give it to the potential participant with the instruction to bring it with her when she comes in for her appointment", then end interview..

*Note: An expiration date of 14 days will be calculated for the RECNUM based on the date this screening ended. If the expiration date falls on a Saturday or Sunday, shift expiration date to the first Monday following the initially calculated expiration date.

If SCR15 = No, skip to SCR16

APPENDIX 6.1 Refusal Questionnaire

SCR16. Are you willing to tell me why you aren't interested in taking part in this study?

- Yes
- No

If SCR16= Yes, ask SCR17

If SCR16= No, **Read:** "Thank you for taking time to answer our questions.", then end interview.

SCR17. Please tell me why you don't want to be part of this study?

Read: Recruiter, please check all responses most similar to reasons verbalized but do not read list of reasons to potential participant, then select "Next".

- doesn't have time
- doesn't want to get tested
- doesn't want to find out if she has HIV
- someone might think she has HIV
- doesn't think she's at risk for HIV
- doesn't trust research studies
- doesn't have transportation
- has young children or others to care for
- someone might get upset if she joins
- can't get treated so why get tested
- study doesn't pay enough

- doesn't believe in HIV/AIDS
- is healthy
- doesn't feel well enough
- it's a waste of time
- needs partner's permission
- other reason not listed

After "next is selected, **Read:** "Thank you for taking time to answer our questions", then end interview.

SCR18. Are you willing to tell me why you don't want to find out if you are eligible for this study?

- Yes
- No

If SCR18= Yes, ask SCR19

If SCR18= No, **Recruiter instructions:** "Please thank the respondent", then end interview

SCR19. Please tell me why you don't want to find out if you are eligible for this study.

Read: Recruiter, please check all responses most similar to reasons verbalized but do not read list of reasons to potential participant, then select "Next".

- doesn't have time
- doesn't want to get tested.
- doesn't want to find out if she has HIV
- someone might think she has HIV
- doesn't think she's at risk for HIV
- doesn't trust research studies
- doesn't have transportation
- has young children or others to care for
- someone might get upset if she joins
- can't get treated so why get tested
- study doesn't pay enough
- doesn't believe in HIV/AIDS
- is healthy
- doesn't feel well enough
- it's a waste of time
- needs partner's permission
- other reason not listed

After "next is selected, **Read:** "Thank you for taking time to answer our questions", then end interview.

