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dd
 MMM
 yy

I will start by asking you some general questions about yourself.

1. What is your date of birth? → If unknown, record age:
dd MMM yy years
2. What is your gender? ☐ male ☒ female
3. Are you currently married? ☐ yes ☐ no
→ If yes, go to item 5.
4. Do you currently have a primary sex partner?
By primary sex partner, I mean a man you have sex with on a regular basis or who you consider to be your main partner. ☐ yes ☐ no
→ If no, go to item 12 on page 2.
5. How old is your husband/primary sex partner?..... years don't know
6. Are you currently living with him? ☐ yes ☐ no
7. Does he have any sex partners other than you? ☐ yes ☐ no don't know
8. Does he provide you with financial and/or material support? ☐ yes ☐ no
9. What is his average monthly income? Record in local currency. don't know no income

Demographics (DEM-1)

Purpose: This form is used to collect participants' demographic and socioeconomic information.

General Information/Instructions: This form is a mixed form—some of the items are interviewer-administered (items 1–17), while other items are not (items 18–19a).

Note: There is no visit code field on this form, since this form is only completed at the Screening and Enrollment Visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. **NOTE:** *participant must be between the ages of 18 and 40 years (inclusive) at the time of screening to be eligible for study participation.*
- **Item 4:** Record whether or not the participant **currently** has a primary sex partner.
- **Item 5:** Read aloud “husband” or “primary sex partner,” depending on the participant's response to item 3 and item 4 (if not currently married). If the participant does not know her husband's or primary partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the “don't know” box.
- **Item 8:** Record whether or not the participant's husband or primary partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 9:** Record the husband's or primary partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	0	0	2	1	4	5
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If the husband's or primary partner's average monthly income is greater than 999,999,999 write “999999999” in the boxes provided, and record the actual value in the white space near the item.

SAMPLE *DO NOT FAX
TO DATAFAX*

MTN 009 (177)

DEM-2 (002)

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Participant ID

Site Number			Participant Number					Chk	

Demographics

10. What is his highest level of education?

- ☐ no schooling
- ☐ primary school, not complete
- ☐ primary school, complete
- ☐ secondary school, not complete
- ☐ secondary school, complete
- ☐ attended college or university
- ☐ don't know

11. Is he circumcised? By circumcised, I mean when the foreskin of the penis is removed.

Use visual aid.

yes no don't know

☐ ☐ ☐

12. Do you earn an income of your own?

yes no

☐ ☐ → **If no, go to item 13.**

12a. What is your average monthly income?

Record in local currency.

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12b. How do you earn your income?

Mark all that apply.

formal employment self-employed other, specify

☐ ☐ ☐



13. What is your highest level of education?

- ☐ no schooling
- ☐ primary school, not complete
- ☐ primary school, complete
- ☐ secondary school, not complete
- ☐ secondary school, complete
- ☐ attended college or university

English: _____

Local
Language: _____

			X
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 Language

Staff Initials / Date

Demographics (DEM-2)

Item-specific Instructions:

- **Item 10:** If the participant does not know her husband or primary partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 11:** The intent of this item is to capture the circumcision status of the participant's husband/primary sex partner at the time this form is administered (Screening and Enrollment Visit). If the participant's husband/primary sex partner (as reported in items 3–4) is circumcised after the Screening and Enrollment Visit, do not update the response to item 11.
- **Item 12a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	0	0	2	1	4	5
---	---	---	---	---	---	---	---	---

If the participant's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 12b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE *Do NOT FAX
TO DATAFAX*

MTN 009 (177)

DEM-3 (003)

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Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Participant Number						Chk

Demographics14. How many children have you given birth to who were alive at birth? # of children15. Do you, or does someone in your family, own the house you are currently living in? yes no
☐ ☐16. How many rooms are in the house you are currently living in? # of rooms17. What is your ethnic group or tribe? ethnic/tribe code
If other, specify:English: _____
Local
Language: _____**Interviewer:** Complete the following items after the interview.18. Where was the participant referred/recruited from? recruitment code19. Did the participant complete the ACASI Questionnaire at this visit? yes no
☐ ☐ → If no, record reason(s) in Comments. End of form.19a. Date ACASI Questionnaire was completed: dd MMM yy

Comments: _____

☐ ☐ ☐ ☒ 17-FEB-10

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Language

Staff Initials / Date

Demographics (DEM-3)

Item-specific Instructions:

- **Item 14:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 15:** Record whether or not the participant (or someone in her extended family) owns the house she lives in.
- **Item 16:** Do not count bathrooms as rooms.
- **Item 17:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant self-identifies with more than one ethnic group or tribe, record "90" (mixed) and document each group or tribe on the "Local Language" line. If the participant self-identifies with an ethnic group or tribe that is not included in the list of codes, record, "99" (other) and the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SOUTH AFRICA
07 - Zulu
08 - Xhosa
09 - Indian
10 - Colored
05 - Other African tribe
06 - White
90 - mixed
99 - other

- **Item 18:** This item asks where the participant was referred/recruited from to pre-screen or screen for an HIV prevention trial. It is not interviewer-administered. Refer to the code list developed and maintained at the site. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

SAMPLE *DO NOT FAX
TO DATAFAX*

MTN 009 (177)

EA-1 (005)

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Participant ID

Site Number			Participant Number				Chk		

Eligibility Assessment

1. Did the participant present to the study site to pre-screen or screen for an HIV prevention trial?.....

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- 1a. For which trial does she plan to pre-screen or screen?

VOICE	other, specify:	
<input type="checkbox"/>	<input type="checkbox"/>	_____
2. Was the participant previously enrolled in MTN-009?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible. End of form.
3. Is the participant between the ages of 18 and 40 years old, as verified per site SOPs?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
4. Was the participant able and willing to provide written informed consent for participation in MTN-009?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- 4a. When was the informed consent form for MTN-009 participation marked or signed?

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd	MMM	yy			
5. Was the participant able and willing to provide written informed consent for specimen storage and future research?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, go to item 6.
- 5a. When was the informed consent form marked or signed to document participant consent for specimen storage and future research?

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd	MMM	yy			
6. Does the participant have any condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achievement of the study objectives?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible. End of form.
7. Did the participant enroll in MTN-009?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, end of form.
- 7a. Date of enrollment:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd	MMM	yy			

Comments: _____

			X
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Language

Staff Initials / Date

Eligibility Assessment (EA-1)

Purpose: This form serves two purposes. It is used to document whether a woman is eligible for MTN-009, per the protocol inclusion and exclusion criteria. It is also used to document a woman's enrollment into MTN-009. This form must be completed for each participant who screens for MTN-009.

General Information/Instructions: This form is NOT interviewer-administered. It is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Screening and Enrollment Visit.

Note: There is no visit code field on this form, since this form is only completed at the Screening and Enrollment Visit.

Item-specific Instructions:

- **Item 2:** Review the Screening and Enrollment Log to verify whether the participant has previously enrolled in MTN-009.
- **Item 3:** Per protocol, a participant must be between the ages of 18 and 40 (inclusive) *at the time of screening* as verified according to site standard operating procedures (SOPs). Participants who are under 18 years or over 40 years of age should not be screened for the study.
- **Item 4a:** If the participant marks the informed consent form using her thumbprint, record the date the thumbprint was made.
- **Item 5:** Mark "yes" only if the participant gave optional consent to have her lab specimens stored for future research testing.
- **Item 7:** Per protocol, enrollment is the act of assigning an MTN-009 Participant ID (PTID) to a participant. Mark "yes" if the participant was assigned an MTN-009 PTID.