

Enrollment Visit

- Enrollment (ENR-1)
- Prior Trial Participation (PTP-1)
- Baseline Family Planning (BFP-1)
- Enrollment Abbreviated Physical Exam (EPX-1)

Site to add:

- Baseline Behavior Assessment (BBA-1~3) – *local-language version*
- Baseline Vaginal Practices (BVP-1) – *local-language version*
- Enrollment Behavior Eligibility (non-DataFax) – *local-language version*
- Enrollment Visit LDMS Specimen Tracking Sheet

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MTN-020 ASPIRE (192)

ENR-1 (070)

Participant ID <input style="width: 30px; height: 20px;" type="text"/> - <input style="width: 60px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <div style="display: flex; justify-content: space-around; font-size: small;"> Site Number Participant Number Chk </div>	
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Enrollment	
1. Date the participant marked or signed the study screening consent form	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <div style="display: flex; justify-content: space-around; font-size: small;"> <i>dd</i> <i>MMM</i> <i>yy</i> </div>
2. Date the participant marked or signed the study enrollment consent form	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <div style="display: flex; justify-content: space-around; font-size: small;"> <i>dd</i> <i>MMM</i> <i>yy</i> </div>
3. Did the participant agree to biological specimen and health data storage?	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>yes</i> <i>no</i> <i>pending</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div>
4. HIV status	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>negative</i> <i>positive</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>
5. Pregnancy status	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>negative</i> <i>positive</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>
6. Randomization number assigned	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>randomization number</i>
7. Date prescription assigned	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <div style="display: flex; justify-content: space-around; font-size: small;"> <i>dd</i> <i>MMM</i> <i>yy</i> </div>
8. Time prescription assigned	<input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> : <input style="width: 30px; height: 20px;" type="text"/> <input style="width: 30px; height: 20px;" type="text"/> <i>24-hour clock</i> <div style="display: flex; justify-content: space-around; font-size: small;"> <i>hr</i> <i>min</i> </div>
9. Was the Baseline ACASI questionnaire completed?	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>yes</i> <i>no</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>
10. Was plasma for archive collected?	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>yes</i> <i>no</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>
11. Was self-collected vaginal fluid swab collected?	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>yes</i> <i>no</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>
12. Was vaginal ring inserted?	<div style="display: flex; justify-content: space-around; font-size: small;"> <i>yes</i> <i>no</i> </div> <div style="display: flex; justify-content: space-around;"> <input type="checkbox"/> <input type="checkbox"/> </div>

Comments: _____

Enrollment (ENR-1)	
Purpose:	This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants randomized.
General Information/Instructions:	Fax this form to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a randomization number).
Item-specific Instructions:	
Item 3:	Consent for left-over specimen and health data storage can be changed if the participant changes her consent decision after enrollment. Update as needed if the participant changes her consent during the study.
Item 4:	Record the participant's HIV status as determined by testing performed on the day of enrollment. If "positive," do not randomize/enroll the participant.
Item 5:	Record the participant's pregnancy status based on testing done on the day of enrollment. If "positive," do not randomize/enroll the participant.
Item 7:	This item must match the "date assigned" recorded for this prescription on the MTN-020 Prescription Tracking Record.
Item 8:	This item must match the "time assigned" recorded for this prescription on the MTN-020 Prescription Tracking Record.
Items 9-12:	Mark the "no" box if the procedure was not completed on the day of enrollment/randomization (date in item 7). Add the reason the item was not completed on the Comments lines. If any procedures are not completed, bring the participant back to the clinic for procedure completion as soon as possible.



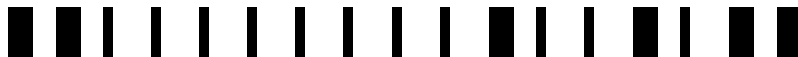
MTN-020 ASPIRE (192)

PTP-1 (077)

<p>Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/></p> <p style="text-align: center; font-size: small;">Site Number Participant Number Chk</p>	
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Prior Trial Participation	
1. Was the participant enrolled in VOICE (MTN-003)?	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> → <i>If no, go to item 2.</i>
1a. VOICE PTID	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>
2. Has the participant previously enrolled in a microbicide trial other than VOICE? This includes HPTN 035, CAPRISA 004, Carraguard, MDP, and any other microbicide trial.	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> → <i>If no, go to item 3.</i>
2a. Record the short title of each study (for example, CAPRISA 004)	<p>_____</p> <p>_____</p>
3. Has the participant previously enrolled in an oral pre-exposure prophylaxis (PrEP) trial for HIV prevention (other than VOICE)? This includes FemPrEP, Partners in PrEP, as well as any other oral PrEP trial.	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> → <i>If no, go to item 4.</i>
3a. Record the short title of each study (for example, FemPrEP)	<p>_____</p> <p>_____</p>
4. Has the participant previously enrolled in any other research studies, including any HIV prevention studies (HPTN studies) or HIV vaccine trials?	<i>yes</i> <input type="checkbox"/> <i>no</i> <input type="checkbox"/> → <i>If no, go to item 5.</i>
4a. Record the short title of each study (for example, HPTN 123)	<p>_____</p> <p>_____</p>
5. How did the participant hear about the ASPIRE trial? <i>Mark all that apply.</i>	
<input type="checkbox"/> 5a. from study staff (includes CAB members and outreach workers)	
<input type="checkbox"/> 5b. from a friend or family member	
<input type="checkbox"/> 5c. from someone in the community other than a CAB member	
<input type="checkbox"/> 5d. from a brochure or poster	
<input type="checkbox"/> 5e. other; specify: _____ _____	

Prior Trial Participation (PTP-1)	
Purpose:	This form is used to collect information on prior trial participation.
General Information/ Instructions:	This form is completed at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study.
Item-specific Instructions:	
Item 1 and 1a:	If this participant was previously enrolled in VOICE (MTN-003), mark the "yes" box and record the participant's PTID.



MTN-020 ASPIRE (192)

BFP-1 (075)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
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Baseline Family Planning

1. What method(s) of contraception/family planning is the participant currently using? *Mark "none" or all that apply.*

1a. none

1b. spermicide

1c. diaphragm

1d. sponge

1e. intrauterine device (IUD) → Date regimen started

dd *MMM* *yy*

1f. oral contraceptives/birth control pills → Date regimen started

dd *MMM* *yy*

1g. injectable contraceptives (such as Depo-Provera) → Date regimen started

dd *MMM* *yy*

1g1. Type: *Depo* *Depo subq* *NET-EN* *Cyclofem* *other*

1h. (Ortho Evra) The Patch → Date regimen started

dd *MMM* *yy*

1i. implants → Date regimen started

dd *MMM* *yy*

1j. female condoms

1k. natural methods such as the withdrawal or rhythm method

1l. male condoms

1m. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)

1n. sex with partner who had a vasectomy

1o. other, specify: _____

↓

Record on Concomitant Medications Log.

2. First day of last menstrual period OR *amenorrheic for past 6 months* → *If amenorrheic, go to item 4.*

dd *MMM* *yy*

3. Last day of last menstrual period OR *ongoing*

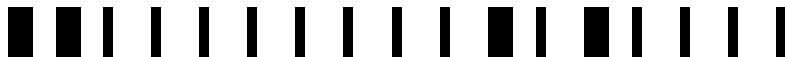
dd *MMM* *yy*

4. How many times has the participant been pregnant? → *If 00, end of form.*

4a. How many live births has the participant had?

Comments: _____

Baseline Family Planning (BFP-1)	
Purpose:	This form is used to document the methods of contraception/family planning used by the participant at baseline.
General Information/ Instructions:	Complete this form only at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study.
Item-specific Instructions:	
Item 1:	Mark the method(s) of contraception/family planning the participant reports currently using.
Item 1e-1i:	<p>If marked, record the date the participant started using the current contraceptive regimen under "Date Regimen Started." For injectables and implants, do not record the date of the most recent injection or implant—this will be captured on the Concomitant Medications Log. Rather, record here the date the participant started using that particular contraceptive method.</p> <p>If the day portion of the date cannot be obtained, line through the "dd" boxes write "UNK" in the white space. At a minimum, a month and year are required.</p> <p>For example:</p> <ul style="list-style-type: none"> For item 1f, for a participant on oral contraceptives starting on 13-MAR-11, record this as the date regimen started (even if she has missed pills or an occasional pill pack during that time). Do not record the start date of her most recent/current pill pack. For item 1g, a participant who has regularly been getting Petogen/Depo Provera injections every 3 months starting on 01-OCT-10, record "01-OCT-10" for date regimen started. Use this as the start date even if the participant missed an occasional injection. Do not record the date of her last injection as date regimen started. For item 1i, for a participant with implants inserted most recently 3 months ago, and has had implants inserted starting 3 years prior (January 2009), record "JAN-09" as the date regimen started, lining through the "dd" boxes and writing "UNK" in the white space.
Item 1g1.:	<p>Mark the specific type of injectable contraception used by the participant.</p> <ul style="list-style-type: none"> Depo for Depo Provera (DMPA, also known as Petogen) injected into the muscle. Depo subq: mark when the sub-cutaneous route of Depo is used. NET-EN: also known as Mesigyna. Cyclofem: also known as Lunelle.
Item 2:	The first day of the last menstrual period is the first day of bleeding.
Item 3:	The last day of the last menstrual period is the last day of bleeding.
Item 4:	Use leading zeros when needed.



MTN-020 ASPIRE (192)

EPX-1 (080)

Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">Site Number Participant Number Chk</p>	Visit Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <p style="font-size: small; text-align: center;">dd MMM yy</p>
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Enrollment Abbreviated Physical Exam

VITAL SIGNS

1. Weight <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> kg	4. Pulse <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> beats per minute
2. Body Temp <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> °C	5. Respirations <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> breaths per minute
3. BP <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> mmHg	

SYMPTOM-DIRECTED FINDINGS *Items 6 and 7 are required assessments. Other items assessed if clinically indicated.*

	<i>not done</i>	<i>normal</i>	<i>abnormal</i>	<i>Notes:</i>
6. General appearance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
7. Abdomen/ Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
8. Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Lymph Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
10. Heart/ Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
11. Lungs/ Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
15. Eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
16. Ears, Nose, Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
17. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Record abnormal findings on Pre-existing Conditions form as applicable.

Enrollment Abbreviated Physical Exam (EPX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study.
General Information/ Instructions:	If abnormal findings are identified, transcribe information onto the Pre-existing Conditions form, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 6-7:	These items are required to be assessed at the Enrollment Visit.
Items 8-17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the "not done" box.
Item 17:	If abnormal, specify the body system being referenced and describe the findings on the Notes line.