Screening Visit

- Demographics (DEM-1)
- Screening Pelvic Exam (SPE-1)
- Screening Visit Physical Exam (SPX-1)
- Screening Menstrual History (SMH-1)
- Screening Laboratory Results (SLR-1)
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- Pre-existing Conditions (PRE-1)
- Concomitant Medications Log (CM-1)
- Screening Specimen Storage (SSS-1)
- Pelvic Exam Diagrams (non-DataFax)
- Eligibility Criteria (ECI-1)
  Complete and fax at Screening Visit only if it is determined the participant will not enroll in ASPIRE. If Enrollment Visit is scheduled, move blank form to Enrollment Visit forms and complete at the Enrollment visit.

Site to add:

- Screening Behavioral Eligibility (non-DataFax; 2 pgs) – *local-language version*
- Screening Visit LDMS Specimen Tracking Sheet

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MTN-020 ASPIRE (192) DEM-1 (001)

Participant ID ☐☐☐ – ☐☐☐☐☐ – ☐ (Site Number – Participant Number – Chk)

Visit Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy)

Demographics

1. Date of birth ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy) → *If unknown, record age:* ☐☐ *years*

2. Is the participant currently married? ☐ *yes* ☐ *no*

3. Highest level of education
   - ☐ no schooling
   - ☐ primary school, not complete
   - ☐ primary school, complete
   - ☐ secondary school, not complete
   - ☐ secondary school, complete
   - ☐ attended college or university

4. Ethnic group or tribe ☐☐ *ethnic tribe code* *If other, specify:* _____

5. Number of alcohol drinks per week ☐☐ *# of drinks* OR ☐ *none*

6. Number of cigarettes per day ☐☐ *# of cigarettes* OR ☐ *none*

7. Does the participant own a mobile phone? ☐ *yes* ☐ *no* → *If no, go to item 8.*

   7a. Does she have her phone with her? ☐ *yes – phone present* ☐ *no – phone not present*

8. How long did it take the participant to travel from home to the clinic today? ☐ *less than 30 minutes* ☐ *30–60 minutes* ☐ *1–2 hours* ☐ *greater than 2 hours*

9. Does the participant earn an income of her own? ☐ *yes* ☐ *no* → *If no, end of form.*

   9a. How does she earn her income? ☐ *formal employment* ☐ *self-employment* ☐ *other*

Comments: _____

☐ ☐ ☐ ☒ 26-APR-12

N:\hivnet\forms\MTN_020\forms\m020_DEM.fm

0 1 English

_____ Staff Initials / Date

Demographics (DEM-1)

Purpose:	This form is used to collect participants' demographic and socioeconomic information.
General Information/ Instructions:	This form is faxed to SCHARP DataFax only if the participant enrolls in the study. This form is completed at the Screening 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.
Item 3:	If the participant attended or completed a post-secondary diploma or certificate program, mark the "attended college or university" box.
Item 4:	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 identifies as "other," record, "99" and the participant's response.

MALAWI	SOUTH AFRICA	UGANDA	ZAMBIA	ZIMBABWE
01 - Chewa	07 - Zulu	11 - Black	12 - Bemba	16 - Shona
02 - Lomwe	08 - Xhosa	06 - White	13 - Chewa	17 - Ndebele
03 - Yao	09 - Indian	99 - Other	14 - Tonga	05 - Other African tribe
04 - Tumbuka	10 - Colored		15 - Lozi	06 - White
05 - Other African tribe	05 - Other African tribe		05 - Other African tribe	99 - Other
06 - White	06 - White		06 - White	
99 - Other	99 - Other		99 - Other	

Item 5:	Record the number of alcohol drinks the participant reports drinking, on average, per week. Mark the "none" box if the participant does not drink alcohol or has less than one drink per week.
Item 6:	Record the number of cigarettes the participant reports smoking, on average, per day. Mark the "none" box if the participant does not smoke cigarettes or smokes less than one cigarette per day.
Item 7a:	Mark the "yes" box if the phone is seen by the interviewer.
Item 8:	If the participant did not travel from home for this visit, ask her to estimate the travel time it will take her to get to the clinic.

MTN-020 ASPIRE (192) SPE-1 (038)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Exam Date ___ ___ ___
dd MMM yy

Screening Pelvic Exam

1. Pelvic exam assessment: ☐ *abnormal findings* ☐ *no abnormal findings* → *If no abnormal findings, go to item 2.*

1a. Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ vulvar edema	☐ vaginal edema	☐ cervical edema and/or friability	☐ odor (vaginal)
☐ vulvar erythema	☐ vaginal erythema	☐ cervical erythema	☐ condyloma, specify location: _____
☐ vulvar rash	☐ vaginal masses (polyps, myomas, possible malignancy)	☐ cervical masses (polyps, myomas, possible malignancy)	☐ adnexal masses (based on bimanual exam; not pregnancy or infection-related)
☐ vulvar tenderness	☐ vaginal abrasions or lacerations	☐ cervical motion tenderness	☐ uterine masses (based on bimanual exam)
☐ Bartholin's or Skene's gland abnormality	☐ vaginal tenderness	☐ cervical discharge	☐ uterine tenderness
Vulvar lesions	Abnormal vaginal discharge	Cervical lesions	☐ adnexal tenderness
☐ ulcer	☐ slight	☐ ulcer	☐ observed blood or bleeding; describe: _____
☐ blister	☐ moderate	☐ blister	
☐ pustule	☐ pooling	☐ pustule	
☐ peeling	Vaginal lesions	☐ peeling	
☐ ecchymosis	☐ ulcer	☐ ecchymosis	
	☐ blister		
	☐ pustule		
	☐ peeling		
	☐ ecchymosis		

☐ 1b. Other abnormal findings, specify (include anatomical location): _____

Record all abnormal findings on Pre-existing Conditions form.

2. Cervical ectopy: ☐ *0%* ☐ *1–25%* ☐ *26–50%* ☐ *51–75%* ☐ *76–100%*

Screening Pelvic Exam (SPE-1)	
Purpose:	This form is used to provide data on the participant's baseline pelvic exam assessment (the pelvic exam performed closest to and prior to the date of enrollment).
General Information/ Instructions:	Complete this form at the participant's Screening Visit pelvic exam. Transcribe information from the Pelvic Exam Diagrams (non-DataFax) source form onto this form for submission to DataFax. Do not fax the form to SCHARP DataFax until the participant has enrolled in the study. If a participant has a second pelvic exam prior to or on the day of Enrollment: Document the repeat screening pelvic exam on a new Pelvic Exam Diagram (non-DataFax) form and a new Screening Pelvic Exam form. If the participant enrolls, only fax the Screening Pelvic Exam form completed for the repeat exam (the exam done closest to enrollment) to SCHARP DataFax. Keep all Pelvic Exam Diagrams and Screening Pelvic Exam forms completed during screening in the participant's study file.
Item-specific Instructions:	
Item 1:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding on the line provided, including anatomical location. Refer to the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)* for more details regarding severity grading information on the abnormal findings listed. Record all abnormal findings onto the Pre-existing Conditions form. In general, use the same text on both forms to describe the abnormal finding (this does not apply to observances of blood or bleeding). Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for baseline documentation purposes. Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the FGGT. Refer to Study-specific Procedures (SSP) manual section 10.6 for more information/ guidance as needed.

MTN-020 ASPIRE (192) SPX-1 (035)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Visit Date ___ ___ ___
dd MMM yy

Screening Visit Physical Exam

VITAL SIGNS

1. Weight ___ *kg*
2. Body Temp ___ . ___ °C
3. BP ___ / ___ *mmHg*
4. Pulse ___ *beats per minute*
5. Respirations ___ *breaths per minute*
6. Height ___ *cm*

FINDINGS

		not done	*normal*	*abnormal*	*Notes:*
7.	General appearance	☐	☐	☐	
8.	Abdomen/ Gastrointestinal	☐	☐	☐	
9.	Neck	☐	☐	☐	
10.	Lymph Nodes	☐	☐	☐	
11.	Heart/ Cardiovascular	☐	☐	☐	
12.	Lungs/ Respiratory	☐	☐	☐	
13.	Extremities	☐	☐	☐	
14.	Neurological	☐	☐	☐	
15.	Skin	☐	☐	☐	
16.	Eyes	☐	☐	☐	
17.	Ears, Nose, Throat	☐	☐	☐	
18.	Other	☐	☐	☐	

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

Screening Visit Physical Exam (SPX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at the Screening Visit. This form is faxed to SCHARP only if the participant enrolls in the study.
General Information/ Instructions:	Complete this form at the Screening Visit. If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions DataFax form.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 7–17:	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 18:	If abnormal, specify the body system being referenced and describe the findings on the Notes line.

MTN-020 ASPIRE (192) SMH-1 (051)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Visit Date ___ ___ ___
dd MMM yy

Screening Menstrual History

1. Age of first menses (menarche) ___ *years*

2. Usual menstrual cycle *regular* ☐ *irregular* ☐ *amenorrheic for past 6 months* ☐ → *Specify:* _____

3. Usual number of days between menses (1st day to 1st day) *minimum* ___ *# of days* TO *maximum* ___ *# of days*

4. Usual number of bleeding days (record range) *minimum* ___ *# of days* TO *maximum* ___ *# of days*

5. First day of last menstrual period ___ *dd* ___ *MMM* ___ *yy*

6. Last day of last menstrual period ___ *dd* ___ *MMM* ___ *yy* OR *ongoing* ☐

7. Usual type of menstrual flow (at heaviest day of menses) *light* ☐ *moderate* ☐ *heavy* ☐

8. Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.

_____
_____
_____
_____
_____
_____
_____
_____

Record usual menstrual symptoms and any irregular bleeding on the Pre-existing Conditions form.

Screening Menstrual History (SMH-1)	
Purpose:	This form is used to document information on the participant's menstrual history at the Screening Visit. This form is faxed to SCHARP only if the participant enrolls in the study.
Item-specific Instructions:	
Item 3:	Record the usual number of days that the participant experiences between menses starting on the first day of her menstrual period up to and including the day before the first day of her next menstrual period.
Item 4:	Record the range (minimum and maximum) of the usual number of bleeding days of the participant's menses. For example, if a participant reports that she has experienced menses that have lasted for a minimum of 3 days and a maximum of 6 days, record "03" for minimum of days and "06" for maximum number of days.
Item 5:	Record the first day of the participant's most recent menstrual period.
Item 7:	This item is based on how the participant describes her heaviest flow day during menses.
Item 8:	During follow-up, occurrences of genital bleeding will be compared to the participant's baseline bleeding pattern (as documented on this form) in order to determine if the episode requires reporting as an AE. With this mind, use this space to describe as best possible the participant's usual genital bleeding pattern. Include details such as number of sanitary pads typically used, any spotting that is experienced, and any additional details on amount/heaviness of flow. Update with additional details as needed at the Enrollment Visit.

MTN-020 ASPIRE (192) SLR-1 (040)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Initial Specimen Collection Date ___ ___ ___
dd MMM yy

Screening Laboratory Results

1. Hemogram	Alternate Collection Date dd ___ MMM ___ yy ___	
1a. Hemoglobin	___.___ g/dL	Severity Grade (if applicable) ___ *Note: Grade 2 or higher is exclusionary.*
1b. Hematocrit	___.___ %	
1c. MCV	___.___ fL	
1d. Platelets	___.___ $x10^3/mm^3$	Severity Grade (if applicable) ___ *Note: Grade 1 or higher is exclusionary.*
1e. WBC	___.___ $x10^3/mm^3$	Severity Grade (if applicable) ___
Differential	Absolute Count	
1f. Neutrophils	___ $cells/mm^3$	Severity Grade (if applicable) ___
1g. Lymphocytes	___ $cells/mm^3$	Severity Grade (if applicable) ___
1h. Monocytes	___ $cells/mm^3$	
1i. Eosinophils	___ $cells/mm^3$	
1j. Basophils	___ $cells/mm^3$	
2. Chemistries	Alternate Collection Date dd ___ MMM ___ yy ___	
2a. AST (SGOT)	___ U/L	Severity Grade (if applicable) ___ *Note: Grade 1 or higher is exclusionary.*
2b. ALT (SGPT)	___ U/L	Severity Grade (if applicable) ___ *Note: Grade 1 or higher is exclusionary.*
2c. Creatinine	___.___ mg/dL OR ___.___ µmol/L	Severity Grade (if applicable) ___ *Note: Grade 2 or higher is exclusionary.*

Screening Laboratory Results (SLR-1)

Purpose:

This form is used to provide data on the participant's baseline laboratory test results (the results obtained closest to and before the date of enrollment).

General Information/ Instructions:

Use this form to report the hematology, differential, and liver and renal function test results obtained from specimens collected at the Screening Visit as they become available. Do not fax the form to SCHARP DataFax until all results are available and the participant has enrolled in the study.

- Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
- Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date.

If a participant has any laboratory results reported on this form repeated (re-drawn) between the Screening and Enrollment Visit:

If any or all of the labs listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated lab results on a new SLR-1 form, and only fax this SLR-1 form to SCHARP (the form completed closest to the time of enrollment). SCHARP can only receive one SLR-1 form per enrolled participant.

- Example 1: Participant has Screening Visit on 22-May-12 and has a grade 2 hemoglobin and grade 2 ALT. All labs are re-drawn on 27-May-12. All results from 27-May-12 are normal (below grade 1). SCHARP will require an SLR-1 with Initial Specimen Collection Date of 27-May-12 (no Alternate Collection Date should be listed). If enrolled, only fax the SLR-1 dated 27-May-12 to SCHARP DataFax. If a SLR-1 was completed for the 22-May-12 results, keep this form in the participant's file but do not fax to SCHARP DataFax.
- Example 2: A participant has Screening Visit on 22-May-12 and all labs are normal except for ALT, which is grade 2. On 27-May-12, a re-draw is performed for ALT, AST, and creatinine only. These results come back normal. SCHARP will require an SLR-1 with the Initial Collection Date of 22-May-12, and results from this day will be recorded for items 1a–1j. For item 2, record an Alternate Collection Date of 27-May-12 and the results from this day in items 2a–2c. If a SLR-1 was completed for the 22-May-12 results (all results from this day), keep this form in the participant's file but do not fax to SCHARP DataFax.

Results Reporting:

- Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-020 Management Team. Note that the following units are equivalent:

  IU/L = U/L I/l x 100 = % 10^9/L = 10^3/mm^3 = 10^3/μL

  For creatinine, only record the result in the units listed on the source document.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
  - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.

Severity Grade:

- If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the result. If value is below Grade 1, leave severity grade box blank.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
  - Treat all missing digits in the lab value as zeros.
  - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- Record any Grade 1 or higher lab values on the Pre-existing Conditions form.

MTN-020 ASPIRE (192) SST-1 (033)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Initial Specimen Collection Date ___ ___ ___
dd MMM yy

Screening STI Test Results

1. Vaginal Wet Prep	Go to item 2. ← Not done/ Not collected ☐	Alternate Collection Date dd ___ MMM ___ yy ___		
☐ 1a. Homogeneous vaginal discharge	Not done	negative ☐	positive ☐	
☐ 1b. pH ___.___ → If > 4.5, mark as positive.	Not done		positive ☐	
☐ 1c. Whiff test	Not done	negative ☐	positive ☐	
☐ 1d. Clue cells ≥ 20%	Not done	negative ☐	positive ☐	
☐ 1e. *Trichomonas vaginalis*	Not done	negative ☐	positive ☐	
☐ 1f. Buds and/or hyphae (yeast)	Not done	negative ☐	positive ☐	
2. Trichomonas Rapid Test	Alternate Collection Date dd ___ MMM ___ yy ___		negative ☐	positive ☐
3. *N. gonorrhoeae*	Alternate Collection Date dd ___ MMM ___ yy ___		negative ☐	positive ☐
4. *C. trachomatis*	Alternate Collection Date dd ___ MMM ___ yy ___		negative ☐	positive ☐

Record STI diagnoses on Pre-existing Conditions form when applicable.

Comments: _____

☐ ☐ ☐ ☒ 19-JUN-12

0 1
English

Staff Initials / Date

Screening STI Test Results (SST-1)	
Purpose:	This form is used to document Vaginal Wet Prep and other STI Test Results performed at the Screening Visit.
General Information/ Instructions:	Complete this form at the Screening Visit, as results become available. • Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required. • Not done/Not collected: Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.
Item-specific Instructions:	
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark the "Not done/Not collected" box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
Item 1a:	Mark the "positive" box if homogeneous vaginal discharge was observed.
Item 1b:	Vaginal fluid pH is required at all semi-annual visits and the PUEV.
Item 1d:	Mark the "positive" box if 20% or more of the cells were clue cells.
Item 1e:	Mark the "positive" box if trichomonads were observed.
Item 1f:	Mark the "positive" box if yeast buds and/or hyphae were observed.

Note: Number pages sequentially (01, 02, 03) for each participant. Page ☐☐

MTN-020 ASPIRE (192) PRE-1 (012)

Participant ID ☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

☐ No pre-existing conditions reported or observed.

Staff Initials/ Date _____ → *End of form. Fax to SCHARP DataFax.*

Pre-existing Conditions

1. Condition	Onset Date *MMM* ☐☐☐ *yy* ☐☐	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

2. Condition	Onset Date *MMM* ☐☐☐ *yy* ☐☐	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

3. Condition	Onset Date *MMM* ☐☐☐ *yy* ☐☐	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

4. Condition	Onset Date *MMM* ☐☐☐ *yy* ☐☐	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

Pre-existing Conditions (PRE-1)	
Purpose:	The Pre-existing Conditions form serves as the "starting point" or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).
General Information/ Instructions:	• At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions occurring prior to Enrollment. • At the Enrollment Visit, review and update as needed. • Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
Condition:	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
Onset Date:	If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required.
Comments:	This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms.
Severity Grade:	For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark the "not gradable" box. Review and update as needed for conditions ongoing at the Enrollment Visit.
Ongoing at Enrollment?	Mark the "yes" box for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form.

Note: Number pages sequentially (001, 002, 003) for each participant. Page

MTN-020 ASPIRE (192) CM-1 (423)

Participant ID – –
Site Number Participant Number Chk

☐ No medications taken at Screening/Enrollment. Staff Initials/Date:

☐ No medications taken throughout study. Staff Initials/Date:

End of form. Fax to SCHARP DataFax.

Concomitant Medications Log

1.

Trade Name | Staff Initials/Log Entry Date

Indication | Taken for a reported AE? ☐ *yes* ☐ *no*

Date Started: *dd* *MMM* *yy* | Date Stopped: *dd* *MMM* *yy* OR ☐ Continuing at end of study | *AE Log page(s):*

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units | Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify:* _____

If contraceptive, was it dispensed at research center? ☐ *yes* ☐ *no*

2.

Trade Name | Staff Initials/Log Entry Date

Indication | Taken for a reported AE? ☐ *yes* ☐ *no*

Date Started: *dd* *MMM* *yy* | Date Stopped: *dd* *MMM* *yy* OR ☐ Continuing at end of study | *AE Log page(s):*

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units | Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify:* _____

If contraceptive, was it dispensed at research center? ☐ *yes* ☐ *no*

Concomitant Medications Log (CM-1)

Purpose:	This form is used to document all medications taken by the participant starting at the Screening Visit. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive medications, intrauterine contraceptive devices, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.
General Information/ Instructions:	When to fax this form: • once the participant has enrolled in the study; • when pages have been updated or additional Log pages have been completed (only fax updated or new pages); • when the participant has completed study participation; and/or • when instructed by SCHARP.
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
No medications taken at Screening/ Enrollment:	Mark this box if no medications were taken by the participant from Screening through the Enrollment Visit. This box should only be marked on Page 01.
No medications taken throughout study:	Mark this box at the Termination/Study Exit Visit if no medications were taken by the participant throughout the entire study.
Trade Name:	Record the trade name of the medication (not the generic name) whenever possible.
Indication:	For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). For recreational drugs, record "recreation."
Start Date:	If the participant is unable to recall the exact date of medication initiation, obtain participant's best estimate. At a minimum, the year is required. For injections, record each injection as a separate entry, with the same date used for start and stop date. For oral contraceptives, record the start date (and stop date) for each pill pack.
Stop Date:	At the participant's Termination/Study Exit Visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.
Frequency:	Below is a list of common frequency abbreviations: **prn**: as needed; **qd**: every day; **tid**: three times daily; **qhs**: at bedtime **once**: one time; **bid**: twice daily; **qid**: four times daily; **other, specify**: alternative dosing schedules
Dose/Units:	If the participant does not know the exact dose or units (for example, "250 mg"), you may record an estimate (such as "1 tablet"). If no information on dose or units is known, draw a single line through the blank response box and initial and date. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).
Route:	Below is a list of common route abbreviations: PO: oral; IV: intravenous; IHL: inhaled; REC: rectal; **other, specify**: alternative routes IM: intramuscular; TOP: topical; VAG: vaginal; SC: subcutaneous
If contraceptive, was it dispensed at research center?	Mark the "yes" box if the medication is a contraceptive and it was dispensed by the study site pharmacy. If a supplier of contraceptive changes, record a new entry rather than updating this item. For example, if at the Screening Visit the participant is taking contraceptive pills dispensed by a local health clinic, then starts receiving oral contraceptives dispensed by the site pharmacy at Month 3, record a new entry for the pills at Month 3 with this item marked "yes" (keep the original "no" response for the pills entry made at the Screening Visit, and add a stop date to this entry as needed).

MTN-020 ASPIRE (192) SSS-1 (049)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Initial Specimen Collection Date ___ ___ ___
dd MMM yy

Screening Specimen Storage

		Alternate Collection Date dd	MMM	yy	stored	not stored	Reason:
1.	Vaginal smear for gram stain				☐	☐ →	
2.	Endocervical swab for biomarkers				☐	☐ →	

→ *Go to item 3.*

2a. Was blood visible on the swab? *yes* ☐ *no* ☐

		Alternate Collection Date dd	MMM	yy
3.	Syphilis Serology			

3a. Syphilis screening test *non-reactive* ☐ *reactive* ☐
→ *If non-reactive, end of form.*

3a1. Syphilis titer **1:** ____

3b. Syphilis confirmatory *negative* ☐ *positive* ☐ *indeterminate* ☐

Comments: _____

☐ ☐ ☐ ☒ 26-APR-12

0 1
English

Staff Initials / Date

Screening Specimen Storage (SSS-1)	
Purpose:	This form is used to document collection and storage of specimens collected during the Screening Visit pelvic exam as well as results of syphilis testing at screening.
General Information/ Instructions:	Complete this form at the Screening Visit. Record test results on this form as they become available. Only fax this form to SCHARP DataFax if the participant enrolls in the study If a repeat screening pelvic exam is performed (between screening and enrollment, or on the day of enrollment), do not collect a second endocervical swab or gram stain specimen during the repeat screening pelvic exam. These specimens should only be collected and stored at the first (Screening Visit) pelvic exam. If the participant does not enroll, these specimens should be destroyed/marked for destruction in LDMS. This form should only be completed once for each participant, even if a repeat screening pelvic exam is performed. • Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. A complete date is required.
Item-specific Instructions:	
Items 1 and 2:	If the specimen is not stored at this visit, mark the "not stored" box and record the reason why on the line provided.
Item 3:	If the syphilis screening test is reactive, items 3a1 and 3b must be completed.
Item 3a1:	Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:16 would be recorded on the form as "1:0016."
Item 3b:	If a result is positive, provide treatment according to WHO guidelines, and report the relevant infection on the Pre-existing Conditions form.

Not a DataFax form. Do not fax to DataFax.

MTN-020 ASPIRE (192)

Pelvic Exam Diagrams

Participant ID ___ – ___ – ___ (Site Number – Participant Number – Chk)

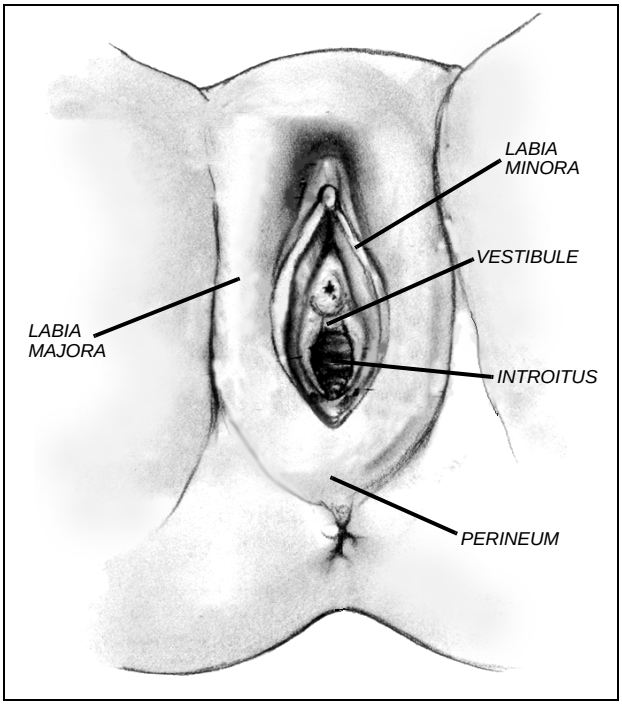
Exam Date ___ ___ ___ (dd MMM yy)

☐ no normal variants or abnormal findings observed

Speculum Type (screening only) *Pederson* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only) *small* ☐ *medium* ☐ *large* ☐

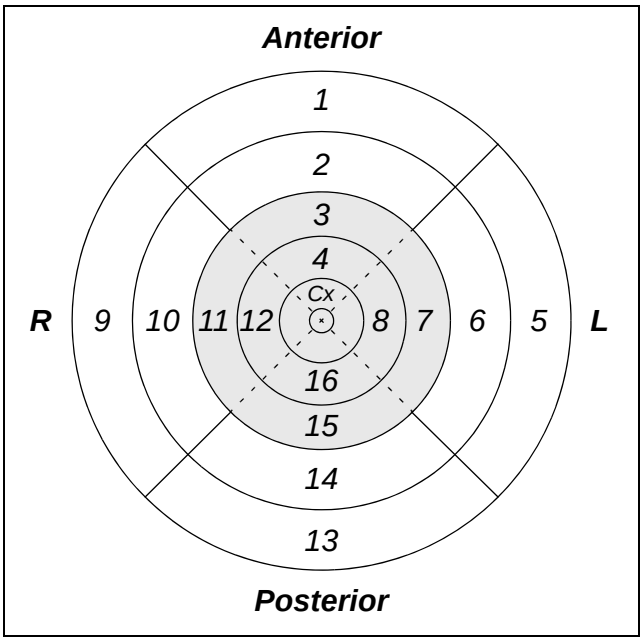
External Genitalia



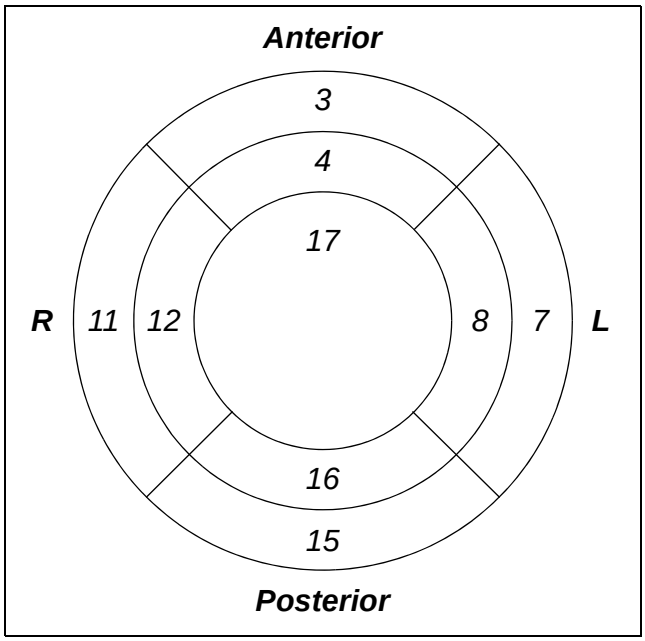
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



☐ ☐ ☐ ☒ 26-APR-12

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0 1 English

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)	
Purpose:	This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).
General Information/ Instructions:	This form is completed at the Screening Visit, each semi-annual visit, at the Product Use End Visit (PUEV), and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes.
Item-specific Instructions:	
Findings:	All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants: • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.
Documenting findings on the cervix:	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).

MTN-020 ASPIRE (192) ECI-1 (023)

Participant ID ___ – ___ – ___
Site Number Participant Number Chk

Form Completion Date ___ ___ ___
dd MMM yy

Eligibility Criteria

1. Does this participant meet all eligibility criteria? ☐ *yes* ☐ *no* → *If no, go to item 2*

1a. Obtain signature _____
Signature of Principal Investigator (or designee) *Date*

1b. Obtain signature _____
Signature of second staff member verifying eligibility *Date*

2. Was the participant enrolled? ☐ *yes* ☐ *no*
→ *If yes, end of form.*

3. Why was the participant not enrolled?

☐ participant did not complete all screening procedures → *End of form.*

☐ eligible but declined enrollment → *End of form.*

☐ not eligible

4. Reason(s) for ineligibility *Mark all that apply.*

☐ 4a. participant < 18 or > 45 years old

☐ 4b. plans for relocation/travel

☐ 4c. participant is pregnant or planning to become pregnant

☐ 4d. participant is breastfeeding

☐ 4e. participant has not had vaginal sex in the last 3 months

☐ 4f. participant has enrolled in another research study in the last 60 days

☐ 4g. participant has participated in VOICE or other HIV prevention trial in the past 12 months

☐ 4h. PEP exposure in the last 6 months

☐ 4i. participant is HIV-positive

☐ 4j. participant declines effective method of contraception

☐ 4k. participant has a grade 2 or higher pelvic exam finding

☐ 4l. participant does not meet laboratory eligibility criteria

☐ 4m. participant does not meet other clinical eligibility criteria

☐ 4n. other reason, including investigator decision. Specify: _____

Comments: _____

Eligibility Criteria (ECI-1)	
Purpose:	This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.
General Information/ Instructions:	Complete this form for each participant screened for this study. Complete and fax this form once it is determined whether the participant will enroll in the study. If not enrolled, this is the only form that is faxed for the participant. If the participant has a second screening attempt, update this form with data from the second screening attempt and refax. Do not complete a new form for the second attempt.
Item-specific Instructions:	
Items 1a and 1b:	Local site Standard Operating Procedures (SOPs) must specify staff members designated to affirm eligibility.
Item 3:	Mark “participant did not complete all screening procedures” when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 28-day screening window.
Item 4:	Mark all reasons for participant ineligibility. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, mark the “other reason, including investigator decision” box and specify ineligibility reason on the line provided.