## Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-003 study visits. The checklists also specify the data collection forms that must be completed at each visit.

### 7.1 Use of Checklists

The visit checklists included in this section are designed to guide site staff in proper study procedures as well as to serve as source documentation of procedures performed at study visits. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to:

- Explain why procedures in addition to those listed on a checklist were performed
- Explain why procedures listed on a checklist were not performed
- Document procedures performed at interim visits
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements)

See Section 3 of this manual for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Enter the participant identification number (PTID) and visit date in the top section of each checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.
- For screening visits, enter the screening attempt number in the top section of the checklist.
- For follow-up visits, enter the visit code in the top section of each checklist.
- Enter your initials only beside the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., "done by {name}" or "done by lab staff."
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

### 7.2 Sequence of Procedures

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with the MTN CORE (FHI), site staff may modify the checklists included in this section to maximize the efficiency of site-specific study operations. Sites may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for screening must be obtained before any screening procedures are performed. Screening procedures are listed in protocol Sections 7.2 and 7.3.
- Informed consent for enrollment must be obtained before any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in protocol Section 7.4. Follow-up procedures are listed in protocol Section 7.5. Note that informed consent for enrollment may be obtained before eligibility criteria are reassessed as part of final screening procedures (protocol section 7.4.1). This will limit venipuncture to a single blood draw during the Enrollment visit for purposes of HIV serology and plasma archive.
- On the day of enrollment, random assignment must take place after administration of the Baseline Behavior Assessment form, Baseline Audio Computer Assisted Self-Interview (ACASI) Questionnaire, collection of blood for plasma archive, and administration of Hepatitis B vaccine, if applicable.
- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists.
- At follow-up visits, behavioral assessment forms and ACASI questionnaires must be administered prior to the delivery of HIV and adherence counseling.

PTID:		Visit Date:
Screeni	ng Attempt:	Visit Code: 1.0
Initials		Procedures
	1. Confirm identity per site SOPs and determine whether a VOICE PTID has	
	previously been assigned to participant.	
	2. Determine screening attempt num	
		uitment source and document per site SOPs.
	$\square$ Second or other attempt $\Rightarrow$ CO	
	3. Check for co-enrollment in other	
	□ NOT enrolled in another study	=
	•	
	$\square$ Enrolled in another study $\Rightarrow$ ST	
		s of legal age to provide informed consent for
	research per site SOPs:	
	☐ Of legal age ⇒ CONTINUE.	OW DI TOTOL D
	$\square$ NOT of legal age $\Rightarrow$ STOP. NO	
	5. Explain, conduct, and document screening informed consent process per site SOPs:	
	-	tten informed consent ⇒ CONTINUE.
	$\square$ NOT willing and able to provide written informed consent $\Rightarrow$ STOP. NOT	
	ELIGIBLE.	
	6. Assign a VOICE PTID (if not done during a previous screening attempt).	
	7. Determine last possible enrollment date for this screening attempt:	
	DD MON YY	
	8. Explain procedures to be performed at today's visit.	
	9. Administer Demographics form.	
	10. Administer Screening Part 1 El	igibility form:
	$\square$ ELIGIBLE thus far $\Rightarrow$ CONTI	- ·
	$\square$ NOT ELIGIBLE $\Rightarrow$ STOP.	
	11. If applicable, refer participant for site medical officer review of tuberculosis status	
	12. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:	
These items	$\square$ NOT pregnant $\Rightarrow$ CONTINUE.	2 2 3
are structured	1 0	
for sites that	☐ Pregnant ⇒ STOP. NOT ELIGIBLE.  13 Perform directick urinalysis for protein, glucose, nitrites and I.E. complete testing.	
perform urine testing	13. Perform dipstick urinalysis for protein, glucose, nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form:	
in-clinic.	-	glucose ⇒ STOP. NOT ELIGIBLE.
Sites that		pstick must be repeated at Screening Part $2 \Rightarrow$
perform esting in the	CONTINUE.	potter must be repeated at bereening I art 2 ->
lab should		reat for UTI per site SOPs only if participant has
modify this item as		chart notes. Participant must complete treatment
needed.		
	and be free of symptoms prior to enrollment ⇒ CONTINUE.  ☐ Otherwise ⇒ CONTINUE.	

PTID:		Visit Date:	
Screening Attempt:		Visit Code: 1.0	
Initials	Procedures  14. Refrigerate remaining urine for gonorrhea and chlamydia SDA.		
	15. Provide and document HIV counseling and testing per site SOPs:  ☐ Provide HIV pre-test counseling		
	☐ Provide HIV/STI risk reduction ☐ Collect blood: ☐ 1 x 6 mL lavender top (EDT) ☐ 1 x 5 mL red top (no additive) ☐ 1 x 10 mL red top (no additive)	A) tube  Volumes shown are approximate. Tailor this item to reflect site-specific	
This item is structured for sites that perform HIV testing in clinic. Sites that perform in-lab testing should modify this	to participant, obtain independed  □ Provide test results and post-test □ If both tests negative ⇒ UN □ If both tests positive ⇒ INF □ If one test positive and one	rform and document two rapid HIV tests per site SOPs. Before disclosing results participant, obtain independent review, verification, and sign-off of both results.  ovide test results and post-test counseling:  If both tests negative $\Rightarrow$ UNINFECTED $\Rightarrow$ ELIGIBLE $\Rightarrow$ CONTINUE.  If both tests positive $\Rightarrow$ INFECTED $\Rightarrow$ STOP. NOT ELIGIBLE.  If one test positive and one test negative $\Rightarrow$ DISCORDANT $\Rightarrow$ PAUSE $\Rightarrow$ WB is required $\Rightarrow$ continue OR defer screening until HIV status is clarified.	
item as needed.	<ul> <li>Provide referrals if needed/requested.</li> <li>Offer HIV counseling and testing for partner(s).</li> </ul>		
	<ul> <li>☐ Transcribe results onto Screening and Enrollment HIV Test Results form.</li> <li>16. Prepare remaining blood for required testing:         <ul> <li>Complete blood count (see protocol Section 7.11)</li> <li>Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>Syphilis serology</li> <li>Hepatitis B surface antigen (HBsAg)</li> <li>Hepatitis B surface antibody (HBsAb)</li> </ul> </li> </ul>		
	17. Measure and document particip Laboratory Results form.	ant weight per site SOPs. Transcribe onto Safety	
	<ul> <li>18. Determine whether participant</li> <li>□ No symptoms ⇒ CONTINUE.</li> <li>□ Symptom(s) present ⇒ evaluate CONTINUE.</li> <li>19. Provide and explain all available.</li> </ul>	e per site SOPs and document in chart notes ⇒	
	20. If RTI/STI is diagnosed, provide partners if indicated; document in a and be free of symptoms prior to en	le treatment and offer testing and/or treatment for chart notes. Participant must complete treatment prollment. CONTINUE.	
	<ul> <li>21. Determine current contraceptive method, review study contraception requirements and provide contraceptive counseling; document per site SOPs.</li> <li>22. [Prescribe/provide/refer for] contraception if indicated per site SOP; document in chart notes.</li> </ul>		

PTID:		Visit Date:
Screening Attempt: Visit Cod		Visit Code: 1.0
Initials		Procedures
	23. Obtain locator information and	
	☐ Adequate locator information =	> CONTINUE.
	□ Inadequate locator information $\Rightarrow$ PAUSE and re-assess:	
	$\square$ Adequate information likely to be available prior to enrollment $\Rightarrow$ CONTINUE.	
	$\square$ Adequate information NOT likely to be available $\Rightarrow$ STOP. NOT ELIGIBLE.	
	24. Provide study informational material: [add site-specific list if desired]	
	25. Provide contact information and instructions to contact the site for additional	
	information and/or counseling if needed before the next visit.	
	26. Schedule next visit.	
	27. Provide reimbursement.	
	28. Ensure chart notes, Screening Consent DataFax form, and all other required visit documentation is completed (hold all DataFax forms until enrollment).	
	29. Review all visit documentation	
	30. Enter participant in co-enrollme	ent database.

# **Between Screening Part 1 and Screening Part 2 Worksheet**

PTID:		Screening Attempt:
1 141 1		
Initials & Date	Procedures	
	1. Review, grade, and assess clinical si	gnificance of Screening Part 1 lab results:
	Complete blood count	
	Liver function tests (AST, ALT)	antinina)
	☐ Renal function tests (phosphate, cr☐ Calculated creatinine clearance rat	
	Syphilis serology	
	☐ Gonorrhea SDA	
	☐ Chlamydia SDA	
	☐ If indicated, HIV WB	
		vailable before Screening Part 2. If results are
	received, review, grade, and assess clin	•
	$\Box$ HBsAg+ and HBsAb- ⇒ not eligib	•
	☐ HBsAg- and HBsAb- ⇒ Hep B su	-
	☐ HBsAg- and HBsAb+ ⇒ not Hep I	report forms (hold forms until enrollment):
	☐ Safety Laboratory Results	report forms (note forms until emornient).
	☐ STI Laboratory Results	
	If indicated:	
	Screening and Enrollment HIV Test Results (if HIV WB was done)	
	4. Assess eligibility based on lab result ☐ Eligible	5.
	☐ Not Eligible ⇒ specify:	
	5. Assess clinical management and refe	erral needs:
	☐ No action needed	
	$\square$ Action needed $\Rightarrow$ specify:	
	6. Complete additional QC/QA review	of Screening Part 1 and subsequent
	documentation per site SOPs.	or serecting rater and subsequent
	7. Perform eligibility review of all Screen	eening Part 1 data per site SOPs:
	☐ Eligible	
	$\square$ Not Eligible $\Rightarrow$ specify:	

PTID:		Visit Date:
Screeni	ing Attempt:	Visit Code: 2.0
Initials		Procedures
	Confirm participant identity and PTID per site SOPs.	
	2. Check for co-enrollment in other s	tudies per site SOPs:
	□ NOT enrolled in another study ⇒	-
	$\square$ Enrolled in another study $\Rightarrow$ STC	
	3. Review previous visit documentation	
	3. Review previous visit documentati	ion.
	A Verify current screening attempt n	umber and confirm last possible enrollment date
	for this attempt:	umber and commit last possible enforment date
	ioi tins attempt.	
	DD	MON YY
		ning test results. Provide post-test counseling if
	HIV WB was performed at Screening	
	6. Explain current eligibility status and procedures to be performed at today's visit:	
	$\square$ ELIGIBLE thus far $\Rightarrow$ CONTINUE.	
	□ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt	
	⇒ CONTINUE.	
	□ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening	
	attempt ⇒ STOP. Provide clinical management as needed. Document in chart	
	notes.	
	7. Review/update locator information and re-assess adequacy per site SOPs:	
	$\square$ Adequate locator information $\Rightarrow$ CONTINUE.	
	$\square$ Inadequate locator information $\Rightarrow$ PAUSE and re-assess:	
	$\square$ Adequate information likely to be available prior to enrollment $\Rightarrow$ CONTINUE.	
	$\square$ Adequate information NOT likely to be available $\Rightarrow$ STOP. NOT ELIGIBLE.	
	8. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:	
	NOT pregnant ⇒ CONTINUE.	
This item is	☐ Pregnant ⇒ STOP. NOT ELIGIBLE.	
structured for sites	9. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis	
that	<u> </u>	urine for possible additional testing (e.g., SDA).
perform		Part 1 dipstick urinalysis results and determine if
urine testing	participant has current urinary sympt	- ·
in-clinic.	11. If 1+ for protein or glucose was identified at Screening Part 1, perform dipstick	
Sites that perform in-		te testing logs; transcribe results onto Safety
lab testing	Laboratory Results form:	5 · 6·, · · · · · · · · · · · · · · · · ·
should	☐ If 2+ or greater for protein OR glu	acose ⇒ STOP. NOT ELIGIBLE.
modify this item as		+ for protein at Screening Part $1 \Rightarrow$ STOP. NOT
needed.	ELIGIBLE.	r
		1+ for glucose at Screening Part 1 $\Rightarrow$ STOP. NOT
	ELIGIBLE.	
	$\square$ Otherwise $\Rightarrow$ ELIGIBLE $\Rightarrow$ CON	ITINUE.

PTID:		Visit Date:
Screening Attempt:		Visit Code: 2.0
Initials		Procedures
	<ul> <li>12. If 1+ proteinuria detected at today's visit, or if participant has urinary symptoms, perform dipstick urinalysis for nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form:</li> <li>☐ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE.</li> <li>☐ Otherwise ⇒ CONTINUE.</li> </ul>	
		nstrual history with documentation of current
	medications and herbal/traditional pr	eparations; document per site SOPs. surement of height and weight; document per site
	SOPs.	surement of neight and weight, document per site
		am per Screening Pelvic Exam Checklist.
	16. If indicated, collect and prepare b	blood for syphilis serology.
Items 16-20		
could be done while awaiting pelvic lab	17. If indicated, collect and prepare blood for other testing needed to determine eligibility (specify):	
test results.	18. If indicated, prepare urine for gonorrhea and chlamydia SDA.	
	19. Verify current contraceptive method, review study contraception requirements,	
	and provide contraceptive counseling; document per site SOPs.	
	20. [Prescribe/provide] contraception if indicated per site SOPs. Update baseline	
	reproductive history documentation and Contraceptives Log form if applicable.  21. Provide and explain available exam findings and lab test results.	
	21. 110 rae and explain available exc	and interings and two test results.
	partners if applicable; document per and be free of symptoms prior to enro	
	24. Administer Screening Part 2/Enro	ollment Behavioral Eligibility form.
	<ul> <li>⇒ PAUSE ⇒ perform and docur Enrollment Visit when participan</li> <li>□ NOT ELIGIBLE and NOT likely attempt ⇒ STOP. Provide clinica notes.</li> </ul>	et eligibility criteria within this screening attempt ment all clinically indicated procedures. Schedule t is likely to be eligible. to meet eligibility criteria within this screening al management as needed. Document in chart
		counseling and condoms. Offer HIV counseling
	and testing for partner(s).	

PTID: Screening Attempt:		Visit Date: Visit Code: 2.0
Initials		Procedures
	27. Provide study informational material: [add site-specific list if desired]	
	28. Provide contact information and instructions to contact the site for information	
	and/or counseling if needed before the next visit.	
	29. Schedule next visit.	
	30. Provide reimbursement.	
	31. Ensure chart notes and all other required visit documentation is completed (hold	
	all DataFax forms until enrollment)	
	32. Review all visit documentation.	
	33. If applicable, update participant record in co-enrollment database.	

PTID:		Exam Date:
Screening Attempt:		Visit Code:
Initials	Procedures	
IIIIIIais	Review relevant documentation from	
	Prepare exam equipment and specimen collection supplies; label as needed.	
	Explain exam procedures to partici	pant and answer any questions.
	Position and drape participant com	fortably.
	Palpate inguinal lymph nodes; identify all normal and abnormal findings.	
	Inspect external genitalia; identify	all normal and abnormal findings.
	Insert speculum, using warm water	as lubricant if needed.
	Inspect cervix and vagina; identify	all normal and abnormal findings.
	If clinically indicated, collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.  Collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.	
	Collect vaginal fluid (1 swab) from lateral vaginal wall for Gram stain at MTN NL. Roll swab across two labeled slides and air dry.	
	If clinically indicated, collect vaginal fluid (1 swab) from lateral vaginal wall for	
	KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube.  Collect vaginal fluid (1 dacron swab) from posterior fornix for biomarker analyses at	
	MTN NL. After tip of swab is saturated, place in labeled cryovial (PBS) and cap vial.  Collect vaginal fluid (1 swab) from lateral vaginal wall for pH assessment. Swab fluid onto pH strip. Record pH on Vaginal Test Results form.  Collect endocervical cells for biomarker analyses at MTN NL:	
	• Remove cervical mucus with large cotton swab to expose cell layer (discard swab).	
	• Insert dacron swab ~1 cm into endocervical canal and rotate two full turns.	
	<ul> <li>Withdraw swab, place in labeled cryovial (PBS), and cap vial.</li> <li>Collect ecto- and endocervical cells for Pap smear per site SOPs.</li> </ul>	
	⇒ NOT required if documented normal Pap within 12 months prior to enrollment	
	Remove speculum and perform bimanual exam.	
	Document exam per site SOPs:	
	• Record all exam findings on Pe	· · · · · · · · · · · · · · · · · · ·
	1	s on Screening and Enrollment Pelvic Exam form.
	<ul> <li>Record all pelvic specimen test results on Vaginal Test Results form.</li> <li>Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet and Specimen Storage/PK form.</li> </ul>	

# Between Screening Part 2 and Enrollment Worksheet Page 1 of 2

	PTID:		Screening Attempt:
Initials & Date  Procedures  1. If applicable per site SOPs, verify participant's locator informat adequacy based on verifiable information; document per site SOPs 2. Based on the Screening Part 2/Enrollment Behavioral Eligibility associated documentation, review participant eligibility re: locator pregnancy outcome, breastfeeding, and contraception:  □ Eligible □ Not Eligible ⇒ specify:		Pr	ocedures
		lment Behavioral Eligibility form, and other cipant eligibility re: locator information, last	
		2. If Hapatitic P toot results were not as	vailable before Screening Part 2, review, grade,
		and assess clinical significance and clin  ☐ HBsAg+ and HBsAb- ⇒ not eligib  ☐ HBsAg- and HBsAb- ⇒ Hep B sus ☐ HBsAg- and HBsAb+ ⇒ not Hep E	nical status: le for study ⇒ counsel and refer sceptible ⇒ offer vaccine if enroll
Items related to Pap smears may be deleted at sites not doing these tests.		3. Review, grade, and assess the clinical	al significance of Pap test result (either result Part 2 or documented Pap within 12 months
		4. Review, grade, and assess the clinical indicated lab tests performed at Screen.  ☐ No clinically indicated lab tests performed.  ☐ Clinically indicated lab tests performed.	rformed
		<ul> <li>5. Complete laboratory test result case</li> <li>Pap Test Result</li> <li>If indicated:</li> <li>Safety Laboratory Results</li> <li>STI Laboratory Results</li> </ul>	report forms (hold forms until enrollment):
		<ul> <li>6. Complete Screening Part 2 Medical all available clinical and laboratory find ☐ Eligible</li> <li>☐ Not Eligible ⇒ specify:</li> </ul>	Eligibility form and assess eligibility based on dings and results:

# Between Screening Part 2 and Enrollment Worksheet Page 2 of 2

PTID:	Screening Attempt:
Initials & Date	Procedures
	7. Assess clinical management and referral needs:
	□ No action needed
	$\square$ Action needed $\Rightarrow$ specify:
	8. Complete additional QC/QA review of Screening Part 2 and subsequent
	documentation per site SOPs.
	9. Perform eligibility review of all Screening Part 1 and Screening Part 2 data per site
	SOPs:
	☐ Eligible
	□ Not Eligible ⇒ specify:

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PTID:		Visit Date:
Screeni	ng Attempt:	Visit Code: 3.0
Initials		Procedures
	1. Confirm participant identity and PTID per site SOPs	
	<ul> <li>2. Check for co-enrollment in other studies per site SOPs:</li> <li>□ NOT enrolled in another study ⇒ CONTINUE.</li> <li>□ Enrolled in another study ⇒ STOP. NOT ELIGIBLE.</li> <li>3. Review previous visit documentation.</li> </ul>	
	4. Verify current screening attempt number and confirm last possible enrollment date for this attempt:	
	5. Provide and explain all prior screening test results.	
	<ul> <li>6. Explain current eligibility status and procedures to be performed at today's visit:</li> <li>□ ELIGIBLE thus far ⇒ CONTINUE.</li> <li>□ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.</li> <li>□ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.</li> </ul>	
	7. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:  ☐ NOT pregnant ⇒ CONTINUE. ☐ Pregnant ⇒ STOP. NOT ELIGIBLE.	
These items are structured  8. Retain aliquot of urine used for pregnancy testing for possible districtured (see #9-11). Refrigerate remaining urine for possible additional terms.		regnancy testing for possible dipstick urinalysis rine for possible additional testing (e.g., SDA).
for sites that perform	9. Review participant's Screening Part 1 and Screening Part 2 dipstick urinalysis results and determine if participant has current urinary symptoms.	
urine testing in-clinic. Sites that perform in- lab testing should modify these items as needed.	have been done at Screening Part 2. or if 1+ for protein or glucose was not dipstick urinalysis for these analytes Safety Laboratory Results form: ☐ If 2+ or greater for protein OR gl☐ If 1+ for protein at this visit and Screening Part 2 ⇒ STOP. NOT☐ If 1+ for glucose at this visit and	1+ for protein at either Screening Part 1 OR ELIGIBLE. 1+ for glucose at either Screening Part 1 OR
	Screening Part 2 $\Rightarrow$ STOP. NOT $\Box$ Otherwise $\Rightarrow$ ELIGIBLE $\Rightarrow$ COI	ELIGIBLE.

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PTID:		Visit Date:
Screeni	ng Attempt:	Visit Code: 3.0
Initials		Procedures
	<ul> <li>11. If 1+ proteinuria detected at today's visit, or if participant has urinary symptoms, perform dipstick urinalysis for nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form:</li> <li>☐ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ PAUSE. NOT ELIGIBLE. ⇒ Schedule another Enrollment Visit when participant is likely to be eligible.</li> <li>☐ Otherwise ⇒ CONTINUE.</li> </ul>	
	12. Provide and document HIV cour	seling and testing per site SOPs:
	☐ Provide HIV pre-test counseling ☐ Provide HIV/STI risk reduction of	
	☐ Collect 4 mL blood in lavender t	op (EDTA) tube  4 mL is approximate.  Tailor to reflect site-specific volume.
This item is structured for sites that perform HIV testing in clinic. Sites that perform in-lab testing should modify this item as needed.	to participant, obtain independen  Provide test results and post-test  If both tests negative \$\Rightarrow\$ UNIN  If both tests positive \$\Rightarrow\$ INFE  If one test positive and one test was required \$\Rightarrow\$ defer further  Provide referrals if needed/reque  Offer HIV counseling and testing  Transcribe results onto Screening  13. Review/update locator information  Adequate locator information \$\Rightarrow\$ Inadequate locator information \$\Rightarrow\$  Inadequate locator information \$\Rightarrow\$  Hadequate locator information \$\Rightarrow\$  Inadequate locator information \$\Rightarrow\$  Medications, and current contraceptices.	I HIV tests per site SOPs. Before disclosing results at review, verification, and sign-off of both results. counseling:  NFECTED ⇒ ELIGIBLE ⇒ CONTINUE.  CTED ⇒ STOP. NOT ELIGIBLE.  st negative ⇒ DISCORDANT ⇒ PAUSE ⇒ er screening until HIV status is clarified.  sted.  g for partner(s). g and Enrollment HIV Test Results form. on and re-assess adequacy per site SOPs:  CONTINUE.
	exam and associated lab tests:  ☐ No exclusionary findings identifie  ☐ Exclusionary finding(s) identifie  attempt ⇒ PAUSE. NOT ELIGI  indicated procedures. Schedule at to be eligible.  ☐ Exclusionary finding(s) identifie	d but likely to resolve within this screening BLE. ⇒ Perform and document all clinically another Enrollment Visit when participant is likely d and NOT likely to resolve within this screening COP. Provide clinical management as needed.

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PTID:		Visit Date:	
Screen	ing Attempt:	Visit Code: 3.0	
Initials		Procedures	
illitiais		cated treatment; document per site SOPs and record on form. If indicated, offer STI testing and/or treatment for	-
		n requirements and provide contraceptive counseling;	
	19. [Prescribe/provide] contract	ception if indicated per site SOPs. Update baseline ation and Contraceptives Log form if applicable.	
	20. Administer Screening Part ☐ ELIGIBLE ⇒ CONTINUE ☐ NOT ELIGIBLE ⇒ STOP		
	counseling as needed; docume		
	form, and determine eligibility  ☐ ELIGIBLE ⇒ CONTINUE ☐ NOT ELIGIBLE but likely ⇒ PAUSE ⇒ perform and another Enrollment Visit w ☐ NOT ELIGIBLE and NOT	mentation, complete Enrollment Medical Eligibility:  E ⇒ proceed to eligibility verification per site SOPs.  to meet eligibility criteria within this screening attempt document all clinically indicated procedures. Schedule then participant is likely to be eligible.  likely to meet eligibility criteria within this screening clinical management as needed. Document in chart	
m refers to cation of and should pleted by a ember other		y per site SOPs: ∃ ⇒ proceed to enrollment informed consent process. Provide clinical management as needed. Document in	
person who nes eligibility revious item.	SOPs:    Willing and able to provide	ament enrollment informed consent process per site written informed consent $\Rightarrow$ CONTINUE. To ovide written informed consent $\Rightarrow$ STOP. NOT	
	this is done, it must clearly be essigning the Enrollment ICF and this	nay be administered early in the visit to allow for one blood draw. If xplained to the participant that eliqibility will be determined after is does not quarantee enrollment into the study. Sites should only ollment visit if they intend to move to one blood draw at enrollment.	
	site SOPs.	ment specimen storage informed consent process per	
	26. Administer Baseline Behav		
	27. Administer Enrollment AC	-	
	lab for plasma archive. Note:	ender top (EDTA) tube; refrigerate pending delivery to  This blood collection may be collected earlier in the  dministered earlier in the visit. See note in item #24.	Formatted: Font: Italic

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PTID:		Visit Date:
Screeni	ng Attempt:	Visit Code: 3.0
Initials		Procedures
	☐ Participant accepted; vaccine warecord on Concomitant Medication☐ Participant refused; refusal was of	locumented.
	31. Verify documentation of enrollment informed consent and assign next sequential Clinic Randomization Envelope to participant per site SOPs. <b>PARTICIPANT IS NOW ENROLLED IN THE STUDY.</b>	
	32. Open the assigned envelope and confirm that the envelope number printed on the prescription contained in the envelope corresponds with the number on the outside of the envelope. Inform participant of her assignment (gel or tablets).	
	33. Complete prescription.	,
	34. Give completed white original prescription to participant to bring to pharmacy to obtain study product. Retain envelope and yellow copy of prescription in participant's study notebook.	
	35. Verify participant received study product. Review product use instructions with participant in detail, using visual aids as needed.	
	36. Ask participant if she has any questions about the product use instructions. If so, address each question.	
	37. Ask participant if she is ready to ☐ If yes, proceed. ☐ If no, note and address all questions.	[insert her gel] / [take her tablets] now. ons and concerns, then proceed.
	standing by in case participant no wrapper and applicator in the bin    For participants assigned to table	provide a private space for gel insertion, while seds assistance; remind participant to discard the provided.  ts, a private space is not required; remind eals and cotton wool in the bin provided.

Enrollment Page 5 of 6

PTID:		Visit Date:
Screening Attempt:		Visit Code: 3.0
Initials		Procedures
	<ul> <li>Was she able to [insert gel] / [to</li> <li>Did she have any difficulties?</li> <li>Does she have any questions about the proof of the proo</li></ul>	formation or instructions?
	40. Provide adherence counseling pedocument per site SOPs.	r Enrollment Adherence Counseling checklist;
	<ul> <li>41. Schedule next visit and remind participant to:</li> <li>Record menstrual bleeding days on appointment card</li> <li>Record date and time of last product use on appointment card</li> <li>Bring appointment card to next visit</li> <li>Bring all unused study product to next visit</li> <li>Bring any other medication she is taking to next visit</li> <li>42. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.</li> </ul>	
	43. Provide reimbursement.	
		ent form, Pre-Existing Conditions form, Baseline required visit documentation is completed.
	46. Update participant entries in co-e	enrollment database.

Enrollment Page 6 of 6

PTID:		Visit Date:
Screeni	ng Attempt:	Visit Code: 3.0
Initials		Procedures
	47. Fax all required DataFax forms t	o SCHARP DataFax:
	☐ Screening Consent	
	<ul><li>Demographics</li></ul>	
		est Results (completed at Screening Part 1)
		est Results (completed at Enrollment)
	☐ Safety Laboratory Results	
	☐ STI Laboratory Results	
	☐ Screening and Enrollment Pelvic Exam	
	☐ Vaginal Test Results	
	Pap Test Results	
	☐ Specimen Storage/PK (completed at Screening Part 2)	
	☐ Specimen Storage/PK (completed at Enrollment)	
	☐ Enrollment	
	☐ Pre-Existing Conditions	
	Concomitant Medications Log	
	☐ Contraceptives Log	
	<ul><li>Baseline Family Planning</li></ul>	
	☐ Baseline Behavior Assessment	
	48. Back-up ACASI questionnaire de	ata.
	49. Upload ACASI questionnaire da	ta to SCHARP.

Month 1 Visit Page 1 of 4

PTID:	Visit Date:	Visit Code: 4.0		
Initials	Procedures			
	1. Confirm participant identity and PTID per site SOPs.			
	<ul> <li>2. Check for co-enrollment in other (non-approved) studies per site SOPs:</li> <li>□ NOT enrolled in another study.</li> <li>□ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT.</li> </ul>			
	Schedule participant to return when a response from PSRT is expected.  3. Instruct participant to return unused study product to pharmacy.			
	4. Review previous visit documentation.			
	5. Review elements of informed consent as needed.			
	6. Explain procedures to be performed at today's visit.			
	7. Review/update locator information.			
	8. Administer Monthly Product Adherence and Behavior Assessment form.			
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:  ☐ NOT pregnant.  ☐ Pregnant, pregnancy first identified at a previous visit:  ☐ Continue to HOLD study product (complete #25 accordingly).  ☐ If applicable, refer to MTN-016; document in chart notes.  ☐ Pregnant, pregnancy newly identified at today's visit:  ☐ HOLD study product (complete #25 accordingly). If applicable, arrange to collect product not returned today within 5 working days.  ☐ Initiate Pregnancy Management Worksheet  ☐ Complete Pregnancy Report and History form.  10. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #15).			
	Refrigerate remaining urine for possible additional testing 11. Administer Monthly Symptoms form.	mg (e.g., <i>e.g.</i> 17).		
	12. Collect interval medical and menstrual history with medications and herbal/traditional preparations; document per sit.	ent per site SOPs.		
	13. Provide contraceptive counseling; document per sit	e surs.		
	14. [Prescribe/provide] contraception if indicated; upda documentation and Contraceptives Log form if applical Family Planning form.	•		

Month 1 Visit Page 2 of 4

PTID:	Visit Date:		Visit Code:	4.0
Initials	Procedures			
	<ul> <li>15. Perform dipstick urinalysis:</li> <li>☐ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only.</li> <li>☐ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE.</li> <li>⇒ If 1+ or greater for protein, nitrites and LE also should be tested.</li> <li>⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7.</li> <li>⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form.</li> <li>Complete testing logs and transcribe results onto Safety Laboratory Results form.</li> </ul>			
	16. Perform physical exam including weight measurement; document per site SOPs.			
	17. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.			
	18. Determine if any clinically indicated urine or blood testing is required.  ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #23-24).			
	19. Provide and explain all available findings and results.			
	20. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.			
	21. If indicated, administer Hepatitis B vaccine; document per site SOPs.			
	22. If required based on all available information, complete AE Log form(s).			
	23. Provide and document HIV counseling and testing per site SOPs:			
	☐ Provide HIV pre-test counseling ☐ Provide HIV/STI risk reduction counseling	g and con	doms	
			es shown are approximation is item to reflect site-species be types and volumes.	ecific
	[additional blood needed for clinically indicated testing also may be collected at this time]  Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.			
	<ul> <li>□ Provide test results and post-test counselin</li> <li>□ All tests negative.</li> <li>□ At least one test positive ⇒ HOLD stud</li> <li>If applicable, arrange to collect product</li> </ul>	ly produc	_	
	<ul> <li>Provide referrals if needed/requested.</li> <li>Offer HIV counseling and testing for partner(s).</li> <li>Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>			

Month 1 Visit Page 3 of 4

PTID:	Visit Date:	Visit Code: 4.0		
Initials	Procedures  24. Prepare remaining blood for required testing:  • Liver and renal function tests (AST, ALT, phosphate, creatinine)			
		, , , , , , , , , , , , , , , , , , , ,		
	If clinically indicated:  • Complete blood count  • Syphilis serology  • Hepatitis B surface antigen			
	<ul> <li>Hepatitis B surface antigen</li> <li>Hepatitis B surface antibody</li> <li>Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>			
	• CD4+ T cell count (as part of sample 2 or per protoc	col Section 7.6.1)		
	25. Assess eligibility to continue product use:			
	<ul> <li>□ ELIGIBLE:</li> <li>□ Review Unused Product Returns slip completed by pharmacy staff.</li> <li>□ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li>□ Schedule next visit.</li> <li>□ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li>□ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook.</li> <li>□ NOT ELIGIBLE:</li> <li>□ Schedule next visit</li> <li>□ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow</li> </ul>			
	copy in participant's study notebook (NA if hold	l initiated at previous visit).		
	☐ Complete Product/Hold Discontinuation Log form (NA if hold initiated at			
	previous visit).			
	26. Reinforce scheduling of next visit and remind part	icipant to:		
	Record menstrual bleeding days on appointment car	d		
	Record date and time of last product use on appoint	ment card		
	Bring appointment card to next visit     Pring all unused study product to payt visit			
	<ul><li>Bring all unused study product to next visit</li><li>Bring any other medication she is taking to next visit</li></ul>	t l		
	27. Provide contact information and instructions to rep			
	information, counseling, study product, or condoms be	• •		
	28. Provide reimbursement.			
	29. Ensure that chart notes and all other required visit	documentation is completed		
	27. Ensure that chart notes and an other required visit	cooumontation is completed.		

Month 1 Visit Page 4 of 4

PTID:	Visit Date:	Visit Code: 4.0	
Initials	Procedures		
	30. Fax all required DataFax forms to SCHARP DataFa  □ Follow-up Visit  □ Monthly Product Adherence and Behavior Assessm  □ Monthly Symptoms  □ Follow-up HIV Rapid Test Results  □ Follow-up Family Planning  □ Product Returns  □ Product Re-supply and Re-issues  □ Safety Laboratory Results  If Applicable:  □ Concomitant Medications Log (new and/or updated of contraceptives Log (new and/or updated of product Pelvic Exam of the variety Vaginal Test Results of the pap Test Results of the product Hold/Discontinuation Log (new and/or updated form of the product Hold/Discontinuation Log (new and/or updated form of the pregnancy Report and History of the pregnancy Outcome of the pregnancy Outcome	form pages) s) ated form pages)	

Monthly Visit Page 1 of 4

PTID:		Visit	Visit	
FIID.		Date:	Code:	
Initials	Procedures			
	1. Confirm participant	1. Confirm participant identity and PTID per site SOPs.		
	<ul><li>2. Check for co-enrollment in other (non-approved) studies per site SOPs:</li><li>☐ NOT enrolled in another study.</li></ul>			
	☐ Enrolled in another	study $\Rightarrow$ product hold may be re-		
	10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT.			
	Schedule participant to return when a response from PSRT is expected.			
	3. Instruct participant to return unused study product to pharmacy.			
	4. Review previous visit documentation.			
	5. Review elements of	informed consent as needed.		
	6. Explain procedures	to be performed at today's visit.		
	7. Review/update locat	tor information.		
	8. Administer Monthly Product Adherence and Behavior Assessment form.			
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:			
	<ul><li>□ NOT pregnant.</li><li>□ Pregnant, pregnancy first identified at a previous visit:</li></ul>			
	Continue to HOLD study product.			
	☐ If applicable, refer to MTN-016; document in chart notes.			
	☐ Pregnant, pregnancy newly identified at today's visit: ☐ HOLD study product (complete #26 accordingly). If applicable, arrange to			
	collect product not returned today within 5 working days.			
	☐ Initiate Pregnancy Management Worksheet.			
	☐ Complete Pregnancy Report and History form.			
		rine used for pregnancy testing for remaining urine for possible add		
	11. Administer Month		<u> </u>	
		edical and menstrual history with al/traditional preparations; documents		
		ive counseling; document per site		
	14 [D 11 / 11]		1 1	
		contraception if indicated; upda ntraceptives Log form if applicat		
	Family Planning form.		sie. Complete I onow op	
	15. If clinically indicat and/or LE:	ed, perform dipstick urinalysis fo	or protein, glucose, nitrites,	
		protein, nitrites and LE also shou		
		protein or glucose, product HOL	D may be required; see	
	protocol Sections 9	.6 and 9.7. es and LE, and participant is sym	ntomatic treat for LITI per site	
		er site SOPs and record on Conco		
		and transcribe results onto Safety		

Monthly Visit Page 2 of 4

DTID		Visit	Visit	
PTID:		Date:	Code:	
Initials		Procedu		
	16. If clinically indicated, measure weight; document per site SOPs.			
	<ul> <li>17. If clinically indicated, perform physical exam; document per site SOPs.</li> <li>18. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.</li> <li>19. Determine if any other clinically indicated urine or blood testing is required.</li> </ul>			
			red for testing should be collected when	
		HIV testing (see #24-25)		
	20. Provide and expla	in all available findings a	ind results.	
	Concomitant Medicat	21. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.		
	22. If indicated, administer Hepatitis B vaccine; document per site SOPs.  23. If required based on all available information, complete AE Log form(s).  24. Provide and document HIV counseling and testing per site SOPs:  □ Provide HIV pre-test counseling □ Provide HIV/STI risk reduction counseling and condoms  □ Collect 5 mL blood in lavender top (EDTA) tube [additional blood needed for clinically indicated testing also may be collected at this time]  □ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.  □ Provide test results and post-test counseling:  □ All tests negative.  □ At least one test positive ⇒ HOLD study product (complete #26 accordingly).  If applicable, arrange to collect product not returned today within 24 hours.			
	☐ Provide referrals is	f needed/requested.		
		ling and testing for partne		
			HIV Rapid Test Results form.	
	25. If clinically indicated in-		ditional testing; tests that may be	
	• Liver function tests			
		s (phosphate, creatinine)		
	Complete blood cou			
	• Syphilis serology			
	<ul> <li>Hepatitis B surface</li> </ul>	antigen		
	Hepatitis B surface	_		
	_	part of sample 2 or per pr	rotocol Section 7.6.1)	
		as part of sample 2 or per	· ·	
	• CD4+ T cell count	(as part of sample 2 or pe	er protocol Section 7.6.1)	

Monthly Visit Page 3 of 4

PTID:	Vi	sit	Visit
FIID.	Da	ate:	Code:
Initials		Procedures	
	26. Assess eligibility to continue product use:		
	<ul> <li>□ ELIGIBLE:</li> <li>□ Review Unused Product Returns slip completed by pharmacy staff.</li> <li>□ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li>□ Schedule next visit.</li> <li>□ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li>□ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook.</li> <li>□ NOT ELIGIBLE:</li> <li>□ Schedule next visit</li> <li>□ Complete Study Product Request Slip marked HOLD or PERMENENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook (NA if hold initiated at previous visit).</li> <li>□ Complete Product/Hold Discontinuation Log form (NA if hold initiated at previous visit).</li> </ul>		
	9	f next visit and remind partic	•
		ng days on appointment card	
		last product use on appointment	ient card
	<ul><li>Bring appointment card t</li><li>Bring all unused study p</li></ul>		
	• • •	ion she is taking to next visit	
		ation and instructions to repo	
	information, counseling, st	udy product, or condoms bef	
	29. Provide reimbursement	i.	
	30. Ensure that chart notes	and all other required visit d	ocumentation is completed.

Monthly Visit Page 4 of 4

PTID:		Visit	Visit		
FIID.		Date:	Code:		
Initials		Procedures			
	31. Fax all required DataFax forms to SCHARP DataFax:				
	☐ Follow-up Visit				
	Monthly Product Adherence and Behavior Assessment				
	☐ Monthly Symptom				
	☐ Follow-up HIV Ra☐ Follow-up Family				
	Product Returns	rianning			
		☐ Product Returns ☐ Product Re-supply and Re-issues			
	induce the supply und the issues				
	If Applicable:				
	☐ Concomitant Medications Log (new and/or updated form pages)				
	Contraceptives Log (new and/or updated form pages)				
	-	☐ Follow-up Pelvic Exam			
	☐ Vaginal Test Resul	<b>Q</b>			
	Pap Test Results				
	STI Laboratory Results				
	☐ Safety Laboratory Results ☐ HIV Western Blot Test Results				
	☐ Specimen Storage/				
	Seroconverter Laborated				
		ontinuation Log (new and/or upd	lated form pages)		
		e Log (new and/or updated form			
	☐ Pregnancy Report a				
	☐ Pregnancy Outcom				

DTID		Visit	Visit	
PTID:		Date:	Code:	
Initials	Procedures 1. Confirm participant identity and PTID per site SOPs.			
	<ul> <li>2. Check for co-enrollment in other (non-approved) studies per site SOPs:  NOT enrolled in another study.  Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.</li> <li>3. Instruct participant to return unused study product to pharmacy.</li> <li>4. Review previous visit documentation.</li> <li>5. Review elements of informed consent as needed.</li> <li>6. Explain procedures to be performed at today's visit.</li> </ul>			
	7. Review/update locator information.			
	8. Administer the appropriate (Oral or Vaginal) Product Adherence and Behavior Assessment form.  9. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.  10. Administer the appropriate follow-up ACASI Questionnaire.  11. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:  NOT pregnant.  Pregnant, pregnancy first identified at a previous visit:  Continue to HOLD study product.  If applicable, refer to MTN-016; document in chart notes.  Pregnant, pregnancy newly identified at today's visit:  HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 5 working days.  Initiate Pregnancy Management Worksheet.  Complete Pregnancy Report and History form.  12. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #17).			
	Refrigerate remaining	urine for possible additional test		
	13. Administer Month			
		dical and menstrual history with l/traditional preparations; docum		
		ive counseling; document per sit	*	
	16. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.			

PTID:		Visit Date:	Visit Code:		
		Date.	Code.		
lociti a la	Dun on themes				
Initials	Procedures				
	<ul> <li>17. Perform dipstick urinalysis:</li> <li>☐ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only.</li> <li>☐ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE.</li> </ul>				
		protein, nitrites and LE also	_		
			HOLD may be required; see		
	protocol Sections 9.		1022 may of required, see		
	*		symptomatic, treat for UTI per site		
			oncomitant Medications Log form.		
	Complete testing logs a	and transcribe results onto S	afety Laboratory Results form.		
	18. Perform physical ex	xam including weight meast	rement; document per site SOPs.		
		ed, perform and document p	elvic exam per Follow-Up Pelvic		
	Exam Checklist.				
		inically indicated urine or b			
		HIV testing (see #25-26).	for testing should be collected when		
		<u> </u>	eaculte.		
	21. Provide and explain all available findings and results.				
	22. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on				
	Concomitant Medications Log form. If indicated, offer STI testing and/or treatment				
	for partners; document per site SOPs.				
	23. If indicated, administer Hepatitis B vaccine; document per site SOPs.				
	24. If required based on all available information, complete AE Log form(s).				
	25. Provide and document HIV counseling and testing per site SOPs:				
	☐ Provide HIV pre-test counseling ☐ Provide HIV/STI risk reduction counseling and condoms				
		C			
	☐ Collect blood:				
		der top (EDTA) tube	Volumes shown are approximate.		
	☐ 1 x 5 mL lavend	cr top (LD171) tube	railor this item to reflect site-specific tube types and volumes.		
	☐ 1 x 5 mL red top				
	[additional blood need	ded for clinically indicated test	ing also may be collected at this time]		
	☐ Perform and docum	ent rapid HIV tests per site	SOPs. Before disclosing results to		
		ndependent review, verifica			
	_				
		and post-test counseling:			
	☐ All tests negative		advet (commists #20 coordinals)		
			oduct (complete #28 accordingly). returned today within 24 hours.		
	☐ Provide referrals if	needed/requested			
		ng and testing for partner(s)			
			V Rapid Test Results form.		

PTID:		Visit	Visit		
		Date:	Code:		
Initials	Dropoduros				
IIIIIIais	Procedures  26. Prepare remaining blood for required testing:  • Liver and renal function tests (AST, ALT, phosphate, creatinine)  • Plasma archive				
	If clinically indicated:  • Complete blood count				
	• Syphilis serology	*110			
	Hepatitis B surface antigen				
	Hepatitis B surface	•			
		part of sample 2 or per proto			
		as part of sample 2 or per pr			
		(as part of sample 2 or per pen Storage/PK form and LD	MS Specimen Tracking Sheet.		
	Z// Compress Specime		and a position reading allows		
	28. Assess eligibility t	to continue product use:			
	☐ ELIGIBLE:				
		Product Returns slip comp	eted by pharmacy staff.		
	☐ Provide product use instructions and adherence counseling per Follow-Up				
	Adherence Counseling Checklist; document per site SOPs.  ☐ Schedule next visit.  ☐ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.  ☐ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook.  ☐ NOT ELIGIBLE:				
	☐ Schedule next visit ☐ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow				
		_			
	copy in participant's study notebook (NA if hold initiated at previous visit).  Complete Product/Hold Discontinuation Log form (NA if hold initiated at				
	previous visit).				
	29. Reinforce schedul	ing of next visit and remind	participant to:		
	Record menstrual b	leeding days on appointmen			
	Bring appointment				
	Bring all unused study product to next visit				
		dication she is taking to nex	t visit o report symptoms and/or request		
		ng, study product, or condor			
	31. Provide reimburse				
	32 Ensure that chart r	notes and all other required	visit documentation is completed.		
	52. Liisure mat chart l	iones and an other required	rish documentation is completed.		

PTID:	Visit		Visit	
	Date	) <u>:</u>	Code:	
Initiale	Dragoduras			
Initials	33. Fax all required DataFax for Follow-up Visit  Oral or Vaginal Product Act Monthly Symptoms Follow-up HIV Rapid Test Follow-up Family Planning Product Returns Product Re-supply and Re-Safety Laboratory Results Specimen Storage/PK  If Applicable: Concomitant Medications In Contraceptives Log (new and Follow-up Pelvic Exam Vaginal Test Results Pap Test Results HIV Western Blot Test Results	dherence and Behavior A Results  issues  Log (new and/or updated nd/or updated form pages	ssessment form pages)	
	<ul> <li>□ Seroconverter Laboratory Test Results</li> <li>□ Product Hold/Discontinuation Log (new and/or updated form pages)</li> <li>□ Adverse Experience Log (new and/or updated form pages)</li> <li>□ Pregnancy Report and History</li> <li>□ Pregnancy Outcome</li> </ul>			
	34. Back-up ACASI questionn	aire data.		
	35. Upload ACASI questionnaire data to SCHARP.			

Page 1 of 1

Follow-up Pelvic Exam conducted semiannually, at PUEV, and when clinically indicated

PTID:		Exam	Visit	
		Date:	Code:	
Initials	Procedures			
	Review relevant documentation from previous and current visits.			
	Prepare exam equipment and specimen collection supplies; label as needed.			
	Explain exam procedures to participant and answer any questions.			
	Position and drape participant comfortably.			
	Palpate inguinal lymph nodes; identify all normal and abnormal findings.  Inspect external genitalia; identify all normal and abnormal findings.  Insert speculum, using warm water as lubricant if needed.  Inspect cervix and vagina; identify all normal and abnormal findings.			
	If clinically indicated, collect vaginal fluid for rapid BV test. Using the cotton swab			
	from an OSOM kit, sw	ab fluid from lateral vaginal wal	l, place swab in labeled tube	
	(plain), and cap tube.			
	Annually, at PUEV, and when clinically indicated, collect vaginal fluid for rapid			
	trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.  Semi-Annually, Annually, and at PUEV, collect vaginal fluid (1 swab) from lateral vaginal wall for Gram stain at MTN NL. Roll swab across two labeled slides and air			
	dry.			
	<b>If clinically indicated,</b> collect vaginal fluid (1 swab) from lateral vaginal wall for KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube.			
	<b>At all exams,</b> collect vaginal fluid (1 dacron swab) from posterior fornix for biomarker analyses at MTN NL. After tip of swab is saturated, place in labeled			
	cryovial (PBS) and cap	o vial.		
		raginal fluid (1 swab) from latera		
		d onto pH strip. Record pH on V		
		ndocervical cells for biomarker a	•	
		ucus with large cotton swab to ex	• .	
		~1 cm into endocervical canal ar		
		ace in labeled cryovial (PBS), and linically indicated, collect ecto-		
	smear per site SOPs.	mineany mulcated, confect ecto-	and endocervical cens for Fap	
		perform bimanual exam.		
	Remove speculari and	perform omandar exam.		
	Document exam per si	te SOPs:		
	<ul> <li>Record all exam fir</li> </ul>	ndings on Pelvic Exam Diagrams	form.	
	Record abnormal experience	xam findings on Follow-Up Pelv	ic Exam form.	
		pecimen test results on Vaginal T		
		bs collected for assessment at the	MTN NL on LDMS Specimen	
	Tracking Sheet and Sp	ecimen Storage/PK form.		

PTID:		Visit	Visit	
1 110.		Date:	Code:	
Initials		Procedures		
	1. Confirm participant identity and PTID per site SOPs.			
	<ol> <li>Check for co-enrollment in other (non-approved) studies per site SOPs:         <ul> <li>NOT enrolled in another study.</li> <li>Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.</li> </ul> </li> <li>Instruct participant to return unused study product to pharmacy.</li> <li>Review previous visit documentation.</li> <li>Review elements of informed consent as needed.</li> <li>Explain procedures to be performed at today's visit.</li> <li>Review/update locator information.</li> <li>Administer the appropriate (Oral or Vaginal) Product Adherence and Behavior Assessment form.</li> <li>Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.</li> <li>Administer the appropriate follow-up ACASI Questionnaire.</li> </ol>			
	<ul> <li>11. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test:</li> <li>NOT pregnant.</li> <li>Pregnant, pregnancy first identified at a previous visit:</li> <li>Continue to HOLD study product.</li> <li>If applicable, refer to MTN-016; document in chart notes.</li> <li>Pregnant, pregnancy newly identified at today's visit:</li> <li>HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 5 working days.</li> <li>Initiate Pregnancy Management Worksheet.</li> <li>Complete Pregnancy Report and History form.</li> </ul>			
	Refrigerate remaining	rine used for pregnancy testing for urine for possible additional testi		
	13. Administer Monthly Symptoms form.			
	medications and herba Concomitant Medication	dical and menstrual history with l/traditional preparations; docum ons Log and/or Contraceptives L	ent per site SOPs. Update og if applicable.	
	Î	ive counseling; document per sit		
	_	contraceptives if indicated; upd ntraceptives Log form if applical	-	

PTID:		sit ate:	Visit Code:
		ate.	Code.
Initials		Procedures	
	test for protein and gluc  ☐ If participant has urinar  ⇒ If 1+ or greater for prot  ⇒ If 1+ or greater for prot  protocol Sections 9.6 ar  ⇒ If positive for nitrites ar  SOPs; document per sit  Complete testing logs and	lysis:  OT have urinary symptoms (pose only.  Ty symptoms, test for protein.  ein, nitrites and LE also shouein or glucose, product HOL and 9.7.  and LE, and participant is symptoms and record on Concord transcribe results onto Safety	ald be tested. D may be required; see aptomatic, treat for UTI per site omitant Medications Log form.
	19. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.		
	<ul> <li>20. Determine if any clinically indicated urine or blood testing is required.</li> <li>⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #25-26).</li> </ul>		
	21. Provide and explain all available findings and results.		
	22. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.		
	vaccination as a separate e	Hepatitis B vaccine; docum ntry on the Concomitant Med as given on the Follow-up V	
	24. If required based on all available information, complete AE Log form(s).		

PTID:		Visit		Visit	
FIID.		Date:		Code:	
Initials		Procedui			
	25. Provide and docum	ent HIV counseling and	testing p	per site SOPs:	
		<ul> <li>□ 1 x 10 mL lavender top (EDTA) tube</li> <li>□ 1 x 5 mL lavender top (EDTA) tube</li> <li>□ 1 x 5 mL red top (no additive) tube</li> </ul> Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.			
	☐ 1 x 5 mL lavend☐ 1 x 5 mL red top				
	<ul> <li>[additional blood needed for clinically indicated testing also may be collected at this time]</li> <li>□ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.</li> <li>□ Provide test results and post-test counseling:</li> <li>□ All tests negative.</li> <li>□ At least one test positive ⇒ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 24 hours.</li> </ul>			s. Before disclosing results to	
	<ul> <li>Provide referrals if needed/requested.</li> <li>Offer HIV counseling and testing for partner(s).</li> <li>Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>				
		blood for required testin	g:		
	Complete blood cour		_		
	<ul> <li>Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>Plasma archive</li> <li>If clinically indicated:</li> </ul>				
	<ul><li>Syphilis serology</li><li>Hepatitis B surface a</li></ul>	ntigan			
	<ul> <li>Hepatitis B surface a</li> </ul>	•			
		art of sample 2 or per pr	otocol S	ection 7.6.1)	
		s part of sample 2 or per			
		as part of sample 2 or pe			
	27. Complete Specime	n Storage/PK form and I	LDMS S	pecimen Tracking Sheet.	

PTID:	Visit		Visit	
FIID.	Date:		Code:	
Initials		Procedures		
	28. Assess eligibility to continue	product use:		
	<ul> <li>□ ELIGIBLE:</li> <li>□ Review Unused Product Returns Slip completed by pharmacy staff.</li> <li>□ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs.</li> <li>□ Schedule next visit.</li> <li>□ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED.</li> <li>□ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook.</li> <li>□ NOT ELIGIBLE:</li> <li>□ Schedule next visit</li> <li>□ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook (NA if hold is continuing from a previous visit).</li> <li>□ Complete Product/Hold Discontinuation Log form (NA if hold is continuing from a previous visit).</li> </ul>			
	<ul> <li>29. Reinforce scheduling of next visit and remind participant to:</li> <li>Record menstrual bleeding days on appointment card</li> <li>Bring appointment card to next visit</li> <li>Bring all unused study product to next visit</li> </ul>			
	• Bring any other medication sh			
	30. Provide contact information	<u> </u>		
	information, counseling, study p			
	31. Provide reimbursement.			
	32. Ensure that chart notes and all other required visit documentation is completed.			

PTID:		Visit	Visit	
FIID.		Date:	Code:	
Initials		Procedures		
	33. Fax all required DataFax forms to SCHARP DataFax:  ☐ Follow-up Visit ☐ Oral or Vaginal Product Adherence and Behavior Assessment ☐ Monthly Symptoms			
	☐ Follow-up HIV Raj			
	☐ Follow-up Family I	•		
	☐ Follow-up Pelvic E ☐ Product Returns and			
	☐ Safety Laboratory I	*		
	☐ Specimen Storage/I			
	☐ Vaginal Test Results			
	agmar rest resur			
	If Applicable: ☐ Concomitant Medications Log (new and/or updated form pages) ☐ Contraceptives Log (new and/or updated form pages) ☐ Pap Test Result ☐ STI Laboratory Results			
	☐ HIV Western Blot Test Results			
	☐ Seroconverter Laboratory Test Results			
	☐ Product Hold/Discontinuation Log (new and/or updated form pages) ☐ Adverse Experience Log (new and/or updated form pages)			
	<ul> <li>Pregnancy Report and History</li> <li>Pregnancy Outcome</li> <li>Missed Visit</li> </ul>			
	IVIISSCU VISIT			
	34. Back-up ACASI qu	estionnaire data.		
	35. Upload ACASI que	estionnaire data to SCHARP.		
	be. opious rierist que			

Annual Visit Page 1 of 5

PTID:		Visit	Visit	
		Date:	Code:	
Initials		Procedures		
IIIIIIais	Confirm participan	t identity and PTID per site SOPs		
	The Committee of the Co	The second secon		
	2. Check for co-enrollment in other (non-approved) studies per site SOPs:			
	NOT enrolled in another study.			
	☐ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the			
		participant and from the other study team — for use when consulting the PSRT.		
		nt to return when a response from	-	
	3. Instruct participant	to return unused study product to	pharmacy.	
	4. Review previous vi	sit documentation.		
	5. Review elements o	f informed consent as needed.		
	6 Evplain procedures	to be performed at today's visit.		
	o. Explain procedures	to be performed at today's visit.		
	7. Review/update loca	ator information.		
	8. Administer the Me	nstrual Practices and Study Discl	osure Assessment form	
	9. Administer the app Assessment form.	ropriate (Oral <u>or</u> Vaginal) Produc	et Adherence and Behavior	
		l time of last study product use ar	nd record on Specimen	
		Collect and file participant source		
	11. Administer the appropriate follow-up ACASI Questionnaire.			
		0 mL), aliquot ~5 mL, and perfor	m pregnancy test:	
	NOT pregnant.	v finat identified at a massicus via	:	
	☐ Continue to HO	y first identified at a previous vis LD study product.	oit.	
		fer to MTN-016; document in cha	art notes.	
		y newly identified at today's visi		
		oduct (complete #30 accordingly)		
	_	not returned today within 5 worki cy Management Worksheet.	ng days.	
		ancy Report and History form.		
		ine used for pregnancy testing for		
	14.Refrigerate remaini	ing urine for gonorrhea and Chlai	mydia SDA testing.	
	15. Administer Monthl	y Symptoms form.		
		dical and menstrual history with		
		erbal/traditional preparations; do	•	
		ications Log and/or Contraceptive counseling; document per site		
	17.110vide contracepti	ive counseiing, document per site	, DOI 8.	
	_	] contraceptives if indicated; upd	-	
		d Contraceptives Log form if app	licable. Complete Follow-Up	
	Family Planning for	orm.		

Annual Visit Page 2 of 5

PTID:		isit ate:	Visit Code:
			<b>3000</b> 1
Initials	Procedures		
	test for protein and glu  ☐ If participant has urina  ⇒ If 1+ or greater for pro  ⇒ If 1+ or greater for pro  protocol Sections 9.6 a  ⇒ If positive for nitrites a  SOPs; document per si  Complete testing logs and	OT have urinary symptoms (pacose only.  Arry symptoms, test for proteinatein, nitrites and LE also shoutein or glucose, product HOL and 9.7.  And LE, and participant is symptoms and record on Concolutranscribe results onto Safety	ald be tested. D may be required; see aptomatic, treat for UTI per site bomitant Medications Log form.
	21.Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.		
		· • • • • • • • • • • • • • • • • • • •	esting should be collected when
	23. Provide and explain all	l available findings and result	s.
	24.If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.		
	25.If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log form, and indicate that the vaccine was given on the Follow-up Visit form.		
	26.If required based on all	l available information, comp	lete AE Log form(s).

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PTID:	Visit	Visit		
PIID.	Date:	Code:		
Initials	Procedu			
	27. Provide and document HIV counseling and	27. Provide and document HIV counseling and testing per site SOPs:		
	☐ Provide HIV pre-test counseling ☐ Provide HIV/STI risk reduction counseling	rovide HIV pre-test counseling rovide HIV/STI risk reduction counseling and condoms		
	☐ Collect blood: ☐ 1 x 10 mL lavender top (EDTA) tube ☐ 2 x 5 mL lavender top (EDTA) tube ☐ 2 x 5 mL red top (no additive) tube	Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes.		
	☐ Perform and document rapid HIV tests per participant, obtain independent review, ver	site SOPs. Before disclosing results to		
	<ul> <li>□ Provide test results and post-test counseling:</li> <li>□ All tests negative.</li> <li>□ At least one test positive ⇒ HOLD study product (complete #30 accordingly). If applicable, arrange to collect product not returned today within 24 hours.</li> </ul>			
	<ul> <li>Provide referrals if needed/requested.</li> <li>Offer HIV counseling and testing for partner(s).</li> <li>Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.</li> </ul>			
	28. Prepare remaining blood for required testing:			
	<ul> <li>Complete blood count</li> <li>Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>Plasma archive</li> <li>Syphilis serology</li> </ul>			
	<ul> <li>If clinically indicated:</li> <li>Hepatitis B surface antigen (required if susceptible but not vaccinated)</li> <li>Hepatitis B surface antibody</li> <li>Plasma archive (as part of sample 2 or per protocol Section 7.6.1)</li> <li>HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1)</li> <li>CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)</li> </ul>			
	29.Complete Specimen Storage/PK form and I	LDMS Specimen Tracking Sheet.		

Annual Visit Page 4 of 5

PTID:	Visit		Visit
FIID.	Date:		Code:
Initials		Procedures	
	30. Assess eligibility to continue	product use:	
		ections and adherence cecklist; document per security and adherence cecklist; document per security and study Product Recyclow copy in participal equest Slip marked HO ompleted white original notebook (NA if hold in the cecklist).	ounseling per Follow-Up site SOPs.  E-SUPPLY; product also may quest Slip to participant to ant's study notebook.  OLD or PERMANENTLY al to pharmacy; retain yellow is continuing from a previous
	<ul><li>31.Reinforce scheduling of next visit and remind participant to:</li><li>Record menstrual bleeding days on appointment card</li></ul>		
	Bring appointment card to nex		
	<ul><li>Bring all unused study product</li><li>Bring any other medication she</li></ul>		
	32. Provide contact information a		
	information, counseling, stud		
	33.Provide reimbursement.	y product, or condomic	
	34.Ensure that chart notes and all	other required visit do	ocumentation is completed.

Annual Visit Page 5 of 5

PTID:	1	Visit	Visit
FIID.		Date:	Code:
Initials		Procedures	
	35.Fax all required DataFax forms to SCHARP DataFax:		
	☐ Follow-up Visit		
		luct Adherence and Behavior A	
		and Study Disclosure Assessme	ent
	☐ Monthly Symptoms		
	Follow-up HIV Rapi		
	Follow-up Family Pl		
	☐ Follow-up Pelvic Example ☐ Product Returns and		
	☐ Safety Laboratory Re	•	
	☐ STI Laboratory Resu		
	☐ Specimen Storage/PH		
	☐ Vaginal Test Results		
	If Applicable:		
	☐ Concomitant Medications Log (new and/or updated form pages)		
	☐ Contraceptives Log (new and/or updated form pages)		
	☐ Pap Test Result		
	☐ HIV Western Blot Test Results		
	Seroconverter Labora		-4 - 1 (f
		tinuation Log (new and/or upd	1 0
	☐ Pregnancy Report an	Log (new and/or updated form	pages)
	Pregnancy Outcome	d History	
	☐ Missed Visit		
	36.Back-up ACASI ques	stionnaire data.	
	37.Upload ACASI quest	tionnaire data to SCHARP.	
	•		

PTID:	Visit	Visit	
	Date:	Code:	
Initials	Procedures		
IIIIIIII	Confirm participant identity and PTID per site	SOPs.	
	<ul> <li>2. Check for co-enrollment in other (non-approved) studies per site SOPs:</li> <li>□ NOT enrolled in another study.</li> <li>□ Enrolled in another study ⇒ Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT.</li> </ul>		
	3. Instruct participant to return unused study prod		
	4. Review previous visit documentation.		
	5. Review elements of informed consent as neede	d.	
	6. Explain procedures to be performed at today's	visit.	
	7. Review/update locator information.		
	8. Administer the Menstrual Practices and Study	Disclosure Assessment form	
	9. Administer the appropriate (Oral <u>or</u> Vaginal) P Assessment form.	roduct Adherence and Behavior	
	10. Determine date and time of last study product storage/PK form. Collect and file participant so	•	
	11. Administer Perceived Product Assessment form.  Clinician to complete item 1 or 2  12. Administer the appropriate follow-up ACASI Questionnaire.		
	13. Collect urine (15-60 mL), aliquot ~5 mL, and p  ☐ NOT pregnant.	perform pregnancy test:	
	☐ Pregnant, pregnancy first identified at a previous	s visit:	
	☐ If applicable, refer to MTN-016; document in		
	☐ Pregnant, pregnancy newly identified at today's	visit:	
	☐ Initiate Pregnancy Management Worksheet.		
	<ul><li>Complete Pregnancy Report and History form</li><li>Retain aliquot of urine used for pregnancy tests</li><li>#20).</li></ul>		
	15. Refrigerate remaining urine for gonorrhea and	Chlamydia SDA testing.	
	16. Administer Monthly Symptoms form.		
	17. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.		
	18. Provide contraceptive counseling; document po	er site SOPs.	
	19. [Prescribe/provide] contraceptives if indicated; documentation and Contraceptives Log form if Family Planning form.		

PTID:	Visit		Visit
1 110.	Date:		Code:
1 . 141 . 1			
Initials	20. Perform dipstick urinalysis:	ires	
	☐ If participant DOES NOT have urinary syn	nptoms (r	per her interval medical history)
	test for protein and glucose only.		•
	☐ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE.		
	⇒ If 1+ or greater for protein, nitrites and LE also should be tested.  ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site		
	SOPs; document per site SOPs and record		
	Complete testing logs and transcribe results or	nto Safety	Laboratory Results form.
	21. Perform physical exam including weight	and heigh	nt measurements; document per
	site SOPs.		
	22. Perform and document pelvic exam per F	follow-Up	Pelvic Exam Checklist and
	site SOPs.	1.1	
	23. Determine if any clinically indicated urin  ⇒ If yes, document per site SOPs; blood requi		
	blood is drawn for HIV testing (see #28-29		sting should be concered when
	24. Provide and explain all available findings	and resu	lts.
	25. If RTI/STI is diagnosed, provide treatmen		•
	on Concomitant Medications Log form. It		d, offer STI testing and/or
	treatment for partners; document per site SOPs.  26. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log, and indicate that the vaccine was given on the Follow-up Visit form.		
	27. If required based on all available information, complete AE Log form(s).		
	28. Provide and document HIV counseling and testing per site SOPs:		
	☐ Provide HIV pre-test counseling		
	☐ Provide HIV/STI risk reduction counseling	g and con	doms
	☐ Collect blood:		
	☐ 1 x 10 mL lavender top (EDTA) tube	Volun	nes shown are approximate.
	☐ 2 x 5 mL lavender top (EDTA) tube	Tailor t	his item to reflect site-specific ube types and volumes.
	☐ 3 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated		
	indicated in control of infiliation indicated	a tosting a	ass may se conceiled at this time]
	Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off.		
	☐ Provide test results and post-test counselin	g	
	☐ Provide referrals if needed/requested.		
	☐ Offer HIV counseling and testing for partn	er(s).	
	☐ Transcribe rapid test results onto Follow-u	p HIV Ra	apid Test Results form.

PTID:		Visit	Visit
	I	Date:	Code:
Initials	Procedures		
IIIIIIIII	<ul> <li>29. Prepare remaining blood for required testing:</li> <li>Complete blood count</li> <li>Liver and renal function tests (AST, ALT, phosphate, creatinine)</li> <li>Plasma archive</li> </ul>		
	• Syphilis serology	,·	
	Hepatitis B surface	antigen	
	If clinically indicated	:	
	Hepatitis B surface	antibody	
		part of sample 2 or per protoco	•
	·	as part of sample 2 or per proto	· ·
		(as part of sample 2 or per prot	
	30. Complete Specif	nen Storage/PK form and LDM	15 Specimen Tracking Sneet.
	31. If applicable, arr	ange to collect product not retu	rned today within 2 working days.
	<ul> <li>32. Reinforce scheduling of next visit and remind participant to:</li> <li>Record menstrual bleeding days on appointment card</li> <li>Bring appointment card to next visit</li> <li>Bring any other medication she is taking to next visit</li> <li>If considered an early termination visit:</li> <li>Schedule a final study contact for disclosure of all remaining exam and lab test results.</li> <li>If applicable, schedule contact to ascertain the participant's pregnancy outcome.</li> <li>If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased severity at this visit.</li> <li>Inform the participant of planned methods and timeframes for unblinding and dissemination of study results.</li> <li>Determine and document whether participant is willing to be contacted about future studies for which she may be eligible.</li> </ul>		
	<ul> <li>Reinforce site contact information, update participant locator information, and determine participant preference for post-study contact.</li> <li>33. Provide contact information and instructions to report symptoms and/or require information, counseling, or condoms before next visit.</li> </ul>		
	34. Provide reimburg	sement.	
	35. Ensure that chart	notes and all other required vi	sit documentation is completed.

# **Product Use End Visit (PUEV)**

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PTID:	Visit		Visit
FIID.	Date:		Code:
Initials	Proced	ures	
	36. Fax all required DataFax forms to SCHA	ARP DataI	Fax:
	☐ Follow-up Visit		
	Oral or Vaginal Product Adherence and E		
	☐ Menstrual Practices and Study Disclosure	e Assessme	ent
	☐ Monthly Symptoms		
	Pap Test Result		V is not completed, only the PPA
	Follow-up HIV Rapid Test Results		orms are to be completed. Do not a Missed Visit form or any other
	Follow-up Family Planning	VOICE CR	F for this visit.
	☐ Follow-up Pelvic Exam ☐ Perceived Product Assessment		
	☐ Product Returns and Dispensations		
	☐ Product Use End Visit		
	☐ Safety Laboratory Results		
	☐ STI Laboratory Results		
	☐ Specimen Storage/PK		
	☐ Vaginal Test Results		
	If Applicable:		
	☐ Concomitant Medications Log (new and/o	•	1 0
	Contraceptives Log (new and/or updated	form page	s)
	HIV Western Blot Test Results		
	Seroconverter Laboratory Test Results	1 . 1 6	
	Adverse Experience Log (new and/or upd	lated form	pages)
	Pregnancy Report and History		
	Pregnancy Outcome		
	37. Back-up ACASI questionnaire data.		
	38. Upload ACASI questionnaire data to SC	CHARP.	

**Note:** Use this checklist only for participants who are completing a scheduled Study Exit Visit approximately 8 weeks after their PUEV. If a participant is completing an early termination visit, use the PUEV checklist instead.

PTID:		Visit	Visit
1 110.		Date:	Code: 89.0
Initials		Procedures	
	Confirm participar	nt identity and PTID per site SOF	S.
	2. Review previous visit documentation.		
	3. Review elements of	of informed consent as needed.	
	4. Explain procedure	s to be performed at today's visit	
	5. Review update loca	ator information.	
	6. Administer the Me	nstrual Practices and Study Disc	losure Assessment form.
	7. Administer the Stu	dy Exit Behavior Assessment fo	rm.
	8. Administer the Pro	oduct hold/Discontinuers/SEV A	CASI Questionnaire.
	□ NOT pregnant. □ Pregnant, pregnanc □ If applicable, ref □ Pregnant, pregnanc □ Initiate Pregnanc □ Complete Pregn □ Explain to the parametric outcome of her 10. Retain aliquot of use (see #15). Refrige 11. Administer Monthl  12. Collect interval meadications and her Concomitant Medianedications/contrate "Continuing at	y first identified at a previous vister to MTN-016; document in chy newly identified at today's visite y Management Worksheet. ancy Report and History form. articipant that she will continue the pregnancy can be ascertained. The used for pregnancy testing for attending urine for possible by Symptoms form.  Idical and menstrual history with the properties of the participant contended and of study' box in the "Date Stive counseling; document per site."	sit: art notes. it: o be followed until the or possible dipstick urinalysis additional testing (e.g., SDA).  documentation of current cument per site SOPs. Update es Log if applicable. For tinues to use at this visit, mark Stopped" field.
		e] contraceptives if indicated; upo	
	_	l Contraceptives Log form if app	-
	☐ If participant has un ⇒ If 1+ or greater for ⇒ If positive for nitrite SOPs; document pe	ed, perform dipstick urinalysis: rinary symptoms, test for protein protein, nitrites and LE also shou es and LE, and participant is sym- er site SOPs and record on Conco- and transcribe results onto Safety	ald be tested.  Aptomatic, treat for UTI per site omitant Medications Log form.

PTID:	Visit		Visit	
	Date:		Code:	89.0
Initials		Drooduros		
Initials	16. If clinically indicated, measure	Procedures	orm physica	Lavam Document
	16. If clinically indicated, measure weight and/or perform physical exam. Document per site SOPs.			
	17. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic			
	Exam Checklist and site SOPs.			
	18. Determine if any clinically indicated urine or blood testing is required.			
	$\Rightarrow$ If yes, document per site SOPs;		esting shoul	ld be collected when
	blood is drawn for HIV testing		14 -	
	19. Provide and explain all availab	ole findings and resu	its.	
	20. If RTI/STI is diagnosed, provi	de treatment: docum	ent per site	SOPs and record on
	Concomitant Medications Log			
	treatment for partners; docume			
	21. If indicated, administer Hepat			
	vaccination as a separate entry			ns Log, and indicate
	that the vaccine was given on	the Follow-up Visit	form.	
	22. If required based on all available	ale information com	nlete AF L	og form(s)
	22. If required based on an available	ne information, com	piete 71L L	og form(s).
	23. Review all Adverse Experience	e Log forms comple	ted for the p	participant and
	update the forms as needed. F			
	status/outcome of the AE to "c	continuing at end of	study partic	ipation."
	Any SAEs/EAEs identified as continuing at this visit must be re-evaluated within 30			
	days. Any previously reported AEs found to have increased in severity at this visit			
	also must be re-evaluated in 30 days. Consult with the IoR/designee to establish a			
	clinically appropriate follow-up pl			
	participant's file.			
	24. Provide and document HIV counseling and testing per site SOPs:			
	Describe HWV was don't seem to live	_		
	<ul><li>Provide HIV pre-test counseling</li><li>Provide HIV/STI risk reduction</li></ul>	_	ndome	
	110vide 111v/3111isk reduction	i counseiing and cor	idoms.	
	☐ Collect blood:			
	☐ 1 x 10 mL lavender top (ED	TA) tube		
	☐ 1 x 5 mL lavender top (EDT			
	[additional blood needed for clinic	ally indicated testing a	also may be c	collected at this time]
	☐ Perform and document rapid H	IV tests ner site SOI	Ds Refored	isclosing results to
	participant, obtain independent			
	r r, oc macpendent		, 0.811 0	
	☐ Provide test results and post-te	st counseling:		
	$\square$ At least one test positive $\Rightarrow$			tional visits and tests
	may be needed to confirm of	r clarify her HIV sta	tus.	
	☐ Provide referrals if needed/reas	acted.		
	<ul><li>Provide referrals if needed/requ</li><li>Offer HIV counseling and testi</li></ul>			
	☐ Transcribe rapid test results on		apid Test R	esults form.
			p	

PTID:	Visit	Visit			
	Date:	Code:	89.0		
lesiticale.	Proceedings	Dungandungan			
Initials	Procedures  25. Prepare remaining blood for required testing:				
	Plasma archive				
	- 1 Inditing at CHITC				
	If clinically indicated:				
	Complete blood count				
	• Liver and renal function tests (AST, ALT, phosphate	, creatinine	)		
	Syphilis serology				
	Hepatitis B surface antigen				
	Hepatitis B surface antibody				
	• HIV-1 RNA PCR (as part of sample 2 or per protoco				
	• CD4+ T cell count (as part of sample 2 or per protoc				
	26. Complete Specimen Storage/PK form and LDMS S	Specimen Ti	racking Sheet.		
	27. If the Termination and PUEV visits are conducted	during the s	ame visit arrange		
	to collect product not returned today within 2 working days.				
	If Termination visit only, all study product should have already been collected				
	prior to termination, so no product collection necessary.				
	28. Reinforce site contact information and:				
	☐ If applicable, schedule a final study contact for disclosure of all remaining exam				
	and lab test results.	closure or al	ir remaining exam		
	☐ If applicable, schedule contact to ascertain the part	icipant's pre	egnancy outcome.		
	☐ If applicable, schedule clinically indicated follow-u				
	and previously reported AEs found to have increas				
	Inform the participant of planned methods and time	etrames for	unblinding and		
	dissemination of study results.  Determine and document whether participant is will	lling to be c	ontacted about		
	future studies for which she may be eligible.	ining to be c	ontacted about		
	Determine participant preference for post-study con	ntact.			
	29. Provide reimbursement.				
	30. Ensure that chart notes and all other required visit of	documentati	on is completed.		

# **Termination/Study Exit Visit**

### Page 4 of 4

PTID:	Visit Date:		Visit Code: 89.0
Initials	Procedures		
Initials	31. Fax all required DataFax forms to Menstrual Practices and Study Discrete Study Exit Behavior Assessment Monthly Symptoms  Follow-up HIV Rapid Test Result Follow-up Family Planning Specimen Storage/PK  End of Study Inventory Study Exit Visit  Termination  If Applicable: Follow-up Pelvic Exam Vaginal Test Results Pap Test Results Safety Laboratory Results STI Laboratory Results HIV Western Blot Test Results Seroconverter Laboratory Test Results Adverse Experience Log (new and Pregnancy Outcome Product Returns and Dispensation	o SCHARP DataF sclosure Assessments  If the Study Exit/Terronly the SEV, TM and completed. Do not cany other VOICE CR  esults d/or updated form	mination Visit is not completed, ad ESI forms are to be complete a Missed Visit form or RF for this visit.
	32. Back-up ACASI questionnaire d	ata.	
	33. Upload ACASI questionnaire da		
	33. Optoau ACASI questionnante da	ia to SCHAIN.	

PTID:	Visit		Visit	
	Date	):	Code:	
Initials	Propoduros			
IIIIIIaiS	Procedures  1. Confirm participant identity and PTID per site SOPs.			
	Tr. Commin participant racinity	und i iib per sue s'ers	•	
	2. Instruct participant to return unused study product, if any, to pharmacy.			
	3. Review previous visit docur	mentation		
	3. Review previous visit docur	nentation.		
	4. Review elements of informe	ed consent as needed.		
	5. Explain procedures to be pe	rformed at today's visit.		
	6. Review/update locator infor	mation.		
	7. Collect interval medical and			
	medications and herbal/traditions. If clinically indicated, perfo			
	o. If elimearly indicated, perio	im physical exam, doed	nent per site ser s.	
	9. If clinically indicated, perfo Exam Checklist.	rm and document pelvic	exam per Follow-Up Pelvic	
	10. Determine if any clinically	indicated urine or blood	testing is required.	
	1		esting should be collected when	
	blood is drawn for HIV testing			
	11. If clinically indicated, collemL if dipstick urinalysis is clin		pregnancy testing; aliquot 5	
	☐ NOT pregnant			
	Pregnant, pregnancy first in	dentified at a previous vis	sit:	
	☐ Continue to HOLD stud	y product.		
	☐ If applicable, refer to M			
	Pregnant, pregnancy newly	•		
	☐ HOLD study product an form.	a complete new Product	Hold/Discontinuation Log	
	☐ Initiate Pregnancy Mana	agement Worksheet		
	Complete Pregnancy Report and History form.			
	12. If clinically indicated, collect urine (or use aliquot from pregnancy testing) and			
	perform dipstick urinalysis for			
	$\Rightarrow$ If 1+ or greater for protein,			
	$\Rightarrow$ If 1+ or greater for protein	•	•	
	indicated; see protocol Sec		ete a new Product	
	Hold/Discontinuation Log		entomatic treat for LITI	
			aptomatic, treat for UTI per site omitant Medications Log form.	
	Complete testing logs and tran		_	
	13. If clinically indicated, refri		·	
	SDA.  14. Provide and explain all ava	ailable findings and rocal	te	
	17. I Tovide and explain all ava	madie iniumgs and iesui	is.	

PTID:		Visit Date:	Visit Code:
		Date.	Code:
Initials	Procedures		
	15. If RTI/STI is diagr		nent per site SOPs and record on
		ons Log form. If indicated, offe	er STI testing and/or treatment
	for partners; documen		
	16. If indicated, admir	nister Hepatitis B vaccine; docum	ment per site SOPs.
	17. If required based of	n all available information, com	aplete AE Log form(s).
	visit, refer to the HIV following steps if indi-	Sample 2 Visit Checklist. Other cated:	
		cument HIV counseling and to	esting per site SOPs.
		if needed/requested. eling and testing for partner(s).	
	Offer the counts	ening and testing for partner(s).	
	<ul><li>19. If clinically indicated, draw and prepare blood for additional testing; tests that may be clinically indicated include:</li><li>HIV serology</li></ul>		
	• Liver function tests	(AST, ALT)	
		(phosphate, creatinine)	
	Complete blood cou	nt	
	<ul> <li>Syphilis serology</li> </ul>		
	Hepatitis B surface	_	
	Hepatitis B surface antibody		
	20. Schedule or reinforce scheduling of next visit and remind participant to:		
		eeding days on appointment car	rd
	Bring appointment of		
	• •	lication she is taking to next visi	
		formation and instructions to rep	
		ng, or condoms before next visit.  ment as needed/indicated.	
	22. I Tovide Tellilouise	ment as necueu/muicateu.	
	23. Ensure that chart n	otes and all other required visit	documentation is completed.

PTID:		Visit		Visit	
		Date:		Code:	
Initials		Proce	edures		
	24. If applicable, fax al	ll completed DataFax	x forms to SO	CHARP DataFax:	
	☐ Interim Visit				
	☐ Concomitant Medic	cations Log (new and	d/or updated	form pages)	
	☐ Contraceptives Log	g (new and/or update	d form pages	s)	
	☐ Follow-up Pelvic E	xam	, ,		
	☐ Vaginal Test Resul	ts			
	☐ STI Laboratory Res	sults			
	☐ Safety Laboratory 1	Results			
	☐ Adverse Experience	e Log (new and/or u	pdated form	pages)	
	☐ Product Returns				
	☐ Product Re-supply	and Re-issues			
	☐ Product Hold/Disco	ontinuation Log			
	☐ Pregnancy Report a	and History			
	☐ Pregnancy Outcom	e			
	☐ HIV Western Blot	Test Results			
	☐ Specimen Storage/l	PK			
	☐ Seroconverter Labor	oratory Test Results			

### **HIV Sample 2 Visit Checklist**

# Page 1 of 1

PTID:	Visit	Visit		
	Date:	Code:		
Initials	Procedures	<u> </u>		
	1. Provide and document HIV counseling and te	sting per site SOPs		
	2. Provide sample 1 test result(s) and counseling			
	3. Provide HIV/STI risk reduction counseling an	nd condoms		
	4. Collect 25 mL blood in lavender top (EDTA)  ☐ Western Blot	tubes and perform the following:		
	☐ Plasma archive  ⇒ Store a minimum of 6x1 mL aliquots	Blood draw volumes shown are approximate. Tailor this item to		
	☐ CD4+ T cell count test☐ HIV-1 RNA PCR test	reflect site-specific tube types and volumes.		
	[additional blood needed for clinically-indicated testing also may be collected at this tim			
	5. Provide referrals if needed/requested			
	6. Offer HIV counseling and testing for partner(s)			
	7. Inform participant of MTN-015 and her poter	tial eligibility		
	8. If the Sample 2 results will be reported to the monthly visit is scheduled/due, schedule an ir	*		
	<ul> <li>9. Fax all required DataFax forms to SCHARP I</li> <li>☐ HIV Western Blot Test Results</li> <li>☐ Specimen Storage/PK</li> <li>☐ Seroconverter Laboratory Test Results</li> </ul>	DataFax:		



### MTN-003B Screening and Enrollment Visit

#### Page 1 of 3

DTID.		Visit	Visit		
PTID:		Date:	Code:	3.0	
Initials	Procedures				
		the participant should be approach			
	_	ing her VOICE study records and	d completing i	tems 1-5 of the	
		MTN-003B Eligibility form:  ☐ Potentially eligible ⇒ CONTINUE.			
		$\Rightarrow$ CONTINUE. gible $\Rightarrow$ STOP. Complete the M	TN 002D Elia	ibility form and	
		gible $\rightarrow$ STOP. Complete the MaraFax. Retain this checklist and			
		oant's VOICE study chart.	tille WITTN-002	D Lingionity	
		king place on a day after the VOI	CE enrollmen	t visit, confirm	
		d VOICE PTID per site SOPs.			
		sing place on a day after the VOI	CE enrollmen	t visit, check for	
	co-enrollment in other	(non-approved) studies per site	SOPs:		
	☐ NOT enrolled in an	nother study $\Rightarrow$ CONTINUE.			
		$r \text{ study} \Rightarrow \text{STOP. Product hold}$	•		
		as much information as possible			
		t and from the other study team			
		ne participant to return when a re		SR1 is expected.	
	4. Explain the purpose and sequence of procedures for today's visit.				
	5. If today's visit is taking place on a day after the VOICE enrollment visit,				
	review/update locator		ICE 11		
		king place on a day after the VOI eviated interval medical history:	CE enrollmen	t visit, perform	
		nt status of conditions that were	ongoing at enr	rollment	
		the participant experienced any n			
	problems since enre		ow symptoms		
	*	ges in contraception or other con	comitant med	ications since	
	enrollment	_			
		history, if needed, as part of #26			
	_	nd document the MTN-003B info	ormed consent	process per site	
	SOPs:	muovida wwitton informad aansa	nt - CONTIN	AT IT	
	_	provide written informed conse ble to provide written informed o			
	STOP. Complete the MTN-003B Eligibility form and fax to SCHARP DataFax. Retain this checklist and the MTN-003B Eligibility form in the participant's				
	VOICE study chart.				
		been tested for pregnancy today?	•		
	$\square \text{ Yes} \Rightarrow \text{CONTINU}$				
		, aliquot ~5 mL, and perform pre	egnancy test:		
	□ NOT pregnant → NOT	⇒ CONTINUE. OT ELIGIBLE ⇒ STOP. Comp	lete the MTN	003B Elizibility	
		SCHARP DataFax. Retain this			
		in the participant's VOICE stud			
		ine (at least 10 mL) for delivery		b for subsequent	
	storage.	, , , , , , , , , , , , , , , , , , ,		1	



# MTN-003B Screening and Enrollment Visit

Page 2 of 3

PTID:	Visit Date:	Visit Code:	3.0	
Initials	Procedures			
	<ul> <li>10. Review all available information and <u>determine</u> elig</li> <li>☐ Eligible ⇒ CONTINUE.</li> <li>☐ Not eligible ⇒ STOP. Complete the MTN-003B El</li> </ul>	ligibility form	and fax to	
	SCHARP DataFax. Retain this checklist and the M' the participant's VOICE study chart.	TN-003B Elig	ability form in	
	11. <u>Verify</u> eligibility for MTN-003B per site SOPs:			
	<ul> <li>☐ Eligible ⇒ CONTINUE.</li> <li>☐ Not eligible ⇒ STOP. Complete the MTN-003B El</li> </ul>	igibility form	and fav to	
	SCHARP DataFax. Retain this checklist and the M' the participant's VOICE study chart.			
	12. Complete MTN-003B Lactation and Contraceptive	History form.		
	13. Administer MTN-003B Food Frequency Questionna	aire.		
	14. Administer MTN-003B Physical Activity Question	naire.		
	15. Based on review of VOICE study records, determin and weight have been measured and documented within ☐ Yes ⇒ Transcribe height and weight onto MTN-003	the past 14 d	ays:	
	<ul> <li>□ No ⇒ Measure height and weight, document per VOICE SOPs, and transcribe onto MTN-003B Visit Procedures form.</li> </ul>			
	Compare current height and weight to baseline, as part of ongoing safety monitoring for VOICE. Follow up if needed as part of #26.			
	16. Assess for physical signs of malnutrition; record findings in chart notes and complete item 2 on the MTN-003B Visit Procedures form.			
	17. Collect 15 mL blood in plain (no additive) tubes; prepare tubes for delivery to the local lab for subsequent storage of serum.			
	18. Verify participant's current age and record on MTN			
	19. Perform DXA scans of spine and hip (two scans of electronically and print copies of each (four print-outs in		cans	
	20. Transcribe DXA scan results onto MTN-003B DXA	Scan form.		
	21. Assess whether any Z-score (age 18-29) or T-score  ☐ No ⇒ CONTINUE.			
	☐ Yes ⇒ Obtain IoR (or designee) opinion on whether should be provided; document in chart notes			
	<ul><li>No, supplementation not indicated</li><li>Yes, supplementation indicated</li></ul>			
	⇒ As part of #23, discuss options for preventio with participant.	n or treatment	t of osteoporosis	
	22. Assess whether DXA scan results meet criteria for A MTN-003B DXA Scan form and mark here:	AE reporting;	document on	
	$\square$ No $\Rightarrow$ source document as needed and CONTINUE.			
	☐ Yes ⇒ source document and complete AE Log form loss."	for "bone mi	neral density	



#### MTN-003B Screening and Enrollment Visit

Page 3 of 3

Visit	Visit		
Date:	Code:	3.0	
	•		
	elementation; update	concomitant	
	. 1 11		
		ailable treatment	
	•		
_		ing unused study	
		to report	
•			
29. Provide reimbursement.			
30. Ensure chart notes, required case report form	ms (see #32). MTN-0	03B LDMS	
32. Back-up DXA scan data (should be done daily on days when scans are performed).			
33. Fax all required DataFax forms to SCHARP DataFax:			
☐ MTN-003B Lactation and Contraceptive History			
MIN-003B DAA Scan			
If applicable:			
	Procedur  23. Provide and explain all available results to proceed discuss options for prevention or treatment of on 24. If indicated (see #21), provide calcium suppromedication documentation per site SOPs.  25. If malnutrition is identified, counsel the para options and sources of nutrition support; documed 26. If today's visit is taking place on a day after applicable, address any other issues, questions, MTN-003B; document per site SOPs; complete 27. Remind participant that her next MTN-003B Reinforce scheduling of next VOICE visit. Resproduct and any medications she is taking to he 28. Reinforce contact information and instruction symptoms and/or request additional information condoms if needed before the next visit.  29. Provide reimbursement.  30. Ensure chart notes, required case report form Specimen Tracking Sheet, and all other required 31. Review all visit documentation (including Experiment) and the process of t	Procedures  23. Provide and explain all available results to participant. If indicate discuss options for prevention or treatment of osteoporosis with participant and commentation per site SOPs.  24. If indicated (see #21), provide calcium supplementation; update of medication documentation per site SOPs.  25. If malnutrition is identified, counsel the participant on locally availurious and sources of nutrition support; document in chart notes.  26. If today's visit is taking place on a day after the VOICE enrollment applicable, address any other issues, questions, or concerns related to MTN-003B; document per site SOPs; complete VOICE case report for farming apricipant that her next MTN-003B visit will to take place Reinforce scheduling of next VOICE visit. Remind participant to be product and any medications she is taking to her next VOICE visit.  28. Reinforce contact information and instructions to contact the site symptoms and/or request additional information, counseling, study products and any medications are report forms (see #32), MTN-003B reeded before the next visit.  29. Provide reimbursement.  30. Ensure chart notes, required case report forms (see #32), MTN-003B provide reimbursement (including DXA scan print-outs).  31. Review all visit documentation (including DXA scan print-outs).  32. Back-up DXA scan data (should be done daily on days when scan scalar required DataFax forms to SCHARP DataFax:  MTN-003B Eligibility  MTN-003B Lactation and Contraceptive History  MTN-003B Physical Activity Questionnaire  MTN-003B DXA Scan  If applicable:	