

Section 6. Visit Checklists

This section contains sample checklists detailing the protocol-specified procedures that must be completed at MTN-015 study visits. The checklists also specify the data collection forms that must be completed at each visit. In addition to the guidance provided on the checklists, detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 8-10 of this manual. Detailed form completion instructions are provided in Section 12 of this manual.

The sample 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

See the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Record the participant identification number (PTID), visit date, and visit code (when applicable) in the top section of each checklist. If information is recorded on the front and back of a checklist, record these details on both sides.
- Record your initials only beside the procedures that you perform. Do not record your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, record, 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 recorded in the top section of the checklist, the date need not be recorded beside each item. If procedures listed on a checklist are performed on multiple dates, record the date upon which each procedure is performed beside each item.
- If a procedure listed on the checklist is not performed, record “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.

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with the MTN CORE, 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 two exceptions:

- Informed consent for must be obtained before any procedures are performed.
- Gynecologic exam procedures must be performed in the sequence shown on the gynecologic exam checklist.

PTID	Visit Date	Visit Code 01.0
Initials	Procedures	
	Explain, conduct, and document the informed consent process per site SOP (mark one): <input type="checkbox"/> Client willing and able to provide written informed consent ⇒ CONTINUE <input type="checkbox"/> Client NOT willing and/or able to provide written informed consent ⇒ STOP	
	Review parent study records to confirm seroconversion (mark one): <input type="checkbox"/> Seroconversion confirmed ⇒ CONTINUE <input type="checkbox"/> Seroconversion NOT confirmed ⇒ STOP	
	Assess for any condition that would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives (mark one): <input type="checkbox"/> No exclusionary condition identified ⇒ CONTINUE <input type="checkbox"/> Exclusionary condition identified ⇒ STOP	
	Determine eligibility (mark one): <input type="checkbox"/> Eligible ⇒ CONTINUE <input type="checkbox"/> Not eligible ⇒ STOP	
	Determine whether participant has used ART (mark one): <input type="checkbox"/> No, participant is enrolling as a Non-ART participant <input type="checkbox"/> Yes, participant is enrolling as an ART participant	
	Assign MTN 015 PTID.	
	Complete Enrollment form.	
	Complete Microbicide Trial Participation form.	
This procedure can be done any time during the visit; please tailor the sequence of procedures to suit visit flow.	Prepare certified copies of relevant parent study records (per SSP Sections 3.2.2, 7, 8.2.1, 8.4, and site SOP for source documentation).	
	Review/update locator information.	
	Administer Demographics form.	
	Administer Baseline Behavioral Questionnaire.	
	Complete Acute Seroconversion Assessment form and Seroconversion Symptoms form.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	If applicable, i.e., if participant reports use of ART: <input type="checkbox"/> Complete ART Enrollment form <input type="checkbox"/> Complete ART Initiation form <input type="checkbox"/> Record ART medications on Antiretroviral Treatment Regimen Log form <input type="checkbox"/> Administer Antiretroviral Therapy Adherence form.	

PTID	Visit Date	Visit Code 01.0
Initials	Procedures	
	Collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form <input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing 	
	Perform complete physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam: <ul style="list-style-type: none"> <input type="checkbox"/> Palpate inguinal lymph nodes <input type="checkbox"/> Inspect external genitalia <input type="checkbox"/> Insert speculum, inspect vagina and cervix, and assess for signs of STI/RTI <input type="checkbox"/> Assess vaginal pH <input type="checkbox"/> If indicated, collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall or posterior fornix, place swab in labeled tube (plain), and cap tube. 	
<div style="background-color: #90EE90; padding: 5px; border: 1px solid black;"> Please tailor this item to reflect site-specific method. </div>	<ul style="list-style-type: none"> <input type="checkbox"/> Collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall or posterior fornix, place swab in labeled tube (plain), and cap tube. <input type="checkbox"/> If indicated, swab vaginal fluids from the lateral vaginal wall for wet prep; proceed immediately to sub-steps listed here OR place the swab in a labeled glass or plastic tube containing approximately six drops (100 µL) of saline to allow for non-immediate slide preparation and evaluation: <ul style="list-style-type: none"> <input type="checkbox"/> Smear vaginal fluids from the swab onto two labeled slides <input type="checkbox"/> Apply KOH to one slide, perform whiff test, then apply coverslip <input type="checkbox"/> Apply saline to the second slide, emulsify, then apply coverslip <input type="checkbox"/> Immediately evaluate saline slide for trichomonads, yeast buds, pseudohyphae, and clue cells <input type="checkbox"/> Evaluate KOH slide for yeast buds and pseudohyphae <input type="checkbox"/> Collect two (2) vaginal fluid swabs from the posterior fornix for archive <input type="checkbox"/> Collect CVL for archive <input type="checkbox"/> If indicated, collect ecto- and endocervical cells for Pap smear <input type="checkbox"/> Perform bimanual exam <input type="checkbox"/> Document exam per site SOP for source documentation <input type="checkbox"/> Record wet prep findings on Sexually Transmitted Diseases Results form <input type="checkbox"/> Record vaginal swab and CVL collection on LDMS Specimen Tracking Sheet and Specimen Storage form 	

PTID	Visit Date	Visit Code 01.0
Initials	Procedures	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or ART. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes <div style="background-color: #90EE90; padding: 5px; display: inline-block; margin-left: 20px;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • Complete blood count (see protocol Appendix VI) • Liver and renal function tests (total bilirubin, AST, ALT, alk phos, creatinine) • Syphilis serology • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Serum archive • Shipment of plasma, PBMC, and serum (and vaginal swabs and CVL) to MTN NL 	
	Complete LDMS Specimen Tracking Sheet.	
	Complete Specimen Storage form.	
	Provide counseling and condoms; use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals (if applicable) <input type="checkbox"/> New referrals (if applicable) 	
	Generate MTN-015 follow-up visit calendar (mark one): <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART <input type="checkbox"/> ART 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	

PTID	Visit Date	Visit Code 01.0
Initials	Procedures	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	If applicable, complete Missed Visit forms for (i) follow-up visits with visit windows that have elapsed as of today's Screening and Enrollment visit and (ii) the follow-up visit window in which today's Screening and Enrollment visit took place.	
	<p>Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Enrollment <input type="checkbox"/> Microbicide Trial Participation <input type="checkbox"/> Demographics <input type="checkbox"/> Baseline Behavioral Questionnaire <input type="checkbox"/> Acute Seroconversion Assessment <input type="checkbox"/> Seroconversion Symptoms <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Sexually Transmitted Diseases Results <p>If Applicable:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> ART Enrollment <input type="checkbox"/> ART Initiation <input type="checkbox"/> Antiretroviral Treatment Regimen Log <input type="checkbox"/> Antiretroviral Therapy Adherence <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Missed Visit(s) 	

PTID	Visit Date	Visit Code 02.0
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation.	
	IF USE OF ART IS REPORTED, STOP. Complete Non-ART Study Visit form, ART Enrollment form and ART Initiation form. Generate ART follow-up visit calendar and determine which ART follow-up visit should be conducted. Then SWITCH to the appropriate ART follow-up visit checklist.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Medications Log form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form <input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or ART. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Syphilis serology IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet.	
	Complete Specimen Storage form.	

Please tailor this item to reflect site-specific tube types and volumes.

PTID	Visit Date	Visit Code 02.0
Initials	Procedures	
	Provide condoms.	
	If indicated, provide counseling (mark all that apply); use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals <input type="checkbox"/> New referrals 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Study Visit <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results If Applicable: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> ART Enrollment <input type="checkbox"/> ART Initiation form <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Pregnancy Report and History 	

PTID	Visit Date	Visit Code 03.0
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation.	
	IF USE OF ART IS REPORTED, STOP. Complete Non-ART Study Visit form, ART Enrollment form and ART Initiation form. Generate ART follow-up visit calendar and determine which ART follow-up visit should be conducted. Then SWITCH to the appropriate ART follow-up visit checklist.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form 	
	<input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or ART. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	<div style="background-color: #90EE90; padding: 5px; display: inline-block;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • Complete blood count (see protocol Appendix IV) • Liver and renal function tests (total bilirubin, AST, ALT, alk phos, creatinine) • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Syphilis serology IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation.	
	IF USE OF ART IS REPORTED, STOP. Complete Non-ART Study Visit form, ART Enrollment form and ART Initiation form. Generate ART follow-up visit calendar and determine which ART follow-up visit should be conducted. Then SWITCH to the appropriate ART follow-up visit checklist.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form 	
	<input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or ART. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	<div style="background-color: #90EE90; padding: 5px; display: inline-block;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • Complete blood count (see protocol Appendix VI) • Liver and renal function tests (total bilirubin, AST, ALT, alk phos, creatinine) • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Syphilis serology IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet.	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Complete Specimen Storage form.	
	Administer Social Harms Assessment.	
	Provide counseling and condoms; use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals (if applicable) <input type="checkbox"/> New referrals (if applicable) 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Study Visit <input type="checkbox"/> Social Harms Assessment <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results If Applicable: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> ART Enrollment <input type="checkbox"/> ART Initiation <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Pregnancy Report and History 	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation.	
	IF USE OF ART IS REPORTED, STOP. Complete Non-ART Study Visit form, ART Enrollment form and ART Initiation form. Generate ART follow-up visit calendar and determine which ART follow-up visit should be conducted. Then SWITCH to the appropriate ART follow-up visit checklist.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Medications Log form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	Collect ~20 mL urine and prepare for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing.	
	IF CLINICALLY INDICATED , before refrigeration of urine: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL urine and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or ART. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes <div style="background-color: #ffff00; padding: 2px; display: inline-block; margin-left: 20px;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • Complete blood count (see protocol Appendix IV) • Liver and renal function tests (total bilirubin, AST, ALT, alk phos, creatinine) • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Syphilis serology 	
	Complete LDMS Specimen Tracking Sheet.	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Complete Specimen Storage form.	
	ONLY AT Month 12 and Month 24, administer Follow-Up Behavior Questionnaire.	
	Administer Social Harms Assessment.	
	Provide counseling and condoms; use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals (if applicable) <input type="checkbox"/> New referrals (if applicable) 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Study Visit <input type="checkbox"/> Follow-Up Behavioral Questionnaire (Months 12 and 24 only) <input type="checkbox"/> Social Harms Assessment <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Sexually Transmitted Diseases Results If Applicable: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> ART Enrollment <input type="checkbox"/> ART Initiation <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Pregnancy Report and History 	

PTID	Visit Date	Visit Code 30.0
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation. If applicable, update Antiretroviral Treatment Regimen Log form.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form <input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or change of ART regimen. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Complete blood count IF CLINICALLY INDICATED • Liver and renal function tests IF CLINICALLY INDICATED • Syphilis serology IF CLINICALLY INDICATED • Shipment of archived plasma to MTN NL for HIV genotypic resistance test IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet.	
	Complete Specimen Storage form.	

Please tailor this item to reflect site-specific tube types and volumes.

PTID	Visit Date	Visit Code 30.0
Initials	Procedures	
	Administer Social Harms Assessment.	
	Provide condoms.	
	If indicated, provide counseling (mark all that apply); use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals <input type="checkbox"/> New referrals 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> ART Study Visit <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Social Harms Assessment If Applicable: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> Antiretroviral Treatment Regimen Log <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Non-ART Study Visit (required if the participant switched to the ART follow-up visit schedule at this visit) 	

PTID	Visit Date	Visit Code 31.0
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation. If applicable, update Antiretroviral Treatment Regimen Log form.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form <input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or change of ART regimen. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes <div style="background-color: #90EE90; padding: 5px; display: inline-block;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • Complete blood count IF CLINICALLY INDICATED • Liver and renal function tests IF CLINICALLY INDICATED • Syphilis serology IF CLINICALLY INDICATED • Shipment of archived plasma to MTN NL for HIV genotypic resistance test IF CLINICALLY INDICATED <div style="border: 1px solid black; padding: 5px; display: inline-block; text-align: center;">No PBMC archive at this visit</div>	
	Complete LDMS Specimen Tracking Sheet.	
	Complete Specimen Storage form.	

PTID	Visit Date	Visit Code 31.0
Initials	Procedures	
	Administer Social Harms Assessment.	
	Provide condoms.	
	If indicated, provide counseling (mark all that apply); use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals <input type="checkbox"/> New referrals 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> ART Study Visit <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Social Harms Assessment If Applicable: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> Antiretroviral Treatment Regimen Log <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Non-ART Study Visit (required if the participant switched to the ART follow-up visit schedule at this visit) 	

PTID	Visit Date	Visit Code 32.0
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation. If applicable, update Antiretroviral Treatment Regimen Log form.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Administer Antiretroviral Therapy Adherence form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form 	
	<ul style="list-style-type: none"> <input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or change of ART regimen. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	<div style="background-color: #90EE90; padding: 5px; border: 1px solid black; display: inline-block;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Complete blood count IF CLINICALLY INDICATED • Liver and renal function tests IF CLINICALLY INDICATED • Syphilis serology IF CLINICALLY INDICATED • Shipment of archived plasma to MTN NL for HIV genotypic resistance test IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet.	

PTID	Visit Date	Visit Code 32.0
Initials	Procedures	
	Complete Specimen Storage form.	
	Did participant initiate ART within 24 months after date of seroconversion? <input type="checkbox"/> No <input type="checkbox"/> Yes → Administer Follow-Up Behavioral Questionnaire	
	Administer Social Harms Assessment.	
	Provide condoms.	
	If indicated, provide counseling (mark all that apply); use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals <input type="checkbox"/> New referrals	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <input type="checkbox"/> ART Study Visit <input type="checkbox"/> Antiretroviral Therapy Adherence <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Social Harms Assessment If Applicable: <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> Antiretroviral Treatment Regimen Log <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Follow-up Behavioral Questionnaire (required if the participant initiated ART within 24 months after date of seroconversion) <input type="checkbox"/> Non-ART Study Visit (required if the participant switched to the ART follow-up visit schedule at this visit)	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation. If applicable, update Antiretroviral Treatment Regimen Log form.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Administer Antiretroviral Therapy Adherence form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	IF CLINICALLY INDICATED , collect ~20 mL urine and: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form 	
	<ul style="list-style-type: none"> <input type="checkbox"/> Prepare remaining urine for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or change of ART regimen. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	<div style="background-color: #90EE90; padding: 5px; display: inline-block;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • Complete blood count (see protocol Appendix VI) • Liver and renal function tests (total bilirubin, AST, ALT, alk phos, creatinine) • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Syphilis serology IF CLINICALLY INDICATED • Shipment of archived plasma to MTN NL for HIV genotypic resistance test IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet.	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Complete Specimen Storage form.	
	Administer Social Harms Assessment.	
	Provide counseling and condoms; use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <ul style="list-style-type: none"> <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals (if applicable) <input type="checkbox"/> New referrals (if applicable) 	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <ul style="list-style-type: none"> <input type="checkbox"/> ART Study Visit <input type="checkbox"/> Antiretroviral Therapy Adherence <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Social Harms Assessment If Applicable: <ul style="list-style-type: none"> <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> Antiretroviral Treatment Regimen Log <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Non-ART Study Visit (required if the participant switched to the ART follow-up visit schedule at this visit) 	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Review/update locator information.	
	Review/update medical history and concomitant medications; document per site SOP for source documentation. If applicable, update Antiretroviral Treatment Regimen Log form.	
	If applicable, record hormonal contraceptives and medications used for OI prophylaxis on Non-ART Concomitant Medications Log form.	
	Administer Antiretroviral Therapy Adherence form.	
	Perform targeted physical exam. Document exam per site SOP for source documentation.	
	Perform gynecologic exam per exam checklist.	
	Collect ~20 mL urine and prepare for gonorrhea and chlamydia SDA at the local lab; refrigerate prior to testing.	
	IF CLINICALLY INDICATED , before refrigeration of urine: <ul style="list-style-type: none"> <input type="checkbox"/> Aliquot ~5 mL urine and perform pregnancy test <input type="checkbox"/> Complete testing logs and transcribe result onto Laboratory Results form 	
	Provide and explain available exam and lab test results.	
	If applicable, provide STI/RTI treatment; offer STI testing and/or treatment for partners if indicated.	
	Assess clinical stage and potential need for CTX and/or change of ART regimen. Provide or refer for follow-up care as needed based on all available information/findings. Document follow-up in chart notes.	
	If applicable, record/update clinical events on HIV/AIDS Associated Events Log form.	
	Collect blood: <ul style="list-style-type: none"> <input type="checkbox"/> X x 5 mL lavender top (EDTA) tubes <input type="checkbox"/> Y x 10 mL lavender top (EDTA) tubes <input type="checkbox"/> Z x 10 mL red top (no additive) tubes 	
	<div style="background-color: #90EE90; padding: 5px; display: inline-block;">Please tailor this item to reflect site-specific tube types and volumes.</div>	
	Required blood testing and processing at the local lab: <ul style="list-style-type: none"> • Complete blood count (see protocol Appendix VI) • Liver and renal function tests (total bilirubin, AST, ALT, alk phos, creatinine) • CD4+ T-cell count • Plasma HIV-1 RNA • Plasma archive • PBMC archive • Syphilis serology • Shipment of archived plasma to MTN NL for HIV genotypic resistance test IF CLINICALLY INDICATED 	
	Complete LDMS Specimen Tracking Sheet.	

PTID	Visit Date	Visit Code
Initials	Procedures	
	Complete Specimen Storage form.	
	ONLY AT Month 12 and Month 24, did participant initiate ART within 24 months after date of seroconversion? <input type="checkbox"/> No <input type="checkbox"/> Yes → Administer Follow-Up Behavioral Questionnaire	
	Administer Social Harms Assessment.	
	Provide counseling and condoms; use counseling worksheet to guide HIV and STI counseling; document per site SOP for source documentation: <input type="checkbox"/> HIV-related (including secondary prevention) <input type="checkbox"/> STI risk reduction <input type="checkbox"/> Contraception <input type="checkbox"/> Follow-up on previous referrals (if applicable) <input type="checkbox"/> New referrals (if applicable)	
	Schedule visit for delivery of test results from this visit and next scheduled visit. If applicable, coordinate scheduling with parent study protocol visits.	
	If applicable, schedule retention contact(s) to occur before next scheduled visit.	
	Provide reimbursement.	
	Document the visit in a signed and dated chart note.	
	Complete and review all required visit documentation.	
	Fax all required DataFax forms to SCHARP DataFax: <input type="checkbox"/> ART Study Visit <input type="checkbox"/> Antiretroviral Therapy Adherence form <input type="checkbox"/> Specimen Storage <input type="checkbox"/> Laboratory Results <input type="checkbox"/> Sexually Transmitted Diseases Results <input type="checkbox"/> Social Harms Assessment If Applicable: <input type="checkbox"/> Non-ART Concomitant Medications Log <input type="checkbox"/> Antiretroviral Treatment Regimen Log <input type="checkbox"/> HIV/AIDS Associated Events Log <input type="checkbox"/> Pregnancy Report and History <input type="checkbox"/> Follow-Up Behavioral Questionnaire (required if the participant initiated ART within 24 months after date of seroconversion) <input type="checkbox"/> Non-ART Study Visit (required if the participant switched to the ART follow-up visit schedule at this visit)	

PTID	Visit Date	Visit Code
Initials	Procedures	
<p>Please tailor this item to reflect site-specific method.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Palpate inguinal lymph nodes <input type="checkbox"/> Inspect external genitalia <input type="checkbox"/> Insert speculum, inspect vagina and cervix, and assess for signs of STI/RTI <p><i>Vaginal pH and rapid trichomonas test are required at annual follow-up visits and at the final visit. At other follow-up visits, perform these procedures only if clinically indicated. If these procedures are not required or clinically indicated at today's visit, record "NA" beside the items, initial and date.</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Assess vaginal pH <input type="checkbox"/> If indicated, collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall or posterior fornix, place swab in labeled tube (plain), and cap tube. 	
	<ul style="list-style-type: none"> <input type="checkbox"/> Collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall or posterior fornix, place swab in labeled tube (plain), and cap tube. <input type="checkbox"/> If indicated, swab vaginal fluids from the lateral vaginal wall for wet prep; proceed immediately to sub-steps listed here OR place the swab in a labeled glass or plastic tube containing approximately six drops (100 µL) of saline to allow for non-immediate slide preparation and evaluation: <ul style="list-style-type: none"> <input type="checkbox"/> Smear vaginal fluids from the swab onto two labeled slides <input type="checkbox"/> Apply KOH to one slide, perform whiff test, then apply coverslip <input type="checkbox"/> Apply saline to the second slide, emulsify, then apply coverslip <input type="checkbox"/> Immediately evaluate saline slide for trichomonads, yeast buds, pseudohyphae, and clue cells <input type="checkbox"/> Evaluate KOH slide for yeast buds and pseudohyphae <input type="checkbox"/> Record findings on Sexually Transmitted Diseases Results form <input type="checkbox"/> Collect two (2) vaginal fluid swabs from the posterior fornix for archive <input type="checkbox"/> Collect CVL for archive EXCEPT AT ART WEEK 2 AND ART MONTH 1 <input type="checkbox"/> If indicated, collect ecto- and endocervical cells for Pap smear <input type="checkbox"/> Perform bimanual exam <input type="checkbox"/> Document exam per site SOP for source documentation <input type="checkbox"/> Record vaginal swab and CVL collection on LDMS Specimen Tracking Sheet and Specimen Storage form 	