

Section 6. Visit Checklists

6.1 Overview of Section 6

This section provides a template checklist for each of the required study visits. Please note the following recommendations when using these checklists.

1) As currently designed, the checklists cannot be used as source documentation.

The rationale behind this statement is two-fold: 1) it is not possible to tell if the person who initials and dates the checklist is actually the person who performed the activity or the person who conducted the QC to ensure that everything required for the visit was completed. 2) Several of the activities on these checklists would be carried out by multiple people (for example, one item has both blood collection and completing the lab-related CRFs - in all likelihood there are at least two (and maybe more) different people performing these activities). You can change these checklists to address these two issues (by identifying who did the activity, adding a separate QC space to initial and date, listing each discrete activity by itself); however, this makes the checklists very long and complicated. The purpose of the checklists is to provide a tool to ensure that all of the required activities for a visit are completed.

2) The checklists are easier to use if there is one designated for the index and one for the Partner.

A common way that checklists are used is for the checklist to follow the participant through the visit; as activities are completed they are checked off the list. The checklists are designed so that there is one for the Index Case and one for the Partner at each visit.

3) When using the checklists, make sure that every item is completed - this can be done with initials/date (to show that it was done), ND (not done), or NA (not applicable).

4) You will need to identify source documentation for some items on the checklist that are in the protocol, but not on the CRFs.

A good example of this is locator information. At each visit, the protocol requires that you confirm and, if necessary, revise locator information. Some of the ways that you can document that this was done at each visit include making a note in the participant's chart, creating a locator information log, or having a review/revision date attached to the locator information itself. The checklist cannot serve as the source for the confirmation of locator information unless you revise it to show who confirmed the information, if there were changes or not, and when this activity took place.

Screening Visit Checklist, Part 1: Potential Index Case or Partner

1. _____ Administer the **Index Case and Partner Screening Informed Consent (non-DF)** form. Answer all
 (initials/date) participant questions; obtain signature or mark, and offer the participant a copy of the consent form to keep. A witness should be present if participant is illiterate. Document the informed consent process.

☞ *If the individual does not consent to screening, **STOP** screening procedures.*

2. _____ Confirm the following criteria:
 (initials/date)

- Man or woman age \geq 18 years.
- Willing to disclose HIV test results to Partner.
- Not intending to relocate out of the area for the duration of study participation and does not have a job or other obligations that may require long absences from the area.
- Does not report a history of injection drug use within the last five years.
- Has not been a previous and/or current participant in an HIV vaccine study.
- Is not in a correctional facility, prison, or jail; or been involuntary incarcerated in a medical facility for psychiatric or physical (e.g. infectious disease) illness.

☞ *If after evaluating the criteria listed above, the participant is not eligible, **STOP** screening procedures. Inform the participant of his/her ineligibility. Document the reason for ineligibility in the Screening Log. Retain documentation completed thus far, but do not fax any forms to SCHARP.*

NOTE 1: Previous HIV screening with positive test results will be accepted as eligibility for the Index Case in this study if:

- the testing occurred within the dictated timeframe for this study (within 60 days of enrollment)
- the testing was performed at the site during a time when the site had an HPTN Network Laboratory certificate of accreditation
- the testing has appropriate documentation (i.e. documentation is consistent with what would otherwise be required for research purposes such as test date, test results, and identification of the testing laboratory)

3. If prior positive HIV test results are not available that meet the criteria listed above, or the potential participant had a prior negative HIV screening test:

3a. _____ Provide HIV pre-test counseling, including risk reduction counseling.
 (initials/date)

3b. _____ Collect blood for HIV testing. If the first test is indeterminate, repeat test using same
 (initials/date) blood sample. It may be necessary to schedule the participant to return to the clinic for their test results at a future date. Document the HIV test results.

3c. _____ Provide test results and post-test counseling per site SOP.
 (initials/date)

4. _____ **IF HIV TEST IS POSITIVE:** Inform the participant that s/he may be eligible as the HIV-positive member
 (initials/date) of the couple (Index Case) and determine if Partner is HIV negative. If Partner is negative, proceed with Screening Visit Procedures, Part 2. If Partner is positive, inform couple that they are ineligible and document reason in the **Screening Log (non-DF)**.

5. _____ **IF HIV TEST IS NEGATIVE:** Inform the participant that s/he may be eligible as the HIV-negative
 (initials/date) member of the couple (Partner) and determine if Partner is HIV positive. If Partner is positive, proceed with Screening Visit Procedures, Part 2. If Partner is negative, inform couple that they are ineligible and document reason in the **Screening Log (non-DF)**.

6. _____ Document the visit in a signed and dated chart note.
 (initials/date)

7. _____ Review all non-DataFax forms for this visit.
 (initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.
 DF= DataFax Form; non-DF= non-DataFax Form

Screening Identification Number: _____ Date(s) of Screening Visit(s): _____

Screening Visit Checklist, Part 2: Potential Index Case

Perform the following procedures only after an HIV-serodiscordant couple is identified

1. _____ Collect identifying and contact information and complete **Locator Forms (non-DF)**.
(initials/date)
2. _____ If the potential Partner and the Index Case are both present, provide couples HIV counseling per site SOP; complete **Couples Counseling Checklist (non-DF)**.
(initials/date)
3. _____ Collect blood for laboratory inclusion criteria. Determine CD4+ cell count, hemoglobin, platelets, AST, ALT, alkaline phosphatase, total bilirubin, creatinine clearance, absolute neutrophil count, and hepatitis B.
(initials/date)
4. _____ If potential Index Case is female, collect urine for pregnancy testing. (If potential Index Case is pregnant, follow guidelines in SSP Section 5.8.2).
(initials/date)
5. _____ Perform a targeted medical history and targeted physical exam to rule out any AIDS-defining illnesses or acute HIV infection. In addition, a concomitant medications assessment should be completed for determining the use of any prohibited medications. Document in signed and dated chart note (clinic note to include symptoms reported, exams performed, findings, treatment, and instructions for treatment if applicable).
(initials/date)
6. _____ Provide site contact information and instructions to contact the site for additional information. Refer to local health care, social services, and/or other providers if needed.
(initials/date)
7. _____ If applicable, provide compensation.
(initials/date)
8. _____ Schedule next visit to occur when the results of the potential Index's screening labs will be available.
(initials/date)
9. _____ Document the visit in a signed and dated chart note.
(initials/date)
10. _____ Review all non-DataFax forms for this visit.
(initials/date)

Note: The next visit may be the enrollment visit if the above eligibility criteria are met and both persons in the couple are present. **The Index Case and the Partner must report together for enrollment.**

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Screening Identification Number: _____ Date(s) of Screening Visit(s): _____

Screening Visit Checklist, Part 2: Potential Partner

Perform the following procedures only after an HIV-serodiscordant couple is identified

1. _____ Collect identifying and contact information and complete **Locator Forms (non-DF)**.
(initials/date)
2. _____ Provide couples HIV counseling per site SOP; complete **Couples Counseling Checklist (non-DF)**.
(initials/date)
3. _____ Provide site contact information and instructions to contact the site for additional information. Refer to
(initials/date) local health care, social services, and/or other providers if needed.
4. _____ If applicable, provide compensation.
(initials/date)
5. _____ Schedule next visit to occur when the results of the potential Index's screening labs will be available.
(initials/date)
6. _____ Document the visit in a signed and dated chart note.
(initials/date)
7. _____ Review all non-DataFax forms for this visit.
(initials/date)

Note: The next visit may be the enrollment visit if the above eligibility criteria are met and both persons in the couple are present. **The Index Case and the Partner must report together for enrollment.**

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.


DF= DataFax Form; non-DF= non-DataFax Form

Enrollment Visit Checklist: Index Case, Day 0*This visit must be performed with both the index and Partner present.***Will the Enrollment procedures listed below this box be conducted on the same day as Screening Part 2?**


Yes → Continue with Enrollment procedures listed below this box.

No → Perform procedures listed below.

- a. _____ Confirm that the screening laboratory tests for the Index Case are within the eligibility range and were conducted in the past 60 days. If results are outside the 60-day window, repeat laboratory tests.
(initials/date)
- b. _____ Confirm that the Index Case meets all eligibility criteria.
(initials/date)

 *If the couple is not eligible based on any entrance criteria, **STOP** procedures. Inform the couple of their ineligibility. Document the reason for ineligibility in the **Screening Log**. Retain documentation completed thus far, but do not fax any forms to SCHARP.*

1. _____ Administer **Index Case Enrollment Informed Consent, Specimen Storage (where applicable)**, and if applicable, **Pregnancy Informed Consent (non-DF)** forms per site SOP. Answer all questions; obtain all signatures or marks and dates, and offer the participants a copy of the consent form to keep. A witness should be present if participant is illiterate. Document the informed consent process.
(initials/date)

 *If either member of the couple does not consent to enrollment, **STOP** enrollment procedures.*

2. _____ Assign the next sequential **Clinic Randomization Envelope** to the index. Document assignment on the **Clinic Randomization Envelope Tracking Record (non-DF)**. Open the envelope; inform the couple whether the Index has been assigned to receive ART immediately or if ART assignment will be delayed. Retain documentation of randomization (letter and envelope) and PTID in participant chart.
(initials/date)
3. _____ Review and update information on **Locator Forms (non-DF)**.
(initials/date)
4. _____ Complete the **Index Demographics (IDM-1, DF)** and **Site-Specific Demographics (DF)** forms.
(initials/date)
5. _____ Collect blood for analysis, storage, and testing for CBC, blood chemistry, LFTs, CD4+ cell count and viral load according to the protocol, SSP Manual, and local SOPs. Complete the **Index Specimen Collection (ISC-1, DF)** form. When the results are available, complete the **Index Complete Hematology (ICH-1)**, **Index Complete Chemistries (ICC-1)**, and the **Index Enrollment CD4/Viral Load Results (IEV-1, DF)** forms.
(initials/date)
6. _____ FOR WOMEN: collect urine and conduct a urine pregnancy test. If positive, complete the **Index Pregnancy Report (IP-1, DF)** form.
(initials/date)
7. _____ FOR MEN: collect urine for gonorrhea and Chlamydia testing.
(initials/date)
8. _____ Obtain a chest x-ray unless already collected during screening.
(initials/date)
9. _____ Perform a complete medical history on the Index Case. Complete **Index Pre-Existing Conditions (IPRE-1, DF)** and if applicable, the **Index Concomitant Medications Log (ICM-1, DF)** form. Grade any pre-existing conditions in the chart notes. Document medical history for the Index Case in a signed and dated chart note. Perform a complete physical exam, including signs and symptoms. Perform a targeted evaluation for HIV and/or AIDS-related conditions. Document physical exam in a signed and dated chart note.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Enrollment Visit Checklist: Index Case, Day 0 (continued)

10. _____ FOR WOMEN, perform a genital and pelvic exam, including endocervical swab or urine sample for
(initials/date) STD diagnosis. NOTE: An FDA-approved GC/CT assay must be used. If an FDA-approved assay is not available for urine samples, an endocervical swab must be collected. In addition, swab any genital ulcer(s) for STD differentiation. If the woman is the Index Case, collect cervical secretions for viral load measurement. Complete **Index Sexually Transmitted Diseases (IST-1)** form, and, if the Index Case is treated for symptoms of a STD, complete the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** form. Complete the **Index Enrollment Pregnancy Report and History (IPR-1)**, and the **Index Specimen Collection (ISC-1, DF)** forms.
11. _____ FOR MEN, perform a genital exam; swab any genital ulcer(s) for STD differentiation. Determine
(initials/date) circumcision status. If the man is the Index Case, provide private location for semen collection. If participant is unable to provide sample during the visit, provide instructions for home collection. DO NOT administer ART until baseline semen sample is collected. Complete **Index Sexually Transmitted Diseases (IST-1, DF)**, and, if the Index Case is treated for symptoms of a STD, complete the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** form. Complete the **Index Specimen Collection (ISC-1, DF)** and the **Index Circumcision Assessment (ICA-1)** form.
12. _____ Provide treatment for conditions found via medical exam, if clinically indicated. Document in a signed
(initials/date) and dated chart note and in the **Index Concomitant Medications Log (ICM-1, DF)**, if appropriate.
13. _____ If a Grade 3 or higher adverse experience occurs after enrollment, complete the **Index Adverse Event
(initials/date) Log (IAE-1, DF)**.
14. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB),
(initials/date) WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified after enrollment, complete an **Index When-to-Start (IWT-1-4, DF)** form.
15. _____ Administer **Index Quality of Life (IQL-1-4, DF)** form.
(initials/date)
16. _____ Administer the **Index Sexual History (ISX-1, DF)** form. NOTE: The counselor performing the
(initials/date) sexual history assessment MUST NOT perform the couples HIV counseling.
17. _____ Perform couples HIV counseling per site SOP. Complete **Couples Counseling Checklist (non-DF)**.
(initials/date)
18. _____ Complete the **Index Enrollment (IEN-1, DF)** form.
(initials/date)
19. _____ Schedule next Follow-up Visit. (One month later if couple is assigned to delayed ART arm, two weeks
(initials/date) later if couple is assigned to immediate ART arm.). If applicable, provide compensation.
20. _____ Document the visit in a signed and dated chart note.
(initials/date)
21. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
22. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Enrollment Visit Checklist: Index Case, Day 0 (continued)**IF INDEX IS RANDOMIZED TO RECEIVE ART IMMEDIATELY**

23. _____ Dispense the study medication to the Index Case according to the site SOP. Provide information
(initials/date) on side effects and instructions for taking ART.
24. _____ Document dispensed medications in **Pharmacy Accountability Records (non-DF)**.
(initials/date)
25. _____ Provide adherence counseling according to the site SOP and complete **Adherence Counseling Checklist
(non-DF)**.
(initials/date)
26. _____ Complete **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** and **Index Pill Count (IPC-1, DF)**
(initials/date) forms.
27. _____ If the Index Case experiences a Grade 3 or higher AE after being exposed to ART, and it qualifies as an
(initials/date) EAE, complete **DAIDS EAE Report Form (non-DF)** and fax within 3 days of site awareness to RCC.


Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.
DF= DataFax Form; non-DF= non-DataFax Form

Enrollment Visit Checklist: Partner, Day 0*This visit must be performed with both the index and Partner present.***Will the Enrollment procedures listed below this box be conducted on the same day as Screening Part 2?**


Yes → Continue with Enrollment procedures listed below this box.

No → Perform procedures (a-c) listed in this box.

- a. _____ Confirm that the HIV-negative test for the Partner was conducted within 14 days. If not, repeat HIV testing
(initials/date)
- b. _____ Confirm that the Partner meets all eligibility criteria.
(initials/date)

 *If the couple is not eligible based on any entrance criteria, **STOP** procedures. Inform the couple of their ineligibility. Document the reason for ineligibility in the **Screening Log**. Retain documentation completed thus far, but do not fax any forms to SCHARP.*

1. _____ Administer **Partner Enrollment and Specimen Storage (where applicable) Informed Consent (non-DF)** forms per site SOP. Answer all questions; obtain all signatures or marks and dates, and offer the participants a copy of the consent form to keep. A witness should be present if participant is illiterate. Document the informed consent process.

 *If either member of the couple does not consent to enrollment, **STOP** enrollment procedures.*

2. _____ Complete the **Partner Enrollment (PEN-1, DF)** form.
(initials/date)
3. _____ Review and update information on **Locator Forms (non-DF)**.
(initials/date)
4. _____ Complete the **Partner Demographics (PDM-1, DF)** and **Site-Specific Demographics (DF)** forms.
(initials/date)
5. _____ Collect blood and urine samples for analysis and storage according to the protocol, SSP Manual, and local SOPs. Complete the **Partner Specimen Collection (PSC-1, DF)** form.
(initials/date)
6. _____ Perform a complete medical history on the Partner. Document medical history for the Partner in a signed and dated chart note. Perform a complete physical exam, including signs and symptoms. Document physical exam in a signed and dated chart note.
(initials/date)
7. _____ FOR WOMEN, perform a genital and pelvic exam, including endocervical swab or urine sample for STD diagnosis. NOTE: An FDA-approved GC/CT assay must be used. If an FDA-approved assay is not available for urine samples, an endocervical swab must be collected. In addition, swab any genital ulcer(s) for STD differentiation. If the Partner is treated for symptoms of a STD, complete the **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** form. Complete the **Partner Sexually Transmitted Diseases (PST-1, DF)** form.
(initials/date)
8. _____ FOR MEN, perform a genital exam; swab any genital ulcer(s) for STD differentiation. If the Partner is treated for symptoms of a STD, complete the **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** form. Determine circumcision status. Complete the **Partner Sexually Transmitted Diseases (PST-1, DF)** and the Partner Circumcision Assessment (PCA-1) form.
(initials/date)
9. _____ Provide treatment for conditions found via medical exam, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
10. _____ Administer the **Partner Sexual History Assessment (PSX-1, DF)** form. NOTE: The counselor performing the sexual history assessment MUST NOT perform the couples HIV counseling.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Enrollment Visit Checklist: Partner, Day 0 (continued)

11. _____ Perform couples HIV counseling per site SOP. An original or a certified copy of the completed **Couples Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
12. _____ Schedule next Follow-up Visit. (One month later if couple is assigned to delayed ART arm, two weeks later if couple is assigned to immediate ART arm.). If applicable, provide compensation.
(initials/date)
13. _____ Document the visit in a signed and dated chart note.
(initials/date)
14. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
15. _____ Submit DataFax forms to SCHARP.
(initials/date)

IF INDEX CASE IS RANDOMIZED TO RECEIVE ART IMMEDIATELY

16. _____ Provide adherence counseling according to the site SOP. An original or a certified copy of the completed **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Follow-Up Visit Checklist: Index Case, ART Initiation Visit

This checklist applies to participants on Arm 2 who initiate ART during the course of the study. (Procedures for ART initiation for participants on Arm 1 are included under the Enrollment Visit). The initiation of ART may begin at an interim visit, but only on a date when a monthly visit would occur. The following clinical procedures and laboratory evaluations should be performed, unless they are already being performed as part of a regularly scheduled study visit.

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form. (If there is a new Partner, not currently enrolled in the study; begin Partner Screening and Enrollment visit procedures.)
(initials/date)
2. _____ Review and update information on **Locator Forms (non-DF)**.
(initials/date)
3. _____ Collect blood for processing and testing for CBC, blood chemistry, LFTs and viral load. Perform any clinical procedures or laboratory tests for toxicity management and disease progression, as dictated by protocol and as clinically indicated. Document in a signed and dated chart note. When results are available complete the **Index Complete Hematology (ICH-1, DF)**, **Index Complete Chemistries (ICC-1, DF)**, and **Index CD4/Viral Load Results (IFV-1, DF)** forms.
4. _____ Perform a targeted medical history, including an assessment of concomitant medications. Document history in a signed and dated chart note. Update the **Index Concomitant Medications Log (ICM-1, DF)** as needed.
(initials/date)
5. _____ Perform a targeted physical exam, driven by signs and symptoms reported by the participant at this visit or since the last visit. Grade all diagnoses or signs and symptoms (if no diagnosis is possible) in the source documentation. Perform targeted evaluation for toxicities to the ART assigned to the participant, for HIV and/or AIDS-related conditions, and for STDs. Document physical exam in a signed and dated chart note. Complete the **Index STD (IST-1, DF)** form as needed. If the Index Case is treated for symptoms of a STD, complete the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** form. FOR WOMEN, complete the **Index Pregnancy Outcome (IPO-1, DF)** form, if applicable.
(initials/date)
6. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note. If applicable, complete **Index STD (IST-1, DF)** form.
(initials/date)
7. _____ If a Grade 3 or higher adverse experience has occurred, complete the **Index Adverse Event Log (IAE-1, DF)**. If the AE qualifies as an EAE, complete **DAIDS EAE Report Form (non-DF)** and fax within 3 days of site awareness to RCC.
(initials/date)
8. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB), WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified, complete an **Index When-to-Start (IWT-1-4, DF)** form.
(initials/date)
9. _____ Dispense the study medication to the Index Case according to the site SOP. Provide information on side effects and instructions for taking ART.
(initials/date)
10. _____ Document dispensed medications in **Pharmacy Accountability Records (non-DF)**.
(initials/date)
11. _____ Complete the **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** and **Index Pill Count (IPC-1, DF)** forms.
(initials/date)
12. _____ Administer adherence counseling per site SOP. Complete **Adherence Counseling Checklist (non-DF)**.
(initials/date)
13. _____ Complete the **Index Follow-up Visit (IFU-1-2, DF)** forms.
(initials/date)
14. _____ Schedule next Follow-up Visit (2-week post ART initiation visit and 3 monthly follow-up visits). If applicable, provide compensation.
(initials/date)
15. _____ Document the visit in a signed and dated chart note.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of ART Initiation Visit(s): _____

Follow-Up Visit Checklist: Partner, ART Initiation Visit

This checklist applies to participants on Arm 2 who initiate ART during the course of the study. (Procedures for ART initiation for participants on Arm 1 are included under the Enrollment Visit). The initiation of ART may begin at an interim visit, but only on a date when a monthly visit would occur. The following clinical procedures and laboratory evaluations should be performed, unless they are already being performed as part of a regularly scheduled study visit.

1. _____ Review and update information on **Locator Forms (non-DF)**.
(initials/date)
2. _____ Administer adherence counseling per site SOP. An original or certified copy of the completed **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
3. _____ Provide treatment for conditions if clinically indicated. Document in a signed and dated chart note. If applicable, complete **Partner Sexually Transmitted Diseases (PST-1, DF)**, **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)**, and **Partner HIV Test Results (PHT-1, DF)** forms.
(initials/date)
4. _____ Complete the **Partner Follow-up Visit (PFU-1, DF)** form.
(initials/date)
5. _____ Schedule next Follow-up Visit (2-week post-ART initiation visit and 3 monthly follow-up visits). If applicable, provide compensation.
(initials/date)
6. _____ Document the visit in a signed and dated chart note.
(initials/date)
7. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
8. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Follow-Up Visit Checklist: Index Case, Post-ART Initiation Visit*Perform these procedures two weeks after the Index Case starts ART.*

1. _____ Review and update information on **Locator Forms (non-DF)**.
(initials/date)
2. _____ Perform couples HIV counseling per site SOP. Complete **Couples Counseling Checklist (non-DF)**.
(initials/date)
3. _____ Collect blood for processing and testing for CBC, blood chemistry, and LFTs. Perform any clinical procedures or laboratory tests for toxicity management and disease progression, as dictated by protocol and as clinically indicated. Document in a signed and dated chart note. When results are available complete the **Index Complete Hematology (ICH-1, DF)** and **Index Complete Chemistries (ICC-1, DF)** forms.
(initials/date)
4. _____ Perform a targeted medical history, including an assessment of concomitant medications. Document history in a signed and dated chart note. Update the **Index Concomitant Medications Log (ICM-1, DF)** as needed.
(initials/date)
5. _____ Perform a targeted physical exam, driven by signs and symptoms reported by the participant at this visit or since the last visit. Grade all diagnoses or signs and symptoms (if no diagnosis is possible) in the source documentation. Perform targeted evaluation for toxicities to the ART assigned to the participant, for HIV and/or AIDS-related conditions, and for STDs. Document physical exam in a signed and dated chart note. Complete the **Index STD (IST-1, DF)** form. FOR WOMEN, the **Index Pregnancy Outcome (IPO-1, DF)** form, if applicable.
(initials/date)
6. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note. If applicable, complete **Index STD (IST-1, DF)** and the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** forms.
(initials/date)
7. _____ If a Grade 3 or higher adverse experience has occurred, complete the **Index Adverse Event Log (IAE-1, DF)**. If the AE qualifies as an EAE, complete **DAIDS EAE Report Form (non-DF)** and fax within 3 days of site awareness to RCC.
(initials/date)
8. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB), WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified, complete an **Index When-to-Start (IWT-1-4, DF)** form.
(initials/date)
9. _____ Collect study drug bottles previously dispensed and count remaining pills (if any); record on the the **Index Pill Count (IPC-1, DF)** form. Complete **Index Treatment Adherence (ITA-1-3, DF)** form. Determine if participant can remain on ART study drug, or if regimen needs to be modified. Dispense additional ART if required. If applicable, complete the **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** form.
(initials/date)
10. _____ Administer adherence counseling per site SOP. Complete **Adherence Counseling Checklist (non-DF)**.
(initials/date)
11. _____ Complete the **Index Follow-up Visit (IFU-1-2, DF)** forms.
(initials/date)
12. _____ Schedule next Follow-up Visit (3 monthly follow-up visits). If applicable, provide compensation.
(initials/date)
13. _____ Document the visit in a signed and dated chart note.
(initials/date)
14. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
15. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____ Date(s) of Post-ART Initiation Visit(s): _____

Follow-Up Visit Checklist: Partner, Post-ART Initiation Visit

Perform these procedures two weeks after the Index Case starts ART.

1. _____ Review and update information on **Locator Forms (non-DF)**.
(initials/date)
2. _____ Perform couples HIV counseling per site SOP. An original or certified copy of the completed **Couples Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
3. _____ Administer adherence counseling per site SOP. An original or certified copy of the completed **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
4. _____ Provide treatment for conditions if clinically indicated. Document in a signed and dated chart note. If applicable, complete **Partner STD (PST-1, DF)**, **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)**, and **Partner HIV Test Results (PHT-1, DF)** forms.
(initials/date)
5. _____ Complete the **Partner Follow-up Visit (PFU-1, DF)** form.
(initials/date)
6. _____ Schedule next Follow-up Visit (3 monthly follow-up visits). If applicable, provide compensation.
(initials/date)
7. _____ Document the visit in a signed and dated chart note.
(initials/date)
8. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
9. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Monthly Visit(s): _____

Follow-Up Visit Checklist: Index Case, Monthly

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form. (If there is a new Partner, not currently enrolled in the study; begin Partner Screening and Enrollment visit procedures.)
(initials/date)
2. _____ Review and update information on **Locator Form (non-DF)**.
(initials/date)
3. _____ Perform couples HIV counseling per site SOP. Complete **Couples Counseling Checklist (non-DF)**.
(initials/date)
4. _____ FOR WOMEN: conduct urine pregnancy test. If positive, complete the **Index Pregnancy Report (IP-1, DF)** form.
(initials/date)
5. _____ Perform a targeted medical history, including an assessment of concomitant medications. Document medical history in a signed and dated chart note. Update the **Index Concomitant Medications Log (ICM-1, DF)** as needed.
(initials/date)
6. _____ Perform a targeted physical exam, driven by signs and symptoms reported by the participant at this visit or since the last visit. Grade all diagnoses or signs and symptoms (if no diagnosis is possible) in the source documentation. Perform targeted evaluation for HIV/AIDS-related conditions and STDs. Document physical exam in a signed and dated chart note. If applicable, complete **Index STD (IST-1, DF)** and **Index Pregnancy Outcome (IPO-1, DF)** FOR WOMEN ONLY) forms.
(initials/date)
7. _____ If a Grade 3 or higher adverse experience has occurred in the Index Case, complete the **Index Adverse Event Log (IAE-1, DF)**.
(initials/date)
8. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB), WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified, complete an **Index When-to-Start (IWT-1-4, DF)** form.
(initials/date)
9. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note. If applicable, complete **Index STD (IST-1, DF)** and the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** form.
(initials/date)
10. _____ Complete **Index Follow-up Visit (IFU-1-2, DF)** forms.
(initials/date)
11. _____ Schedule next Follow-up Visit. If applicable, provide compensation.
(initials/date)
12. _____ Document the visit in a signed and dated chart note.
(initials/date)
13. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
14. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Monthly Visit(s): _____

Follow-Up Visit Checklist: Index Case, Monthly (continued)

IF INDEX CASE IS ON ART

15. _____ (initials/date) Collect blood for processing and testing for CBC, blood chemistry, LFTs, and viral load [mandatory for Month 1 (including viral load) and 2 (without viral load) after ART initiation ONLY]. Perform any clinical procedures or laboratory tests for toxicity management and disease progression, as dictated by protocol and as clinically indicated. Document in a signed and dated chart note.
16. _____ (initials/date) When results are available, complete the **Index Complete Hematology (ICH-1, DF)**, **Index CD4/Viral Load Results (IFV-1, DF)**, and **Index Complete Chemistries (ICC-1, DF)** forms.
17. _____ (initials/date) Perform any clinical procedures or laboratory tests for toxicity management related to the ART assigned to the participant as dictated by protocol and as clinically indicated. Document in a signed and dated chart note.
18. _____ (initials/date) If the Index Case experiences a Grade 3 or higher AE after being exposed to ART, and it qualifies as an EAE, complete DAIDS EAE Report Form (non-DF) and fax within 3 days of site awareness to RCC.
19. _____ (initials/date) Collect study drug bottles previously dispensed and count remaining pills (if any); record on **Pharmacy Accountability Record (non-DF)** and on the **Index Pill Count (IPC-1, DF)** form. Complete the **Index Treatment Adherence (ITA-1-3, DF)** form. Determine if participant can remain on ART study drug, or if regimen needs to be modified. Dispense additional ART. If applicable, complete the **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** form.
20. _____ (initials/date) Administer adherence counseling per site SOP. Complete **Adherence Counseling Checklist (non-DF)**.

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Monthly Visit(s): _____

Follow-Up Visit Checklist: Partner, Monthly

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form.
(initials/date)
2. _____ Review and update information on **Locator Form (non-DF)**.
(initials/date)
3. _____ Perform couples HIV counseling per site SOP. An original or certified copy of the completed **Couples Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
4. _____ If index is on ART, administer adherence counseling per site SOP. An original or certified copy of the completed **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
5. _____ Provide treatment for conditions if clinically indicated. Document in a signed and dated chart note. If applicable, complete **Partner STD (PST-1, DF)**, **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** and **Partner HIV Test Results (PHT-1, DF)** forms.
(initials/date)
6. _____ Complete **Partner Follow-up Visit (PFU-1-2, DF)** form.
(initials/date)
7. _____ Schedule next Follow-up Visit. If applicable, provide compensation.
(initials/date)
8. _____ Document the visit in a signed and dated chart note.
(initials/date)
9. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
10. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Quarterly Visit(s): _____

Follow-Up Visit Checklist: Index Case, Quarterly

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form. (If there is a new Partner, not currently enrolled in the study; begin Partner Screening and Enrollment visit procedures.)
(initials/date)
2. _____ Review and update information on **Locator Form (non-DF)**.
(initials/date)
3. _____ Administer and complete the **Index Sexual History Assessment (ISX-1, DF)** form. Note: The counselor who administers the sexual history assessment **MUST NOT** perform the couples counseling.
(initials/date)
4. _____ Perform couples HIV counseling per site SOP. Complete **Couples Counseling Checklist (non-DF)**. Note: The counselor who performs the couples counseling **MUST NOT** administer the sexual history assessment.
(initials/date)
5. _____ Collect blood for processing and testing for CBC, blood chemistry, LFTs, CD4 cell count, HIV viral load and sample storage (if participant has signed specimen storage informed consent form). Complete the **Index Specimen Collection (ISC-1, DF)** form. When results are available, complete the **Index Complete Hematology (ICH-1, DF)**, **Index CD4/Viral Load Results (IFV-1, DF)**, and **Index Complete Chemistries (ICC-1, DF)** forms.
(initials/date)
6. _____ FOR WOMEN: conduct urine pregnancy test. If positive, complete the **Index Pregnancy Report (IP-1, DF)** form.
(initials/date)
7. _____ Perform a targeted physical exam, driven by signs and symptoms reported by the participant at this visit or since the last visit. Grade all diagnoses or signs and symptoms (if no diagnosis is possible) in the source documentation. Perform targeted evaluation for HIV/AIDS-related conditions and STDs. Document physical exam in a signed and dated chart note. If applicable, complete **the Index STD (IST-1, DF)**, **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)**, and/or **Index Pregnancy Outcome (IPO-1, DF)** (FOR WOMEN ONLY) forms.
(initials/date)
8. _____ Perform a targeted medical history, including an assessment of concomitant medications. Document medical history in a signed and dated chart note. Update the **Index Concomitant Medications Log (ICM-1, DF)** as needed.
(initials/date)
9. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
10. _____ If a Grade 3 or higher adverse experience has occurred in the Index Case, complete the **Index Adverse Event Log (IAE-1, DF)**.
(initials/date)
11. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB), WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified, complete an **Index When-to-Start (IWT-1-4, DF)** form.
(initials/date)
12. _____ Administer **Index Quality of Life (IQL-1-4, DF)** form.
(initials/date)
13. _____ Complete **Index Follow-up Visit (IFU-1-2, DF)** forms.
(initials/date)
14. _____ Schedule next Follow-up Visit. If applicable, provide compensation.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Quarterly Visit(s): _____

Follow-Up Visit Checklist: Index Case, Quarterly (continued)

15. _____ Document the visit in a signed and dated chart note.
(initials/date)
16. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
17. _____ Submit DataFax forms to SCHARP.
(initials/date)

IF INDEX CASE IS ON ART

18. _____ Perform any clinical procedures or laboratory tests for toxicity management related to the ART
(initials/date) assigned to the participant as dictated by protocol and as clinically indicated. Document in a signed and dated chart note.
19. _____ If the Index Case experiences a Grade 3 or higher AE after being exposed to ART, and it
(initials/date) qualifies as an EAE, complete DAIDS EAE Report Form (non-DF) and fax within 3 days of site awareness to RCC.
20. _____ Collect study drug bottles previously dispensed and count remaining pills (if any); record on
(initials/date) **Pharmacy Accountability Record (non-DF)** and on the **Index Pill Count (IPC-1, DF)** form. Complete the **Index Treatment Adherence (ITA-1-3, DF)** form. Determine if participant can remain on ART study drug, or if regimen needs to be modified. Dispense additional ART. If applicable, complete the **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** form.
21. _____ Administer adherence counseling per site SOPs. Complete **Adherence Counseling Checklist.**
(initials/date) **(non-DF).**

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Quarterly Visit(s): _____

Follow-Up Visit Checklist: Partner, Quarterly

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form.
(initials/date)
2. _____ Review and update information on **Locator Form (non-DF)**.
(initials/date)
3. _____ Administer and complete the **Partner Sexual History Assessment (PSX-1, DF)** form. Note: The counselor who administers the sexual history assessment **MUST NOT** perform the couples counseling.
(initials/date)
4. _____ Perform couples HIV counseling per site SOP. An original or certified copy of the completed **Couples Counseling Checklist (non-DF)** should be included with the Partner's source documentation. Note: The counselor who performs the couples counseling **MUST NOT** administer the sexual history assessment.
(initials/date)
5. _____ If Index is on ART, administer adherence counseling per site SOP. An original or certified copy of the completed **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
6. _____ Conduct HIV pre-test and risk reduction counseling and complete **Pre-HIV Test Checklists (non-DF)**.
(initials/date)
7. _____ Collect blood for HIV testing and sample storage (if participant has signed specimen storage informed consent form). Complete the **Partner Specimen Collection (PSC-1, DF)** and **Partner HIV Test Results (PHT-1, DF)** forms.
(initials/date)
8. _____ Conduct HIV post-test counseling and complete **Post-HIV Test Checklists (non-DF)**.
(initials/date)
9. _____ Perform a targeted physical exam and history, driven by signs and symptoms reported by the participant at this visit or since the last physical exam. Perform targeted evaluation for STDs. Document physical exam in a signed and dated chart note. If applicable, complete the **Partner STD (PST-1, DF)** and/or **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** forms.
(initials/date)
10. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
11. _____ Complete **Partner Follow-up Visit (PFU-1, DF)** form.
(initials/date)
12. _____ Schedule next Follow-up Visit. If applicable, provide compensation.
(initials/date)
13. _____ Document the visit in a signed and dated chart note.
(initials/date)
14. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
15. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Follow-Up Visit Checklist: Index Case, Yearly

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form. (If there is a new Partner, not currently enrolled in the study; begin Partner Screening and Enrollment visit procedures.)
(initials/date)
2. _____ Review and update information on **Locator Form (non-DF)**.
(initials/date)
3. _____ Administer and complete the **Index Sexual History Assessment (ISX-1, DF)** form. Note: The counselor who administers the sexual history assessment **MUST NOT** perform the couples counseling.
(initials/date)
4. _____ Perform couples HIV counseling per site SOP. Complete **Couples Counseling Checklist (non-DF)**. Note: The counselor who performs the couples counseling **MUST NOT** administer the sexual history assessment.
(initials/date)
5. _____ Collect blood for processing and testing for CBC, blood chemistry, LFTs, CD4 cell count, HIV viral load, syphilis, and sample storage (if participant has signed specimen storage informed consent form). Complete the **Index Specimen Collection (ISC-1, DF)** form. When results are available, complete the **Index Complete Hematology (ICH-1, DF)**, **Index CD4/Viral Load Results (IFV-1, DF)** and **Index Complete Chemistries (ICC-1, DF)** forms.
(initials/date)
6. _____ FOR WOMEN: collect urine for pregnancy test. If positive, complete the **Index Pregnancy Report (IP-1)** FOR MEN: collect urine for gonorrhea and Chlamydia testing.
(initials/date)
7. _____ Perform a targeted physical exam, driven by signs and symptoms reported by the participant at this visit or since the last visit. Grade all diagnoses or signs and symptoms (if no diagnosis is possible) in the source documentation. Perform targeted evaluation for HIV/AIDS-related conditions and STDs. Document physical exam in a signed and dated chart note. If applicable, complete the **Index Pregnancy Outcome (IPO-1, DF)** (FOR WOMEN ONLY) form.
(initials/date)
8. _____ Perform a targeted medical history, including an assessment of concomitant medications. Document medical history in a signed and dated chart note. Update the **Index Concomitant Medications Log (ICM-1, DF)** as needed.
(initials/date)
9. _____ FOR WOMEN, perform a genital and pelvic exam, including endocervical swab or urine sample for STD diagnosis. NOTE: An FDA-approved GC/CT assay must be used. If an FDA-approved assay for urine is not available, an endocervical swab must be collected. In addition, swab any genital ulcer(s) for STD differentiation. If the woman is the Index Case, collect cervical secretions for viral load measurement. Complete the **Index Sexually Transmitted Diseases (IST-1, DF)** and, if applicable, the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** forms. For the female index, complete the **Index Specimen Collection (ISC-1, DF)** form.
(initials/date)
10. _____ FOR MEN, perform a genital exam and swab any genital ulcer(s) for STD differentiation. Determine circumcision status. If the man is the Index Case, provide private location for semen collection. If participant is unable to provide sample during the visit, provide instructions for home collection. Complete **Index Sexually Transmitted Diseases (IST-1, DF)** and, if applicable, the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** and the **Index Circumcision Assessment (ICA-1)** form. For the male index, complete the **Index Specimen Collection (ISC-1, DF)** form.
(initials/date)
11. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
12. _____ If a Grade 3 or higher adverse experience has occurred in the Index Case, complete the **Index Adverse Event Log (IAE-1, DF)**.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Follow-Up Visit Checklist: Index Case, Yearly (continued)

13. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB),
(initials/date) WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified, complete an **Index When-to-Start (IWT-1-4, DF)** form.
14. _____ Administer **Index Quality of Life (IQL-1-4, DF)** form.
(initials/date)
15. _____ Complete **Index Follow-up Visit (IFU-1-2, DF)** forms.
(initials/date)
16. _____ Schedule next Follow-up Visit. If applicable, provide compensation.
(initials/date)
17. _____ Document the visit in a signed and dated chart note.
(initials/date)
18. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
19. _____ Submit DataFax forms to SCHARP.
(initials/date)

IF INDEX CASE IS ON ART

20. _____ Perform any clinical procedures or laboratory tests for toxicity management related to the ART
(initials/date) assigned to the participant as dictated by protocol and as clinically indicated. Document in a signed and dated chart note.
21. _____ If the Index Case experiences a Grade 3 or higher AE after being exposed to ART, and it
(initials/date) qualifies as an EAE, complete **DAIDS EAE Report Form (non-DF)** and fax within 3 days of site awareness to RCC.
22. _____ Collect study drug bottles previously dispensed and count remaining pills (if any); record on
(initials/date) **Pharmacy Accountability Record (non-DF)** and on the **Index Pill Count (IPC-1, DF)** form. Complete the **Index Treatment Adherence (ITA-1-3, DF)** form. Determine if participant can remain on ART study drug, or if regimen needs to be modified. Dispense additional ART. If applicable, complete the **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** form.
23. _____ Administer adherence counseling per site SOPs. Complete **Adherence Counseling Checklist
(initials/date) (non-DF).**

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Follow-Up Visit Checklist: Partner, Yearly

1. _____ Confirm status of couple. Complete the **Couples Status (CPS-1, DF)** form.
(initials/date)
2. _____ Review and update information on **Locator Form (non-DF)**.
(initials/date)
3. _____ Administer and complete the **Partner Sexual History Assessment (PSX-1, DF)** form. Note: The counselor who administers the sexual history assessment **MUST NOT** perform the couples counseling.
(initials/date)
4. _____ Perform couples HIV counseling per site SOP. An original or certified copy of the completed **Couples Counseling Checklist (non-DF)** should be included with the Partner's source documentation. Note: The counselor who performs the couples counseling **MUST NOT** administer the sexual history assessment.
(initials/date)
5. _____ If index is on ART, administer adherence counseling per site SOP. An original or certified copy of the completed **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
(initials/date)
6. _____ Conduct HIV pre-test and risk reduction counseling and complete **Pre-HIV Test Checklists (non-DF)**.
(initials/date)
7. _____ Collect blood for HIV and syphilis testing, as well as sample storage (if participant has signed specimen storage informed consent form). Complete the **Partner Specimen Collection (PSC-1, DF)** and **Partner HIV Test Results (PHT-1, DF)** forms.
(initials/date)
8. _____ Conduct HIV post-test counseling and complete **Post-HIV Test Checklists (non-DF)**.
(initials/date)
9. _____ Perform a targeted physical exam and history, driven by signs and symptoms reported by the participant at this visit or since the last physical exam. Perform targeted evaluation for STDs. Document physical exam in a signed and dated chart note.
(initials/date)
10. _____ FOR WOMEN, perform a genital and pelvic exam, including endocervical swab or urine sample for STD diagnosis. NOTE: An FDA-approved GC/CT assay must be used. If an FDA-approved assay for urine is not available, an endocervical swab must be collected. In addition, swab any genital ulcer(s) for STD differentiation. Complete **Partner Sexually Transmitted Diseases (PST-1, DF)** and, if applicable, the **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** form.
(initials/date)
11. _____ FOR MEN, perform a genital exam and swab any genital ulcer(s) for STD differentiation. Determine circumcision status. Complete the **Partner Sexually Transmitted Diseases (PST-1, DF)** and, if applicable, the **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** and the **Partner Circumcision Assessment (PCA-1)** form.
(initials/date)
12. _____ FOR MEN: Collect urine sample for gonorrhea and Chlamydia testing.
(initials/date)
13. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
14. _____ Complete **Partner Follow-up Visit (PFU-1, DF)** form.
(initials/date)
15. _____ Schedule next Follow-up Visit. If applicable, provide compensation.
(initials/date)
16. _____ Document the visit in a signed and dated chart note.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Yearly Visit(s): _____

Follow-Up Visit Checklist: Partner, Yearly (Continued)

17. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
18. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.
DF= DataFax Form; non-DF= non-DataFax Form

Partner Seroconversion Visit Checklist: Index Case

These procedures and tests should be performed IN ADDITION to the procedures and tests already being performed at the scheduled visit. If the procedures are already part of the scheduled visit, they do not need to be duplicated.

1. _____ Collect blood for HIV viral load, HIV genotyping, and storage (if participant has signed specimen storage informed consent form). Complete the **Index Specimen Collection (ISC-1, DF)** and, when results are available, complete the **Index CD4/Viral Load Results (IFV-1, DF)** form.
(initials/date)
2. _____ FOR WOMEN, perform a pelvic exam, swab any ulcer(s) that are observed, and collect cervical secretions for viral load measurements. Complete the **Index STD (IST-1), Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** (if applicable), and **Index Specimen Collection (ISC-1, DF)** forms.
(initials/date)
3. _____ FOR MEN, provide private location for semen collection. If participant is unable to provide a sample during the visit, provide instructions for home collection. If clinically indicated, conduct a genital exam and swab any ulcer(s) that are observed. Complete **Index STD (IST-1), Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** (if applicable) and **Index Specimen Collection (ISC-1, DF)** forms.
(initials/date)
4. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
5. _____ Remind the participant that he or she will continue in the study, although his or her Partner will not.
(initials/date)
6. _____ Document the visit in a signed and dated chart note.
(initials/date)
7. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
8. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.
DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____ Date(s) of Partner Seroconversion Visit(s): _____

Partner Seroconversion Visit Checklist: Partner

These procedures and tests should be performed IN ADDITION to the procedures and tests already being performed at the scheduled visit. If the procedures are already part of the scheduled visit, they do not need to be duplicated.

1. _____ Collect blood for CBC, blood chemistry, LFTs, CD4+ cell count, HIV viral load, HIV genotyping, and storage (if participant has signed specimen storage informed consent form). When results are available, complete the **Partner CD4/Viral Load Results (PVL-1, DF)**, **Partner Complete Hematology Results (PCH-1, DF)**, and **Partner Complete Chemistries (PCC-1, DF)** forms. Complete the **Partner Specimen Collection (PSC-1, DF)** form.
(initials/date)
2. _____ Perform a targeted medical history and physical exam, driven by signs and symptoms reported by the participant at this visit or since the last physical exam. Document in a signed and dated chart note.
(initials/date)
3. _____ FOR WOMEN, perform a genital and pelvic exam, including vaginal and cervical swab. In addition swab any genital ulcer if one is observed. Collect cervical secretions for viral load measurements. Complete the **Partner STD (PST-1)**, **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** (if applicable), and **Partner Specimen Collection (PSC-1, DF)** forms.
(initials/date)
4. _____ FOR MEN, perform a genital exam and swab any genital ulcer if observed. Provide private location for semen collection. If participant is unable to provide sample during the visit, provide instructions for home collection. Complete the **Partner STD (PST-1)**, **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** (if applicable), and **Partner Specimen Collection (PSC-1, DF)** forms.
(initials/date)
5. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note.
(initials/date)
6. _____ Remind the participant that this is his or her last study visit and that participation in the study has ended.
(initials/date)
7. _____ Complete **Partner Termination (PTM-1, DF)** form.
(initials/date)
8. _____ Document the visit in a signed and dated chart note.
(initials/date)
9. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
10. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Virologic Failure Visit(s): _____

Confirmed Virologic Failure Visit Checklist: Index Case

These procedures and tests should be performed IN ADDITION to the procedures and tests already being performed at the scheduled visit. If the procedures are already part of the scheduled visit, they do not need to be duplicated.

1. _____ Collect blood for HIV viral load, HIV genotyping, and storage (if participant has signed specimen storage informed consent form). Complete the **Index (ISC-1, DF) Specimen Collection** and **Index CD4/Viral Load Results (IFV-1, DF)** forms.
(initials/date)
2. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note. If applicable, complete the **Index STD (IST-1, DF)** and **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** forms.
(initials/date)
3. _____ Complete the **Index Treatment Adherence (ITA-1-3, DF)** forms.
(initials/date)
4. _____ Administer adherence counseling per site SOP. Complete **Adherence Counseling Checklist (non-DF)**.
(initials/date)
5. _____ If the ART regimen changes, complete the **Index Antiretroviral Treatment Regimen Log (ITX-1, DF)** form. (NOTE: Index Cases in whom failure to respond is believed to be due to non-adherence, systemic illness, vaccination, or other circumstances determined by the study clinicians, will not be required to switch therapy.)
(initials/date)
6. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
7. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Virologic Failure Visit(s): _____

Confirmed Virologic Failure Visit Checklist: Partner

These procedures and tests should be performed IN ADDITION to the procedures and tests already being performed at the scheduled visit. If the procedures are already part of the scheduled visit, they do not need to be duplicated.

1. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated.
(initials/date) Document in a signed and dated chart note. If applicable, complete **Partner STD (PST-1, DF)** and **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** forms.
2. _____ Administer adherence counseling per site SOP. An original or certified copy of the completed
(initials/date) **Adherence Counseling Checklist (non-DF)** should be included with the Partner's source documentation.
3. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
4. _____ Submit DataFax forms to SCHARP, if any have been completed.
(initials/date)

Initial and date when completed, write **N/A (not applicable)**, or **ND (not done)** next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Interim Visit(s): _____

Unscheduled (Interim) Visit Checklist: Index Case

1. _____ Conduct targeted medical history and physical exam. Perform any required laboratory tests for diagnosis. Grade all diagnoses or signs and symptoms (if no diagnosis is possible) in the source documentation. Document in a signed and dated chart note. If applicable, complete the **Index STD (IST-1, DF)** and **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** forms.
(initials/date)
2. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated. Document in a signed and dated chart note. Update the **Index Concomitant Medications Log (ICM-1, DF)**, as required.
(initials/date)
3. _____ If a Grade 3 or higher adverse experience has occurred in the Index Case, complete the **Index Adverse Event Log (IAE-1, DF)**.
(initials/date)
4. _____ If any HIV/AIDS-related illnesses (WHO Stage 4, severe bacterial infections, and pulmonary TB), WHO Stage 2 and 3 clinical events, or other targeted medical conditions as per protocol Appendix IV have been identified, complete an **Index When-to-Start (IWT-1-4, DF)** form.
(initials/date)
5. _____ Complete the **Index Interim Visit (IIV-1, DF)** form and all other clinically indicated forms.
(initials/date)
6. _____ Complete the **Index Follow-up (IFU-1-2, DF)** forms.
(initials/date)
7. _____ Document the visit in a signed and dated chart note.
(initials/date)
8. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
9. _____ Submit DataFax forms to SCHARP.
(initials/date)

IF INDEX CASE IS ON ART

10. _____ If the Index Case experiences a Grade 3 or higher AE after being exposed to ART, and it qualifies as an EAE, complete **DAIDS EAE Report Form (non-DF)** and fax within 3 days of site awareness to RCC.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Interim Visit(s): _____

Unscheduled (Interim) Visit Checklist: Partner

1. _____ Conduct targeted medical history and physical exam. Perform any required laboratory tests for diagnosis.
(initials/date) Document in a signed and dated chart note. If applicable, complete the **Partner STD (PST-1)**, **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)**, and **Partner HIV Test Results (PHT-1, DF)** forms.
2. _____ Provide treatment for conditions found via medical exam or laboratory tests, if clinically indicated.
(initials/date) Document in a signed and dated chart note.
3. _____ Complete the **Partner Interim Visit (PIV-1, DF)** form and all other clinically indicated forms.
(initials/date)
4. _____ Complete the **Partner Follow-up (PFU-1, DF)** form.
(initials/date)
5. _____ Document the visit in a signed and dated chart note.
(initials/date)
6. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
7. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

Termination Visit Checklist: Index Case

Termination visits may be conducted when a participant, either Index Case or Partner, will no longer continue in the study. The termination visit may be conducted at a regularly scheduled visit or at an interim visit.

*The termination visit needs to include the same procedures as the yearly visit, unless a quarterly visit has been done within the previous 60 days prior to termination. If a quarterly visit has not been completed, follow the checklist for the annual visit and complete an **Index Termination (ITM-1, DF)** form. If a quarterly visit has been completed, use this checklist.*

1. _____ Collect blood for processing and testing for syphilis and for sample storage (if participant has signed specimen storage informed consent form). Complete the **Index Specimen Collection (ISC-1, DF)** and the **Index Sexually Transmitted Diseases (IST-1, DF)** forms.
(initials/date)
2. _____ FOR WOMEN, perform a genital and pelvic exam, including endocervical swab or urine sample for STD diagnosis. NOTE: An FDA-approved GC/CT assay must be used. If an FDA-approved assay for urine is not available, an endocervical swab must be collected. In addition, swab any genital ulcer(s) for STD differentiation. Complete **Index Sexually Transmitted Diseases (IST-1, DF)** and, if applicable, the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** form. For the female index, complete the **Index Specimen Collection (ISC-1, DF)** form.
(initials/date)
3. _____ FOR MEN, perform a genital exam and swab any genital ulcer(s) for STD differentiation. Determine circumcision status. Collect urine for gonorrhea and Chlamydia testing. Complete **Index Sexually Transmitted Diseases (IST-1, DF)** and, if applicable, the **Index Symptomatic Sexually Transmitted Diseases (ISS-1, DF)** forms. For the male index, complete the **Index Specimen Collection (ISC-1, DF)** form.
(initials/date)
4. _____ Complete the **Index Follow-up (IFU-1-2, DF)** forms.
(initials/date)
5. _____ Complete the **Index Termination (ITM-1, DF)** form.
(initials/date)
6. _____ Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
(initials/date)
7. _____ Submit DataFax forms to SCHARP.
(initials/date)

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form

PTID: _____

Date(s) of Termination Visit(s): _____

Termination Visit Checklist: **Partner**

Termination visits may be conducted when a participant, either Index Case or Partner, will no longer continue in the study. The termination visit may be conducted at a regularly scheduled visit or at an interim visit.

The termination visit needs to include the same procedures as the yearly visit, unless a quarterly visit has been done within the previous 60 days prior to termination. If a quarterly visit has not been completed, follow the checklist for the annual visit and complete a **Partner Termination (PTM-1, DF)** form. If a quarterly visit has been completed, use this checklist.

1. _____
(initials/date) Collect blood for syphilis testing and for sample storage (if participant has signed specimen storage informed consent form). Complete the **Partner Specimen Collection (PSC-1, DF)** and the **Partner Sexually Transmitted Diseases (PST-1, DF)** forms.
2. _____
(initials/date) FOR WOMEN, perform a genital and pelvic exam, including endocervical swab or urine sample for STD diagnosis. NOTE: An FDA-approved GC/CT assay must be used. If an FDA-approved assay for urine is not available, an endocervical swab must be collected. In addition, swab any genital ulcer(s) for STD differentiation. Complete the **Partner Sexually Transmitted Diseases (PST-1, DF)** and, if applicable, the **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** form. For the female Partner, complete the **Partner Specimen Collection (PSC-1, DF)** form.
3. _____
(initials/date) FOR MEN, perform a genital exam and swab any genital ulcer(s) for STD differentiation. Determine circumcision status. Collect urine sample for gonorrhea and Chlamydia testing. Complete the **Partner Sexually Transmitted Diseases (PST-1, DF)** and, if applicable, the **Partner Symptomatic Sexually Transmitted Diseases (PSS-1, DF)** form. For the male Partner, complete the **Partner Specimen Collection (PSC-1, DF)** form.
4. _____
(initials/date) Complete the **Partner Follow-up (PFU-1, DF)** form.
5. _____
(initials/date) Complete the **Partner Termination (PTM-1, DF)** form.
6. _____
(initials/date) Review all forms for this visit for completeness and accuracy, including non-DataFax forms.
7. _____
(initials/date) Submit DataFax forms to SCHARP.

Initial and date when completed, write N/A (**not applicable**), or ND (**not done**) next to each item.

DF= DataFax Form; non-DF= non-DataFax Form