

5. Study Procedures Overview

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5.1 Overview of Section 5

This section provides a brief overview of requirements and procedures during follow-up (e.g., once a participant is enrolled in the study). Additional procedure-specific details can be found in the HPTN 083 protocol and relevant SSP manual sections (e.g., clinical, laboratory, data management procedures).

5.2 Study Overview

All participants enrolled in the study will follow three steps:

- Step 1: All study participants will receive two blinded daily oral tablets for 5 weeks; either oral CAB and daily oral placebo for TDF/FTC (Arm A) or Daily oral TDF/FTC and daily oral placebo for CAB (Arm B).

Note: Participants in Step 1 of the study who do not transition to Step 2 of the study for any reason other than HIV infection will be asked to attend annual visits, until three years from the date of Enrollment. The last annual visit at the three-year time point does not have to be exactly three years from the date of Enrollment; however, sites should strive to schedule it as close to the three year time point as possible.

The Annual Visit procedures are described in Section 5.11 and Appendix ID of the HPTN 083 Protocol and Section 5.3.1 of this SSP below.

- Step 2: All participants will receive an injection administration and daily oral tablets at two time points four weeks apart (Week 5 (first injection) and Week 9 (second injection)), and every 8 weeks thereafter until Week 153, which is approximately three years from the date of the Enrollment visit.
 - Arm A: Will receive CAB LA injections and daily oral placebo.
 - Arm B: Will receive daily oral TDF/FTC and placebo injections.

All participants will be simultaneously unblinded after the last participant concludes their participation in Step 2.

NOTE: Participants in Step 2 of the study who prematurely stop receiving injections before their study participation ends for any reason other than HIV infection will remain blinded to their study assignment and will transition to Step 3 of the study, starting no later than 8 weeks after their last injection. Once that participant has completed the required 48 weeks on Step 3, they will then be asked to attend annual visits until three years from the date of Enrollment (as above, it does not have to be exactly three years from the date. The timepoint at which they transition to Step 3 will determine whether they will be asked to attend annual visits following completion of Step 3; it will not be necessary if the completion of Step 3 post-dates three years from the date of Enrollment.

- Step 3: All participants (except those who become HIV-infected), including those who permanently discontinue receiving injections before their Step 2 participation in the study ends, will receive study-provided open-label TDF/FTC 300 mg/200 mg fixed dose combination daily oral tablets, one tablet daily for up to 48 weeks. The timeline for the 48 weeks of open label TDF/FTC for Step 3 begins 8 weeks from the last administered injection of Step 2, irrespective of actual date of TDF/FTC initiation.
- Participants who complete the full three years of follow-up in Step 2 at the Week 153 visit will ideally begin Step 3 on the same day, which will be considered Day 0 of Step 3. On this day, participants will begin study-provided open-label daily oral TDF/FTC for approximately 48 weeks. For participants who prematurely transition to Step 3 before completing three years of follow-up in Step 2, Step 3 will start no later than 8 weeks after their last injection (the timing of the last injection visit and duration of provision of daily oral TDF/FTC may vary according to when the last participant reaches their final Step 2 visit or if the study endpoints are reached earlier).
- All participants will be transitioned to locally-available HIV prevention services, including services for PrEP, if available, when their participation in the study ends, or if they transition to annual visits in Step 1 or Step 3.

5.3 Study Visits

Protocol-required visits: Step 1, Step 2, and Step 3 have regular protocol required study visits, which are described in Section 5 and Appendices 1A to 1D of the Protocol, as well as described in Section 13 of the SSP manual (Data Management).

Visit windows for each required study visit are described in Section 13.5 of the SSP. As outlined in the protocol, visits conducted outside of the target visit windows are allowable without restriction. Efforts should be made to conduct study visits within the target visit window and may be conducted over multiple days within the target visit window if necessary (see below regarding Split visits).

Interim visits: Interim contacts and visits may take place between regularly-scheduled visits. These contacts/visits may be done at participant request (e.g., to receive further counseling or clarify any questions) or as deemed necessary by the

investigator or designee at any time during the study (e.g., to follow-up on an adverse event). Procedures to be performed during these contacts/visits will be based on the reason for it.

Split visits: A Split visit is defined as visits conducted over multiple days. Ideally, all procedures specified by the protocol to be performed at a visit will be completed at a single visit on a single day. In the event that all required procedures cannot be completed on a single day (e.g., because the participant must leave the study site before all required procedures are performed), the remaining procedures may be completed on subsequent day(s), ideally within the target visit window. When this occurs, the visit is considered a split visit. All case report forms completed for a split visit are assigned the same visit code (even though the dates recorded on the case report forms may be different).

Considerations for Split Visits:

- HIV testing is required on the second day of a split visit only if was not already performed on the first day of that split visit OR if study product will be dispensed/administered on that day – even if the required HIV testing was performed at the first part of the split visit. Please remember, the required HIV testing must be performed and resulted prior to the administration of study product (please see additional information regarding 4th generation EIA in Example 2 below). Below are two examples describing this requirement:
 - Example 1: Split visit where study product is dispensed/administered on the first part of the split visit (Day 1):
 - Day 1: All procedures have been performed, including all required HIV testing and sample storage, except for administration of a CASI interview.
 - Day 2: Only the administration of the CASI interview is required. HIV testing does not have to be repeated.

Note the following for this case: If a visit at which a CASI interview is required is conducted as a split visit, the entire CASI interview must be completed on one day. If a CASI interview is begun, but not completed, on Day 1 of a split visit, the entire CASI questionnaire must be administered (starting from the beginning) on Day 2 of the split visit. If this occurs, the SDMC does not need to be notified.
 - Example 2: Split visit where study product IS NOT dispensed/administered on the first part of the split visit (Day 1):
 - Day 1: All procedures have been performed, including all required HIV testing and sample storage, except study product was not dispensed/administered.
 - Day 2: A rapid HIV test (including pre- and post-HIV counseling) must be performed and a plasma sample must be stored (even if Day 2 is the next day). This is also true if the second part of the split visit

occurs within 6 days of Day 1. For example, if Day 1 is on a Wednesday and the participant comes in the following Tuesday, a rapid HIV test and plasma storage is required. If the second part of the split visit is on Day 7 or beyond, a rapid HIV test AND a 4th generation EIA test is required, as well as plasma storage. The result of the 4th generation EIA is not required prior to study product dispensation/administration. For example, if Day 1 is on a Wednesday and the participant comes in the following Wednesday, a rapid HIV test, a 4th generation EIA test and plasma storage are required.

- Plasma storage collection is required whenever HIV testing is done, even when HIV testing is performed multiple times during a split visit.
- For Week 4, given the implications for transition to Step 2, every effort should be made to remind participants to return study product at this visit. If a participant does not bring study product at this visit for in-person pill counting, a split visit can be done, taking into consideration the following requirements:
 - If the Week 4 visit occurs within the target window, then study product must be provided for in-person pill counting within the same target window; meaning, both parts of the split visit must be done within the target window.
 - For example, a participant presents to the clinic on Day 26 (target window is Day 25 to Day 31) for Week 4 visit but does not bring the study product for pill counting. Participant returns on Day 30 and brings study product. Since the second part of the visit took place within the target window, adherence calculated at this visit can be taken into consideration for transition to Step 2.
 - If the Week 4 visit occurs outside the target window, then study product must be provided for in-person pill counting within 72 hours of the first part of the split visit, meaning, if a participant comes for Visit 4 outside the target window, the participant should be asked to return to the clinic and bring study product for in-person pill counting within 72 hours (3 days) from first part of the split visit.
 - For example, a participant presents to the clinic on Day 32 (target window is Day 25 to Day 31) for Week 4 visit but does not bring the study product. In this case, the participant must bring study product to the clinic by Day 35 (72 hours after the first part of the split visit) for adherence to be taken into consideration for transition to Step 2.
 - If the participant is unable to attend the clinic in a way to allow in-person pill counts to be done according to the above requirements, they will not be allowed to continue to Step 2, and instead will be offered annual study visits until the randomized blinded portion of the study is over.

Missed or Late Visits:

Even though study visits are “allowed” anytime during the study, for data management purposes, if a visit is not conducted within the allowable window, per Section 13 of the SSP, a Missed Visit e-CRF should be completed if a visit is missed and cannot be made up.

In general, when a visit is missed altogether and a participant reports to the site for the next scheduled visit, the procedures from the missed visit that are not also required for the current visit should be performed. Important considerations for a missed visit or late visit:

- Missed visit during Step 1 and Step 3 (blinded and open label oral steps, respectively) of the study: the CMC does not need to be consulted in advance regarding additional clinical considerations for the timing of the visit.
 - During Step 1, a participant cannot transition to Step 2 if more than 120 days have lapsed since the day of Enrollment; therefore, the Week 2 and 4 visits must be conducted during this timeframe. If a participant has missed one or both of these visits and presents back to the site after 120 days have lapsed, conduct Week 4 visit procedures and transition the participant to annual follow-up visits until three years from the date of Enrollment. A missed visit form should be completed for the Week 2 study visit. Consult the CMC for further guidance if a participant has missed visits during Step 1 and it is less than 120 days from the day of Enrollment.
- Missed visit during Step 2 of the study: action taken will depend on which type of visit is missed:
 - It is not required to contact the CMC for out of target window safety visits no matter when they occur; however, an injection visit may never be completed without a preceding safety visit being completed. All laboratory results from this visit must be available and reviewed, and deemed within the protocol approved range, to be able to receive the next injection.
 - Missed injection visit: It is not required to contact the CMC for out of target visit window injection visits provided that they are a minimum of 6 weeks and a maximum of 15 weeks from the last injection. It is required to contact the CMC for guidance in cases outside of these parameters.

Note: For Week 9 study visits – Given the timeframe between Week 5 and Week 9 injection visits, CMC consultation is required if the visit occurs less than 3 weeks from Week 5 or 11 weeks from Week 5 injection visit.

Merged Study Visits: In unforeseen circumstances, and at sites with the capacity of rapidly (same day) receiving laboratory tests results, including all required HIV test

results (FDA-cleared HIV rapid test, and 4th or 5th generation HIV immunoassay), missed safety visit procedures can be merged with an injection study visit. In this case, all laboratory test results must be received and reviewed prior to administration of study product - without repeating laboratory testing. Although safety visit procedures are conducted, sites should use the visit code for the injection visit for all laboratory testing and study procedures. Sample test results should only be used (once) to meet the requirements of one visit and not duplicated for a second visit on the same day. Meaning, one sample test result cannot have two different visit codes. The safety visit should be considered missed and documented as such.

Because of the nature of study procedures required to be performed during the study, all visits are expected to be completed at the study clinic only. Sites should contact the Clinical Management Committee (CMC) regarding any questions about procedures performed outside of the study clinic if the situation arises (e.g., participant is incapacitated and cannot report to the clinic). Details regarding the CMC are described in SSP manual Section 9.

5.3.1 Follow-up Visit Procedures

Some important general considerations for study visits include:

- All follow-up visits will include the following procedures, in addition to the procedures as outlined in the HPTN 083 protocol that are specified for each visit:
 - Review/update locator information
 - Targeted medical history and targeted physical exam, with concomitant medications update, as well as weight, blood pressure, and pulse data entry to Medidata Rave
 - HIV pre and post-test counseling
 - HIV testing and plasma storage
 - Adherence counseling
 - Offer condoms and lubricant
- CBC, chemistry, and liver function testing will be done at all visits for Step 1. At Step 2 this testing will be done at all visits with the exception of Week 5. At Step 3 no CBC testing will be done (unless clinically indicated) and chemistry and liver function tests will be done only at weeks 24 and 48.
- If a participant is unable to read the CASI questionnaire, the staff may read it to the participant and enter the information on their behalf. However, the participant must agree to allow staff to enter the information given the sensitive nature of the questions. If the participant does not agree to have staff enter the information on their behalf, then document that the questionnaire will be missed.
- Participants with pill counts resulting in less than 50% adherence as assessed by pill count at the Week 4 visit, will not be allowed to transition to Step 2. These

participants will be asked to report for annual visits until three years from the date of Enrollment.

- The final visit of Step 2 will take place at Week 153, which is also Day 0 of Step 3. An injection will not be administered, and blinded oral study product will not be dispensed at this visit. All other procedures required for Week 153/Day 0 will be performed. Any remaining blinded oral study product will be collected from the participant as part of the conclusion of Step 2. Open-label oral product will be dispensed at this visit as part of Day 0 of Step 3. The procedures required at Week 153 (except for administration of the injection) and results of testing from Week 153 will also apply to Day 0 of Step 3 unless otherwise noted below and otherwise directed by the CMC. If the Week 153 visit is missed or has already occurred or passed at the time Version 3.0 of the protocol is approved and implemented at a site, the final visit of Step 2/first visit of Step 3 will take place at the next visit the participant attends; the CMC may be contacted if additional guidance is required in these cases, though this is not required. Please refer to Section 6 of the SSP and Section 5.8, Appendix IB, and Appendix IC of the Protocol.

If a participant in Step 2 transitions prematurely to Step 3, the procedures listed in Section 5.8 of the Protocol will be performed as part of the last visit of Step 2 (whenever that occurs)/Day 0 of Step 3 to the extent possible. All assessments are identical to Week 153/Day 0 listed above with the following exceptions:

- Behavioral assessment – do not administer if done within the last month before entering Step 3
- Acceptability assessment (not listed above) – this should be administered at this visit if it was not done in the last 6 months before entering Step 3
- Urine collection and testing for GC/CT – do not collect/do not perform test if testing occurred within 3 months prior to entering Step 3
- Rectal swab collection and testing for GC/CT – do not collect/do not perform test if testing occurred within 3 months prior to entering Step 3
- Syphilis testing – do not perform test if testing occurred within 3 months prior to entering Step 3
- For participants who transition prematurely to Step 3, the timeline for Day 0 begins 8 weeks after that participant’s last injection, even if the participant does not report to the Day 0 visit (or subsequent visits.). The timeline for Step 3 continues whether or not a participant attends any study visits. Although not required, sites may contact the CMC for questions regarding participants who transition prematurely to Step 3 and miss subsequent study visits.
- Participants that do not transition from Step 1 to Step 2 will be asked to stay on study for annual visits until three years from the date of Enrollment, per Appendix ID of the protocol. The procedures to be performed at these annual visits are:
 - Review/update locator information
 - Targeted medical history and targeted physical exam, with concomitant medications update, as well as weight, blood pressure, and pulse data entry to Medidata Rave

- HIV pre and post-test counseling
- HIV testing, plasma storage, DBS storage
- Offer condoms and lubricant
- Participants who prematurely end participation in Step 2 will move to Step 3 and receive 48 weeks of open label TDF/FTC, followed by annual follow-up until three years from the date of Enrollment. The timepoint during Step 2 that a participant transitions to Step 3 will determine whether they will be asked to attend annual visits following the completion of Step 3. If the completion of open label TDF/FTC for Step 3 post-dates three years from the date of Enrollment, no further annual follow-up is required. Once a participant has completed three years of follow-up, they will then be transitioned to local prevention services.
- In general, participants should not be withdrawn from the study during the blinded, randomized portion of the study except in the case of a) explicit withdrawal of consent by the participant; b) death; c) extreme/unusual circumstances to protect participant safety; or d) if they are unwilling or unable to comply with required study procedures. Any such safety-related participant terminations should only be implemented after consultation with the Protocol Chair, Division of AIDS (DAIDS) Medical Officer, Statistical and Data Management Center (SDMC) Protocol Statistician, representatives from the Laboratory Center (LC), the Leadership and Operations Center (LOC) Clinical Research Manager (CRM), and others.

In general, for participants who withdraw consent from the study prematurely during a study visit, the requirements for that visit should be completed to the extent possible **except for provision of study product** and will be considered their final visit. When possible, a plan should be made to give final laboratory results to the participant. For participants who inform the site in between visits that they wish to withdraw consent from the study, sites should make every effort to have the participant return any unused study product.

Note: Participants who wish to prematurely discontinue injections in Step 2 due to an injection site reaction AE must follow procedures detailed in Appendix III, Guidance for Injection Site Reactions (ISRs) prior to discontinuation of Step 2 procedures.

- If a participant receives a buttock implant or fillers during the study, they will no longer be able to receive the study injections. If the implant/filler procedure is done during Step 1, the participant will not transition to Step 2 and will be followed annually until three years from the date of Enrollment. If the participant receives the implant/filler during Step 2 (after receiving injections), the participant will stop injections and transition to Step 3 of the study.
- It is recommended that sites dispense sufficient oral study product in order to ensure coverage in case a participant cannot attend the next study visit as originally scheduled, as follows:
 - At Enrollment, two bottles of each study product (TDF/FTC or placebo and CAB or placebo)

- Beginning of Step 2 (Week 5): Two new bottles of oral TDF/FTC or placebo. At this visit, bottles dispensed during Step 1 should be collected and not returned to participants.
- All dispensation visits in Step 2: Three bottles at each dispensation visit to ensure an extra month supply between visits.
- All dispensation visits in Step 3: Four bottles at each study visit, except for last study visit, to ensure an extra month supply between visits.

Participants should be advised to bring open bottles to appointments, finish an open bottle before opening a new one, and should not combine or transfer pills between open bottles. A formal pill count is not required in Step 2 or Step 3, but an open bottle can be used to assist with determining refill quantity (that is, whether there is sufficient remaining oral study product supply in the participant's possession that only two bottles need be dispensed and still maintain a three-month supply in the participant's possession).

NOTE: Provision of study product cannot be more than the amount specified above. For example, if a participant reports at Week 17 that he/she will be traveling for 6 months and will not have access to another HPTN 083 site, the maximum amount of product to be dispensed is three bottles of oral product (two months plus one month of overage). Alternatively, a participant could be transitioned to Step 3 and be provided with four bottles of open label TDF/FTC (three months plus one month overage), and counseled regarding access to locally available resources for protection, then return to the site immediately upon his/her return.

- During Step 2, participants must receive both oral and injectable study products, or neither product at injection visits. Participants should not receive oral product if the injection is withheld. This requirement is also applicable to split visits. For example, if the injection is not administered during the first part of the split visit, oral study product should not be dispensed either.

Dispensing additional oral supply without an injection is only acceptable in the case of lost, stolen, or damaged oral study product. For example, if participant presents to the clinic before the next scheduled injection visit, and reports that their Truvada/placebo study product was lost or stolen, replacement product sufficient until next study visit can be dispensed. If this occurs, site needs to clearly document the rationale for dispensing oral product without an injection. In cases when this type of oral product dispensation occurs during an interim visit, rapid HIV testing should be done and be negative/non-reactive prior to product dispensation. No other procedures are required.

NOTE:

- The visit window for the DXA scan/dietary calcium and Vitamin D assessment at Week 57 and 105 is \pm 8 weeks.
- For participants in the DXA subset who prematurely transition to Step 3 and have not completed all three required DXA scans, any remaining follow-up

DXAs will not be performed during Step 3.

If a participant in the DXA subset prematurely transitions out of Step 2 to Step 3 or annual visits, and the transition occurs close to the Week 57 or Week 105 DXA timepoints, the CMC may authorize that a DXA be performed

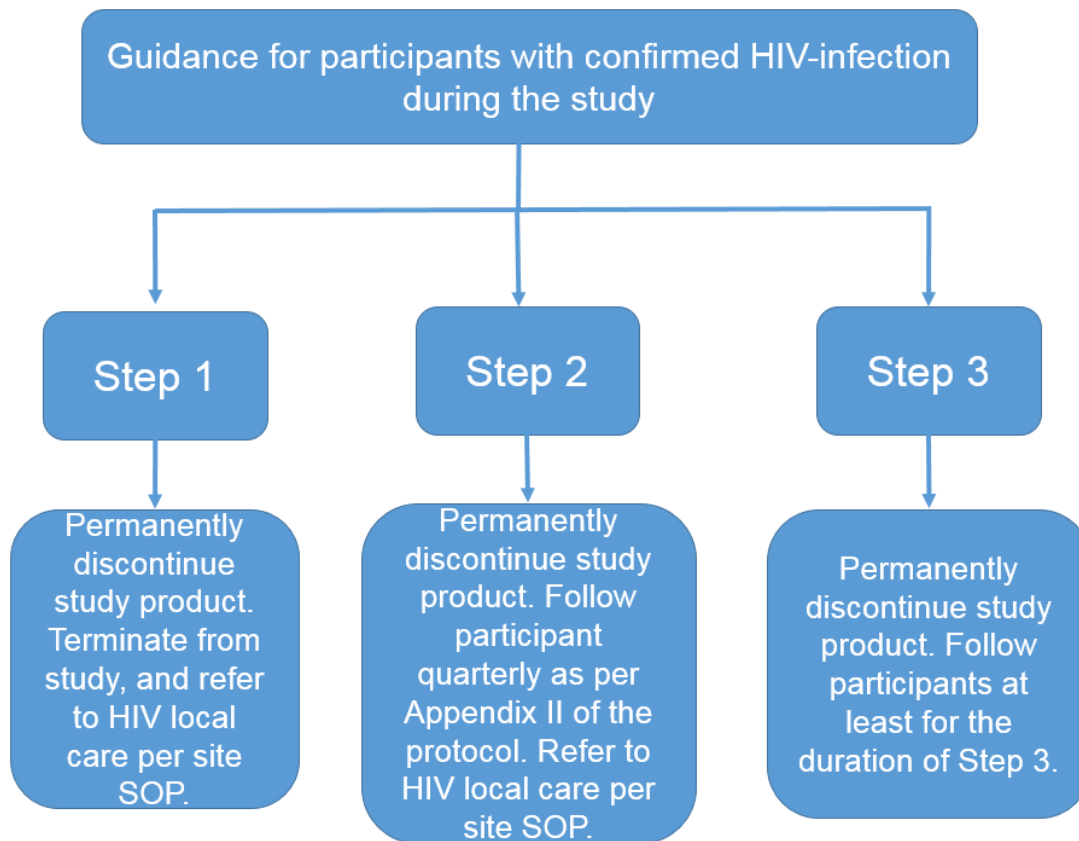
5.4 HIV Testing Considerations During Follow-Up

At all follow-up visits, HIV test results from previous visits and at least one HIV test result from the current visit must be available and reviewed by designated staff. HIV test results must be confirmed to be negative/non-reactive prior to study product administration. Sites must ensure the HIV testing algorithm at follow-up visits (Appendix ID of the Protocol and Figure 11.3 of the SSP) is being followed without deviation and all required samples are collected. To avoid missing a required test, site-specific tracking documents of study procedures (e.g. visit checklists) must include all the required HIV tests per algorithm. If a participant has a reactive or positive HIV test, product will be held. Further testing for confirmation will be done per Appendix II of the Protocol. Procedures for participants with discordant or discrepant HIV test results are outlined in Appendix V of the SSP. Procedures for participants who test positive during follow-up are described in Section 5.14 of the Protocol. **Do not** notify or consult the CMC about any HIV seroconversions during the study. This is in order to maintain the blind to the primary endpoint. Rather, email the 083 HIV team (083HIV@hptn.org), which is an independent group that is available for sites to seek guidance regarding the requirements of HIV confirmation testing as well as clinical management of HIV infected participants as necessary.

Further considerations for participants that have confirmed HIV-infection during each study Step include:

- Step 1: Permanently discontinue study product and terminate participant from the study. Refer participant for HIV-related care as per site-specific SOP.
- Step 2: Permanently discontinue study product and follow participant at quarterly intervals for one year as outlined in Appendix II of the protocol. Refer participant for HIV-related care as per site-specific SOP.
- Step 3: Permanently discontinue study product and follow participants at least for the duration of Step 3. Procedures for participants who become HIV-infected during Step 3 will depend on at what point during the follow-up period the seroconversion occurred and will be dictated by the team at 083HIV@hptn.org. Refer participant for HIV-related care as per site-specific SOP.
- Annual Visits: Participants will be followed per Appendix II of the protocol. Refer participant for HIV-related care as per site-specific SOP.

Please refer to the diagram below for a visual of how to proceed with participants confirmed to be HIV infected during each Step of the study.



5.5 Participant Transfers

During the course of the study, participants may leave the area where they enrolled. If they move to the vicinity of another HPTN 083 study site, they should be encouraged to transfer to that study site and continue study participation. To accomplish this, study staff at both sites will complete the participant transfer process. The same process should be followed for temporary or permanent transfers. If there is no way that the participant can return to the clinic where he/she enrolled and he/she is not close to another HPTN 083 clinic to transfer, the participant should remain in the study in case the situation changes and the participant returns or moves to a location where there is an HPTN 083 site. If participant is in Step 1, see guidance provided in Section 5.3 regarding missed study visits during Step 1. For participants in Step 2, sites can choose the following:

- Stay on Step 2 in case the participant returns – in this case, sites will submit missed visit forms for each visit missed, with documented attempts to contact the participant during the time of absence in the study chart.
- Transition participant to Step 3. Prior to relocation, provide participant with 4 months of open label TDF/FTC (3 months + 1 month overage) and indicate to the participant that is expected for him or her to attend the Step 3 visits and annually thereafter until three years from the time of Enrollment. Missed visit

forms should be submitted for any visits missed and documentation of attempts to contact the participant should be included in the study chart.

Upon identifying the need for a participant transfer to another site, the transferring site is responsible for notifying the HPTN 083 LOC Senior Clinical Research Managers, HPTN 083 SDMC Protocol Manager, the HPTN 083 LC Representatives, and the DAIDS Protocol Pharmacist (see Section 1.2 of the SSP manual for contact information). Also, the alias list ‘sc.083cdm.org’ should be included on the email. SCHARP staff included on the alias will facilitate the process within MediData Rave. Sites should allow 2-3 U.S. business days after the Transfer form has been completed and the IoR has signed off on all forms for the participant casebook to be transferred to the receiving site. Please refer to Appendix IV of the SSP - ‘Participant Transfer and Receipt Process within Medidata Rave – for further information. The transferring site is also responsible for contacting the site to which the participant wishes to transfer (the “receiving site”). After the logistical details of the transfer have been agreed upon, the following steps will be completed:

- The transferring site will explain the transfer arrangements to the participant and obtain written permission for the release of information that will authorize the transfer of his study records to the receiving site.
- Both the transferring and receiving sites should follow the instructions for participant transfers within Medidata Rave in Appendix IV of the SSP manual.
- For all other study records not found in Medidata Rave, the transferring site will ship **certified copies*** (see below) of all the participant’s study records to the receiving site via courier or overnight mail service. The transferring site will track the shipment and the receiving site will confirm receipt of the shipment with the HPTN LOC, SDMC, and the transferring site. The receiving site will verify receipt of said materials with the transferring site. At this point in time, follow-up of the participant becomes the receiving site’s responsibility.
- The transferring site will email the HPTN LC representative confirming transfer to the new site. The transferring site will retain archived samples for the participant unless otherwise instructed by the HPTN LC.
- Study drug supply should be discussed with the DAIDS Protocol Pharmacist in cases of participant transfer.
- The receiving site will establish contact with the participant, obtain a copy of the original screening and enrollment consent (and any others), along with his/her informed consent to continue in the study (have the participant sign a consent at the receiving site).
- Upon receipt of the Participant Transfer form and confirmation that the transferring IoR has signed off on the participant’s eCRF casebook, the SDMC will re-map the participant’s ID number (PTID) and any e-CRFs in the study database to reflect the change in study site follow-up responsibility. This will ensure that future questions and/or QCs will be sent to the appropriate site. The participant’s original ID number, treatment-arm assignment, and follow-up visit schedule will remain unchanged.

- The receiving site will complete a Participant Receipt eCRF to complete the transfer process.
- If the participant returns to the clinic where she/he enrolled, the same process should be followed to complete the transfer process. However, the certified copies to be sent to the enrolling site will only include those applicable to the visits conducted at the non-enrolling site. This is because the original records are at the enrolling site and the only records needed would be those for visits conducted at the non-enrolling site.

* See Appendix 1 of Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (<https://www.niaid.nih.gov/sites/default/files/sourcedocappndx.pdf>) listed under Copies: Certified) for requirements for certification.