5. Participant Follow Up

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 094 protocol and relevant SSP manual sections (e.g., clinical, laboratory, data management procedures).

5.2 Study Overview

All participants enrolled in the study will have scheduled visits at Week 26 and Week 52. Those participants randomized to the intervention arm will have their healthcare managed from the mobile unit through Care Visits as needed through Week 26. Active control arm participants will be navigated to local clinics to manage their health needs.

5.3 Study Visits

Protocol-required visits: All participants will have two regular protocol-required study visits, at week 26 and week 52, which are described in Appendices IA and IB of the Protocol, as well as described in Section 12 of the SSP manual (Data Management).

Visit windows for each required study visit are described in Section 12.5 of the SSP. As outlined in the protocol, visits conducted outside of the target visit windows are allowable. 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).

Care Visits: It is expected that participants randomized to the intervention arm will use the services of the mobile unit as needed through week 26. These visits are

considered Care Visits. They are not Interim Visits. Expectations for Care Visits are found in Appendices IA and IB of the protocol.

Interim Visits: Interim visits may take place between the regularly scheduled visits (Enrollment, Week 26 and Week 52). Interim visits occur when procedures are conducted with a participant outside of a regularly scheduled visit. Some examples of interim visits include:

- A participant tests positive for HIV for the first time at their Week 26 visit and returns three days later for confirmatory testing
- A participant completes all the required procedures of their Week 26 visit, but a syphilis test result is inconclusive and the participant returns to the van for additional testing

Note that an interim visit is different from a split visit (see below). If a participant cannot complete all of the required procedures for a visit the first time they are seen at the van, and so return on a later date to complete the remaining procedures, that is split visit; the participant's second encounter at the van is not an interim visit.

For the intervention arm, visits between Enrollment and Week 26 visits will be classified as clinical care visits, so for this arm, interim visits will only occur between Week 26 and Week 52 visits. For active control arm participants, any visit to the mobile unit where study procedures are performed outside of the regularly scheduled visits will be an interim visit. Procedures to be performed during interim visits will be based on the reason for the visit.

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.

Missed Visits:

If a protocol-required visit is not completed within the allowable window, per Section 12.5 of the SSP, a Missed Visit eCRF should be completed. A Missed Visit CRF should not be completed for any Care Visit.

5.3.1 Follow-up Visit Procedures

- Refer to Protocol Appendices for the Schedule of Evaluations.
- Assessment for COVID-19 must be completed at EVERY encounter during

follow-up. COVID-19 assessment should follow local guidelines as outlined in the site's SOP. Any participant with suspected or confirmed COVID-19 will have their in-person visit deferred until such a time that the CDC or local guidelines state that it is safe to resume.

- Peer navigation contacts will occur in both arms from Enrollment through Week 26. See Appendix 1 for the frequency and details of these encounters.

- If a participant is unable to read the ACASI 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 may withdraw from the study for any reason at any time. IoRs may, in consultation with the HPTN 094 Clinical Management Committee (CMC), withdraw participants before their scheduled termination visit to protect their safety, and/or if participants are unable or unwilling to comply with study procedures. The CMC also should be consulted regarding procedures to be performed in the case of early termination (e.g., final HIV testing, etc.), if a participant is willing to undergo such procedures.

- While Screening, Enrollment and Care visits will occur on the mobile unit, the Week 26 and 52 visits may occur on the mobile unit or at the CRS. To relieve pressure on the mobile unit, Week 26 and 52 visits may be completed at other locations in the community that are acceptable to the population with prior approval of OCSO.

5.3.2 Split Follow-up Visits

- Week 26 and Week 52 visits can be split, if necessary.

- A split visit can occur anytime within the Week 26 or Week 52 window (see protocol Section 6.7 or SSP Section 12.5), but sites are strongly encouraged to complete split visits in as small a window as possible, preferably within a target date of 10 days.

- If a Week 26 visit must be split, sites should prioritize collecting the samples necessary for primary outcome assessment at the first encounter (visit). These are:
    - Urine for MOUD testing
    - Blood for VL testing (HIV+)
    - DBS for PrEP testing (HIV-)

- It is expected that often the reason a Week 26 or Week 52 visit will be split is because a blood draw cannot be completed at the first encounter. The site must complete the MOUD log (all participants) and either the ART (for PLWH) or

PrEP log (for HIV negative) on the date the blood draw is obtained, even if the log was completed at a previous encounter where visit procedures were conducted.

- If any laboratory tests (other than HIV rapid tests) are repeated during the encounters of a split visit, sites should contact the SDMC and LC for guidance about recording those data into the study database.

5.4 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 094 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 094 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 094 site.

Upon identifying the need for a participant transfer to another site, the transferring site is responsible for notifying the HPTN 094 LOC Clinical Research Managers, HPTN 094 SDMC Protocol Manager, and the HPTN 094 LC Representatives, (see Section 1.2 of the SSP manual for contact information). SCHARP staff will facilitate the process within Rave. Sites should allow 2-3 business days after the Participant 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 A of this SSP section - '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 Rave in Appendix A of this SSP section.
- For all other study records not found in 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. Consult the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* for further information
- 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 eCRFs 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.

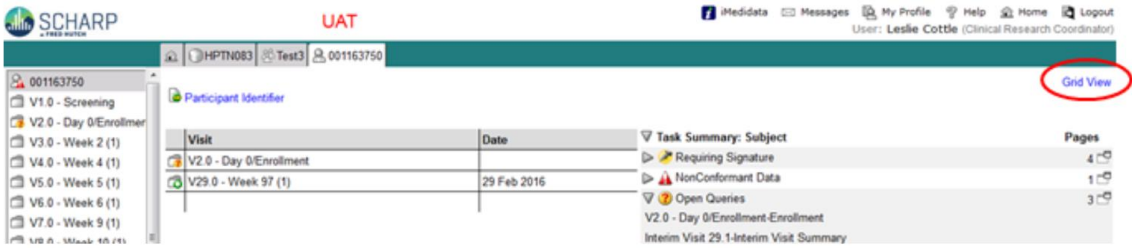
* See Appendix 1 of Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (https://www.niaid.nih.gov/sites/default/files/sourcedocappndx.pdf) listed under Copies: Certified) for requirements for certification. (See DADS SCORE Manual)

Appendix A

Participant Transfer and Receipt Process within Medidata Rave

Transferring site:

1. Mark 'Participant Transfer' under the Additional Forms section on the appropriate Date of Visit CRF; The Transfer form now appears in that visit folder.
2. Complete and save the Transfer form.
3. Ensure all data queries placed within the Rave database for the participant are resolved and all required eCRFs have been completed;
4. Investigator of Record or designee must verify that the data is complete and accurate by signing off on the participant's eCRFs as follows:
    - IoR (or designee) logs into Medidata and selects transferring PTID. On the Participant page, select "Grid View":



- Grid View lists all forms completed and expected for a participant.
- To sign off on all completed forms for the PTID, select "All" forms while in Grid View and then click "Sign and Save".