

## Section 5. Participant Follow-up

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### 5.1 Overview of Section 5

This section provides an overview of requirements and procedures for participant follow-up in the study. Additional procedure-specific details can be found in the visit checklists in Section 6 as well as in Section 9.

### 5.2 Follow-up Periods

Study participant accrual will last twelve months and the follow-up period will also last twelve months. Most participants will have an enrollment visit and follow-up visits at six and twelve months, but about one third of participants are expected to only complete the enrollment visit.

### 5.3 Follow-up Visits

Certain participants will be invited to participate in focus groups and individual qualitative interviews. Since the visit at which an individual will participate in one of these components will occur shortly after the individual is enrolled, this visit is not covered here but only in Section 4, participant accrual.

Three types of follow-up visits may be conducted: protocol-required visits, peer health navigation encounters and interim visits.

- **Protocol-required visits** are those specified to be conducted during follow-up per the study protocol. The HPTN 061 protocol specifies that the in-person follow-up visits occur every 6 months (at 26 weeks and 52 weeks). Protocol-required follow-up visits are pre-assigned a visit code as described in Section 9.
- **Peer Health Navigation Encounters** are those contacts between a participant and their peer health care system navigator (PHN) at which they address the participant's health care and other needs. The number, frequency and timing of these encounters will be dependent upon the interest and needs of the participant. To qualify as an encounter, the contact between the PHN and participant need not be face-to-face, but must involve two-way communication. So phone contacts or emails could be encounters as long as there is a response from the participant, but leaving a message on a participant's voicemail would not be an encounter. Most Peer Health Navigation Encounters that take place outside of an enrollment or follow-up visit will not qualify as study visits because no CRFs will be completed and faxed. However, if a social harm is reported or an unscheduled laboratory test is performed during an encounter with a PHN, then CRFs would be completed and the encounter would be considered an interim visit.

- **Interim visits**, or unscheduled visits, occur when the participant visits the study site outside of the regular study visit schedule. See Sections 9.6.1 Interim Visit Codes and 9.7 Study Visit Timing for more information. Visit Codes are only assigned to an interim visit if study procedures are performed and data is collected during that visit. In general, interim visits are only expected for unscheduled HIV testing (participant suspects he may be infected or has had an exposure) and reporting of Social Harms. As noted above, if a participant reports a Social Harm or requests an additional HIV test during a health navigation encounter, then this visit will be considered an interim visit and should be documented appropriately.

## **5.4 Follow-up Visit Scheduling**

### **5.4.1 Target Visit Dates**

Target visit dates for all subsequent study visits should be calculated based on the date that the participant is enrolled into the study (defined as when the participant is assigned a participant identification number after providing informed consent). The date of enrollment is considered to be Day 0 for purposes of calculating target dates and visit windows.

### **5.4.2 Visit Windows**

Acknowledging that it will not always be possible to complete follow-up visits on the targeted dates, visits may be completed within a window, called the “Allowable Window,” around the target date, and should be completed within a narrower window called the “Target Window.” See Section 9.7 Study Visit Timing for the Allowable and Target Windows for HPTN 061. If the visit is not completed within the Target Window it will be counted as either “early” or “late” in the study retention report. If the visit is not completed within the Allowable Window, the visit will be considered to be missed per the protocol, and study retention report. SCHARP will provide the Protocol Team and HPTN leadership with routine recruitment and retention reports that will include information about early, late, and missed visits for purposes of monitoring adherence to the follow-up visit schedule.

Please note that there is no target or allowable window for health navigation encounters or qualitative component visits. If a participant is eligible for health navigation and accepts this service during either their enrollment or 6 month follow-up visit, then there is expected to be at least one encounter between 6 month visits. If no encounter occurs, then the PHN should document the reasons for this on either the ENR-2 or FUV-2 in the comments section depending on when health navigation was accepted by the participant.

Note that phone contacts will not be included in the routine retention reports.

### **5.4.3 Split Visits (Visits Conducted Over Multiple Days)**

All procedures required by the study protocol to be performed at a particular follow-up visit should be completed at a single visit on a single day.

In the event that all required procedures cannot be completed on a single day (for example because the participant must leave the study site before all required procedures are performed), site staff should make every effort to complete the procedures within the target visit window. If necessary, procedures can be completed during the allowable visit window. When a visit is split over more than one day, sample collection procedures should take place on the same day that the ACASI questionnaire is completed. See Section 9 for relevant visit coding and data collection instructions.

### **5.4.4 Missed Visits**

Efforts should be made to contact any participant who does not complete a protocol-required visit prior to the end of the allowable window period. A Missed Visit CRF should be completed to document a missed follow-up visit at the end of the allowable window period. A Missed Visit CRF should not be completed because of a missed Peer Health Navigation encounter see Section 5.4.2 for how to document a situation where a participant has no health navigation encounters

## **5.5 Follow-up Visit Procedures**

An overview is provided below of the procedural requirements for all follow-up visits.

### **5.5.1 Week 26 and 52 Protocol-Required In-Person Follow-up Visits**

The following procedures must be performed at week 26 and 52 in person follow-up visits:

- Review/update locator information of participants (must also be performed at interim visits)
- Ongoing informed consent
- Solicit information about study-related social harms and other racial, homophobic or partner violence. Refer for assistance if applicable. For HPTN 061, study-related social harms are defined as any untoward social occurrences that happen to a participant as a result of their participation in the study. Examples of social harms could include difficulties with family members, friends, or partners, difficulties obtaining or keeping health insurance, difficulties obtaining or keeping housing, being refused medical or dental care, or being treated poorly by a health care provider, being turned down by or told to leave an educational program, etc., if resulting from participation in the study.

- Complete necessary CRFs for the visit as described in SSP Section 9.10-HPTN061 Schedule of Forms.
- Complete ACASI questionnaire.
- Provide post-ACASI counseling and/or refer for further assessment or care, as needed.
- Collect information about up to 5 social and 10 sexual network members using Social-Sexual Network Assessment tool.
- Provide HIV pre-test counseling, if participant willing to undergo HIV testing. (NOTE: HIV pre-test counseling and HIV testing are not necessary at follow-up visits for participants with a prior HIV-positive diagnosis.)
- Collect information about initiation of HAART since the last visit from HIV-positive participants not previously receiving HAART.
- Provide STI pre-test counseling, if participant willing to undergo STI tests.
- Provide sexual risk reduction counseling per site SOP.
- Collect venous blood draw for HIV rapid test, syphilis test, WB, CD4 cell count, HIV viral load, and plasma storage as required by the protocol (See Appendix I, Schedule of Study Visits and Procedures for HPTN 061. Note that HIV rapid testing is not performed at 26 or 52 weeks if HIV infection was confirmed at a prior visit.).
- Collect urine for GC/CT NAAT testing.
- Collect rectal swab for GC/CT NAAT testing (52-wk visit only).
- Provide HIV and/or STI test results, post-test counseling, and treatment/referral for treatment, if applicable. (NOTE: HIV WB and STI test results will be provided at the post-test visit after the study visit, scheduled for a time soon after the results are expected to be available.)
- Exit Visit administrative procedures, as needed (e.g. TM-1) if applicable for participants terminating from the study.
- Schedule the next contact or visit, if applicable (after the participant has received results of HIV rapid test).
- Referrals for management of symptomatic STIs and additional services, as necessary.
- Offer condoms and lubricant.

- If participant was eligible but refused peer health care system navigation at enrollment visit, offer again (at week 26 visit only).

### **5.5.3 Post-Test Visits For Persons Who Have a Reactive HIV Rapid Test After Enrollment**

If a participant has a reactive HIV rapid test result during follow-up, the following procedures will be performed:

- Provide counseling about interpretation of result.
- Schedule a follow-up visit for a time when confirmatory results will be available.
- Refer the participant to peer health care system navigation (if eligible), and clinical and social services as necessary.

If a participant has an indeterminate or positive initial WB, but does not have a positive WB on repeat (confirmatory) testing, the site will contact the NL to determine whether additional HIV testing is needed to determine the participant's HIV infection status. See Section 11 for more details.

### **5.5.4 Participant Withdrawal and Termination**

Participants may voluntarily withdraw from the study for any reason at any time. The site investigator also may withdraw participants from the study, after consultation with the protocol co-chairs, lead biostatistician, and the chair of the Study Monitoring Committee (SMC) (or the Network PI if the SMC Chair is unavailable) in order to protect the participants' safety and/or the safety of study staff or fellow participants. Participants also may be withdrawn if the study is terminated prior to its planned end date. No participants should be withdrawn from the study solely for non-attendance at study visits or refusal of study procedures. Study staff will record the reasons for all withdrawals from the study in participants' study records and complete the appropriate CRF(s).

Staff will make every reasonable effort to complete a final evaluation of a participant who chooses to terminate from the study prior to their 52-week visit. In such cases, the staff will attempt to complete as many of the procedures of the 52-week visit as the participant is willing to undertake at their final visit. Priority should be given (as appropriate for the participant) to HIV counseling and testing, other laboratory tests, and HAART history. Study staff will record the reason(s) for all withdrawals from the study in participants' study records and any applicable CRFs (CRF TM-1).

## **5.6 Follow-up Visit Locations**

Study visits may take place at any location identified by study staff which assures adequate privacy and confidentiality, such as recruitment venues, study clinical

sites, mobile vans or other public areas. If sites wish to have off-site visits (not related to health navigation or the qualitative component) with participants, they should develop a site-specific SOP detailing their plans and procedures. The site-specific SOP for off-site visits should provide a detailed description of the following: 1) the resources necessary per visit and how this impacts the site, 2) a chain of custody for samples as proper documentation, 3) the availability of appropriately qualified and trained study staff, 4) participant confidentiality, 5) data management and accessibility of records, 5) participant availability and retention, 6) mode of transportation for staff and supplies (if necessary) and 7) staff safety.

## 5.7 Follow-up Visit Scenario

Presented below is one example of a follow-up visit schedule and study scenario that may occur during HPTN 061. The examples illustrate that the allowable visit windows impact whether a completed visit will be considered a protocol-required visit or an interim visit. It may be helpful to refer to a calendar when attempting to calculate visit target dates. Due to the potential complexities that may be encountered when scheduling and completing follow-up visits, it is recommended that sites use a participant visit tracking sheet similar to the example provided at the end of this section.

### 5.7.1 Suppose a participant is enrolled into the study on 3 August 2009. What are the target and allowable dates for his visits through 12 months of follow-up?

Visit	Target Date	Target Window	Allowable Window
<b>Week 26</b>	1 February 2010 (day 182)	18 January 2010-15 February 2010 (days 168-196)	21 December 2010-21 June 2010 (days 140-322)
<b>Week 52</b>	2 August 2010 (day 365)	19 July 2010-16 August 2010 (days 351-379)	22 June 2010- until site closes (days 323-until site closes)

You can see from this example that it may be acceptable to schedule the participant's visit on the same day of the month (e.g., the 22<sup>nd</sup> of the month is within the target window for both visits) and easier for the participant to remember.

## Sample Participant Visit Tracking Sheet for HPTN 061

<b>Participant ID Number</b>	
<b>Participant Enrollment Date</b>	

***Instructions:** For HPTN 061, the Participant Enrollment Date is defined as the date upon which the participant is assigned a PTID. Once the enrollment date is determined, enter all Target Visit Dates, Target Window Date and Allowable Visit Windows for the participant’s follow-up period (12 months) in the chart below.*

Follow-up Timepoint	Target Visit Date	Target Visit Window	Allowable Visit Window	Scheduled Visit Date	Actual Visit Date
26 Week “6 Month” (In-person)					
52 Week “12 Month” (In person)					

## 5.8 Participant Transfers

During the course of the study, participants may move away from the metropolitan area where they enrolled on a temporary or permanent basis. If they move to the vicinity of another HPTN 061 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 process if a participant transfers as delineated below. Even if a participant moves away from the study area to a location where they cannot continue the study, sites are strongly encouraged to leave the participant enrolled and not terminate them, since participants do change their minds and return to the city they have left.

Upon identifying the need for a participant transfer to another site, the site where the participant enrolled (the “transferring site”) is responsible for notifying the HPTN CORE, SCHARP, the HPTN Network Lab, and 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:

- SCHARP will notify the transferring site of all outstanding data QC notes for the transferring participant; the transferring site will resolve these QCs.
- The transferring site will explain the transfer arrangements to the participant and obtain written permission for the release of information from the participant authorizing transfer of their study records to the receiving site.
- The transferring site will ship **certified copies** (the originals should always be kept at the transferring site) of all of the participant’s source documents to the receiving site via courier or overnight mail service (DAIDS guidance on certified copies is provided in the DAIDS Source Documentation Requirements document). Copies should also be shipped or faxed of non-source document files (or CRFs), but these do not need to be certified. If the files are being shipped, the transferring site will track the shipment and the receiving site will confirm receipt of the shipment with the HPTN CORE, SCHARP, and the transferring site. The receiving site will verify receipt of these 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 complete and fax a Participant Transfer form to SCHARP DataFax .
- The transferring site will forward a copy of the Participant Transfer form to the HPTN Network Lab representative for informational purposes. The transferring site will retain archived samples for the participant unless otherwise instructed by the Network Lab.

- The receiving site will establish contact with the participant, obtain a copy of the original enrollment consent (and any others), and have the participant sign a new enrollment consent at the receiving site. The receiving site will then complete and fax a Participant Receipt form to SCHARP DataFax.
- Upon receipt of the Participant Transfer and Participant Receipt forms, SCHARP will re-map the participant's ID number 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 PTID number and follow-up visit schedule will remain unchanged.

## **5.9 Protocol-Required and Interim Visits at Sites Other Than Where Participants or Participants Enrolled**

During the course of the study, it may happen that a participant is temporarily in another location where there is an HPTN 061 site other than the one in which they originally enrolled (their "home clinic") at a time when they have a scheduled study visit or when they wish to have an interim visit. These protocol-required or interim visits may be conducted at the alternative clinic ("temporary clinic") if both sites have a SOP in place to cover this situation. In addition, the local EC/IRBs must have agreed to the procedures outlined in the site-specific SOP, which must cover the following areas:

- Whether or not informed consent will need to be re-administered at the temporary clinic.
- A method to transfer study information from the temporary to the home clinic.
- A standard method of communication between the two sites prior to the initiation of any procedure, for clinical information, and determination of the duration of time during which care and visits will be conducted at the temporary clinic.

Since there are only two follow-up visits in HPTN 061 with large allowable windows, it should be possible in almost all cases to schedule a visit around a participant's temporary absence from the home clinic area. If a participant anticipates being in the temporary clinic area for both follow-up visits, or for an extended period of time after the 26-week visit but before the 52-week visit, a participant transfer should be considered.