

## Section 6. Visit Checklists

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### 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) Checklists as provided in this SSP Section are not designed to be used as source documentation.**

The purpose of the checklists is to provide a tool to ensure that all of the required activities for each visit are completed according to the visit schedule. Source documentation of these activities will typically be made on other study records, such as CRFs and in chart notes. Sites are encouraged to work with the 061 CRM to modify the checklists in a way that makes them both user-friendly and reflective of required study procedures, and to discuss what adjustments are necessary to use them as source documentation.

**2) One checklist should be used for each participant.**

A common way that checklists are used is for staff to check off activities as they are completed during each visit.

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

**4) When checklists are not used as source documents, sites will need to identify source documentation for items on the checklist that are in the protocol, but not included on any CRF.**

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 on the locator information sheet itself. The checklist cannot serve as the source for the confirmation of locator information unless you revise it to show who confirmed the information and if any changes were made.

Participant

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Initial Contact Date

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**Enrollment Visit:**

**Visit 01.0**

**CLINIC ACTIVITIES**

| <u>Initial</u> | <u>Done</u> |  |
|----------------|-------------|--|
| _____          | _____       | Obtain informed consent for study enrollment per the site-specific informed consent SOP and prior to any other study procedures. Document consent in a signed and dated chart note or on an ICF cover page. If participant is willing, obtain informed consent for long-term storage of specimens (not required for enrollment). |
| _____          | _____       | Assign PTID number and record on source document and enrollment log.   |
| _____          | _____       | Complete locator form (non-DataFax).   |
| _____          | _____       | Review the eligibility criteria for all items with the potential participant and document his eligibility in the appropriate source documents.   |
| _____          | _____       | Obtain sign off of Investigator of Record or designee on the individual participant eligibility verification checklist.  |
| _____          | _____       | For those who are eligible, explain about qualitative component of study (focus group or interview) and offer participation. If participant agrees, schedule the date of their participation.  |
| _____          | _____       | Complete CRFs: demographics [DEM1-4], Enrollment [ENR] items 1, 5, 5a, 8, 8a, 8b, Baseline Prevention Research Questionnaire [BPR-1], Health Care Utilization [HCU-1-4].   |
| _____          | _____       | Log participant into the web-based ACASI. Instruct participant on use of ACASI system and allow him to complete self-guided ACASI interview.   |
| _____          | _____       | Provide post-ACASI counseling per HPTN 061 Counseling Manual.  |
| _____          | _____       | Provide HIV and STI pre-test counseling, for those consenting to HIV testing and STI testing, respectively, per site SOP. If participant identifies as HIV positive and refuses testing, follow SSP Section 4.5.1 for confirming status using acceptable alternative documentation.  |

**Participant**

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**Initial Contact Date**

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| <u>Initial</u>  | <u>Done</u> |   |
|---|-------------|---|
| Conduct appropriate clinical/sample collection procedures, per site SOPs: |             |   |
|   |             | _____ _____ Blood draw for laboratory tests and sample storage.   |
|   |             | _____ _____ Urine for Gonorrhea/Chlamydia (GC/CT NAAT) testing.   |
|   |             | _____ _____ Rectal swab GC/CT testing.  |
|   |             | _____ _____ Examine participant for circumcision (unless participant refuses or identifies that he has had gender reassignment surgery) and document on the Enrollment [ENR-2] items 9 and 9a CRF.  |
| _____   | _____       | As results are available, complete HIV Test Results [HTR-1, 2] and Enrollment STI Laboratory Results [ELR-1] forms.   |
| _____   | _____       | Collect information about up to 5 social and 10 sexual network members using the Social-Sexual Network Assessment tool.   |
| If participant qualifies as an index participant:                         |             |   |
|   |             | _____ _____ Request that the participant refer up to 5 Black sexual network members to the site.  |
|   |             | _____ _____ Discuss barriers and motivators to referring network members with participant and provide training on techniques for motivating network members to come to the study site. Discuss risk of social harms or violence with the participant.   |
|   |             | _____ _____ Provide up to 5 referral cards to participant.  |
| _____   | _____       | Provide HIV and STI test results, when available, including post-test and risk-reduction counseling per site SOP. Document study visit in patient chart notes. <ul style="list-style-type: none"> <li>• For participants receiving reactive HIV rapid test results, explain procedural implications for WB confirmation, CD4 cell count and viral load testing, and the necessity of returning to the site to receive these results.</li> <li>• For participants receiving positive STI test results, offer treatment or referral for treatment.</li> </ul> |
| _____   | _____       | If the counselor has identified a need for referral to services, the counselor should provide a referral, or arrange for health navigator (if eligible) to provide the referral if that is the participant's preference. Counselor offers a copy of services inventory to all participants. Document referral in chart notes and on the Referral Log CRF [RL-1].  |

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**Participant**

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**Initial Contact Date**

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| <input type="text"/> | <input type="text"/> | If participant qualifies, introduce peer health navigation. Introduce participant to his assigned Peer Health Navigator (PHN) or arrange for a meeting with PHN at a later date. If participant is not interested in PHN services, complete questions 7 and 7a in Enrollment CRF [ENR-2] about reasons for refusal of health care navigation. If the participant meets their PHN, the PHN should complete the Peer Health Navigation Encounter Form [PHE1-3] and Referral Log [RL-1] if appropriate. |
| <input type="text"/> | <input type="text"/> | Offer condoms and lubricant. Provide reimbursement.  |
| <input type="text"/> | <input type="text"/> | Schedule next visit. If the participant has agreed to qualitative component of study, schedule the visit for that activity.  |

Participant

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Initial Contact Date

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**Enrollment Visit:  
Visit 01.0**

**LABORATORY ACTIVITIES**

| <u>Initial</u> | <u>Done</u> |   |
|----------------|-------------|---|
| _____          | _____       | HIV rapid test from whole blood.  |
| _____          | _____       | HIV WB for participants with a reactive HIV rapid test.                 |
| _____          | _____       | CD4 cell count testing for participants with a reactive HIV rapid test. |
| _____          | _____       | HIV viral load for subjects with a positive WB result.                  |
| _____          | _____       | GC/CT NAAT from urine.  |
| _____          | _____       | Syphilis serology (including titer).                                    |
| _____          | _____       | Prepare rectal swabs for shipment to NL.                                |
| _____          | _____       | Plasma sample storage, for subsequent shipment to NL.                   |

**Participant**

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**Initial Contact Date**

**Enrollment Visit:**

**Visit 1.0**

**Case report forms completed and/or updated**

| <u>Initial</u>       | <u>Done</u>          |  |
|----------------------|----------------------|--|
| <input type="text"/> | <input type="text"/> | Demographics (DEM)                               |
| <input type="text"/> | <input type="text"/> | Enrollment (ENR)                                 |
| <input type="text"/> | <input type="text"/> | Baseline Prevention Research Questionnaire (BPR) |
| <input type="text"/> | <input type="text"/> | Health Care Utilization (HCU)                    |
| <input type="text"/> | <input type="text"/> | HIV Test Results (HTR)                           |
| <input type="text"/> | <input type="text"/> | Enrollment STI Laboratory Results (ELR)          |
| As needed:           |                      |  |
| <input type="text"/> | <input type="text"/> | Referral Log (RL)                                |
| <input type="text"/> | <input type="text"/> | Peer Health Navigation Encounter (PHE)           |
| <input type="text"/> | <input type="text"/> | Medical Records Review (MRR)                     |
| <input type="text"/> | <input type="text"/> | Additional HIV Test Results (AHT)                |

**Participant**

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**Initial Contact Date**

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**Follow-up Visit:  
26 weeks after enrollment  
Visit 2.0**

| <u>Initial</u>   | <u>Done</u> |   |
|--|-------------|---|
| _____  | _____       | Update locator form (non-DataFax) and confirm continued consent to participate.   |
| _____  | _____       | Discuss whether participant has joined another HIV interventional study since the last visit and (if applicable) discuss the burden to the participant of participating in more than one HIV study at a time.               |
| _____  | _____       | Complete CRFs: Health Care Utilization [HCU], Follow-Up Visit [FUV] items 3-6, and Follow-up Prevention Research Questionnaire [FPR]  |
| _____  | _____       | Log participant into the web-based ACASI questionnaire. Instruct participant on use of ACASI system and allow to complete self-guided ACASI interview.  |
| _____  | _____       | Provide post-ACASI counseling per HPTN 061 Counseling Manual.   |
| _____  | _____       | Provide STI pre-test counseling if participant is willing to be tested. If the participant not previously confirmed HIV-positive, and is willing to be tested, provide HIV pre-test counseling. Follow site counseling SOP. |
| Conduct appropriate sample collection procedures, per site SOPs: |             |   |
| _____  | _____       | Blood draw for laboratory tests and sample storage.   |
| _____  | _____       | Urine for Gonorrhea/Chlamydia (GC/CT) testing.  |
| _____  | _____       | Conduct HIV rapid test, if participant has agreed to HIV testing and has not been identified as HIV positive at a prior visit.  |
| _____  | _____       | Review and update information about up to 5 social and 10 sexual network members using Social-Sexual Network assessment tool.   |
| _____  | _____       | Provide sexual risk reduction counseling per site SOP.  |
| _____  | _____       | Solicit information about study-related social harms. Record any social harms on Social Impact Log [SIL]  |
| _____  | _____       | As results are available, complete HIV Test Results [HTR] and Follow-up STI Laboratory Results [FLR].   |

**Participant**

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**Initial Contact Date**

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|-------|-------|---|
| _____ | _____ | <p>Provide HIV and STI test results, when available, including post-test counseling.</p> <ul style="list-style-type: none"> <li>• For participants receiving reactive HIV rapid test results, explain procedural implications for WB confirmation, CD4 cell count and viral load testing, and the necessity of returning to the site to receive these results.</li> <li>• For participants receiving positive STI test results, offer treatment or referral for treatment.</li> </ul>   |
| _____ | _____ | <p>If the counselor has identified a need for referral to services, the counselor should provide a referral, or arrange for PHN to provide the referral if that is the participant's preference. Counselor offers a copy of services inventory to all participants. Document referral in chart notes and on Referral Log CRF [RL-1].</p>  |
| _____ | _____ | <p>If participant is eligible but previously declined to work with a peer health navigator, offer an introduction to PHN at this visit. If offer is accepted, introduce PHN or arrange for meeting with PHN at a later time. If participant is not interested in PHN services, complete questions 7 and 7a in Follow-Up Visit CRF [FUV] about reasons for refusal of health care navigation. If the participant meets their PHN, the PHN should complete the Peer Health Navigation Encounter Form [PHE] and Referral Log CRF [RL-1] if applicable.</p> |
| _____ | _____ | <p>Offer condoms and lubricant. Provide reimbursement.</p>  |
| _____ | _____ | <p>Schedule next visit.</p>   |

**Participant**

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**Initial Contact Date**

**Follow-up Visit:**

**Visit 2.0**

**LABORATORY ACTIVITIES**

| <u>Initial</u>       | <u>Done</u>          |  |
|----------------------|----------------------|--|
| <input type="text"/> | <input type="text"/> | HIV Rapid test (if participant has not tested HIV positive at a prior study visit) |
| <input type="text"/> | <input type="text"/> | HIV WB test to confirm reactive HIV rapid test result.                             |
| <input type="text"/> | <input type="text"/> | CD4 cell count for subjects with a reactive HIV rapid test                         |
| <input type="text"/> | <input type="text"/> | HIV viral load testing for subjects after their first positive WB result           |
| <input type="text"/> | <input type="text"/> | Syphilis serology (including titer).   |
| <input type="text"/> | <input type="text"/> | GC/CT NAAT from urine.   |
| <input type="text"/> | <input type="text"/> | Plasma sample storage, for subsequent shipment to NL.                              |

**Participant**

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**Initial Contact Date**

**Follow-up Visit:  
Visit 2.0**

**Case report forms completed and/or updated**

| <u>Initial</u>       | <u>Done</u>          |   |
|----------------------|----------------------|---|
| <input type="text"/> | <input type="text"/> | Follow-up Visit (FUV)                             |
| <input type="text"/> | <input type="text"/> | Follow-up Prevention Research Questionnaire (FPR) |
| <input type="text"/> | <input type="text"/> | Follow-up STI Laboratory Results (FLR)            |
| <input type="text"/> | <input type="text"/> | Health Care Utilization Questionnaire (HCU)       |
| As needed            |                      |   |
| <input type="text"/> | <input type="text"/> | Interim Visit (IV)                                |
| <input type="text"/> | <input type="text"/> | Medical Records Review (MRR)                      |
| <input type="text"/> | <input type="text"/> | HIV Test Results (HTR)                            |
| <input type="text"/> | <input type="text"/> | Additional HIV Test Results (AHT)                 |
| <input type="text"/> | <input type="text"/> | Peer Health Navigation Encounter (PHE)            |
| <input type="text"/> | <input type="text"/> | Referral Log (RL)                                 |
| <input type="text"/> | <input type="text"/> | Social Impact Log (SIL)                           |
| <input type="text"/> | <input type="text"/> | Missed Visit (MV)                                 |
| <input type="text"/> | <input type="text"/> | Participant Transfer (PT)                         |
| <input type="text"/> | <input type="text"/> | Participant Receipt (PRC)                         |
| <input type="text"/> | <input type="text"/> | Termination (TM-1)                                |

**Participant**

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**Initial Contact Date**

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**Follow-up Visit:**

**Visit 2.0**

**Case report forms completed and/or updated**

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| <input type="text"/> | <input type="text"/> | End of Study Inventory (ESI-1) |
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**Participant**

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**Initial Contact Date**

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| <b>Follow-up Visit:<br/>52 weeks after enrollment<br/>Visit 3.0</b> |             |   |
|---|-------------|---|
| <u>Initial</u>  | <u>Done</u> |   |
| _____   | _____       | Update locator form (non-DataFax) and confirm continued consent to participate.   |
| _____   | _____       | Complete CRFs: Health Care Utilization [HCU], Follow-Up Visit [FUV] items 3-6, and Follow-up Prevention Research Questionnaire [FPR].   |
| _____   | _____       | Log participant into the web-based ACASI questionnaire. Instruct participant on use of ACASI system and allow to complete self-guided ACASI interview.  |
| _____   | _____       | Provide post-ACASI counseling per HPTN 061 Counseling Manual.   |
| _____   | _____       | Provide STI pre-test counseling if participant is willing to be tested. If the participant not previously confirmed HIV-positive, and is willing to be tested, provide HIV pre-test counseling. Follow site counseling SOP. |
| Conduct appropriate sample collection procedures, per site SOPs:    |             |   |
| _____   | _____       | Blood draw for laboratory tests and sample storage.   |
| _____   | _____       | Urine for Gonorrhea/Chlamydia (GC/CT) testing.  |
| _____   | _____       | Swabs for rectal GC/CT testing.   |
| _____   | _____       | Conduct HIV rapid test, if participant has agreed to HIV testing and has not been identified as HIV positive at a prior visit.  |
| _____   | _____       | Review and update information about up to 5 social and 10 sexual network members using Social-Sexual Network assessment tool.   |
| _____   | _____       | Provide sexual risk reduction counseling per site SOP.  |
| _____   | _____       | Solicit information about study-related social harms. Record any social harms on Social Impact Log [SIL]  |
| _____   | _____       | As results are available, complete HIV Test Results [HTR] and STI Follow-up Laboratory Results [FLR]  |

**Participant**

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**Initial Contact Date**

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|----------------------|----------------------|---|
| <input type="text"/> | <input type="text"/> | <p>Provide HIV and STI test results, when available, including post-test counseling.</p> <ul style="list-style-type: none"> <li>For participants receiving reactive HIV rapid test results, explain procedural implications for WB confirmation, CD4 cell count and viral load testing, and the necessity of returning to the site to receive these results.</li> <li>For participants receiving positive STI test results, offer treatment or referral for treatment.</li> </ul> |
| <input type="text"/> | <input type="text"/> | Provide referrals for any services. Counselor offers a copy of services inventory to all participants. Document referral in chart notes and on Referral Log CRF [RL-1].   |
| <input type="text"/> | <input type="text"/> | Thank participant for their participation in the study.   |
| <input type="text"/> | <input type="text"/> | Offer condoms and lubricant. Provide reimbursement.   |
| <input type="text"/> | <input type="text"/> | Schedule visit to receive HIV or STI results if applicable.   |

**Participant**

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**Initial Contact Date**

**Follow-up Visit:**

**Visit 3.0**

**LABORATORY ACTIVITIES**

| <u>Initial</u> | <u>Done</u>   |  |
|----------------|---------------|--|
| <u>      </u>  | <u>      </u> | HIV Rapid test (if participant has not tested HIV positive at a prior study visit).                                  |
| <u>      </u>  | <u>      </u> | HIV WB test to confirm reactive HIV rapid test result.   |
| <u>      </u>  | <u>      </u> | CD4 cell count for subjects with a reactive HIV rapid test, and for all previously identified HIV-positive subjects. |
| <u>      </u>  | <u>      </u> | HIV viral load testing for all HIV positive subjects.  |
| <u>      </u>  | <u>      </u> | Syphilis serology (including titer).   |
| <u>      </u>  | <u>      </u> | GC/CT NAAT from urine.   |
| <u>      </u>  | <u>      </u> | Prepare rectal swab samples for shipment to NL.  |
| <u>      </u>  | <u>      </u> | Plasma sample storage, for subsequent shipment to NL.  |

**Participant**

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**Initial Contact Date**

**Follow-up Visit:  
Visit 3.0**

**Case report forms completed and/or updated**

| <u>Initial</u>       | <u>Done</u>          |   |
|----------------------|----------------------|---|
| <input type="text"/> | <input type="text"/> | Follow-up Visit (FUV)                             |
| <input type="text"/> | <input type="text"/> | Follow-up Prevention Research Questionnaire (FPR) |
| <input type="text"/> | <input type="text"/> | Follow-up STI Laboratory Results (FLR)            |
| <input type="text"/> | <input type="text"/> | Health Care Utilization (HCU)                     |
| <input type="text"/> | <input type="text"/> | HIV Test Results (HTR)                            |
| <input type="text"/> | <input type="text"/> | End of Study Inventory (ESI)                      |
| <input type="text"/> | <input type="text"/> | Termination (TM)                                  |
| <b>As needed</b>     |                      |   |
| <input type="text"/> | <input type="text"/> | Interim Visit (IV)                                |
| <input type="text"/> | <input type="text"/> | Medical Records Review (MRR)                      |
| <input type="text"/> | <input type="text"/> | Referral Log (RL)                                 |
| <input type="text"/> | <input type="text"/> | Additional HIV Test Results (AHT)                 |
| <input type="text"/> | <input type="text"/> | Social Impact Log (SIL)                           |
| <input type="text"/> | <input type="text"/> | Missed Visit (MV)                                 |
| <input type="text"/> | <input type="text"/> | Participant Receipt (PRC)                         |