6. Visit Checklists

6.1. Overview of Section 6

This section provides a template checklist for each of the required study visits. The use of visit checklists is optional.

6.2. Visit Checklists as Source Documentation

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).

These checklists can be modified to address these two issues (e.g., 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 for the sites to ensure that all of the required activities for a visit are completed. Sites are encouraged to work with the HPTN 074 central resources team (HPTN LOC, SDMC, LC) to modify the checklists in a way that makes them both user-friendly and reflective of required study procedures.

6.3. Use of the Checklists

One checklist should be used for each participant. **Note that there are different checklists for the INDEX PARTICIPANT and their HIV-uninfected NETWORK INJECTION 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 each visit.

When using the checklists, it is important that every item is completed - this is done by initialing and dating each step of the checklist (to show that the step was completed), or by entering ND (not done), or NA (not applicable) if a procedure is not performed.

The source documentation for the procedure will need to be identified for some items that are in the protocol, but not captured on the CRFs.

A good example of this is locator information. At each visit, the protocol requires that locator information is confirmed and, if necessary, updated. Some of the ways that the "act" of confirming or updating can be documented at each visit include writing a note in the participant's chart, creating a locator information log, or having a review/revision log attached to the locator information itself. The checklist cannot serve as the source for the confirmation of locator information unless it is revised to show who confirmed the information, if changes were made to the form.

6.4 Checklists for the Study Extension

Index participants re-enrolling in the study extension will have up to four (4) visits (Visits 41.0, 42.0, 43.0, and 44.0) over the course of 9-12 months after termination from the main study. Partners are not eligible for the extension. Re-enrollment in the study extension (i.e., the enrollment visit) will take place during the participant's first study extension visit. Then, 2 quarterly visits (months 3 and 6) will occur, followed by an exit visit – for a total of (up to) 4 study extension visits.

The only eligibility criteria for the study extension is to have previously been an index in the main study and be willing to undergo another HIV test (during re-enrollment).

Sites should follow the quarterly visit schedule below for the re-enrollment, month 3, and month 6 visits in the extension. Sites should follow the exit visit schedule for the index's last visit in the extension.

6.5 Template Eligibility Checklists

Eligibilty Checklist For Screening **INDEX PARTICIPANT** **PTID:** ☐☐☐ ☐☐☐☐ ☐ ☐				
These are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.				
Demographic/Medical/Behavioral	Initials of person performing assessment	Eligible	Not Eligible	
	_____	Yes ☐	No ☐	Age 18-60 years confirmed by identification
	_____	Yes ☐	No ☐	Provided written informed consent
	_____	Yes ☐	No ☐	Active injection drug user: self-report of: injecting drugs at least twelve times during the past three months and six times the past month

	____	Yes ☐	No ☐	Active injection drug user: a PWID in the opinion of site staff
	____	Yes ☐	No ☐	Reports sharing needles/syringes or drug solutions at least once in the last month
	____	Yes ☐	No ☐	Willing and able to identify, recruit, and have enrolled at least one HIV-uninfected network injection partner who is eligible for study participation according to the criteria below NOTE FIRST ENROLLED **PARTNER** PTID HERE: ☐☐☐ ☐☐☐☐ ☐ ☐
	____	Yes ☐	No ☐	Have no plans to move outside the study area for at least one year after study enrollment
	____	Yes ☐	No ☐	Willing to participate in intervention activities, including regular phone contact
Blood Samples	____	Yes ☐	No ☐	HIV-infected based on a study-defined testing algorithm (defined in the SSP Manual)
	____	Yes ☐	No ☐	Viral load ≥1,000 copies/mL at Screening

Eligibilty Checklist For Screening

NETWORK INJECTION PARTNER

PTID: ☐☐☐ ☐☐☐☐ ☐ ☐

These are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.

	Initials	Eligible	Not Eligible	
Demographic/ Medical/Behavioral	____	Yes ☐	No ☐	Age 18-60 years confirmed by identification
	____	Yes ☐	No ☐	Provided written informed consent

	____	Yes ☐	No ☐	Active injection drug user: self-report of: injecting drugs at least twelve times during the past three months and six times the past month
	____	Yes ☐	No ☐	Active injection drug user: a PWID in the opinion of site staff
	____	Yes ☐	No ☐	Confirmed injection partner, using referral identification cards or other means of identification from the index participant NOTE **INDEX** PTID HERE: ☐☐☐ ☐☐☐☐ ☐ ☐
	____	Yes ☐	No ☐	Have no plans to move outside the study area for at least one year after study enrollment
Blood Samples	____	Yes ☐	No ☐	HIV-uninfected based on the study-defined testing algorithm* (defined in the Study SSP Manual)

INDEX PARTICIPANT

These are exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.

	Initials	Eligible	Not Eligible	
Demographic/ Behavioral/Medical	____	No ☐	Yes ☐	Current participation in any HIV prevention study
	____	No ☐	Yes ☐	Previous or current participation in an HIV vaccine trial
	____	No ☐	Yes ☐	Appearance of psychological disturbance or cognitive impairment that would limit the ability to understand study procedures, as determined by the investigators
	____	No ☐	Yes ☐	Any other condition that, in the opinion of the investigators, would make participation in the study unsafe, or otherwise interfere with the study activities
	____	No ☐	Yes ☐	Prior screening as a potential network member of another index participant in this study

	_____	No ☐	Yes ☐	Currently or previously a partner of an index participant

NETWORK INJECTION PARTNER ***These are exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.***				
Demographic/ Behavioral/Medical	Initials	Eligible	Not Eligible	
	_____	No ☐	Yes ☐	Current participation in any HIV prevention study
	_____	No ☐	Yes ☐	Previous or current participation in an HIV vaccine trial
	_____	No ☐	Yes ☐	Any reactive or positive HIV test at Screening or Enrollment, even if the individual is confirmed to be HIV-uninfected
	_____	No ☐	Yes ☐	Appearance of psychological disturbance or cognitive impairment or any other condition that in the opinion of the investigator would limit the ability to understand study procedures, would make participation in the study unsafe, or otherwise interfere with the study activities
	_____	No ☐	Yes ☐	Any other condition that, in the opinion of the investigators, would make participation in the study unsafe, or otherwise interfere with the study activities
	_____	No ☐	Yes ☐	Previously named and enrolled as a partner of another index participant

6.6 Template Visit Checklists

Screening Visit **INDEX PARTICIPANT**		
_____	☐	Obtain written consent for screening *If the individual does not consent to screening, **STOP** screening procedures.*
_____	☐	Verify age
_____	☐	Assign Participant ID and record on the screening log
_____	☐	Collect locator information (including cell phone), only after written informed consent obtained. Note: **No** identifiable data will be collected prior to obtaining written informed consent.
_____	☐	Collect demographic information
_____	☐	Conduct brief assessment of injection risk behavior, substance use, substance use treatment, and ART use for eligibility (record information collected)
_____	☐	Provide HIV pre-test counseling.
_____	☐	Collect blood for: • HIV testing • CD4 cell count (if an HIV test is reactive or positive) • HIV viral load (if an HIV test is reactive or positive) • Plasma storage
_____	☐	Provide HIV post-test counseling including: ☐ brief, standardized injection and sexual transmission risk reduction counseling, ☐ referral to substance use treatment, ☐ referral to needle and syringe exchange programs (if legal and available) ☐ and referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate).
_____	☐	Provide referral identification cards marked with PTID to facilitate the recruitment of their network members.
*If at any time during the screening visit, the participant is not eligible, **STOP** screening procedures (except for risk-reduction counseling and referrals). Inform the participant of his/her ineligibility. Document the reason for ineligibility in the Screening Log. Retain documentation completed thus far, and fax only the Screening Outcomes CRF to the HPTN SDMC.*		
_____	☐	Schedule enrollment visit, if eligible thus far.
_____	☐	Provide participant reimbursement.

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Enrollment/Randomization*, Week 0 INDEX PARTICIPANT		
_____	☐	Confirm identity of participant and eligibility of participant including that **at least one eligible partner** has been enrolled.
_____	☐	Obtain written consent for enrollment *If the individual does not consent to enrollment, **STOP** enrollment procedures.*
_____	☐	Confirm locator information.
_____	☐	Conduct baseline sexual behavior, injection risk behaviors, substance use, substance use treatment and ART use and adherence interviews
_____	☐	Complete assessment of barriers and facilitators to HIV care and substance use treatment, mediators and moderators of key outcomes.
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct social impact assessment
_____	☐	Provide HIV pre-test counseling
_____	☐	Collect blood for HIV testing
_____	☐	Collect urine for: ☐ Urine testing for substances of abuse ☐ Urine storage ☐ Dried urine storage
_____	☐	Provide HIV post-test counseling including brief, standardized injection and sexual transmission risk reduction counseling
_____	☐	Randomize participant
_____	☐	Referral for ART (If clinically indicated according to national guidelines and/or participant is randomized to the intervention group)
_____	☐	Referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate)
_____	☐	Schedule next visit
_____	☐	Provide participant reimbursement, if applicable

NOTE: *For re-enrollment in the study extension, please use the Quarterly Visit checklist.

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Week 4 Visit INDEX PARTICIPANT		
_____	☐	Confirm identity of participant
_____	☐	Confirm locator information
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct follow up sexual behavior, substance use, substance use treatment and ART experience interviews
_____	☐	Complete assessment of barriers and facilitators to HIV care and substance use treatment, mediators and moderators of key outcomes
_____	☐	Complete brief, standardized injection and sexual transmission risk reduction counseling
_____	☐	Conduct social impact assessment
_____	☐	Conduct adverse event assessment
_____	☐	Provide referral for diagnosis and treatment of STIs, HBV, HCV and TB (as needed)
_____	☐	Provide a referral for ART (if clinically indicated according to national guidelines and/or participant is randomized to the intervention group)
_____	☐	Collect blood for plasma storage
_____	☐	Collect urine for urine testing for substances of abuse and urine storage
_____	☐	Schedule next study visit
_____	☐	Provide participant reimbursement, if applicable

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Quarterly Visits Main Study and Study Extension* INDEX PARTICIPANT		
_____	☐	Confirm identity of participant
_____	☐	Confirm locator information
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct follow up sexual behavior, substance use, substance use treatment and ART experience interviews
_____	☐	Complete assessment of barriers and facilitators to HIV care and substance use treatment, mediators and moderators of key outcomes
_____	☐	Complete brief, standardized injection and sexual transmission risk reduction counseling
_____	☐	Conduct social impact assessment
_____	☐	Conduct adverse event assessment
_____	☐	Referral to substance use treatment (in extension only)
_____	☐	Provide referral for diagnosis and treatment of STIs, HBV, HCV and TB (as needed)
_____	☐	Provide a referral for ART (If clinically indicated according to national guidelines and/or participant is randomized to the intervention group)
_____	☐	Collect blood for: ☐ plasma storage ☐ CD4 cell count [Weeks 26, 52, 78 and 104 only in main study; Months 3 and 6 (Weeks 130 and 143) only in study extension]
_____	☐	Collect urine for: ☐ urine testing for substances of abuse ☐ urine storage ☐ dried urine storage (weeks 26 and 52)
_____	☐	Schedule next study visit
_____	☐	Provide participant reimbursement, if applicable.

NOTES: *Quarterly visits will occur at Weeks 13, 26, 39, 52, 65, 78, 91, and 104. Note that Weeks 52, 65, 78, 91, 104, 117, 130, 143 or 156 may be an Exit visit for some participants, depending on the timing of the participant's enrollment relative to the enrollment period at the site.

**Re-enrollment in the study extension may occur at the first of up to 4 visits in the extension. Quarterly study extension visits will occur at months 6 and 9 (as possible).

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

Exit Visits INDEX PARTICIPANT		
_____	☐	Confirm identity of participant
_____	☐	Confirm locator information
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct exit sexual behavior, substance use, substance use treatment and ART experience interviews
_____	☐	Complete assessment of barriers and facilitators to HIV care and substance use treatment, mediators and moderators of key outcomes
_____	☐	Complete brief, standardized injection and sexual transmission risk reduction counseling
_____	☐	Conduct social impact assessment
_____	☐	Conduct adverse event assessment
_____	☐	Provide referral for diagnosis and treatment of STIs, HBV, HCV and TB (as needed)
_____	☐	Collect blood for: ☐ plasma storage ☐ CD4 cell count (Weeks 26, 52, 78 and 104 only)
_____	☐	Collect urine for: ☐ urine testing for substances of abuse ☐ urine storage ☐ dried urine storage (weeks 26 and 52)
_____	☐	Provide participant reimbursement, if applicable

**NOTE: ***Weeks 52, 65, 78, 91,104, 117, 130, 143 or 156 may be an Exit visit for some participants, depending on the timing of the participant's enrollment relative to the enrollment period at the site.

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Screening Visit NETWORK INJECTION PARTNER		
_____	☐	Obtain written consent for screening *If the individual does not consent to screening, **STOP** screening procedures.*
_____	☐	Verify age
_____	☐	Assign Participant ID and record on the screening log
_____	☐	Collect locator information (including cell phone), if written informed consent obtained. Note: No identifiable data will be collected prior to obtaining written informed consent.
_____	☐	Collect demographic information
_____	☐	Conduct brief assessment of injection risk behavior, substance use, and substance use treatment for eligibility
_____	☐	Confirmation via local procedures of relationship to an index participant (network association)
_____	☐	Provide HIV pre-test counseling
_____	☐	Collect blood for: • HIV testing • Plasma storage
_____	☐	Provide HIV post-test counseling including: ☐ brief, standardized injection and sexual transmission risk reduction counseling, ☐ referral to substance use treatment, ☐ referral to needle and syringe exchange programs (if legal and available), ☐ and referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate).
*If at any time during the screening visit, the participant is not eligible, **STOP** screening procedures (except for risk-reduction counseling and referrals). Inform the participant of his/her ineligibility. Document the reason for ineligibility in the Screening Log. Retain documentation completed thus far, and fax only the Screening Outcomes CRF to the HPTN SDMC.*		
_____	☐	Schedule enrollment visit, if eligible thus far
_____	☐	Provide participant reimbursement

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Enrollment/Randomization, Week 0 NETWORK INJECTION PARTNER		
_____	☐	Confirm identity of participant and eligibility of participant
_____	☐	Obtain written consent for enrollment *If the individual does not consent to enrollment, STOP enrollment procedures.*
_____	☐	Confirm locator information
_____	☐	Conduct baseline sexual behavior, injection risk behaviors, substance use and substance use treatment interviews
_____	☐	Conduct assessment of barriers and facilitators to substance use treatment, mediators and moderators of key outcomes
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct social impact assessment
_____	☐	Provide HIV pre-test counseling.
_____	☐	Collect blood for: ☐ HIV testing ☐ plasma storage
_____	☐	Collect urine for: ☐ Urine testing for substances of abuse ☐ Urine storage ☐ Dried urine storage
_____	☐	Provide HIV post-test counseling including brief, standardized injection and sexual transmission risk reduction counseling
_____	☐	Provide referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate)
_____	☐	Schedule next study visit
_____	☐	Provide participant reimbursement, if applicable

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Week 4 visit NETWORK INJECTION PARTNER		
_____	☐	Confirm identity of participant
_____	☐	Confirm locator information
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct follow up sexual behavior, substance use and substance use treatment interviews
_____	☐	Complete assessment of barriers and facilitators to substance use treatment, mediators and moderators of key outcomes
_____	☐	Conduct social impact assessment
_____	☐	Conduct adverse event assessment
_____	☐	Provide HIV pretest counseling
_____	☐	Collect blood for ☐ HIV testing ☐ Plasma storage
_____	☐	Provide HIV post-test counseling including: ☐ brief, standardized injection and sexual transmission risk reduction counseling, ☐ and referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate).
_____	☐	Collect urine for: ☐ Urine testing for substances of abuse ☐ Urine storage
_____	☐	Schedule next study visit
_____	☐	Provide participant reimbursement, if applicable

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Quarterly Visits NETWORK INJECTION PARTNER		
_____	☐	Confirm identity of participant
_____	☐	Confirm locator information
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct follow up sexual behavior, substance use and substance use treatment interviews
_____	☐	Complete assessment of barriers and facilitators to substance use treatment, mediators and moderators of key outcomes
_____	☐	Conduct social impact assessment
_____	☐	Conduct adverse event assessment
_____	☐	Provide HIV pretest counseling
_____	☐	Collect blood for: ☐ HIV testing ☐ Plasma storage
_____	☐	Provide HIV post-test counseling including: ☐ brief, standardized injection and sexual transmission risk reduction counseling, ☐ and referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate)
_____	☐	Collect urine for: ☐ Urine testing for substances of abuse ☐ Urine storage ☐ Dried urine storage (Weeks 26,52 and Exit only)
_____	☐	Schedule next study visit
_____	☐	Provide participant reimbursement, if applicable

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

Exit Visit NETWORK INJECTION PARTNER		
_____	☐	Confirm identity of participant
_____	☐	Confirm locator information
_____	☐	Complete social network interview (non-CRF)
_____	☐	Conduct exit sexual behavior, substance use, and substance use treatment experience interviews
_____	☐	Complete assessment of barriers and facilitators to substance use treatment, mediators and moderators of key outcomes
_____	☐	Conduct social impact assessment
_____	☐	Conduct adverse event assessment
_____	☐	Provide HIV pretest counseling
_____	☐	Collect blood for ☐ HIV testing ☐ Plasma storage
_____	☐	Provide HIV post-test counseling including: ☐ brief, standardized injection and sexual transmission risk reduction counseling, ☐ and referral for diagnosis and treatment of STIs, HBV, HCV and TB (as appropriate).
_____	☐	Collect urine for: ☐ Urine testing for substances of abuse ☐ Urine storage ☐ Dried urine storage (Weeks 26,52 and Exit only)
_____	☐	Provide participant reimbursement, if applicable

Note: Weeks 52, 65, 78, 91 or 104 may be an Exit visit for some participants, depending on the timing of the participant's enrollment relative to the enrollment period at the site.