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 strongly recommended but is optional; sites may modify them as needed.

6.2 Visit Checklists as Source Documentation

Checklists are convenient tools, which may serve as source documentation if designed and completed appropriately. These checklists alone may not be sufficient for documenting all procedures but can be used to indicate that the procedure was completed and by whom. Additional information could be documented on the checklist comment sections and/or chart notes. It is up to each site to determine whether and how to use the visit checklists as source documentation.

It also should be noted that the visit checklists outlined below depict the visit schedule for a participant completing all protocol-specified study visits. In what is hoped to be a rare occurrence, there may be cases where a participant may have a modified study visit; in which case, any modifications to the procedures could be noted in in the comment section of the checklists.

6.3 Use of the Checklists

One checklist should be used for each participant. 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. Sites may modify order of procedures to maximize the efficiency of site-specific study operations, with the following exceptions/considerations:

- Informed consent must be obtained before any study procedures are performed.
- Once informed consent is obtained, the first procedure to be performed should be assignment of PTID.

- At the enrollment visit, randomization assignment must take place after final confirmation and verification of eligibility (for sites that do split enrollment visits due to physical location constraints, randomization can take place prior to performing the rapid HIV test required at the Enrollment Visit , which in most cases would be performed on the second day of the split visit), and collection of blood for plasma storage. If a participant is subsequently found to be ineligible and is not randomized, the plasma archive sample should be destroyed.
- During follow-up visits, behavioral assessment and acceptability assessments should be administered prior to the delivery of HIV and adherence counseling.
- It is recommended that procedures for determining eligibility for continued product use be conducted early in the visit to ensure sufficient time is allowed for product to be available for administration.
- Collect blood early in the visit so participants can have something to eat or drink immediately after blood collection.

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. See checklist instructions for further information.

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.

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

6.4 Visit Checklist Templates

Eligibility Checklist (Template)

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

Initials/Date	Eligible	Not Eligible	
_____	Yes ☐	No ☐	Age 18 to 60 at screening
_____	Yes ☐	No ☐	Provided written informed consent
_____	Yes ☐	No ☐	Able to successfully complete a sample informed consent assessment tool
_____	Yes ☐	No ☐	Urine test positive for recent opioid use and with evidence of recent injection drug use ("track marks")
_____	Yes ☐	No ☐	Diagnosed with OUD per Diagnostic and Statistical Manual of Mental Disorders (DSM) 5
_____	Yes ☐	No ☐	Willing to start MOUD treatment
_____	Yes ☐	No ☐	Self-reported sharing injection equipment and/or condomless sex in the last three months with partners of HIV-positive or unknown status
_____	Yes ☐	No ☐	Able to provide adequate locator information
_____	Yes ☐	No ☐	Confirmed HIV status, as defined in the HPTN 094 SSP Manual

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

Initials	Eligible	Not Eligible	
_____	No ☐	Yes ☐	Received MOUD in the 30 days prior to enrollment by self-report *(medication received in detoxification program is not considered MOUD)*
_____	No ☐	Yes ☐	Co-enrollment in any other interventional study unless approved by the Clinical Management Committee (CMC)

Participant ID | **Visit Date**

INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

The Investigator of Record or a Physician Sub-investigator listed on the Investigator of Record form, must review the eligibility checklist, as well as reports of information pertinent to the study, and sign and date the checklist to document his/her review and confirmation of eligibility prior to randomization. Signature must be signed prior to randomization (but can be signed on different dates, as long as it is prior to randomization).

_____ _____

Signature Line: Investigator of Record or designated Physician Sub-investigator

Date

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Screening Visit			
Initial/date	**Completed**	**Procedure**	**Comments**
		Assess for COVID-19	
_____	☐	Confirm participant identity and age per site SOPs.	
_____	☐	Determine screening attempt (Verify if HPTN 094 PTID has previously been assigned) ❒ First attempt ❒ Second attempt ❒ Third attempt	
_____	☐	Obtain written consent for screening/enrollment *If the individual does not consent to screening, **STOP** screening procedures.*	
_____	☐	Assign Participant ID and record on the screening log	
_____	☐	Collect locator information per site SOP	
_____	☐	Collect demographic information	
_____	☐	Targeted medical history to include MOUD treatment history, HIV risk behaviors, participation in other research studies	
_____	☐	Collect urine for: ❒ MOUD testing (urine dip stick) ❒ Substance use testing (urine dip stick)	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ❒ HIV testing ❒ FDA-cleared HIV rapid test ❒ Laboratory based HIV testing ❒ Plasma for storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Provide/facilitate access to harm reduction	
_____	☐	Offer condoms and lubricant	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Screening Visit			
Initial/date	**Completed**	**Procedure**	**Comments**
If after evaluating the criteria listed above, the participant is not eligible, ***STOP*** *screening procedures. 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 and site contact information, if applicable	

Notes for Screening Visit: Please refer to Sections 5.1 and 6.1 of the HPTN 094 Protocol

Comments: _____

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_____

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Enrollment			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Confirm participant eligibility to continue with Enrollment Visit. Provide participant with test results. *Reminder: Enrollment cannot take place on same day as screening.*	
_____	☐	Verify participant is within the screening window. ❒ Within 30 days screening	
_____	☐	Assess for COVID-19	
_____	☐	Confirm that informed consent was obtained and review elements of the consent as needed	
_____	☐	Review/update locator information	
_____	☐	Assessment for OUD, recent injection drug use (track marks)	
_____	☐	Targeted medical history to include MOUD treatment history, HIV risk behaviors, participation in other research studies	
_____	☐	Perform basic physical exam: ❒ vital signs, general appearance, head, ear, nose and throat, neck, chest, abdomen, extremities, skin ❒ brief neurologic exam. *Additional elements at clinician's discretion for patient care.*	
_____	☐	Screen for mental health needs and refer for services as indicated	
_____	☐	Enrollment ACASI	
_____	☐	Collect swabs for STI testing (GC/CT NAAT)	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Enrollment			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Collect urine for: ❒ MOUD testing (urine dip stick) ❒ Substance use testing (urine dip stick) ❒ Pregnancy testing (urine), for those who can become pregnant ❒ STI testing (GC/CT NAAT), for male participants ❒ Urine storage	
_____	☐	Provide HIV pre-test counseling	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Enrollment			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Collect blood for: ❒ HIV rapid testing ❒ Laboratory-based HIV testing, for HIV- participants ❒ HIV viral load, for HIV+ participants ❒ CD4 cell count, for HIV+ participants ❒ STI testing (syphilis) ❒ Hepatitis testing ❒ HCV Ab testing ❒ HCV RNA (viral load), for HCV+ participants ❒ HBV testing (HBsAg, HBsAb, HBcAb) ❒ Other HBV-related testing, as needed ❒ HAV testing (HAV IgG) ❒ Heme/Chem testing ❒ Hemoglobin ❒ Creatinine ❒ ALT ❒ AST ❒ Total bilirubin *Sites may obtain heme/chem testing values by ordering a complete blood count and comprehensive metabolic panel* ❒ Plasma storage ❒ DBS storage, for participants who enrolled HIV- ❒ Serum storage	
_____	☐	Empiric treatment of STIs (if symptomatic)	
_____	☐	Provide HIV post-test counseling	
_____	☐	Randomize participant and complete randomization CRF.	
_____	☐	MOUD counseling	

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Enrollment			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	COWS assessment and initiate mobile unit-based MOUD treatment program (intervention arm only), as needed	
_____	☐	Initiate (intervention) or refer for HIV treatment (intervention or active control), if needed for HIV+ participants	
_____	☐	PrEP initiation (intervention arm) or referral (active control arm), for HIV- participants	
_____	☐	Introduction to peer navigator	
_____	☐	Provide/facilitate access to harm reduction	
_____	☐	Develop a clinical plan	
_____	☐	Offer condoms and lubricant	
_____	☐	Schedule next study visit. If possible, generate and review with participant the visit calendar for upcoming visits.	
_____	☐	Provide site contact information and clarify any questions	
_____	☐	Provide participant reimbursement, if applicable	

Notes for Enrollment: Please refer to Section 6.2 of the HPTN 094 protocol

Comments: _____

_____

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_____

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Weeks 26 and 52 Circle the appropriate visit number			
Initials/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Assess for COVID-19	
_____	☐	Review/update locator information	
_____	☐	Collect history hospitalization since last visit	
		Screen for mental health needs and refer for services as indicated	
_____	☐	ACASI completion	
_____	☐	Swabs for STI testing (GC/CT NAAT)	
	☐	Collect urine for: ❒ MOUD testing (urine dip stick) ❒ Substance use testing (urine dip stick) ❒ Pregnancy testing (urine), if indicated for those who can become pregnant ❒ STI testing (GC/CT NAAT), for male participants ❒ Urine storage	
_____	☐	Provide HIV pre-test counseling	

Participant ID | **Visit Date**

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

_____	☐	Collect blood for: ❒ HIV rapid testing, for HIV- participants ❒ Laboratory-based HIV testing, for HIV- participants ❒ HIV viral load, for HIV+ participants ❒ STI testing (syphilis, GC/CT NAAT) ❒ Hepatitis testing ❒ HCV Ab testing (week 52 only) ❒ HCV RNA (viral load), for HCV+ participants ❒ Plasma storage ❒ DBS storage, for participants who enrolled HIV- ❒ Serum storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Provide lab-based STI results, and, if indicated, referral	
_____	☐	Empiric treatment of STIs (if symptomatic	
_____	☐	Provide MOUD counseling	
_____	☐	Provide/facilitate access to harm reduction	
_____	☐	Refer for HCV treatment, as indicated (week 52 only)	
_____	☐	Discuss conclusion of peer navigation (week 26 only)	
_____	☐	Offer condoms and lubricant	
_____	☐	Schedule next study visit (week 26 only)	
_____	☐	Provide site contact information and clarify any questions	
_____	☐	Provide participant reimbursement, if applicable	

Notes for week 26 and week 52: Please refer to Section 6.4 and 6.5 of the HPTN 094 protocol

Comments: _____

Participant ID | **Visit Date**

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Care Visit Care visits occur at any time throughout the study and are unscheduled. They are not interim visits.			
Initials/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Assess for COVID-19	
_____	☐	Collect targeted medical history to include MOUD treatment history, HIV risk behaviors, participation in other research studies, as needed	
_____	☐	Perform basic physical exam, if indicated: ❒ Vital signs, general appearance, head, ear, nose and throat, neck, chest, abdomen, extremities, skin ❒ Brief neurologic exam. *Additional elements at clinician's discretion for patient care.*	
_____	☐	As needed, screen for mental health needs and refer for services as indicated	
		As needed, collect urine for: ❒ Substance use testing (urine dip stick) ❒ Pregnancy testing (urine), if indicated for those who can become pregnant ❒ STI testing (GC/CT NAAT), for male participants	
_____	☐	As needed, collect swabs for STI testing (GC/CT NAAT)	
_____	☐	Provide HIV pre-test counseling	
_____	☐	As needed, collect blood for: ❒ HIV rapid testing, for HIV- participants ❒ Laboratory-based HIV testing, for HIV- participants	

Participant ID | **Visit Date**

INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

		❒ HIV viral load, for HIV+ participants ❒ CD4 cell count, for HIV+ participants ❒ STI testing (syphilis) ❒ Plasma storage, for any visit where HIV testing was performed	
_____	☐	Provide HIV post-test counseling	
_____	☐	Empiric treatment of STIs (if symptomatic)	
		Provide lab-based STI results and, if indicated, treatment (intervention arm) or referral (active control arm)	
		Hepatitis vaccine and/or treatment referral (indicate which were completed): ❒ HAV vaccine referral ❒ HBV vaccine referral ❒ HBV treatment/treatment referral ❒ HCV treatment referral	
		Provide clinical management of MOUD and HIV infection, including medication or prescription dispensation, as indicated	
_____	☐	Provide MOUD counseling	
_____	☐	Provide/facilitate access to harm reduction	
		Initiate (intervention) or refer for HIV treatment (intervention or active control), if needed	
_____	☐	Offer condoms and lubricant	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Schedule next study visit	
_____	☐	Provide participant reimbursement, if applicable	

Participant ID | **Visit Date**

INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, please refer to SSP Section 12.12, HPTN 094 Schedule of Forms

Notes for Care Visits: Please refer to Section 5.2 and 5.3 and 6.3 of the HPTN 094 Protocol

Comments: _____

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_____