4. Recruitment, Screening and Enrollment

4.1 Overview of Section 4

This section provides an overview of requirements and procedures for recruiting, screening, and enrolling participants in the study. Additional procedure-specific details can be found in the visit checklists in Section 6, and Protocol Sections 4.0 – 4.4.

4.2 Target Enrollment

Approximately 860 people who inject drugs (PWID) with opioid use disorder (OUD) and not receiving treatment with medication for OUD (MOUD) will be included in this study. The study targets enrollment of a minimum 25% women and 25% aged 18-29. Participants will be at risk for transmitting or acquiring HIV through drug injection and/or sex. Approximately 460 HIV-positive and 400 HIV-negative participants will be enrolled. The specific inclusion and exclusion criteria for HPTN 094 participants are provided in Sections 4.1 and 4.2 of the study protocol. The study-wide accrual period is approximately two and a half years. Site-specific accrual periods may vary depending on when sites are activated to the study and enroll their first participant.

For each site, accrual will begin after all applicable approvals are obtained and a Site-Specific Study Activation Notice is issued by the LOC.

Screening and enrollment data will be captured on electronic case report forms (eCRFs) within the electronic data capture system.

The SDMC will provide information on the number of participants screened and enrolled based on data received and entered into the study database.

4.3 Recruitment Plan

Each site is responsible for establishing a community engagement work plan and/or a recruitment plan/SOP for this study, and for updating the plan if needed to meet the targeted enrollment goals. The work plan/SOP should contain the following elements as necessary and as applicable to the study:

- Site-specific accrual goals
- Methods for tracking actual accrual versus accrual goals
- Recruitment methods and venues
- Methods for ensuring participants are not co-enrolled in another interventional study unless approved by the Clinical Management Committee (CMC)
- Methods for identifying the recruitment source of participants who present to the site for screening
- Methods for timely evaluation of the utility of recruitment methods and venues

- Pre-screening activities
- Recruitment timelines
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QA/QC procedures related to the above (if not specified elsewhere)
- Attached copies of recruitment worksheets, scripts, and other operational tools

4.4 Accrual Tips and Reminders

Recruitment can be more challenging than expected. Therefore, it is important to plan ahead, closely monitor recruitment data throughout the accrual period, and make adjustments as needed.

Recruitment methods and venues should be assessed on an ongoing basis. The usefulness or "yield" of various recruitment sources should be tracked over time. Sites should identify recruitment sources of participants who screen and enroll and track methods for timely evaluation of the usefulness of recruitment methods and venues. The following point should be considered:

- Of all participants contacted through a particular method or at a particular venue, how many eventually enroll in the study?
    - If this number (percentage) is high, keep using that method or venue.
    - If not, try different recruitment methods or identify new venues.
- Designate a Recruitment Coordinator who is responsible for tracking accrual rates and managing recruitment efforts over time.
- Engage community representatives on accrual issues and strategies throughout the accrual period.
- Consider characteristics of a "good candidate", e.g., is a prospective participant at high risk for HIV acquisition, likely to be retained for the duration of the study, and willing to attend all clinic visits?

4.5 Eligibility Determination

It is the responsibility of the site IoR and other designated staff, to ensure that only participants who meet the study eligibility criteria are enrolled in the study. As a condition for study activation, study sites must establish an SOP that describes how study

staff will fulfill this responsibility. It is recommended that this SOP contain the following elements:

- Eligibility determination procedures, including:
  - Screening visit eligibility assessment procedures
  - Post-screening visit eligibility assessment, confirming procedures and timelines
  - Final confirmation and sign-off procedures prior to enrollment
  - Documentation
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QC/QA procedures related to the above (if not specified elsewhere)

Sites may choose to conduct pre-screening activities, as determined by local SOPs and standard of care practices.

Section 3 (Documentation Requirements) includes tables that sites may wish to use as a template to adapt to a site-specific format for source documents that can be used to demonstrate participant eligibility. Sites may choose to develop their own site-specific documentation to specify the source for each eligibility criteria.

4.5.1 Study-Specific Eligibility Determination

The following clarifications are provided for how sites will assess the eligibility criteria found in the HPTN 094 Protocol.

For the criteria: **"Urine test positive for recent opioid use and with evidence of recent injection drug use ("track marks")"**

- Urine collected at screening will be tested for the presence of opioids. If opioids are not detected, the participant will not be eligible for enrollment. Collecting a second urine to retest for opioids is not recommended. However, if the site investigator believes that a person with a negative opioid test at screening is regularly using opioids and would be a strong candidate for the study (i.e., the negative urine test at screening was a chance event), the investigator may permit one additional urine collection and testing within the screening window. If this second urine test is also negative for opioids, the participant will be a screen fail.

  If a candidate has tested positive for opioids as part of screening procedures prior to the date of the enrollment visit, it is not necessary that the candidate have a positive opioid test at enrollment to enroll; the positive screening test will satisfy the enrollment criterion of recent opioid use. If an investigator authorizes a second urine collection for opioid screening, that collection can occur on the same

date as a planned enrollment visit. If the sample is positive for opioids by rapid test, the participant can proceed to enrollment procedures the same day, assuming all other enrollment criteria have been met, and this urine will be considered the enrollment sample, with an aliquot stored per protocol. If the rapid urine is negative for opioids, this sample will be considered a second screening sample and enrollment will need to be rescheduled within the screening window after the results of laboratory testing for fentanyl are available (if laboratory testing is positive for fentanyl) or be canceled (if laboratory fentanyl testing is negative).

- Site clinicians may assess evidence of recent injection drug use ("track marks") at the screening visit to screen out persons without recent injection evidence from further evaluation. Sites must see evidence of recent injection drug use at the enrollment visit in order to randomize (enroll).

For the criterion: **"Self-reported sharing injection equipment and/or condomless sex in the last three months with partners of HIV-positive or unknown status"**

- Site teams may assess this criterion at screening to screen out persons without injection or sexual risk from further evaluation. Sites must confirm that the injection or sexual risk is within the stated time frame as of the date of enrollment before randomizing (enrolling).
- For this criterion, which is assessing risk of HIV transmission or acquisition, "condomless sex" refers to insertive or receptive vaginal or anal sex. Oral sex without a condom does not fulfill this criterion.

For the criterion: **"Received MOUD in the 30 days prior to enrollment by self-report"**

- "Received MOUD" is defined as a participant having taken medication that was prescribed for them for MOUD maintenance therapy. This definition excludes medication for opioid use disorder that is provided for short-term assistance in avoiding withdrawal symptoms (for example "bridge"-type programs that provide buprenorphine to stabilize a patient while the patient connects with a maintenance provider). It also excludes detoxification programs that utilize naltrexone and other opioid antagonists that have shown no influences on reducing opioid overdoses, while methadone and buprenorphine reliably reduce these risks.(1). The team recognizes that while antagonist treatments can produce drug-free outcomes, these treatments also increase risks for opioid overdoses.(2) Overdose and consequences resulting from overdose are inconsistent with outcomes the team values when delivering MOUD.(3) This definition also excludes buprenorphine that a person may acquire on the street not prescribed for them.

4.5.2 Informed Consent Process

Informed consent is a process by which an individual voluntarily expresses his/her willingness to participate in research, after having been informed of all aspects of the research that are relevant to his/her decision. Informed consent is rooted in the ethical principle of respect for persons. It is not merely a form or a signature, but a process, with four key considerations — information exchange, comprehension, voluntariness, and documentation — each of which is described below. See Section 4.8 of the ICH GCP

guideline and the informed consent section of the *DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00)* for detailed guidance on the informed consent process and documentation requirements. (see DAIDS SCORE Manual)

During the screening process, participants will be administered the IRB-approved informed consent form prior to the administration of any study procedures. If a participant meets the eligibility criteria for the study and the study staff agree that the participant can fulfill the study requirements, they will be asked to enroll. For enrolled participants, informed consent should be considered as an ongoing process that continues throughout the duration of the study.

U.S. regulations specify the elements of informed consent that must be conveyed to research participants through the informed consent process (45 CFR 46 and 21 CFR 50). It is the responsibility of the IoR, and his/her delegated staff, to deliver all required information to potential research participants.

Based on the technical and regulatory reviews that are completed as part of the HPTN protocol development and study activation processes, there is adequate assurance that once the HPTN LOC has "activated" a site for study implementation, the site-specific informed consent form specifies all information required by the regulations. However, responsibility for informed consent does not end with preparation of an adequate informed consent form. It also is the responsibility of the IoR and designated study staff to perform the activities described in these sections.

4.5.2.1. Deliver All Required Information in a Manner that is Understandable to Potential Participants

If the participant is literate, give them a copy of the informed consent form to read during the screening/enrollment visits. Also provide the participant with other (IRB-approved) informational materials developed to complement the informed consent form, if any**.** If the participant is not literate, the materials may be read to him/her verbatim. After the participant has read the written material (or had it read to him/her), verbally review the information provided. A checklist or the informed consent form itself may serve as a useful guide for this. For example, you may note the main points described in each paragraph of the informed consent form and ask if the participant has questions or concerns about each point. Listen carefully to the questions or concerns expressed by the participant and discuss these thoroughly. Take as much time as needed to address each question and concern.

If the participant is illiterate, **an impartial witness must be present during the entire informed consent discussion**. The witness will be asked to sign and date the informed consent form to attest that the information in the consent form was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant. The ICH GCP guideline identifies an "impartial" witness as a person who is independent of the study, who cannot be unfairly influenced by people involved with the study. Each site must specify its procedures for obtaining informed

consent from illiterate persons in its SOP for obtaining informed consent. The SOP should define who may serve as an impartial witness to the informed consent process. It is recommended that each site seek IRB review and approval of these procedures.

4.5.2.2. Assure That Informed Consent is Obtained in a Setting Free of Coercion and Undue Influence

During the informed consent discussion, take care to not overstate the possible benefits of the study, nor to understate the risks. Also emphasize to the participant that medical care and other services routinely available from the clinic or hospital associated with the site will not be affected by their decision whether or not to take part in the study. Encourage the participant to take as much time as he/she needs — and to talk about his/her potential participation with others, if he/she chooses — before making a decision.

4.5.2.3. Confirm the Participant Comprehends the Information

The participant must not be asked to agree to take part in the screening/study, or to sign the informed consent form, until he/she fully understands the screening process/study. Study staff are responsible for implementing procedures to ensure that each participant understands the screening process and the study prior to signing the screening and enrollment informed consent forms, respectively, and undertaking any screening or study procedures.

One approach to assessing comprehension is to use a “quiz” (either oral or written) or other assessment tool that participants complete as part of the consent process. Another approach is to use open-ended questions to ascertain participant understanding during the informed consent discussion. It is possible to incorporate a scoring system into these assessment tools and to re-review the contents of the informed consent until the potential participant can answer a certain percentage of the questions correctly. Table 4-1 includes a sample informed consent assessment tool that sites may choose to adapt for their local use. For sites that choose to adopt tools such as those included in this section, detailed instructions for their use must be specified in the site SOP for obtaining informed consent.

Regardless of the method used to assess comprehension, if the assessment results indicate misunderstanding of certain aspects of the study, review those aspects again until the participant fully understands them. If after all possible efforts are exhausted, the participant is not able to demonstrate adequate understanding of the study, do not ask him/her to sign the informed consent form or screen/enroll in the study. Similarly, if the participant has concerns about possible adverse impacts on him/her if he/she were to take part in the study, or indicates that he/she may have difficulty adhering to the study requirements, do not ask him/her to sign the informed consent form to screen/enroll in the study.

4.5.2.4. Document the Process

U.S. regulations require that informed consent be documented by "the use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent."

To fulfill this requirement, complete all signature and date blocks on the informed consent form per IRB requirements. Per *The DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00* participants must sign the informed consent form using their complete last name (not just initials); the policy also recommends, but does not require, that the participant's complete first name (not just an initial or nickname) be used as well. It is essential that the date documented on the form either precedes or coincides with the (first) study screening date. In addition, enter a note in the participant chart documenting that informed consent was obtained prior to the initiation of any study procedures. Some sites find it helpful to use a cover sheet attached to the Informed Consent Forms to document all items in this process. See Table 4.2 for a sample coversheet that sites may wish to adapt and use. Finally, regulations require that participants be offered a signed copy of the informed consent forms. If a participant opts not to receive a copy, document this in the research record.

The *DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00* provides detailed requirements and suggestions for documenting the informed consent process. All requirements listed in the *DAIDS Policy* must be met. In order to also meet some of the suggestions listed in the DAIDS Policy, site staff may consider the use of an informed consent "coversheet" similar to the example included in this section. Complete information on Source Documentation can be found in the DAIDS SCORE Manual.

4.5.2.5. Continue the Informed Consent Process throughout the Study

The previous sections describe aspects of obtaining informed consent from study participants prior to initiating their involvement in the study. Given the ongoing nature of informed consent, key elements of informed consent should also be reviewed at study follow-up visits. At these visits, study staff should review key elements of informed consent with the participant, focusing on the remainder of their study participation. For example, participants should be encouraged to ask questions as they arise and recognize that poor adherence to their study drug regimen will not affect their continued participation in the trial.

4.5.2.6. ICF Requirements for Protocol Amendments

According to DAIDS policy (Protocol Registration Policy and Procedure Manual), the IRB is ultimately responsible for determining whether study participants need to be re-consented for a protocol amendment. The details of re-consent for a protocol amendment will be determined based on the extent and content of the amendment, and instructions will be provided to sites in this regard, after consultation with DAIDS.

4.5.2.7. Informed Consent SOP

As a condition for study activation, each study site must establish an SOP for obtaining informed consent from potential study participants. This SOP should reflect all of the information provided in this section and minimally should contain the following elements:

- The minimum legal age to provide independent informed consent in the study site locale
- Procedures for ascertaining participant identity and age
- Procedures for ascertaining participant literacy (if applicable – some sites may choose to enroll only literate participants. The study allows illiterate participants.)
- Procedures for providing all information required for informed consent to the participant
- Procedures for ascertaining participant comprehension of the required information
- Procedures to ensure that informed consent is obtained in a setting free of coercion and undue influence
- Procedures for documenting the informed consent process
- Storage locations for blank informed consent forms
- Storage locations for completed informed consent forms

- Procedures for implementing a change in the version of the informed consent form used
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QA/QC procedures related to the above (if not specified elsewhere)
- Attached copies and instructions for use of all forms, worksheets, or checklists to be used during the informed consent process

4.6 Screening and Enrollment

The study screening and enrollment procedures are described in detail in the HPTN 094 Protocol Sections 6.1 and 6.2 and are outlined in the checklists in the SSP Section 6.

4.6.1 Assignment of Participant ID Numbers (PTID) for Screening and Enrollment

Each time a participant screens for the study, she/he will receive a new PTID; therefore, if the participant screens out and re-screens at a later time, a new PTID will be provided. Refer to Section 12 of the SSP for further details related to PTIDs.

4.6.2 Screening and Enrollment Logs

The *DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00* requires study sites to document screening and enrollment activity on screening and enrollment logs. Screening and enrollment logs may be maintained separately or combined into one document. Table 4-3 includes a sample screening and enrollment log that sites may choose to adapt for local use. This may also be used as a link log, if sites plan to separate participant identifying information files.

The *DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00)* specifies that participant initials be recorded on screening and enrollment logs, in addition to PTID numbers. However, per HPTN policy and in agreement with DAIDS, participant initials need not be recorded on screening and enrollment logs if doing so presents a potential threat to participant confidentiality. In such cases, a separate document must be available to document the link between a participant's name and PTID.

4.6.3 Screening and Enrollment Tracking

In addition to maintaining the screening and enrollment log as described above, sites will use the electronic data capture system to document screening outcomes for all participants. For ineligible participants, this will include the exclusion criteria met/inclusion criteria not met from the protocol as reasons for the screening failure. The HPTN SDMC will maintain a by-site randomization report on the Atlas website (atlas.scharp.org).

4.7 Screening Visit Procedures

A full list of screening procedures is included in the HPTN 094 protocol Sections 6.1 and Appendix IA and IB. Section 9 of the SSP includes details on clinical considerations for screening. Here are some other important considerations for screening:

- Potential participants may be screened for eligibility only after providing written informed consent.

- Screening may occur over one or more visits depending on availability of the participant and clinic staff.

- A positive urine test for opioids is an enrollment criterion. Sites will be able to test for most common opioids using dipstick test strips on the mobile unit at the time of the visit. A positive test for any of these opioids is sufficient for eligibility purposes. As of the time of the writing of this SSP, no fentanyl test strips had been FDA approved or CLIA waived for clinical use. However, a urine immunoassay can be performed in a CLIA laboratory to detect fentanyl, so a participant who appears to have OUD and is otherwise eligible but who tests negative for other opioids may require laboratory testing to document their fentanyl use and eligibility.

- Site specific SOPs should describe how staff will assess enrollment criteria where different approaches or standards might be possible. For example, how will participant age be determined? What are site specific procedures for determining identity or willingness to start MOUD treatment? These SOPs should be developed in conformation with the DAIDS SCORE manual

- Individuals deemed not eligible will be informed that they do not meet eligibility criteria for the study and will be referred for appropriate medical care, if necessary. At the discretion of the IoR or designee, a potential participant may have up to two additional screening attempts.

- Participants determined to have symptoms consistent with COVID-19 at the time of screening will be deferred from screening and referred for community-available services, care, or treatment.

- Sites will follow the HIV testing algorithm for screening included in Section 11 of the SSP. Additional testing to confirm HIV infection will be performed in accordance with local guidelines.

In addition to above, there are other criteria that have specific time periods for the participant that must be adhered to, which are:

- Enrollment must occur within 30 days of initiation of screening. Initiation of screening and enrollment may not occur on the same day. The screening to enrollment window (30 days) starts as soon as screening is initiated, defined as the date the consent is signed. If all screening and enrollment procedures are not completed within 30 days of initiation of screening, the participant must repeat the entire screening process. Rescreening a participant will begin with re-consent of

the participant, including signing of a new ICF to document participant's understanding and agreement to undergo a new screening process. The term "screening attempt" is used to describe each time a participant screens for the study (i.e., each time s/he provides written informed consent for participation in the study).

4.7.1 Participants Found to be Ineligible (Screen Failures)

Screening procedures should be discontinued when the participant is determined to be ineligible. If the participant is found to be ineligible at the beginning of the screening visit, sites may choose to continue with HIV testing as a service to the participant, per their site SOPs. HIV test results should be provided and explained to participants within a reasonable timeframe per local standards, regardless of eligibility determination, and a referral provided to participants for ART or PrEP, as indicated. For all screened out participants, the following documentation should be in place:

- Completed ICF
- Reason(s) for ineligibility, with date of determination
- Documentation that results were communicated to the participant if HIV testing was performed and record on file of any referrals made
- All source documentation completed up until the time that ineligibility was determined
- Chart notes completed up until the time ineligibility was determined
- Indication of what visit procedures were conducted (on visit checklists)

4.8 Enrollment Visit Procedures

A full list of enrollment visit procedures can be found in Section 6.2 and Appendix IA and IB of the protocol. Section 6 of this SSP also includes sample visit checklists and an eligibility checklist which can be modified by sites for their use. Section 9 of this SSP includes clinical considerations for enrollment.

Other important considerations for the Enrollment Visit include:

- Site staff should confirm all inclusion and exclusion criteria the day of enrollment as some criteria assessed at screening may have changed by the time of the enrollment Visit.

- The definition of enrollment is the point of randomization. That is, if a site successfully randomizes a participant in the randomization system, that participant is considered enrolled. In general, if the participant changes his or her mind once randomization has occurred, that participant will still be considered enrolled and cannot be replaced. Contact the HPTN 094 CMC for further guidance if a participant changes his or her mind directly after randomization. If the site accidentally randomizes in the database before they intend to enroll the participant, they should contact the SDMC and CMC immediately and the randomization may be able to be reversed.

- Randomization may only occur after the following procedures from Appendices IA and IB in the protocol have been completed:
    - Locator information
    - MOUD counseling
    - HIV risk reduction counseling, rapid testing and test results
    - Demographic information
    - Behavioral data collection
    - Assessment for COVID-19
    - Targeted medical history including MOUD treatment, HIV risk behaviors, participation in other research studies
    - Assessment for OUD, recent injection drug use (track marks)
    - Basic physical (wellness) exam
    - Blood collection
    - Urine collection
    - Swabs for STI testing
    - MOUD testing (urine)
    - Substance use testing (urine)
    - Pregnancy testing (urine)

- Participants randomized to the intervention arm have to be in a state of withdrawal before MOUD treatment can begin. The majority of participants will be expected to begin MOUD at least one day after enrollment.

- It is not expected that participants in the intervention arm will routinely be initiated on ART or PrEP until a care visit days after enrollment, subsequent to being initiated on MOUD. Some participants may be initiated on PrEP or ART at the enrollment visit if initiation is a high priority and is supported by a clinician.

Staff will assess potential participants for COVID-19 as part of enrollment procedures. If a person is suspected to have COVID-19, enrollment will be deferred until they meet criteria for discontinuation of isolation per CDC guidelines or applicable local guidelines. Depending on length of deferral, screening procedures may have to be repeated to establish eligibility.

4.8.1 Split Enrollment Visits

- Split enrollment visits are allowed.

- Sites should make every effort to complete a split enrollment within 10 days of the first encounter (visit) where enrollment procedures are begun (the target window).

- The last day a participant may complete enrollment (be randomized) is 30 days after screening.

- If a participant fails to complete the required procedures and be randomized within

30 days of screening, they will fail enrollment and will need to start the screening process over again to enroll.

- If an enrollment visit is split, the site will need to confirm eligibility at the start of each encounter where enrollment procedures are performed until randomization (enrollment) has taken place. With regard to the requirement for confirmed HIV status, a rapid HIV test must be performed at the first encounter where enrollment procedures are performed and this test result must be consistent with the screening result, as described in SSP Section 11, for the potential participant to remain eligible. For participants who tested HIV negative at screening, a rapid HIV test must be performed at each encounter where enrollment procedures are performed. For participants who had an HIV positive status at screening, once the rapid HIV test is positive at the first encounter where enrollment procedures are performed, further rapid HIV testing is not required at subsequent enrollment encounters. If rapid results conducted as part of enrollment are not consistent with the screening result, the participant will fail enrollment.

- Because those testing HIV negative at screening will have repeat rapid HIV testing at each encounter of a split enrollment visit, there will be multiple rapid test results. Sites should record all rapid test results in source documents. Sites should enter the HIV rapid test result from the date of randomization in the enrollment CRF for HIV negative participants.

- Plasma storage is required at all study visits when blood is collected by phlebotomy and laboratory-based HIV testing is performed. This has been clarified in the protocol and SSP Manual Section 11. Plasma must be stored from at least one of the split enrollment visits. 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.

- It is expected that often the reason an enrollment visit will be split is because a blood draw cannot be completed at the first encounter. The site must complete the ART (for PLWH) or PrEP log (for HIV negative) on the date the blood draw is obtained, even if the log was completed previously in the enrollment process.

- The date of randomization will be Day 0 of that participant's time on study.

Table 4-1: HPTN 094 Sample Informed Consent Assessment Tool

	Date: **Participant ID:**			**Staff name/initials**
		Participant's Response	**Correct Answer**	**Notes**
1	Participation in this research study is voluntary	□ True □ False	☒ True □ False	
2	This study's purpose is to see if providing health services in a van, combined with peer navigation improves MOUD use and improves use of ART or PrEP.	□ True □ False	☒ True □ False	
3	This research study is part of the regular medical care offered here at [clinic name].	□ True □ False	□True ☒ False	
4	We will ask you to provide blood, urine and swabs to test you for HIV, sexually transmitted infections and hepatitis.	□ True □ False	☒ True □ False	
5	You must be willing to start medication for opioid use disorder	□ True □ False	☒ True □ False	
6	In this study all participants will receive peer navigation to care. One arm will receive care in the van; the other arm will receive care in the community.	□ True □ False	☒ True □ False	
7	You have an equal chance, like the flip of a coin, of being assigned to one study group or the other.	□ True □ False	☒ True □ False	
8	If you join this research study, you must stay in the study for as long as the study staff says.	□ True □ False	□True ☒ False	
9	You will have a physical exam	□ True □ False	☒ True □ False	
10	During this study we will ask you to complete a visit at 6 months and at 12 months.	□ True □ False	☒ True □ False	
11	Your participation in the study will last about 1 year.	□ True □ False	☒ True □ False	
12	No matter which group you are assigned to, you will receive free medication in the van.	□ True □ False	□True ☒ False	
13	Both groups in the study will receive recommendations for clinical care to improve your health.	□ True □ False	☒ True □ False	

14	There are no risks in taking part in this research study.	□ True □ False	□True ☒ False	
15	One of the risks in taking part in this research study include having your information accidently released without your permission	□ True □ False	☒ True □ False	
16	If you have questions, you can contact the site at any time.	□ True □ False	☒ True □ False	

Table 4-2: Sample Informed Consent Coversheet for HPTN 094

Participant name:	
Date of informed consent discussion:	
Start time of informed consent discussion	
Version number/date of informed consent form used during informed consent process/discussion:	
Name of study staff person completing informed consent discussion (and this coversheet):	
In what language was informed consent obtained?	English Spanish (circle one) (note whether this was written and/or verbal)
Was this a re-consent of a participant who had previously consented?	☐ Yes ☐ No
Were all participant questions answered?	☐ Yes ☐ No ⇒ Explain in Notes/Comments. ☐ NA (participant had no questions)
Did the participant accept a copy of the informed consent form (circle one option)?	☐ Yes ☐ No
End time of informed consent process/discussion:	
Notes/Comments (not documented elsewhere):	

Table 4-3: Sample HPTN 094 Screening and Enrollment Log

(May be adapted as needed for local use)

	Participant ID	**Participant Name**	**Date Screened**	**Eligible**	**Date of enrollment (if not enrolled, note N/A)**	**If not enrolled, specify reason** *(site may create reason codes)*	**Staff name/ Initials**
1				Y N			
2				Y N			
3				Y N			
4				Y N			
5				Y N			
6				Y N			
7				Y N			
8				Y N			
9				Y N			
10				Y N			

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