HIV Prevention Trials Network

Letter of Amendment # 2 to:

HPTN 094

INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for Addiction, HIV, HCV and Primary Care

DAIDS Study ID: 38715

Version 1.0, dated 15 July 2020

Date of Letter of Amendment: 10 November 2021

LETTER OF AMENDMENT SIGNATURE PAGE

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable US Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study."

Signature of Investigator of Record

Date

Name of Investigator of Record
(printed)

HIV Prevention Trials Network

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The following information impacts the HPTN 094 study and must be forwarded to all responsible Institutional Review Boards/Ethics Committees (IRBs/ECs) as soon as possible for their information and review. This Letter of Amendment (LoA) must be approved by all responsible IRBs/ECs before implementation.

The information contained in this LoA does impact the informed consent forms (ICFs).

Upon receiving final IRB/EC approval for this LoA, sites should implement the LoA immediately. Sites are required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). As part of the registration package, sites must submit the Letter of Amendment Investigatory Signature Page, signed and dated by the Investigator of Record. Sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the required LoA registration documents have been received and are complete. A LoA registration notification from the DAIDS PRO is not required prior to implementing the LoA. A copy of the LoA registration notification along with the LoA and any IRB correspondence should be retained in the site's regulatory files.

If the full HPTN 094 protocol is amended in the future, the changes in this LoA will be incorporated into the next version.

Summary of Revisions and Rationale

1. Because the study does not limit enrollment to people who inject opioids as long as participants inject drugs and have moderate to severe opioid use disorder, language in protocol Sections 1 and 4 were revised to describe study participants more accurately: PWID with OUD. Similarly, edits were made to Section 5 to remove to remove language about injecting opioids.
2. Edits were made to protocol Section 4 to modify two enrollment criteria: removing the upper age limit and removing the requirement for PWID to meet HIV risk criteria. Edits to Sections 4 & 5 were made to clarify enrollment criteria, either directly in the protocol or by inserting references to clarifying guidance in the study specific procedures manual (SSP).
3. Edits were made to the Appendices IA and IB to clarify enrollment criteria, to add the assessment for OUD and for evidence of recent injection drug use to the screening visit, to add a separate line for fentanyl testing, and to edit language about HAV testing. Footnote numbers were updated accordingly. Section 10.1 was also updated to reflect the HAV changes, the addition of urine fentanyl tests, and typographical edits. The informed consent form was updated to reflect inquiry about opioid use history at screening as part of OUD assessment.
4. Edits were made to protocol Section 6.7 to clarify procedures for conducting split enrollment visits. Table 4 was updated to add target and allowable visit windows for the enrollment visit. The informed consent form was revised to move four procedures earlier in the enrollment visit, prior to randomization.
5. Small, typographical edits were made in the study schema, List of Abbreviations and Acronyms, Tables 2 and 3, and Sections 1, 5, 6, 7. Small edits were made in Section 1 to define the acronyms ART and PrEP at first use. Two references to “interim visits” were corrected to “clinical care visits” in Section 6.2. One addition, one name change, and two deletions were made to the Protocol Team Roster.
6. Edits were made to the study schema, Table 2, and Sections 5 and 6 clarifying that participants with recent exposure to COVID-19 will be referred for further treatment and evaluation. Edits were made to Section 6.3 to clarify that CDC and local guidelines will be followed regarding quarantine of staff with potential exposure to persons with known or suspected COVID-19.
7. At the request of the PAB pharmacist, the study team revised the protocol to refer to study medication provided centrally as “study products.” Corresponding edits were made to Section 5 and 7. Edits were made to Table 2 to remove obsolete language about ART and PrEP donations to the study being pending.
8. Edits were made to Table 1 to clarify the HIV testing done at the Screening, Week 26, and Week 52 Visits. Additionally, edits were made to match the summary of services provided in the mobile unit to the schedule of events.
9. Edits were made to Section 7.1 to clarify that fatal overdoses are examples of SAEs and that overdoses are examples of a life-threatening event.
10. Edits were made to Section 8.4 to correct the all-site and individual site rates of expected new enrollees per month.

11. Section 6.3 has been revised to include information concerning the handling of persons who seroconvert during the study. Additionally, a new section (6.6) has been added providing procedures to be completed for participants who are negative at enrollment and subsequently seroconvert. The previous Sections 6.6 and 6.7 are now Sections 6.7 and 6.8, respectively. Appendix IC has been updated to reflect these changes regarding seroconversion after enrollment. The informed consent form has been updated to indicate that confirmation of seroconversion will require additional blood collection.

Deletions to the protocol text are indicated by ~~strikethrough~~; additions are indicated in **bold**.

Revision 1: Section 1.2 Rationale for Study Design

[…]
The INTEGRA integrated strategy accomplishes two important objectives of the HIV Prevention Trials Network (HPTN): (1) To conduct HIV research in at-risk **PWID with OUD** ~~opioid injectors~~ and measure linked MOUD and HIV outcomes in the US; and (2) to address the multiplicity of challenges and barriers to primary care, HIV and HCV prevention and care, and MOUD/harm reduction programs. This study is well suited to make use of the resources of the HPTN to conduct high impact HIV prevention work in **PWID with OUD**~~opioid injectors~~, a key priority population for the HPTN.
[…]

Revision 1: Section 4.3 Recruitment Process

[…]
Recruitment of **PWID with OUD** ~~persons who inject opioids~~ who are living with HIV or who are HIV-negative and at high-risk will need attention at regular intervals to ensure adequate enrollment for the study in the time allotted. A recruitment plan will be developed at each site to guide outreach to and enrollment of participants. Outreach activities will be consistently conducted at "hot spots" - facilities and venues where ~~persons who inject opioids~~**PWID** are commonly found and can be contacted for possible enrollment in the study.
[…]

Revision 1: Section 4.5 Participant Retention

It is expected that this population under study (**PWID**~~persons who inject opioids~~ **with OUD** who are not in MOUD treatment) will present challenges exceeding those encountered in traditional HPTN protocols.
[…]

Revision 1: Section 5.2.1~~0~~ – Medical Services – Intervention Arm

[…]
Participants who also use stimulants (methamphetamine, cocaine) in addition to ~~injection~~ opioids, will be referred to 12-step meetings available locally such as crystal meth anonymous, narcotics anonymous and alcoholics anonymous.

[…]

Revision 2: Section 4.1- Inclusion Criteria

Adults who meet all of the following criteria are eligible for inclusion in this study:

- **At least** 18 ~~to 60~~ years of age
- Urine test positive for recent opioid use and with evidence of recent injection drug use ("track marks")
- Diagnosed with OUD per Diagnostic and Statistical Manual of Mental Disorders (DSM)-5
- Able and willing to give informed consent
- Willing to start MOUD treatment
- Able to successfully complete an Assessment of Understanding
- **For those who are HIV-negative:** Self-reported sharing injection equipment and/or condomless sex in the last three months with partners of HIV-positive or unknown status
- Able to provide adequate locator information
- Confirmed HIV status, as defined in the HPTN 094 SSP Manual

See SSP Section 4 for further guidance on assessment of inclusion criteria.

Revision 2: Section 4.2- Exclusion Criteria

[…]
See SSP Section 4 for further guidance on assessment of exclusion criteria.
[…]

Revision 2: Section 5.1 Initial Assessment and Provision of Services in the Mobile Unit- All Participants

[…]
~~During the Enrollment Visit, all~~**All** participants will be assessed for OUD diagnosis per the DSM-5~~,~~ **at either the Sscreening or Eenrollment Visit and** will **be** asked about any MOUD treatment in the past 30 days and will meet with their peer navigators for the first time.
[…]

Revision 3: Section 10.1 Local Laboratory Specimens

As described in Section 6.0, the following types of specimens will be collected:

- Blood
- Urine
- Swabs (oropharyngeal-, rectal, vaginal)

As described in Section 6.0, the following types of testing will be performed in the mobile unit or at the local laboratory:

- HIV testing – see SSP Manual
- CD4 cell count and HIV viral load testing (if HIV positive)

- Hepatitis testing, including HBsAg, HBsAb, HBcAb, HCV Ab, HAV **Ab** ~~IgG~~, HCV RNA (if HCV positive), and HBV DNA (if needed for clinical management**)**
- Syphilis testing and GC/CT by NAAT: oropharyngeal swab and rectal swab (all), vaginal swab (women only), urine (men and women as a less prefe**r**red alternative to ~~-~~vaginal swab~~-)~~.
- The schedule of GC/CT testing by NAAT may be adjusted or prioritized at the discretion of the site investigator if there is a potential for shortage of supplies for collection and/or testing. Please see CDC recommendation September 8, 2020~~.~~ https://www.cdc.gov/std/general/DCL-Diagnostic-Test-Shortage.pdf
- Urine substance use testing ~~–~~(must include opioid, cocaine, amphetamines, benzodiazepines)
- **Urine fentanyl testing**

[…]

Revision 3: Appendix IA

APPENDIX IA: SCHEDULE OF STUDY VISITS AND PROCEDURES FOR PARTICIPANTS WHO ARE HIV POSITIVE AT ENROLLMENT

	Screening	Enrollment	Care visit(s)[1]	26 Weeks	52 Weeks
Administrative and Behavioral Procedures					
Informed consent	X				
Locator information	X	X	X	X	X
MOUD counseling	X	X	X	X	X
HIV risk reduction counseling and, at screening, test results	X	X	X	X	X
Offer condoms and lubricant	X	X	X	X	X
Provide/facilitate access to harm reduction	X	X	X	X	X
Demographic information	X				
Randomization		X			
Behavioral data		X		X	X
Introduction to peer navigator		X			
Conclusion of peer navigation				X	
Clinical Evaluations/Procedures					
Assessment for COVID-19[2]	X	X	X	X	X
Assessment for OUD[3], recent injection drug use (track marks)[4~~2~~]	**X**	X			
Targeted medical history to include MOUD treatment history, HIV risk behaviors, participation in other research ~~studies~~**studies**[54~~7~~]	X	X	(X)	X[64]	X[46]
Basic physical exam[7~~5~~]		X	(X)		
Screen for mental health needs and refer for services as indicated		X	(X)	X	X

Initiate or refer for HIV treatment		(X[8~~6~~])	(X[6~~8~~])		
COWS assessment and initiate mobile unit-based MOUD treatment program (intervention arm only)		(X[7~~9~~])	(X[7~~9~~])		
Provide clinical management of MOUD and HIV infection, including medication or prescription dispensation, as indicated			X		
HAV vaccination referral			X[10~~8~~]		
HBV vaccination referral			X[9~~11~~]		
HBV treatment/treatment referral			X[10~~8~~,11~~9~~]		
HCV treatment referral			X[10~~8~~]		X
Development of a clinical plan		X			
Empiric treatment of STIs (if symptomatic)		(X)	(X)	(X)	(X)
Provide lab-based STI results and, if indicated, treatment (intervention arm) or referral (active control arm)			X[12~~0~~]		
Provide lab-based STI results, and, if indicated, referral				X[12~~0~~]	X[12~~0~~]
Provide clinical assessment and management or referral for other medical conditions			X		
Blood collection	X	X	(X)	X	X
Urine collection	X	X	(X)	X	X
Swabs for STI testing[13~~1~~]		X	(X)	X	X
Laboratory Evaluations/Procedures					
HIV rapid testing	X	X			
Laboratory-based HIV testing (see SSP Manual)	X[12~~4~~]				
HIV viral load		X	(X)	X	X
CD4 cell count		X	(X)		
MOUD testing (urine)[15~~3~~]	X	X		X	X
Substance use testing (urine)[16~~4~~]	X	X	(X)	X	X
Fentanyl testing (urine)	**X**	**(X)**	**(X)**		
Pregnancy testing (urine)[15~~7~~]		X	(X)	(X)	(X)
STI testing (syphilis, GC/CT NAAT)		X	(X)	X	X
HCV Ab testing[18~~6~~]		X			X
HCV RNA (viral load)[19~~7~~]		X		X	X
HBV testing (HBsAg, HBsAb, HBcAb)		X			
Other HBV-related testing[20~~18~~]		(X)			

HAV **Ab** testing ~~(HAV IgG)~~		X			
Heme/Chem testing[21~~19~~]		X			
Plasma storage[22~~20~~]	X	X		X	X
Urine storage[23~~21~~]		X		X	X
Serum storage for SARS-CoV-2 testing[24~~22~~]		X		X	X

Footnotes for Appendix IA

Parentheses around an X indicate that this procedure will be done as needed.

[1] Between the Enrollment Visit and the 26-week visit, participants in the intervention arm will engage with study staff for clinical care in the mobile unit at a frequency determined by clinical need. These are considered care visits. Specimen collection and testing at care visits will be as needed for clinical care. Active control arm participants will not have these visits.

[2] Assessment for COVID-19 will consist of a symptom screen and temperature. Details included in the SSP Manual.

[3] Assessment for OUD will be performed using a tool provided in ~~the SSP Manual. All sites will use the same tool.~~**Section 9 of the SSP Manual. ~~-~~Sites may assess for OUD at either the Sscreening or Eenrollment V~~v~~isit. If OUD is confirmed at screening, it does not need to be reassessed (confirmed) at enrollment.**

[4] ~~History of hospitalization only.~~

[4] See SSP Section 4 for further guidance about eligibility assessment related to evidence of recent injection drug use and sharing of injection equipment.

[5] See SSP Section 4 for further guidance about eligibility assessment related to MOUD history and HIV risk behaviors.

[6] ~~History of hospitalization only.~~Targeted medical history to include participation in other interventional studies, overdose events, and follow-up of unresolved AEs/SAEs identified previously.

[7~~5~~] Physical exam at enrollment to include vital signs, height, weight, general appearance, mouth and throat, neck, chest, abdomen, extremities and skin. Additional elements at clinician's discretion for patient care.

[8~~6~~] HIV treatment (or referral) will be offered at the first visit where HIV infection is confirmed, for those participants not already in treatment. Intervention arm participants will be offered HIV treatment in the mobile unit if the available regimen is appropriate for them. Intervention arm participants who require a different regimen and active control arm participants will be referred for treatment. Initiation of MOUD treatment will be the clinical priority, so HIV-positive participants may defer initiating HIV treatment until established on MOUD.

[9~~7~~] The exact timing of COWS assessment and MOUD initiation will depend on clinician judgment, the readiness of the participant to begin treatment and other factors. See Section 6.2.

[10~~8~~] Vaccination referral or treatment/treatment referral will be offered at the first visit where results from testing are available.

[11~~9~~] ~~——~~For participants in the intervention arm receiving care in the mobile health delivery unit, ART regimens can be selected by study clinicians that treat HIV as well as HBV. Active control arm participants will receive referrals indicating their dual infection with HIV and HBV so that they may also receive appropriate treatment.

[12~~0~~] STI results and referrals provided on a date after results are available, coded as a "split visit".

[13~~1~~] The types of samples collected (oropharyngeal, rectal, vaginal) are specified in the SSP Manual.

[14~~2~~] Other HIV-related testing may be performed for clinical care. This may include HIV drug resistance testing and/or HLA-B5701 testing. If indicated, this testing should be performed at a local laboratory; these results will not be reported to the HPTN SDMC.

[13~~5~~] Testing for medications used to treat substance use (see SSP Manual).

[16~~4~~] ~~——~~Testing for substances of abuse~~. (see SSP Manual)~~. **See SSP Manual Section 4 for guidance about eligibility related to detection of opioids in urine.**

[17~~5~~] Testing for pregnancy (urine human chorionic gonadotropin [HCG] testing) for any participant who could potentially be pregnant at that visit (unless already known to be pregnant).

[16~~8~~] Perform HCV Ab testing at enrollment for all participants; perform HCV Ab testing at week 52 for participants who tested HCV negative at enrollment.

[17~~9~~] Perform HCV viral load testing at enrollment, 26 weeks, and 52 weeks for participants who have a positive HCV Ab test. HCV RNA viral load testing may be performed on a date after HCV Ab results are available.

[20~~18~~] Perform HBV viral load testing for participants with chronic HBV infection (HBsAg+) or isolated HBcAb positive for clinical care management (intervention arm only).

[21~~19~~] The following tests are required: hemoglobin, creatinine, ALT, AST and total bilirubin. Sites may obtain these values by ordering a complete blood count and comprehensive metabolic panel if that is standard practice or less costly than performing individual tests.

[20~~2~~] Stored plasma will be used for testing at the HPTN LC, as described in Section 10.

[23~~1~~] Stored urine will be used for testing at the HPTN LC, as described in Section 10.

[22~~4~~] Stored serum will be used for retrospective testing at the HPTN LC to determine the prevalence of SARSCoV2 seropositivity at baseline, 26 and 52 weeks; stored samples may also be used for specialized testing related to COVID-19 (see Section 10 and SSP Manual).

Abbreviations: **Ab: antibody;** ART: antiretroviral treatment; aPTT: activated partial thromboplastin time; COWS: Clinical Opiate Withdrawal Scale; GC/CT: gonorrhea/chlamydia; HAV: hepatitis A virus; HBV: hepatitis B virus; HBcAb: HBV core antibody; HBsAb: HBV surface antibody; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HLA: Human Leukocyte Antigen; ~~IgG; immunoglobulin G;~~ MOUD: medications for opioid use disorder; NAAT: nucleic acid amplification test; OUD: opioid use disorder; PT: prothrombin time; SDMC: Statistical and Data Management Center; SSP: Study specific protocol; STI: sexually transmitted infection.

Revision 3: Appendix IB

APPENDIX IB: SCHEDULE OF STUDY VISITS AND PROCEDURES FOR PARTICIPANTS WHO ARE HIV NEGATIVE AT ENROLLMENT

	Screening	Enrollment	Care visit(s)[1]	26 Weeks	52 Weeks
Administrative and Behavioral Procedures					
Informed consent	X				
Locator information	X	X	X	X	X
MOUD counseling	X	X	X	X	X
HIV risk reduction counseling and test results	X	X	(X)	X	X
Offer condoms and lubricant	X	X	X	X	X
Provide/facilitate access to harm reduction	X	X	X	X	X
Demographic information	X				
Randomization		X			
Behavioral data collection		X		X	X
Introduction to peer navigator		X			
Conclusion of peer navigation				X	
Clinical Evaluations/Procedures					
Assessment for COVID-19[2]	X	X	X	X	X
Assessment for OUD[3], recent injection drug use (track marks)[4]	**X**	X			
Targeted medical history including MOUD treatment, HIV risk behaviors, participation in other research studies[5]	X	X	(X)	X[64]	X[46]
Basic physical (wellness) exam[75]		X	(X)		
Screen for mental health needs and refer for services as indicated		X	(X)	X	X
PrEP initiation (intervention arm) or referral (active control arm)		(X)	(X)		
COWS assessment and initiate mobile unit-based MOUD treatment program (intervention arm only)		(X[6])	(X[86])		
Provide clinical management of MOUD and PrEP, including medication or prescription dispensation, as indicated			X		
HAV vaccination referral			X[97]		
HBV vaccination referral			X[97]		
HBV treatment/treatment referral			X[79,108]		
HCV treatment referral			X[97]		X
Development of a clinical plan		X			

Empiric treatment of STIs (if symptomatic)		(X)	(X)	(X)	(X)
Lab-based STI results provided and, if indicated, treatment (intervention arm) or referral (active control arm)			X[11~~9~~]		
Provide lab-based STI results, and, if indicated, referral				X[11~~9~~]	X[11~~9~~]
Provide clinical assessment and management or referral for other medical conditions			X		
Blood collection	X	X	(X)	X	X
Urine collection	X	X	(X)	X	X
Swabs for STI testing[12~~0~~]		X	(X)	X	X
Laboratory Evaluations/Procedures					
HIV rapid testing	X	X	(X)	X	X
Laboratory-based HIV testing (see SSP Manual)	X	X	(X)	X	X
MOUD testing (urine)[13~~1~~]	X	X		X	X
Substance use testing (urine)[14~~2~~]	X	X	(X)	X	X
Fentanyl testing (urine)	**X**	**(X)**	**(X)**		
Pregnancy testing (urine)[15~~3~~]		X	(X)	(X)	(X)
STI testing (syphilis, GC/CT NAAT)		X	(X)	X	X
HCV Ab testing[16~~4~~]		X			X
HCV RNA (viral load)[17~~5~~]		X		X	X
HBV testing (HBsAg, HBsAb, HBcAb)		X			
Other HBV-related testing[18~~6~~]		(X)			
HAV **Ab** testing ~~(HAV IgG)~~		X			
Heme/Chem testing[19~~7~~]		X			
Plasma storage[20~~18~~]	X	X	(X)	X	X
Urine storage[21~~19~~]		X		X	X
DBS storage[22~~0~~]		X		X	X
Serum storage for SARS-CoV-2 testing[23~~1~~]		X		X	X

Footnotes for Appendix IB

Parentheses around an X indicate that this procedure will be done as needed.

[1] Between the Enrollment Visit and the 26-week visit, participants in the intervention arm will engage with study staff for clinical care in the mobile unit at a frequency determined by clinical need. These are considered care visits. Specimen collection and testing at care visits will be as needed for clinical care. Active control arm participants will not have these visits.

[2] Assessment for COVID-19 will consist of a symptom screen and temperature. Details included in the SSP Manual.

[3] **Assessment for OUD will be performed using a tool provided in Section 9 of the SSP Manual. Sites may assess for OUD at either the Screening or Enrollment Visit. If OUD is confirmed at screening, it does not need to be reassessed (confirmed) at enrollment.** ~~Assessment for OUD will be performed using a tool provided in the SSP Manual. All sites will use the same tool.~~

[4] **See SSP Section 4 for further guidance about eligibility assessment related to evidence of recent injection drug use and sharing of injection equipment.**

[5] **See SSP Section 4 for further guidance about eligibility assessment related to MOUD history and HIV risk behaviors.**

[46] ~~History of hospitalization only.~~**Targeted medical history to include participation in other interventional studies, overdose events, and follow-up of unresolved AEs/SAEs identified previously.**

[75] ~~——~~Physical exam at enrollment to include vital signs, height, weight, mouth and throat, neck, chest, abdomen, extremities and skin. Additional elements at clinician's discretion for patient care.

[68] The exact timing of COWS assessment and MOUD initiation will depend on clinician judgment, the readiness of the participant to begin treatment and other factors. See Section 6.2.

[97] Vaccination referral or treatment/treatment referral will be offered at the first visit where results from testing are available.

[810] ~~——~~For participants in the intervention arm receiving clinical care in the mobile unit, a patient-centered discussion will take place between the clinician and the participant regarding the potential risks and benefits of starting PrEP with HBV infection; whether to take PrEP will be the participant's choice. Study staff will provide results and a referral to those in the active control arm with HBV infection, instructing them to discuss the potential risks and benefits of HBV treatment/PrEP with their provider.

[119] STI results and referrals provided on a date after results are available, coded as a "split visit".

[102] The types of samples collected (oropharyngeal-, rectal, vaginal) are specified in the SSP Manual.

[113] ~~——~~Testing for medications used to treat substance use (see SSP Manual).

[124] ~~——~~Testing for substances of abuse**.** ~~(see SSP Manual).~~**See SSP Manual Section 4 for guidance about eligibility related to detection of opioids in urine.**

[153] Testing for pregnancy (urine human chorionic gonadotropin [HCG] testing) for any participant who could potentially be pregnant at that visit (unless already known to be pregnant).

[164] Perform HCV Ab testing at enrollment for all participants; perform HCV Ab testing at week 52 for participants who tested HCV negative at enrollment.

[175] Perform HCV viral load testing at enrollment, 26 weeks, and 52 weeks for participants who have a positive HCV Ab test. HCV RNA viral load testing may be performed on a date after HCV Ab results are available.

[186] Perform HBV viral load testing for participants with chronic HBV infection (HBsAg+) or isolated HBcAb positive for clinical care management (intervention arm only).

[197] The following tests are required: hemoglobin, creatinine, ALT, AST and total bilirubin. Sites may obtain these values by ordering a complete blood count and comprehensive metabolic panel if that is standard practice or is less costly than performing individual tests.

[2018] Plasma will be stored at screening, enrollment, 26 and 52 week visits and at any visit where **laboratory-based** HIV testing is performed. Stored plasma will be used for testing at the HPTN LC, as described in Section 10. This includes testing to determine the seroprevalence of SARS-CoV-2 at baseline, 26 and 52 weeks.

[2119] Stored urine will be used for testing at the HPTN LC, as described in Section 10.

[220] Stored DBS will be used for testing at the HPTN LC, as described in Section 10.

[231] Stored serum will be used for retrospective testing at the HPTN LC to determine the prevalence of SARS-CoV-2 seropositivity at baseline, 26 and 52 weeks**; stored samples may also be used for specialized testing related to COVID-19** (see Section 10 and SSP Manual).

Abbreviations: **Ab: antibody;** aPTT: activated partial thromboplastin time; COWS: Clinical Opiate Withdrawal Scale; DBS: dried blood spot; GC/CT: gonorrhea/chlamydia; HAV: hepatitis A virus; HBV: hepatitis B virus; HBcAb: HBV core antibody; HBsAb: HBV surface antibody; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HLA: Human Leukocyte Antigen; ~~IgG; immunoglobulin G~~; MOUD: medications for opioid use disorder; NAAT: nucleic acid amplification test; OUD: opioid use disorder; PrEP: pre-exposure prophylaxis; PT: prothrombin

time; SDMC: Statistical and Data Management Center; SSP: Study specific protocol; STI: sexually transmitted infection.

Revision 3: Appendix II: Sample Informed Consent Form- Main Study

[…]

- Ask you questions about your sexual and drug use behaviors **and drug use history**

[…]

Revision 4: Section 6.7 Study Visit Windows

[…]

For the enrollment visit, the date of randomization is day 0. If necessary, enrollment visit procedures may take place at more than one visit (a "split visit"). Sites are strongly encouraged to complete a split enrollment visit within 10 days of the first enrollment visit encounter, but all procedures and randomization must be completed by 30 days after screening. If the potential participant is not randomized within 30 days of screening, they will be an enrollment failure and will need to be re-screened if the site wishes to enroll them. Potential participants will only be randomized once all procedures expected for the day of enrollment (see SSP) have been completed.

Revision 4: Table 4: Study Visit Windows

Table 4: Study Visit Windows

Visit	Target Visit Day	Target Visit Window	Allowable Visit Window
Screening			Up to 30 days before enrollment
Enrollment	Day 0	**Split visit completed within 10 days**	**Randomization completed within 30 days after screening**
Week 26	Day 182	Day 168 - 210	Day 126 - 308
Week 52	Day 365	Day 351 - 393	Day 309 – until the study is closed at the site

Revision 4: Appendix II: Sample Informed Consent Form- Main Study

[…]

During the Enrollment Visit, we will first determine if you are eligible to enroll in the study. If you are enrolled, you will complete additional activities. **We expect all Enrollment Visit activities to be completed on the same day. If they cannot be completed on the same day, you will need to come back to finish the procedures on another day.**

[…]

Revision 4: Appendix II: Sample Informed Consent Form- Main Study

At the Enrollment Visit, before you're enrolled in the study, we will:

[…]

- Ask you questions about your medical history including MOUD treatment, HIV risk behaviors, and participation in other research studies. We will also ask you about your history of being in jail or prison, and about experiences of depression, anxiety or trauma, and your use of tobacco, alcohol and other drugs.
- Collect swabs from you to test for STIs. These swabs may be taken from the throat, rectum and vagina.
- Give you a physical exam, that includes measuring your height, weight, heart rate, temperature and blood pressure; looking into your mouth and throat; listening to your heart and lungs, feeling your neck and abdomen, looking at your skin, arms and legs, additional procedures if indicated for your care and asking you about any medicines you are taking.
- Give you the results of tests that are available during the visit and discuss your health needs.

[…]

If you are eligible to participate in the study, you will be enrolled during the Enrollment Visit. You will then be placed by random chance into either the group that will receive medical care in the mobile health delivery unit, or the group that will not. After that, the Enrollment Visit will continue and we will:

- ~~Ask you questions about your medical history including MOUD treatment, HIV risk behaviors, and participation in other research studies. We will also ask you about your history of being in jail or prison, and about experiences of depression, anxiety or trauma, and your use of tobacco, alcohol and other drugs.~~
- ~~Collect swabs from you to test for STIs. These swabs may be taken from the throat, rectum and vagina.~~
- ~~Give you a physical exam, that includes measuring your height, weight, heart rate, temperature and blood pressure; looking into your mouth and throat; listening to your heart and lungs, feeling your neck and abdomen, looking at your skin, arms and legs, additional procedures if indicated for your care and asking you about any medicines you are taking.~~
- ~~We will s~~**S**tore blood and urine samples for other testing related to this study. This may include tests for drugs, medications used to treat HIV, and medications to treat substance use. Tests may also be performed to characterize HIV and the body's response to HIV. Similar testing may be performed for hepatitis viruses. The stored blood samples may also be used to learn more about how HIV is spread throughout the community. Blood samples will also be used to test for possible exposure to the virus that causes COVID-19 and to learn more about how the body responds to COVID-19. Results from testing using stored samples will not be returned to you or the study site.
- Introduce you to a peer navigator, someone who has been trained to help you get medical services and be successful in getting treatment for OUD.
- ~~Give you the results of tests that are available during the visit and discuss your health needs.~~

Revision 5: LIST OF ABBREVIATIONS AND ACRONYMS

[…]

SUSAR	**Suspected Unexpected Serious Adverse Reaction**

[…]

Revision 5: PROTOCOL TEAM ROSTER

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[…]

Revision 5: Schema: Exploratory Objectives

[…]

Stored samples may also be used **to** characterize HCV strains and the relationship between HIV and HCV infections, and to explore issues related to COVID-19.

Revision 5: Section 1.1 Background and Rationale

[...]
PWID living with or at risk of HIV who are not engaged in MOUD face the nearly impossible task of getting care from bricks and mortar clinics that provide separate, siloed care for opioid addiction (methadone, buprenorphine), HIV (**antiretroviral therapy [**ART**]** and **pre-exposure prophylaxis [**PrEP**]**)
[…]

Revision 5: Section 1.2 Rationale for Study Design

[…]
Younger PWID. The median age for PWID in the US-[30] is in the mid-40s, but those 18-29 years engage in HIV risk behaviors
[…]

Revision 5: Section 5.1- Initial Assessment and Provision of Services in the Mobile Unit - All Participants

[…]
These procedures may take place remotely (e.g~~.~~**.,** over the telephone) or outside of the mobile unit, per guidelines.
[…]

Revision 5: Table 2 – Overview of Medical Care Provided in the Mobile Unit for the Intervention Arm Participants

Condition	Notes
OUD	MOUD will be managed on the mobile unit. Will include dispensation of drugs ~~(~~ to include: • Buprenorphine-based medicine (sublingual and possibly injectable regimens) • Participants who prefer methadone will be referred to community-based services if available

[…]

Pregnancy	Pregnant participants may utilize the mobile unit. • Participants who are pregnant will continue to be seen for MOUD, ART, PrEP and other services on the mobile unit. **A**~~a~~ll pregnant participants will be referred for obstetric care with an OB/GYN provider comfortable treating pregnant women who inject drugs treated

	with MOUD. Study clinicians will endeavor to coordinate with the obstetric care provider to optimize care.

[…]

Revision 5: Section 5 Study Interventions

[…]
Table 1 (p.3~~2~~**3)** summarizes services that will be provided to participants in the two arms. Table 2 (p.3~~6~~**7)** provides details of the medical services that will be provided in the mobile unit to intervention arm participants.

Revision 5: Section 6.2 Enrollment Visit

[…]
This flexibility-- to start MOUD either at Enrollment or a~~n interim~~ **later clinical care** visit-- is reflected in the schedule of evaluations (Appendix I).

Similarly, it is expected that most participants in the intervention arm will not initiate ART or PrEP until after they are initiated on MOUD, at a~~n interim~~ **clinical care** visit some days after Enrollment.
[…]

Revision 5: Section 6.5 Week 52 Visit

[…]
Also as described for week 26 visits, ~~a~~ concerns related to the COVID-19 epidemic might necessitate making accommodations to complete the week 52 visits using on-line and distance procedures
[…]

Revision 5: Table 3- Sampling frame for in-depth interviews

Table 3- Sampling frame for in-depth qualitative interviews

Source	Selection strategy	Sample size per site
PWID	~10% of PWID enrolled at each study site will be purposefully sampled. Sampling criteria will aim to select PWID enrolled in the study ~~that~~ **who** are demographically representative of the local injection community in terms of age, gender, race, and HIV status.	n=17
Mobile Unit staff	Staff who support integrated healthcare delivered in the mobile unit at each site will be sampled. This includes clinicians delivering MOUD and ARV treatment (n=2), peer navigat~~i~~ors (n=3), and frontline staff routinely engaged with PWID rec**r**uitment and tracking activities (n=2)	n=7

Community stakeholders	Key community stakeholders will be identified through the study's formative landscape analysis to map community assets and gaps in the pre-imp**l**~~ee~~l**i**mentation phase. This process will identify regularly available MOUD, HIV, harm reduction, and primary care ser~~i~~v**i**ces at each study site. Through this process we will invite up to 3 stakeholders from each of the following service domains who would be involved in the coordination and future sustainabili**t**y of integrated health care and peer naviga~~i~~t**i**on: HIV services (n=3), MOUD services -(n=3), harm reduction services (n=3), primary care -(n=3), and public health officials- (n=3).	n=15

Revision 5: Section 7. Clinical Care and Navigation Visits Between Enrollment and Week 26

[…]
See Section 7.~~6~~**4** below for further information about how possible serious or unanticipated risks will be reported and addressed.
[…]

Revision 5: Section 7.2 Social Impact Reporting

[…]
See Section 7.~~6~~**4** below for further information about how possible serious or unanticipated risks will be reported and addressed.
[…]

Revision 5: Section 7.4 Safety Monitoring and Clinical Data Review

[…]
This study also will be monitored by an HPTN SMC-, which will meet at least annually to review safety and efficacy data. More frequent or *ad hoc* reviews of safety data may be conducted by the SMC as needed. The -SMC may make recommendations based on review of safety and efficacy data.

Revision 5: Section 8.2.1 Primary Endpoints

[…]

- Documented current use of MOUD: alive, retained, with biological evidence of MOUD (any detectable medications) at the week 26- visit and a MOUD prescription current at 26 weeks after enrollment

[…]

Revision 5: Section 8.8.2 Secondary Analyses

[…]
The analysis for each objective will be iterative, whereby the implementa**t**i~~t~~on team meets monthly to review the incoming data for ideas, themes, and patterns that emerge from the data

pertaining to the PRISM framework's multi-level factors that influence the implementation process that will be used to define a set of analytic coding categories.
[…]

Revision 6: Study Schema

[…]
participants with suspected COVID-19 **or recent exposure** -will be referred for further evaluation, care and/or treatment, as available.
[…]

Revision 6: Section 5.1 Initial Assessment and Provision of Services in the Mobile Unit – All Participants

[…]
Persons with suspected COVID-19 **or recent exposure** will be deferred from enrollment until they meet the criteria for discontinuation of isolation per CDC guidelines or applicable local guidelines
[…]

Revision 6: Section 5.2.1 Medical Services – Intervention Arm

[…]
Participants with suspected COVID-19 **or recent exposure** will be referred for services in the community and facilitated in accessing those services.
[…]

Revision 6: Table 2 – Overview of Medical Care Provided in the Mobile Unit for Intervention Arm Participants

[…]

COVID-19	Clinicians will assess participants for COVID-19 at each encounter. Those with suspected COVID-19 **or recent exposure** will be referred for further evaluation, care and treatment, as appropriate and available. CDC and local guidelines for discontinuation of isolation will direct when participants with suspected COVID-19 **or recent exposure** can resume in-person visits. Distance procedures to collect data and monitor health will be implemented to the extent possible.

[…]

Revision 6: Section 6.1 Screening Visit

[…]

Those with suspected COVID-19 **or recent exposure** will be deferred from screening and referred for community-available services/care/treatment.
[…]

Revision 6: Section 6.3 Clinical Care and Navigation Visits Between Enrollment and Week 26

[…]
CDC and local guidelines will be followed regarding quarantine of staff with potential exposure to persons with **known or** suspected COVID-19.
[…]

Revision 7: Section 5.4 Study Medication Considerations

[…]
this study does not involve any investigational ~~study~~ products. **Some of the drugs provided from the mobile unit will be procured locally by the study teams and others will be provided centrally by the study to the sites. Those drugs provided centrally are referred to as "study products".**
[…]

Revision 7: Section 5.4.1 Study Products for HIV

Study ~~Supplied Medications~~Products for HIV

The following ~~are medications~~**study products** ~~that~~ will be centrally supplied by the study to the sites, and ~~that that~~ will be offered to participants in the intervention arm, as appropriate, for HIV treatment or prevention (ART or PrEP). Study ~~medications~~ **products** must be stored in the original bottles and in accordance with the manufacturer's recommendations.

~~Study-supplied~~ PrEP

- Emtricitabine/tenofovir disoproxil fumarate 200mg/300mg (FTC/TDF, Truvada®)
- Emtricitabine/tenofovir alafenamide 200mg/25mg (FTC/TAF, Descovy®)

~~Study-supplied~~ ART

- Bictegravir/emtricitabine/tenofovir alafenamide 50mg/200mg/25mg (BIC/F/TAF, Biktarvy®)

Revision 7: Section 5.4.2 Study Products Acquisition and Accountability

Study Product ~~Supplied Medication~~ Acquisition and Accountability

FTC/TDF 200 mg/300 mg tablets (Truvada®), FTC/TAF 200 mg /25 mg tablets (Descovy®), and BIC/F/TAF 50mg/200mg/25mg tablets (Biktarvy®) are manufactured and provided by Gilead Sciences, Inc. and will be supplied by the National Institute of Allergy and Infectious Diseases (NIAID) Clinical Research Products Management Center (CRPMC). The study site pharmacist can obtain ~~the~~ study-~~supplied medications~~ **products** through the CRPMC by following the instructions in the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trial Networks*, and instructions in the SSP Manual.

The site pharmacist is required to maintain complete records of all study-~~supplied medications~~ **product** received from the CRPMC and subsequently dispensed to study participants. All ~~study-supplied medications~~**study product** must be stored in the pharmacy. All unused ~~supplied medications~~**study product** must be returned to the CRPMC after the study is completed or terminated or otherwise instructed by the study sponsor. The procedures to be followed are provided in the Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks.

Revision 7: Table 2 – Overview of Medical Care Provided in the Mobile Unit for Intervention Arm Participants

[…]

HIV-ART	ART will be managed from the mobile unit for those not already in HIV care, including: • Dispensation of one first-line, single-pill regimen to participants for whom this is indicated ~~(pending donation)~~ • Prescription provided for fulfillment at a pharmacy if a different regimen is indicated
HIV-PrEP	PrEP will be managed from the mobile unit including: • Dispensation of single pill regimens for PrEP ~~(pending donation)~~ • Prescription provided for fulfillment at a pharmacy if a different regimen is indicated

[…]

Revision 7: Section 7.1 Adverse Event Definition and Reporting

[…]
Therefore, monitoring and reporting of unanticipated treatment-related risks will be limited to the following: Suspected Unexpected Serious Adverse Reactions (SUSARs) to **study products (those** drugs provided centrally by the study for ART or PrEP**)** will be collected and reported in an expedited manner to the DAIDS Adverse Event Reporting System (DAERS)
[…]

All SAEs will be entered into the study data base, with appropriate levels of documentation and notification of the IRB and sponsors. SAEs will be assessed for relatedness to ~~centrally~~

~~supplied~~**study product(s)** ~~medication(s)~~ (**centrally-supplied** ART or PrEP) by the site study clinician. SAEs are included in reports to the Study Monitoring Committee (SMC) for review.
[…]

Revision 7: Section 7.1.3 SUSAR Assessment

[…]
An SAE with onset after exposure to ~~centrally supplied medications~~**study product**(s) (**centrally-supplied** ART or PrEP) will be reported as a SUSAR if the SAE is deemed both related and unexpected.
[…]

Revision 8: Table 1 – Summary of Services Provided to the Intervention and Active Control Arms

Table 1- Summary of Services Provided to the Intervention and Active Control Arms

Service		Summary
Diagnostic Testing	**Screening/ Enrollment**	Screening and Enrollment will occur on the mobile unit for all participants. **Screening Visit:** • HIV rapid testing • Urine testing for substances of abuse and MOUD. • ~~—~~**Collection of blood for local laboratory testing for HIV. Laboratory results will not be immediately available.** **Enrollment Visit:** **In both arms**, • HIV rapid testing ~~performed for HIV~~ • Rapid pregnancy testing, as appropriate • Collection of blood, urine and swab specimens for local laboratory testing for HIV, STIs, HAV/HBV/HCV, and hematology/chemistry assessments. Laboratory results will not be immediately available. **In the intervention arm,** laboratory results should be provided at the next mobile unit care visit, within days of enrollment. If this is not possible, laboratory results will be conveyed by a navigator, clinician or trained staff member, as appropriate, in person or by phone, medical app, or letter. **In the active control arm**, laboratory results will be conveyed by navigator, clinician or trained staff member, as appropriate, in person or by phone, medical app, or letter.

	After Enrollment	**<u>Between Enrollment and week 26</u>** **In the intervention arm,** • As needed, further/repeat testing for clinical care related to MOUD, HIV, STIs, hepatitis or pregnancy. **In the active control arm,** no diagnostics will be performed in the mobile unit or as part of the study during this time (all care & diagnostics will need to be provided from community-based services). **<u>At week 26 and 52 Visits</u>** **In both arms,** • HIV rapid testing (for those not previously confirmed to be HIV positive) • Rapid pregnancy testing (as appropriate) • Urine testing performed for substances of abuse and MOUD. • Collection of blood and swabs for laboratory testing for HIV **(for those not previously confirmed to be HIV positive)**, STIs and (week 52 only) incident HCV infection in those who were ~~anti-~~HCV negative at study entry. Those with chronic HCV will receive HCV RNA testing at week **26 and** 52. Laboratory results will not be available until after the visit; clinically-relevant results will be conveyed by navigator, clinician or trained staff member, as appropriate, in person or by phone, medical app, or letter.

[…]

Revision 9: Section 7.1 Adverse Event Definition and Reporting

[…]
Examples of SAEs that can be expected to occur during this study include deaths (e.g., **<u>fatal</u>** overdoses or other addiction-related deaths) and life-threatening events requiring intervention (e.g. **<u>overdoses</u>**/overdose reversals).
[…]

Revision 10: Section 8.4 Accrual and Retention

[…]
The study cohort (n=860) will be enrolled over the course of approximately 2.5 years and followed for 52 weeks each. This corresponds to a rate of approximately ~~5~~**3**0 new enrollees per month, or, approximately **7**~~12 13~~ new enrollees per month at each of the five sites.
[…]

Revision 11: Section 6.3 Clinical Care and Navigation Visits Between Enrollment and Week 26

[…]

These will be considered “care visits”.

Intervention arm participants who have a reactive/positive test at a clinical care visit and are confirmed to have HIV infection based on testing at the Confirmatory visit will follow the Schedule of Events for participants who are HIV positive at Enrollment (see Appendix 1A) at all future visits.

If a participant has a documented positive HIV status outside of the study (hospital record, for example) after enrollment and before the week 26, confirmatory testing should occur at a clinical care visit (see section 6.6).

Control arm participants who are first diagnosed with HIV outside of the study will be allowed to come to the mobile unit before week 26 for an interim visit for HIV testing and/or Confirmatory visit (see section 6.6). If HIV infection is confirmed at that study visit, these participants will follow the Schedule of Events for participants who are HIV positive at Enrollment (Appendix 1A) at all future visits.

These same procedures will be followed for participants who seroconvert between the week 26 and week 52 visits. Please refer to Section 6.6 and the SSP Manual for further information.

~~**As f**~~**F**or navigation visits […]

Revision 11: Section 6.6 Procedures for participants who are HIV uninfected at Enrollment and have a reactive or positive HIV test after study enrollment

6.6 Procedures for Participants Who are HIV Uninfected at Enrollment and have a Reactive or Positive HIV Test after Study Enrollment

A participant who has a reactive or positive HIV test at a care visit, interim visit, week 26, or week 52 visit after enrollment must have a confirmatory visit (see Appendix IC). A ~~C~~onfirmatory visit must also be performed if the participant or a health care provider provides written documentation of HIV test results from testing performed outside of the study that indicate a positive HIV status (see SSP Manual for documentation requirements). Prior to documentation of HIV positive status at an in-study confirmatory visit, participants should continue to be followed using the Schedule of Events for participants who were HIV negative at enrollment (Appendix 1B). Procedures at these visits (described in Appendix 1B) may be combined with procedures for the in-study confirmatory visit (described in Appendix 1C) in the following three scenarios:

- **(1) Written documentation of positive HIV status obtained outside of the study was first provided to study staff at an interim or care visit, but the participant did not return for the in-study confirmatory visit before the week 26 or week 52 visit, or**
- **(2) Written documentation of positive HIV status obtained outside of the study is first provided to study staff at the time of the week 26 or week 52 visit, or**
- **(3) The participant tested positive for HIV infection in the study at an interim or care visit but did not return for the in-study ~~C~~confirmatory visit before the week 26 or week 52 visit**

Participants who report that they were diagnosed with HIV outside of the study but cannot provide written documentation of that testing will follow standard study procedures and will have HIV testing performed in the study at two study visits conducted on separate dates.

In all cases, confirmatory visits must follow procedures shown in Appendix IC.

If the testing from the confirmatory visit indicates a positive HIV status, participants will follow the Schedule of Events for participants who were HIV positive at enrollment at all future visits (see Appendix IA). If the testing performed at the confirmatory visit does not confirm the HIV positive status, notify the Site PI and HPTN LC and schedule the participant for another visit for HIV testing and HIV counseling. Please refer to the SSP Manual for further information.

Revision 11: Section 6.7 Implementation Evaluation and Cost-Effectiveness Data Collection Procedures

Formerly section 6.6.

Revision 11: Section 6.8 Study Visit Windows

Formerly section 6.7.

Revision 11: Section 6.8 Study Visit Windows

APPENDIX IC: ADDITIONAL PROCEDURES FOR PARTICIPANTS WHO HAVE A REACTIVE OR POSITIVE HIV TEST AFTER ENROLLMENT

	Confirmatory visit
Administrative and Behavioral Procedures	
HIV counseling and test results	X
Clinical Evaluations/Procedures	
Initiate **or refer for** HIV treatment[1]	X
Blood collection	X
Laboratory Evaluations/Procedures	
HIV testing (see SSP Manual)[1][2]	X
HIV viral load	X
CD4 cell count	X
Other HIV related testing[2][3]	X
Plasma storage[3][4]	X
DBS storage[4][5]	X

[1] **For participants with documentation of confirmed HIV infection (see SSP Manual).**

[2] Site should also ensure that local guidelines for HIV confirmatory testing are followed.
[32] Other HIV testing may be performed for clinical care. This may include HIV drug resistance testing and/or HLA-B5701 testing. If indicated, this testing should be performed at a local laboratory; these results will not be reported to the HPTN SDMC.
[4] [3]Stored plasma will be used for testing at the HPTN LC, as described in Section 10.
[45] Stored DBS will be used for testing at the HPTN LC, as described in Section 10.

Revision 11: Appendix II: Sample Informed Consent Form- Main Study

[…]

11. If you acquire HIV during the study, we will help you get care and support.

We will test your blood for HIV during this study. If you are HIV-negative **when you join the study** and ~~get~~ **test positive for** HIV while you are in the study, you will stop taking PrEP if you started PrEP~~.~~**. You will be asked to come to another visit to provide an additional ~*XX* mL (about *x* teaspoons) [*sites to complete*] blood to confirm the HIV result and to provide additional samples for other assessments. You will also be asked to complete the remaining study visits (26 and/or 52 weeks).**~~and w~~**W**e will provide or help you find the care and support you need. You will still continue to receive peer navigation through six months and will continue to receive medical care in the mobile unit, if you are in the group that receives care in the mobile unit.

[…]