

Form: Date of Visit

Did the participant complete this visit? Yes

No

Visit date _____

Did the participant exit/terminate the study at this visit? Yes

No

If "Yes", complete Termination form.

ADDITIONAL PROCEDURES/FORMS

Chemistry Panel

Hematology

Participant Receipt

Participant Transfer

Physical Examination

Pregnancy Outcome

Pregnancy Report

Pregnancy Test Results

Form: Interim Visit

Interim visit code	_____
Date of visit	_____
What is/are the reason(s) for this interim visit? Mark all that apply.	
Participant missed or will miss all or part of a regularly scheduled study visit and is outside of visit window.	<input type="checkbox"/>
Participant contacted site to report serious adverse event(s).	<input type="checkbox"/>
Update Serious Adverse Event log.	
Repeat specimen collection	<input type="checkbox"/>
Follow-up of abnormal safety assessment	<input type="checkbox"/>
Interim HIV testing (not due to redraw request)	<input type="checkbox"/>
Redraw for HIV testing requested by the lab	<input type="checkbox"/>
Other reason	<input type="checkbox"/>
If "Other reason", specify (max. 200 characters): _____	
Did the participant exit/terminate the study at this visit?	Yes <input type="radio"/>
	No <input type="radio"/>
If "Yes", complete Termination form.	
FORMS COMPLETED AT INTERIM VISIT:	
CD4 Test Results/Viral Load	<input type="checkbox"/>
Chemistry Panel	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
Hepatitis Test Results	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Interim HIV Test	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Physical Examination	<input type="checkbox"/>
Pregnancy Outcome	<input type="checkbox"/>
Pregnancy Report	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Specimen Collection	<input type="checkbox"/>
STI Test Results	<input type="checkbox"/>
OUJ Test Results	<input type="checkbox"/>

Form: Clinical Care Visit

Clinical care visit code _____

Date of visit _____

Length of session

0-5 min

6-15 min

16-30 min

31-60 min

>60 min

What is/are the reason(s) for this clinical care visit? Mark all that apply.

Participant contacted site to report serious adverse event(s).

Update Serious Adverse Event log.

Specimen collection

Follow-up of abnormal safety assessment

Interim HIV testing (not due to redraw request)

Redraw for HIV testing requested by the lab

Medication management

Illness

Other reason

If "Other reason", specify (max. 200 characters): _____

Did the participant exit/terminate the study at this visit? Yes

If "Yes", complete Termination form. No

FORMS COMPLETED AT CLINICAL CARE VISIT:

CD4 Test Results/Viral Load

Chemistry Panel

Hematology

Hepatitis Test Results

HIV Test Results

Interim HIV Test

Participant Receipt

Participant Transfer

Physical Examination

Pregnancy Outcome

Pregnancy Report

Pregnancy Test Results

Specimen Collection

Form: Clinical Care Visit

STI Test Results

OUD Test Results

Form: Antiretroviral Treatment Regimen

Log Page #: _____

 Is the participant currently taking ART? Yes

 If "Yes" go to "Medication". No

 Since the previous visit has the participant taken ART? (At Enrollment visit ask if the participant has ever taken ART) Yes
No
 If "No", go to "Stop/Refusal code".

Medication	Emtricitabine (FTC; Emtriva) <input type="radio"/>
	Lamivudine (3TC; Epivir) <input type="radio"/>
	Stavudine (d4T; Zerit) <input type="radio"/>
	Stavudine Extended Release Capsules (d4T XR; Zerit XR) <input type="radio"/>
	Tenofovir Disoproxil Fumarate (TDF; Viread) <input type="radio"/>
	Zidovudine (AZT, ZDV, Retrovir) <input type="radio"/>
	Delavirdine mesylate (DLV; Rescriptor) <input type="radio"/>
	Efavirenz (EFV; Sustiva; Stocrin) <input type="radio"/>
	Etravirine (Intelence) <input type="radio"/>
	Nevirapine (NVP; Viramune) <input type="radio"/>
	Rilpivirine (RPV; Edurant) <input type="radio"/>
	Doravirine (Pifeltro) <input type="radio"/>
	Amprenavir (APV; Agenerase) <input type="radio"/>
	Atazanavir (ATV; Reyataz) <input type="radio"/>
	Darunavir (DRV; Prezista) <input type="radio"/>
	Fosamprenavir (FPV; Lexiva; Telzir) <input type="radio"/>
	Indinavir (IDV; Crixivan) <input type="radio"/>
	Nelfinavir (NFV; Viracept) <input type="radio"/>
	Ritonavir (RTV; Norvir) <input type="radio"/>
	Saquinavir Hard-Gel Capsules (SQV; Invirase) <input type="radio"/>
	Saquinavir Soft-Gel Capsules (SQV; Fortovase) <input type="radio"/>
	Tipranavir (Aptivus) <input type="radio"/>
	Prezcobix (darunavir/cobicistat) <input type="radio"/>
	Evotaz (atazanavir/cobicistat) <input type="radio"/>
	Raltegravir (Isentress) <input type="radio"/>
	Dolutegravir (DTG; Tivicay) <input type="radio"/>
	Elvitegravir <input type="radio"/>
	Enfuvirtide (ENF; Fuzeon) <input type="radio"/>
	Maraviroc (Selzentry) <input type="radio"/>
	Fostemsavir (Rukobia) <input type="radio"/>
	Abacavir/Lamivudine (ABC/3TC; Epzicom; Kivexa) <input type="radio"/>

Form: Antiretroviral Treatment Regimen

Log Page #: _____

-
- Abacavir/Lamivudine/Zidovudine (3TC/AZT/ABC; Trizivir)
- Efavirenz/Emtricitabine/Tenofovir (Atripla; Odimune; Atroiza; Tribuss)
- Emtricitabine/Tenofovir (FTC/TDF; Truvada)
- Lamivudine/Zidovudine (3TC/AZT; Combivir)
- Lopinavir/ritonavir (LPV/RTV; Kaletra; Aluvia)
- Lamivudine/Stavudine/Nevirapine (Triomune)
- Zidovudine/Lamivudine/Nevirapine (Duovir-N)
- Emtricitabine/Rilpivirine/Tenofovir DF (FTC/RPV/TDF; Complera)
- Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF (EVG/COBI/FTC/TDF; Stribild)
- Lamivudine (3TC; Epivir)/Tenofovir (TDF; Viread)
- Dolutegravir/Abacavir/Lamivudine (Triumeq)
- Tenofovir/Lamivudine/Efavirenz [TDF/3TC/EFV]
- Tybost (Cobicistat; COB)
- Genvoya (Elvitegravir/Cobicistat/Emtricitabine/Tenofovir AF [EVG/COBI/FTC/TAF])
- Emtricitabine/Tenofovir alafenamide (FTC/TAF; Descovy)
- Bictegravir/Emtricitabine/Tenofovir alafenamide (BIC/FTC/TAF; Biktarvy)
- Doravirine/tenofovir disoproxil fumarate/lamivudine (Delstrigo)
- Dolutegravir/lamivudine (DTG/3TC; Dovato)
- Dolutegravir/rilpivirine (DTG/RPV; Juluca)
- Rilpivirine/emtricitabine/tenofovir alafenamide (R/FTC/TAF; Odefsey)
- "Darunavir/cobicistat/tenofovir alafenamide/emtricitabine (DRV/c/FTC/TAF; Symtuza)"
- Cabotegravir/rilpivirine (Cabenuva)
- Unknown
-

Dose

Dose Units

Grams Micrograms Milligrams

Form: Antiretroviral Treatment Regimen

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	Milliliters <input type="radio"/>
	Capsules <input type="radio"/>
	Drops <input type="radio"/>
	Puffs <input type="radio"/>
	Sachets <input type="radio"/>
	Suppository <input type="radio"/>
	Tablets <input type="radio"/>
	Units <input type="radio"/>
	Unknown <input type="radio"/>
	Other <input type="radio"/>

If "Other", specify: _____

Frequency	As needed <input type="radio"/>
	Daily <input type="radio"/>
	Twice per day <input type="radio"/>
	Three times per day <input type="radio"/>
	Four times per day <input type="radio"/>
	At hour of wake <input type="radio"/>
	At hour of sleep <input type="radio"/>
	ONCE <input type="radio"/>
	Other <input type="radio"/>

If "Other", specify: _____

Route	Oral <input type="radio"/>
	Intramuscular <input type="radio"/>
	Intravenous <input type="radio"/>
	Other <input type="radio"/>

If "Other", specify: _____

How was ART obtained?	Mobile unit: Home induction <input type="radio"/>
	Mobile unit: Induction at van <input type="radio"/>
	Other doctor/clinic <input type="radio"/>
	Other <input type="radio"/>

Date Started _____

Date Stopped _____

Or

Continuing at end of study _____

Stop/Refusal Code 1 _____

Stop/Refusal Code 2 _____

Stop/Refusal Code 3 _____

Form: Behavioral Questionnaire Part A

Thank you for joining this study. The following survey will ask you questions about your life, your beliefs, and your behavior.

Some of the questions ask about topics that you may consider to be private or confidential. We are asking these questions because your answers could help us to understand how someone's experiences, beliefs and behaviors may be related to their uptake of health care for substance use or HIV. The information you provide is an important contribution to this study and will be kept confidential.

You can skip any question that makes you feel uncomfortable or stop taking the survey at any time.

Some questions will ask you about your behavior during a specific time period (for example, "in the past month"). Please pay close attention to the time period and only tell us about your behavior during that specific time.

CONTROLLED ENVIRONMENT

In the last month, how many days were you staying in a place (jail, hospital, treatment center, etc.) where you could not have access to drugs or alcohol?

ALCOHOL USE

In the last month, how often did you have a drink containing alcohol?

If "Never", go to "Tobacco Use".

- Never
- Monthly or less
- 2 to 4 times a month
- 2 to 3 times a week
- 4 or more times a week

In the last month, how many drinks containing alcohol do you have on a typical day when you are drinking?

- 1 or 2
- 3 or 4
- 5 or 6
- 7, 8, or 9
- 10 or more

In the last month, how often did you have six or more drinks on one occasion?

- Never
- Less than monthly
- Monthly
- Weekly
- Daily or almost daily

Add the alcohol use scores together.

TOBACCO USE

How many cigarettes do you usually smoke per day?

- None
- Less than half pack/day
- At least half pack, but less than 1 pack
- 1 pack/day or more, but less than 2 pack

Form: Behavioral Questionnaire Part A

_____ 2+ packs/day

_____ Refuse to answer

SUBSTANCE USE

In the last year [six months at 26 and 52 weeks], have you tried or taken cannabis (marijuana)? Yes

_____ No

_____ In the past month, how many days did you use cannabis? _____

In the past month, what ways have you usually used cannabis? Oral - Eat

_____ Vaping

_____ Smoked

In the last year [six months at 26 and 52 weeks], have you tried or taken amphetamines/methamphetamines? Yes

_____ No

_____ In the past month, how many days did you use amphetamines/methamphetamines? _____

In the past month, in what ways have you usually used amphetamines/methamphetamines? Oral

_____ Snorting

_____ Smoked

_____ Injection

In the last year [six months at 26 and 52 weeks], have you tried or taken cocaine? Yes

_____ No

_____ In the past month, how many days did you use cocaine? _____

In the past month, in what ways have you usually used cocaine? Oral

_____ Snorting

_____ Smoked

_____ Injection

In the last year [six months at 26 and 52 weeks], have you tried or taken heroin? Yes

_____ No

_____ In the past month, how many days did you use heroin? _____

In the past month, in what ways have you usually used heroin? Oral

_____ Snorting

_____ Smoked

_____ Injection

In the last year [six months at 26 and 52 weeks], have you tried or taken fentanyl? Yes

_____ No

_____ In the past month, how many days did you use fentanyl? _____

In the past month, in what ways have you usually used fentanyl? Oral

_____ Snorting

_____ Smoked

Form: Behavioral Questionnaire Part A

	Injection <input type="checkbox"/>
In the last year [six months at 26 and 52 weeks], have you tried or taken opioid medications – such as oxys, vicodin, norco – not prescribed for you or not as prescribed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
In the past month, how many days did you use these other opioids?	_____
In the past month, in what ways have you usually used opioids?	Oral <input type="checkbox"/> Snorting <input type="checkbox"/> Smoked <input type="checkbox"/> Injection <input type="checkbox"/>
In the last year [six months at 26 and 52 weeks], have you tried or taken K2, Spice, or other synthetic marijuana?	Yes <input type="checkbox"/> No <input type="checkbox"/>
In the past month, how many days did you use K2 or other synthetic marijuana?	_____
In the past month, in what ways have you usually used K2 or other synthetic marijuana?	Oral - Eat <input type="checkbox"/> Vaping <input type="checkbox"/> Smoked <input type="checkbox"/>
In the last year [six months at 26 and 52 weeks], have you tried or taken buprenorphine (not prescribed for you)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
In the past month, how many days did you use buprenorphine (not prescribed for you)?	_____
In the past month, in what ways have you usually used buprenorphine (not prescribed for you)?	Oral <input type="checkbox"/> Injection <input type="checkbox"/>
In the last year [six months at 26 and 52 weeks], have you tried or taken methadone (not prescribed for you)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
In the past month, how many days did you use methadone (not prescribed for you)?	_____
In the past month, in what ways have you usually used methadone (not prescribed for you)?	Oral <input type="checkbox"/> Injection <input type="checkbox"/>
In the last year [six months at 26 and 52 weeks], have you tried or taken benzodiazepines-such as Xanax, Valium, Ativan (not prescribed for you)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
In the past month, how many days did you use benzodiazepines (not prescribed for you)?	_____
In the past month, in what ways have you usually used benzodiazepines (not prescribed for you)?	Oral <input type="checkbox"/> Snorting <input type="checkbox"/> Smoked <input type="checkbox"/>
In the last year [six months at 26 and 52 weeks], have you tried or taken other drugs to get high or relieve withdrawal?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Drug names, specify:	_____
In the past month, how many days did you use these drugs?	_____

Form: Behavioral Questionnaire Part A

In the past month, in what ways have you usually used? Oral
Snorting
Smoked
Injection

In the last year [six months at 26 and 52 weeks], have you tried or taken mixtures of two or more of these drugs? Yes
No

Drug names, specify: _____

In the past month, how many days did you use these mixtures? _____

In the past month, in what ways have you usually used? Oral
Snorting
Smoked
Injection

OVERDOSE HISTORY

How many times have you overdosed in the past year [6 months at 26 and 52 weeks]?

If "0", go to "Readiness to Quit".

What did you overdose on? Meth/stimulants
Cocaine
Opioids
Benzodiazepines (benzos)

How many times have you overdosed in the past month?

What did you overdose on? Meth/stimulants
Cocaine
Opioids
Benzodiazepines (benzos)

Form: Behavioral Questionnaire Part B

READINESS TO QUIT

How much do you want to get treatment for your drug use right now? Zero means you don't want treatment at all now and 10 means you want treatment the most possible.

0

1

2

3

4

5

6

7

8

9

10

How determined are you to control your drug use? Zero means you are not determined at all and 10 means you are the most determined possible.

0

1

2

3

4

5

6

7

8

9

10

How confident are you that you will be able to control your drug use? Zero means you have no confidence and 10 means you have the most confidence possible.

0

1

2

3

4

5

6

7

8

9

10

MENTAL HEALTH

Over the last 2 weeks, how often have you been bothered by the following problems?

Feeling nervous, anxious or on edge

0 - Not at all

1 - Several days

Form: Behavioral Questionnaire Part B

	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Not being able to stop or control worrying	0 - Not at all <input type="radio"/>
	1 - Several days <input type="radio"/>
	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Worrying too much about different things	0 - Not at all <input type="radio"/>
	1 - Several days <input type="radio"/>
	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Trouble relaxing	0 - Not at all <input type="radio"/>
	1 - Several days <input type="radio"/>
	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Being so restless that it is hard to sit still	0 - Not at all <input type="radio"/>
	1 - Several days <input type="radio"/>
	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Becoming easily annoyed or irritable	0 - Not at all <input type="radio"/>
	1 - Several days <input type="radio"/>
	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Feeling afraid as if something awful might happen	0 - Not at all <input type="radio"/>
	1 - Several days <input type="radio"/>
	2 - More than half the days <input type="radio"/>
	3 - Nearly every day <input type="radio"/>
Add the mental health scores together.	
If you experienced any of these problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all <input type="radio"/>
	Somewhat difficult <input type="radio"/>
	Very difficult <input type="radio"/>
	Extremely difficult <input type="radio"/>

Now, I will ask some questions about how you have been feeling in the last week. The following is a list of ways you might have felt or behaved.

How often have you felt this way during the past week?

During the past week, I was bothered by things that usually don't bother me. 0 - Rarely or none of the time (Less than 1 day)

Form: Behavioral Questionnaire Part B

	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I had trouble keeping my mind on what I was doing.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I felt depressed.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I felt that everything I did was an effort.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I felt hopeful about the future.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I felt fearful.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, my sleep was restless.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I was happy.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>

Form: Behavioral Questionnaire Part B

	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I felt lonely.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>
During the past week, I could not get going.	0 - Rarely or none of the time (Less than 1 day) <input type="radio"/>
	1 - Some or a little of the time (1-2 days) <input type="radio"/>
	2 - Occasionally or a moderate amount of time (3-4 days) <input type="radio"/>
	3 - Most or all of the time (5-7 days) <input type="radio"/>

Add the CESD-10 scores together. _____

Now we are going to ask you some questions about any stressful or difficult times that you may have experienced in the last 6 months.

In the last 6 months, have you ever had any experience that was so frightening, horrible, or upsetting that you...

...have had nightmares about it or thought about it when you did not want to?	Yes <input type="radio"/>
	No <input type="radio"/>
	Prefer not to answer <input type="radio"/>
...tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	Yes <input type="radio"/>
	No <input type="radio"/>
	Prefer not to answer <input type="radio"/>
...were constantly on guard, watchful, or easily startled?	Yes <input type="radio"/>
	No <input type="radio"/>
	Prefer not to answer <input type="radio"/>
...felt numb or detached from others, activities, or your surroundings?	Yes <input type="radio"/>
	No <input type="radio"/>
	Prefer not to answer <input type="radio"/>

Add the PTSD scores together. _____

CRIMINAL JUSTICE ENGAGEMENT

How many times in your life [in the past 6 months at 26 and 52 weeks] have you been held in a jail, prison, and/or a detention center for at least one day or more?

Or

Don't know _____

Form: Behavioral Questionnaire Part B

Or

Refused

How long were you in jail, prison, and/or a detention center in your lifetime, combined [in the past 6 months at 26 and 52 weeks]? Days

Weeks

Example: 18 months would be "Length of time in jail unit" = "months"; "Length of time in jail" = "18".

Months

Years

Length of time in jail unit

Length of time in jail _____

Or

Don't know

Or

Refused

In the past 6 months, have the police taken, confiscated or destroyed your needles, syringes or other injection equipment without arresting or citing you? Yes

No

Don't know

Refused

If "Yes," how many times? _____

In the past 6 months, have you been arrested by police? Yes

No

Don't know

Refused

If "Yes," how many times? _____

In the past 6 months, have you been arrested or cited for possession of needles, syringes or other injection equipment? Yes

No

Don't know

Refused

If "Yes," how many times? _____

In the past 6 months, how many times have you been held in the following for at least one day or more? If none, enter 0.

Jail _____

Prison _____

Detention center _____

Other incarceration _____

COMMUNITY CONNECTION/RESOURCE INSECURITY _____

Form: Behavioral Questionnaire Part B

How many people in your life can you talk with about personal matters? _____

How many people in your life could help you with grocery shopping or other physical chores? _____

How many people in your life could help you with \$25 or something valuable if you needed it? _____

How many people in your life can you rely on for health advice? _____

How many people in your life do you regularly hang out with? _____

How many people in your life could help you out with more than one of the issues we just discussed? _____

How many people in your life can you trust with a check? _____

How many people in your life do you provide the kind of support we were just talking about _____

ACCESS TO HEALTH CARE

What kind of health insurance do you currently have? _____

Private health insurance

VA-Veterans Administration

MediCal/Medicaid/LA Care/Molina

Medicare

Ryan White

ADAP

Healthy Families

No insurance

Other

When was your most recent visit to a doctor, nurse, or other health care provider? _____

Within the past 6 months

6-12 months ago

More than 12 months ago

When was your most recent visit to the dentist? _____

Within the last year

1-2 years ago

2-5 years ago

Never

In the the last year [past 6 months at 26 and 52 weeks], how many times did you visit a provider who treated you for: If none, enter 0.

Primary care _____

Mental health _____

Substance use _____

Infectious disease _____

DRUG TREATMENT EXPERIENCE

What type of drug treatment program or programs have you used in the last year [past 6 months at 26 and 52 weeks]?

Drug free/abstinence-based counseling Yes

No

Don't know

Refused

Form: Behavioral Questionnaire Part B

Methadone	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know <input type="radio"/>
	Refused <input type="radio"/>
<hr/>	
Buprenorphine (or Suboxone or Subutex)	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know <input type="radio"/>
	Refused <input type="radio"/>
<hr/>	
Naltrexone (Vivitrol)	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know <input type="radio"/>
	Refused <input type="radio"/>
<hr/>	
Other, specify _____	
Other, specify _____	
<hr/>	
In the last year [six months at 26 and 52 weeks], have you gotten any new sterile needles? By new sterile needle, I mean no one - not even you - had ever used it before.	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know <input type="radio"/>
	Refused <input type="radio"/>
<hr/>	
If "No", "Don't know", or "Refused", go to "In the past 12 months [6 months for follow-up visits], have you gotten any other new injection supplies, such as cookers, cotton, or water?"	
From which of the following places or people did you get new sterile needles in the past? You may choose more than one option.	<input type="checkbox"/>
<hr/>	
Needle or syringe exchange program	
Someone who got them from a needle exchange	<input type="checkbox"/>
Pharmacy or drug store	<input type="checkbox"/>
Doctor's office, clinic, or hospital	<input type="checkbox"/>
HIV/AIDS-focused organization	<input type="checkbox"/>
Some other place	<input type="checkbox"/>
<hr/>	
In the last year [six months at 26 and 52 weeks], have you gotten any other new injection supplies, such as cookers, cotton, or water?	Yes <input type="radio"/>
	No <input type="radio"/>
	Don't know <input type="radio"/>
	Refused <input type="radio"/>
<hr/>	
If "No", "Don't know", or "Refused", end of form.	
Which place or places on this list did you get those new injection supplies from? You may choose more than one option.	<input type="checkbox"/>
<hr/>	
Needle or syringe exchange program	

Form: Behavioral Questionnaire Part B

Someone who got them from a needle exchange	<input type="checkbox"/>
Pharmacy or drug store	<input type="checkbox"/>
Doctor's office, clinic, or hospital	<input type="checkbox"/>
HIV/AIDS-focused organization	<input type="checkbox"/>
Some other place	<input type="checkbox"/>

Form: CASI Tracking

CASI collection date	_____
CASI ID	_____
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If yes, please describe	_____

Form: CD4 Test Results/Viral Load

ABSOLUTE CD4+

Was a sample collected for absolute CD4+ count?

Yes

No

Specimen collection date _____

Absolute CD4+ _____

Fixed Unit: cells/mm³

Unable to analyze

HIV RNA

Was HIV RNA PCR testing completed?

Yes

No

Specimen collection date _____

HIV RNA viral load result _____

Fixed Unit: viral copies/mL

HIV RNA PCR target detected, under the lower limit of quantification

Lower limit of quantification _____

Fixed Unit: viral copies/mL

HIV RNA PCR target detected, above the upper limit of quantification

Upper limit of quantification _____

Fixed Unit: viral copies/mL

HIV RNA PCR target not detected

Form: Chemistry Panel

Was a sample collected for serum chemistries? Yes
No

Specimen collection date _____

LIVER FUNCTION TESTS

AST (SGOT) _____

AST (SGOT) severity grade Not gradable
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

ALT (SGPT) _____

ALT (SGPT) severity grade Not gradable
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Total Bilirubin _____

Total Bilirubin severity grade Not gradable
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

RENAL FUNCTION TESTS

Creatinine _____

Creatinine severity grade Not gradable
Grade 1 (Mild)
Grade 2 (Moderate)
Grade 3 (Severe)
Grade 4 (Potentially life-threatening)

Comments (max. 200 characters): _____

Form: Couple Tracking

Does the participant have a sexually intimate partner who is enrolling in the trial? Yes
No

PTID of partner _____

Partnership type Spouse/domestic partner
Boyfriend/girlfriend/regular sexually intimate partner
Other

If "Other", specify: _____

How long have the participant and this partner been sexually intimate partners? Less than 6 mos
6-12 mos
1-2 years
3-5 years
More than 5 years

Does the participant currently live with this partner? Yes
No

Mark if a second Couple Tracking eCRF is needed for this participant

Form: Demographics

Date of birth _____

Age _____ Fixed Unit: yrs

Sex assigned at birth _____ Male

Female

Ethnicity _____ Hispanic or Latino

Not Hispanic or Latino

Not reported

Unknown

Race

Mark all that apply.

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or other Pacific Islander

White

Other race

Other race, please specify: _____

What is the participant's current gender identity?

Mark all that apply.

Man

Woman

Transgender Man

Transgender Woman

Gender Nonconforming/Gender Variant

Genderqueer

Additional identity, please specify: _____

Decline to answer

How do you identify your sexual orientation?

Bisexual

Gay/Lesbian/Homosexual

Queer

Straight/Heterosexual

Two Spirit

Additional identity

Not sure

Prefer not to answer

Form: Demographics

If "Additional identity", specify: _____

Form: Hematology

HEMOGRAM

Was a hematology sample collected?

Yes

No

Hematology collection date

Hemoglobin

Hemoglobin severity grade

Not gradable

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially
life-threatening)

Comments (max. 200 characters):

Form: Hepatitis Test Results

Was a hepatitis test done? Yes

If "No", specify reason in "Comments". End of form. No

Specimen collection date _____

HEPATITS A

Hepatitis A virus antibody (HAV Total) Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

Was the participant referred for Hepatitis A vaccination? Yes

No

HEPATITS B

Hepatitis B Surface Antibody (HBsAb) Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

Hepatitis B Core Antibody (HBcAb) Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

Hepatitis B surface antigen (HBsAg) Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

HEPATITS B DNA TEST

Hepatitis B DNA specimen collection date _____

Hepatitis B DNA Test Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Form: Hepatitis Test Results

_____ Indeterminate

HBV DNA quantitative results _____

HBV DNA quantitative results unit IU/mL

log IU/mL

HEPATITS B VACCINATION OR TREATMENT

Was the participant referred for Hepatitis B vaccination? Yes

No

Was Hepatitis B treatment initiated or was the participant referred for treatment? Yes

No

HEPATITIS C

Hepatitis C Antibody (HCV Ab) Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

HEPATITS C RNA TEST

Hepatitis C RNA specimen collection date _____

Hepatitis C RNA Test Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

HCV RNA quantitative results _____

HCV RNA quantitative results unit IU/mL

log IU/mL

HEPATITS C TREATMENT

Was the participant referred for Hepatitis C treatment? Yes

No

Comments (max. 200 characters): _____

Form: HIV Test Results

Was HIV testing performed? Yes
No

Where was HIV testing performed? Mobile unit
Other doctor/clinic

Specimen Collection Date _____

HIV RAPID TEST

HIV Rapid 1 specimen collection date _____

HIV Rapid 1 Non-reactive
Reactive/Positive
Not done

HIV LABORATORY BASED TESTING

HIV laboratory based testing specimen collection date _____

HIV EIA or CMIA Non-reactive
Reactive/Positive
Not done

HIV 1/2 Discriminatory Assay Result Assay result not provided
HIV Negative
HIV-1 Positive
HIV-2 Positive
HIV-2 Positive with HIV-1 Cross-Reactivity
HIV-1 Positive, Untypable
HIV-1 Indeterminate
HIV-2 Indeterminate
HIV Indeterminate
Not done
Other

If "Other", specify: _____

HIV-1 RNA Non-reactive/Not detected
Reactive/Detected
Not done

FINAL HIV STATUS

Final HIV status Negative
Positive
Additional testing needed

Form: Informed Consent

Date initial informed consent signed _____

Initial informed consent version _____

Types of consents signed on this date

Mark all that apply.

Enrollment

Long term specimen storage - Blood

Long term specimen storage - Urine

ADDITIONAL INFORMED CONSENTS

Informed consent date _____

Informed consent version _____

Types of consents signed on this date

Mark all that apply.

Enrollment

Long term specimen storage - Blood

Long term specimen storage - Urine

Form: Interim HIV Test

Instructions: Complete this form any time a participant or clinician requests an interim HIV test at the site.

Request Participant request

Clinician request

What is the reason(s) for HIV testing? Mark all that apply.

Recent or current symptoms

If symptoms reported, describe symptoms _____

Needed STI testing

Required or recommended by a medical provider not associated with this study

PrEP/PEP initiation or monitoring

Missed regularly scheduled visit

Redraw requested

Required for insurance purposes

Recent or possible exposure

If "recent or possible exposure", mark all that apply

Condom-less sexual contact with known HIV-infected individual

Condom-less sexual contact with unknown HIV status individual

Condom broke during sexual contact with known HIV infected individual

Condom broke during sexual contact with unknown HIV-infected individual

Shared inject drug use equipment (i.e, needles, syringe, cotton, cooker)

Other

If 'Other', specify: _____

Form: Medical History

Log Page #: _____

Date medical history collected _____

Description of medical history condition/event _____

Is condition/event gradable? Yes

No

Severity grade Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Start date of pre-existing condition/event _____

Is the condition ongoing? Yes

No

Date medical history/condition ended/resolved _____

Comments (max. 200 characters): _____

Form: Medication for Opioid Use Disorder

Log Page #: _____

Is the participant currently taking MOUD? Yes

If "Yes" go to "A prescription for MOUD has been verified". No

Since the previous visit has the participant taken MOUD? (At Enrollment visit ask if the participant has ever taken MOUD) Yes

If "No", go to "Stop/Refusal Code." No

A prescription for MOUD has been verified Yes

No

Medication Methadone

Buprenorphine/naloxone sublingual (Suboxone, Zubsolv)

Buprenorphine monoprodu ct sublingual (Subutex)

Buprenorphine injectable (Sublocade, Brixadi)

Buprenorphine patch (Belbuca, BuTrans)

Buprenorphine implantable (Probuphine)

Long acting naltrexone (Vivitriol)

Dose _____

Dose units Grams

Micrograms

Milligrams

Milliliters

Capsules

Drops

Puffs

Sachets

Suppository

Tablets

Units

Unknown

Other

If "Other", specify: _____

Frequency As needed

Daily

Twice per day

Three times per day

Four times per day

At hour of wake

At hour of sleep

Form: Medication for Opioid Use Disorder

Log Page #: _____

ONCE

Other

If "Other", specify: _____

Route Oral

Intramuscular

Subcutaneous

Sublingual

Transdermal

Implantable

Other

If "Other", specify: _____

How was MOUD obtained? Mobile unit: Home induction

Mobile unit: Induction at van

Other doctor/clinic

Other

Date Started _____

Date Stopped _____

Or

Continuing at end of study _____

Stop/Refusal Code 1 _____

Stop/Refusal Code 2 _____

Stop/Refusal Code 3 _____

Form: Missed Visit

Target visit date _____

Reason visit was missed

Unable to contact participant

Participant unable to schedule visit within window

Participant refused visit

Participant incarcerated

Participant admitted to healthcare facility

Participant withdrew from study

Participant deceased

Other

If "Other", specify: _____

Steps taken to address the missed visit (corrective action plan) _____

Form: Navigation Session

Log Page #: _____

Date of navigation session _____

Navigator _____

Location of Session _____ In Person

Virtual

Length of session _____ 0-5 min

6-15 min

16-30 min

31-60 min

>60 min

Topics addressed

Mark all that apply.

MOUD _____

HIV care

PrEP

Other

If "Other", specify: _____

Form: OUD Test Results

Was an OUD test done? Yes

If "No", specify reason in "Comments". End of form. No

Specimen collection date _____

MOUD RESULTS

Methadone Not done
Not detected/Negative
Detected/Positive/Reactive
Equivocal
Invalid
Indeterminate

Buprenorphine Not done
Not detected/Negative
Detected/Positive/Reactive
Equivocal
Invalid
Indeterminate

Naltrexone Not done
Not detected/Negative
Detected/Positive/Reactive
Equivocal
Invalid
Indeterminate

SUBSTANCE USE RESULTS

Amphetamines Not done
Not detected/Negative
Detected/Positive/Reactive
Equivocal
Invalid
Indeterminate

Methamphetamines Not done
Not detected/Negative
Detected/Positive/Reactive
Equivocal
Invalid
Indeterminate

Opioid Dipstick Not done
Not detected/Negative

Form: OUD Test Results

	Detected/Positive/Reactive <input type="radio"/>
	Equivocal <input type="radio"/>
	Invalid <input type="radio"/>
	Indeterminate <input type="radio"/>

Benzodiazepines	Not done <input type="radio"/>
	Not detected/Negative <input type="radio"/>
	Detected/Positive/Reactive <input type="radio"/>
	Equivocal <input type="radio"/>
	Invalid <input type="radio"/>
	Indeterminate <input type="radio"/>

Cocaine Metabolite	Not done <input type="radio"/>
	Not detected/Negative <input type="radio"/>
	Detected/Positive/Reactive <input type="radio"/>
	Equivocal <input type="radio"/>
	Invalid <input type="radio"/>
	Indeterminate <input type="radio"/>

Oxycodone	Not done <input type="radio"/>
	Not detected/Negative <input type="radio"/>
	Detected/Positive/Reactive <input type="radio"/>
	Equivocal <input type="radio"/>
	Invalid <input type="radio"/>
	Indeterminate <input type="radio"/>

FENTANYL USE RESULTS

Fentanyl specimen collection date _____

Fentanyl	Not done <input type="radio"/>
	Not detected/Negative <input type="radio"/>
	Detected/Positive/Reactive <input type="radio"/>
	Equivocal <input type="radio"/>
	Invalid <input type="radio"/>
	Indeterminate <input type="radio"/>

OTHER SUBSTANCE USE RESULTS

Other	Not done <input type="radio"/>
	Not detected/Negative <input type="radio"/>
	Detected/Positive/Reactive <input type="radio"/>
	Equivocal <input type="radio"/>
	Invalid <input type="radio"/>
	Indeterminate <input type="radio"/>

If "Other", specify (max. 200 characters): _____

Participant ID: _____

HTPN 094

Visit Code: _____

Form: OUD Test Results

Comments (max. 200 characters): _____

Form: Participant Receipt

Name of receiving study site	New York - Bronx Prevention	<input type="checkbox"/>
	Washington DC - Washington Circle	<input type="checkbox"/>
	Houston AIDS Research Team CRS	<input type="checkbox"/>
	Philadelphia	<input type="checkbox"/>
	Los Angeles - Care Center	<input type="checkbox"/>

Name of transferring study site	New York - Bronx Prevention	<input type="checkbox"/>
	Washington DC - Washington Circle	<input type="checkbox"/>
	Houston AIDS Research Team CRS	<input type="checkbox"/>
	Philadelphia	<input type="checkbox"/>
	Los Angeles - Care Center	<input type="checkbox"/>

Date participant received by site	_____
-----------------------------------	-------

Form: Participant Transfer

Name of transferring study site	New York - Bronx Prevention	<input type="checkbox"/>
	Washington DC - Washington Circle	<input type="checkbox"/>
	Houston AIDS Research Team CRS	<input type="checkbox"/>
	Philadelphia	<input type="checkbox"/>
	Los Angeles - Care Center	<input type="checkbox"/>

Name of receiving study site	New York - Bronx Prevention	<input type="checkbox"/>
	Washington DC - Washington Circle	<input type="checkbox"/>
	Houston AIDS Research Team CRS	<input type="checkbox"/>
	Philadelphia	<input type="checkbox"/>
	Los Angeles - Care Center	<input type="checkbox"/>

Visit of last completed contact with participant	Visit 1.0 - Screening	<input type="checkbox"/>
	Visit 2.0 - Enrollment	<input type="checkbox"/>
	Visit 3.0 - 26 weeks	<input type="checkbox"/>
	Visit 4.0 - 52 weeks	<input type="checkbox"/>
	Care Visit	<input type="checkbox"/>
	Interim Visit	<input type="checkbox"/>
	Navigation Session	<input type="checkbox"/>

If "Care visit" or "Interim visit", specify visit code. _____

Date participant's records were sent to receiving study site _____

Form: Pre-exposure Prophylaxis

Log Page #: _____

Is the participant currently taking PrEP? Yes

If "Yes" go to "Medication". No

Since the previous visit has the participant taken PrEP? (At Enrollment visit ask if the participant has ever taken PrEP) Yes

If "No", go to "Stop/Refusal Code". No

Medication name Emtricitabine/Tenofovir

alafenamide (FTC/TAF; Descovy)

Emtricitabine/Tenofovir (FTC/TDF; Truvada)

Cabotegravir (pending FDA approval)

Other

Type of usage: Continuous

If continuous, go to "How was PrEP obtained". Intermittent

If "Intermittent", record frequency of usage (average days per week). 5-6 days

3-4 days

1-2 days

<1 day

How was PrEP obtained? Mobile unit: Home induction

Mobile unit: Induction at van

Other doctor/clinic

Other

If "Other", specify: _____

Date started _____

Date stopped _____

Or

Continuing at end of study _____

Stop/Refusal Code 1 _____

Stop/Refusal Code 2 _____

Stop/Refusal Code 3 _____

Form: Pregnancy Outcome

Is the outcome of this pregnancy obtainable? Yes

If "No", end of form. No

How many pregnancy outcomes resulted from this reported pregnancy? _____

Outcome Date _____

Place of delivery/outcome

Home

Hospital

Clinic

Unknown

Other

If "Other", specify: _____

Specify outcome

Full term live birth (greater than or equal to 37 weeks)

Premature live birth (less than 37 weeks)

Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks)

Spontaneous abortion (less than 20 weeks)

Ectopic pregnancy

Therapeutic/elective abortion

Other

If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?".

If "Other", specify: _____

Method

C-section

Standard vaginal

Operative vaginal

Vaginal

Provide a brief narrative of the circumstances (max. 400 characters). _____

Were there any complications related to the pregnancy outcome? Yes

If "No", go to "Were any fetal/infant congenital anomalies identified?". No

Delivery-related complications. Mark "None" or all that apply.

None

Intrapartum hemorrhage

Postpartum hemorrhage

Non-reassuring fetal status

Chorioamnionitis

Other

Form: Pregnancy Outcome

If "Other", specify: _____

Non-delivery related complications. Mark "None" or all that apply.

None

Hypertensive disorders of pregnancy

Gestational diabetes

Other

If "Other", specify: _____

Were any fetal/infant congenital anomalies identified? Mark all that apply. Yes

No

If "No" or "Unknown", go to "Complete the infant items below for live births only." Not assessed

Unknown

Central nervous system, cranio-facial

Central nervous system, spinal

Cardiovascular

Renal

Gastrointestinal

Pulmonary

Musculoskeletal/extremities

Physical defect

Skin

Genitourinary

Chromosomal

Cranio-facial (structural)

Hematologic

Infectious

Endocrine/metabolic

Other

Describe congenital anomaly/defect (max. 200 characters). _____

Complete SAE Log for congenital anomaly/defect. _____

Complete the infant items below for live births only. Otherwise, end of form. Male

Female

Infant sex _____

Form: Pregnancy Outcome

Infant birth weight Fixed Unit: kg

Or

Infant birth weight unavailable

Infant birth length Fixed Unit: cm

Or

Infant birth length unavailable

Infant birth head circumference

Or

Infant birth head circumference unavailable

Infant birth abdominal circumference Fixed Unit: cm

Or

Infant birth abdominal circumference unavailable

Infant gestational age by examination in weeks Fixed Unit: Weeks

Infant gestational age by examination in days Fixed Unit: Days

Or

Infant gestational age by examination unavailable

If unavailable, end of form.

Method used to determine gestational age Ballard
Dubowitz
Other

If "Other", specify (max. 200 characters): _____

Form: Pregnancy Report

Date pregnancy reported to site _____

Visit at which this pregnancy was reported

Visit 1.0 - Screening

Visit 2.0 - Enrollment

Visit 3.0 - 26 weeks

Visit 4.0 - 52 weeks

Care Visit

Interim Visit

Navigation Session

If "Care visit" or "Interim visit", specify visit code. _____

Date of onset of last menstrual period _____

Or _____

Amenorrheic for past 6 months

Estimated date of delivery _____

What primary information was used to estimate the date of delivery?

Last menstrual period

Initial ultrasound <20 weeks

Initial ultrasound >=20 weeks

Physical examination

Conception date by assisted reproduction

Other

If "Other", specify: _____

Is this the participant's first pregnancy since enrollment in this study? Yes

No

Form: Pregnancy Test Results

Was a pregnancy test performed? Yes

No

If no, specify reason not done. Not of reproductive potential

Participant is pregnant

Other

If Other, specify: _____

Specimen date _____

Collection time _____

Pregnancy test result Positive

Negative

Form: Protocol Deviations

Log Page #: _____

Site awareness date _____

Deviation date _____

Has or will this deviation be reported to local IRB/EC? Yes

No

Has or will this deviation be reported to DAIDS as a critical event? Yes

No

Type of deviation Inappropriate enrollment

Failure to follow randomization or blinding procedures

Conduct of non-protocol procedure

Improper SAE

Unreported SAE

Breach of confidentiality

Physical assessment deviation

Lab assessment deviation

Staff performing duties that they are not qualified to perform

Use of non-IRB/EC-approved materials

Informed consent process deviation

Other

Description of deviation _____

Plans and/or action taken to address the deviation _____

Plans and/or action taken to prevent future occurrences of the deviation _____

Deviation reported by _____

Form: Receipt of Community Services

At the 26 week visit, was the participant receiving MOUD from a provider in the community? Yes

No

If "No", select the reason the participant was not receiving MOUD from a community provider. If "Information not available", go to "For participants who tested positive for HIV during screening..."

Participant reports they never went to a community MOUD provider after enrollment

Participant reports they went to a community MOUD provider at least once after enrollment, but never started MOUD

Participant reports they started MOUD at a community MOUD provider at least once after enrollment, but were no longer on MOUD at the 26 week visit

Information not available

Give a brief description of the reason the participant was not receiving MOUD from a community provider (max. 450 characters): _____

For participants who tested positive for HIV during screening or during the first 26 weeks of the study:

If the participant never tested positive for HIV, go to "For participants who did not test positive for HIV during screening or during the first 26 weeks of the study".

At the 26 week visit, was the participant receiving ART from a provider in the community? Yes

No

If "No", select the reason the participant was not receiving ART from a community provider. If "Information not available", end of form.

Participant reports they never went to a community ART provider after enrollment

Participant reports they went to a community ART provider at least once after enrollment, but never started ART

Participant reports they started ART at a community ART provider at least once after enrollment, but were no longer on ART at the 26 week visit

Information not available

Give a brief description of the reason the participant was not receiving ART from a community provider (max. 450 characters): _____

End of form. _____

For participants who did not test positive for HIV during screening or during the first 26 weeks of the study:

At 26 week visit, was the participant receiving PrEP from a provider in the community? Yes

No

If "No", select the reason the participant was not receiving PrEP from a community provider. If "Information not available", end of form.

Participant reports they never went to a community PrEP provider after enrollment

Participant reports they went to a community PrEP provider at least once after enrollment, but never started PrEP

Form: Receipt of Community Services

Participant reports they started PrEP at a community PrEP provider at least once after enrollment, but were no longer on PrEP at the 26 week visit

Information not available

Give a brief description of the reason the participant was not receiving PrEP from a community provider (max. 450 characters): _____

Form: Screening and Enrollment

Has the participant screened before? Yes
No

Enter the first RAVE PTID assigned _____
Eligibility status Eligible and enrolled
If "Incomplete screening", end of form. Eligible/Not enrolled
Ineligible
Incomplete Screening

Enrollment date _____
End of Form. _____
Study arm _____

Date participant was found "Eligible/Not Enrolled" or "Ineligible" _____

- Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible".
- Wasn't 18 to 60 years of age
 - Urine test wasn't positive for recent opioid use and/or no evidence of recent injection drug use
 - Wasn't diagnosed with OUD per Diagnostic and Statistical Manual of Mental Disorders
 - Wasn't able and/or willing to give informed consent
 - Wasn't willing to start MOUD treatment
 - Wasn't able to successfully complete an Assessment of Understanding
 - Did not report sharing injection equipment and/or condomless sex in the last three months with partners of HIV-positive or unknown status
 - Wasn't able to provide adequate locator information
 - HIV status not confirmed
 - Received MOUD in the 30 days prior to enrollment
 - Co-enrollment in another interventional study
 - Investigator decision
 - Individual changed their mind
 - Unable to contact/no show
 - Wasn't at least 18 years of age

If "Investigator decision", specify (max. 200 characters): _____

Form: Serious Adverse Event

Log Page #: _____

Date SAE reported to site _____

Serious adverse event (SAE) _____

Onset date _____

At which visit was this serious adverse event first reported?

Visit 1.0 - Screening

Visit 2.0 - Enrollment

Visit 3.0 - 26 weeks

Visit 4.0 - 52 weeks

Care Visit

Interim Visit

Navigation Session

If "Care visit" or "Interim visit", specify visit code. _____

Is the SAE still ongoing? Yes

No

If "No", outcome date _____

Was the SAE an overdose or did the SAE involve an overdose? Yes

No

Severity grade

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Grade 5 (Death)

If "Grade 5 (Death)", source of report of death

Mark all that apply.

Report from community member/friends/family

- Hospital/Medical record
- Coroner/Medical Examiner report
- Death certificate
- Police Report
- Other source

Other source, please specify: _____

If "Grade 5 (Death)", was overdose the cause of death? Yes

No

Form: Serious Adverse Event

Log Page #: _____

Action(s) taken: _____

Mark "None" or all that apply.

None

Medication(s) _____

Therapeutic procedure/surgery _____

Diagnostic procedure _____

Other _____

If "Other", specify (max. 200 characters): _____

Status/Outcome Recovered/Resolved

If "Severity/Frequency increased" is selected, report as a new serious adverse event. Recovering/Resolving

Recovered/Resolved with Sequelae

Not recovered/Not resolved

Fatal

Severity/Frequency increased

If status or outcome is "Severity/Frequency increased", select serious adverse event. _____

Check which of following criteria makes this a "Serious Adverse Event". _____

Results in death

Is life-threatening _____

Requires inpatient hospitalization or prolongation of existing hospitalization _____

Results in persistent or significant disability/incapacity _____

Is a congenital anomaly/birth defect _____

Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above _____

Was this SAE related to the participant's receipt of peer navigation services or receipt of medical care in the mobile health delivery unit? Yes
No

Was this SAE a worsening of a baseline medical condition? Yes
No

Relationship to study product Related to ART
Related to PrEP
Not Related

Was this SAE reported as a SUSAR? Yes

Participant ID: _____

HTPN 094

Visit Code: _____

Form: Serious Adverse Event

Log Page #: _____

_____ No

If reported as a SUSAR, EAE number

Begin number with 4-digit year, followed by 6-digit EAE number
(no dashes or spaces).

Comments (max. 450 characters): _____

Form: Social Impact

Log Page #: _____

Date reported to site _____

Concisely describe social impact (max. 200 characters). _____

Onset date _____

Reported at visit code

Visit 1.0 - Screening

Visit 2.0 - Enrollment

Visit 3.0 - 26 weeks

Visit 4.0 - 52 weeks

Care Visit

Interim Visit

Navigation Session

If "Interim visit", specify interim visit code. _____

Social impact

Personal Relationships - Had any negative experiences with family, friends, significant others, or sex partners.

Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.

Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work.

Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school.

Medical/Dental - Been told you have an HIV test by a health care provider, been refused medical or dental treatment or treated negatively by a health care provider.

Health Insurance/Medical Aid/Hospital Plan - Lost your health insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy.

Form: Social Impact

Log Page #: _____

Life Insurance/Funeral Coverage
 - Lost your life insurance policy or funeral cover policy, had a problem getting new life insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy.

Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing.

Military/Other Government Agency - Had a problem with the military or any other government agencies.

Other - Had other problems not covered in the list above.

If "Other", specify (max. 200 characters): _____

What impact has this situation had on the participant's quality of life?

No disturbance

Minimal disturbance

Moderate disturbance, no significant impact

Major disturbance with significant impact

Describe what was done by staff and participant to address social impact (max. 200 characters). _____

Participant _____

Staff _____

Record current status.

Unresolved

Unresolved at end of study

Unable to resolve no further action taken

Resolved

If social impact status is "Unable to resolve", "No further action taken" or "Resolved", record closure date. _____

Form: Specimen Collection

Specimen type Plasma
Dried Blood Spot for PK
Serum
Urine

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters). _____

Specimen type Plasma
Dried Blood Spot for PK
Serum
Urine

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters). _____

Specimen type Plasma
Dried Blood Spot for PK
Serum
Urine

Was specimen collected? Yes
No

If "No", record reason why sample was not collected (max. 200 characters). _____

Specimen collection date _____

Specimen collection time _____

Was sample stored? Stored
Not stored

Form: Specimen Collection

If "Not stored", record reason why sample was not stored (max. 200 characters).

Specimen type

Plasma

Dried Blood Spot for PK

Serum

Urine

Was specimen collected?

Yes

No

If "No", record reason why sample was not collected (max. 200 characters).

Specimen collection date

Specimen collection time

Was sample stored?

Stored

Not stored

If "Not stored", record reason why sample was not stored (max. 200 characters).

Form: STI Test Results

Specimen collection date _____

SYPHILIS TESTING

Not done/Not collected

Algorithm used Traditional

Reverse

Treponemal Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

Non-Treponemal Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

Syphilis titer if indicated _____

Or

N/A

Second Treponemal test Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

N. GONORRHEA AND C. TRACHOMATIS

N. gonorrhoea – vaginal swab Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

C. trachomatis - vaginal swab Not collected

Not done

Not detected/Negative

Form: STI Test Results

	Positive/Reactive	<input type="checkbox"/>
	Invalid	<input type="checkbox"/>
	Indeterminate	<input type="checkbox"/>
<hr/>		
N. gonorrhoea – urine	Not collected	<input type="checkbox"/>
	Not done	<input type="checkbox"/>
	Not detected/Negative	<input type="checkbox"/>
	Positive/Reactive	<input type="checkbox"/>
	Invalid	<input type="checkbox"/>
	Indeterminate	<input type="checkbox"/>
<hr/>		
C. trachomatis –urine	Not collected	<input type="checkbox"/>
	Not done	<input type="checkbox"/>
	Not detected/Negative	<input type="checkbox"/>
	Positive/Reactive	<input type="checkbox"/>
	Invalid	<input type="checkbox"/>
	Indeterminate	<input type="checkbox"/>
<hr/>		
N. gonorrhoea – rectal swab	Not collected	<input type="checkbox"/>
	Not done	<input type="checkbox"/>
	Not detected/Negative	<input type="checkbox"/>
	Positive/Reactive	<input type="checkbox"/>
	Invalid	<input type="checkbox"/>
	Indeterminate	<input type="checkbox"/>
<hr/>		
C. trachomatis - rectal swab	Not collected	<input type="checkbox"/>
	Not done	<input type="checkbox"/>
	Not detected/Negative	<input type="checkbox"/>
	Positive/Reactive	<input type="checkbox"/>
	Invalid	<input type="checkbox"/>
	Indeterminate	<input type="checkbox"/>
<hr/>		
N. gonorrhoea – oropharyngeal swab	Not collected	<input type="checkbox"/>
	Not done	<input type="checkbox"/>
	Not detected/Negative	<input type="checkbox"/>
	Positive/Reactive	<input type="checkbox"/>
	Invalid	<input type="checkbox"/>
	Indeterminate	<input type="checkbox"/>
<hr/>		
C. trachomatis - oropharyngeal swab	Not collected	<input type="checkbox"/>
	Not done	<input type="checkbox"/>
	Not detected/Negative	<input type="checkbox"/>
	Positive/Reactive	<input type="checkbox"/>

Form: STI Test Results

Invalid
Indeterminate

If any tests were "Positive/Reactive", action(s) taken:

Mark "None" or all that apply.

None	<input type="checkbox"/>
Medication(s)	<input type="checkbox"/>
Therapeutic procedure/surgery	<input type="checkbox"/>
Diagnostic procedure	<input type="checkbox"/>
Referral	<input type="checkbox"/>
Other	<input type="checkbox"/>

If "Other", specify (max. 200 characters): _____

Mark if a new STI/GTI Test Results eCRF is required to complete specimen collection requirements for this visit.

Comments (max. 200 characters): _____

Form: Study Co-Enrollment

Has this participant enrolled in another interventional research study since enrolling in HPTN 094? Yes

No

If "Yes", which study? (max. 200 characters) _____

Form: Study Termination

Date of study exit _____

Primary reason for completion/discontinuation

Scheduled exit visit/end of study

Death

Participant refused further participation

Lost to follow-up

Investigator decision

Early study closure

Protocol deviation

Serious adverse event

Withdrawal of consent by participant

Study terminated by sponsor

Other

If "Other", specify (max. 200 characters): _____

If "Death", enter date of death. _____

If "Serious Adverse event", select applicable adverse event. _____
