

**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**

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"/>
Urine Dipstick Test	<input type="checkbox"/>

**Form: Clinical Care Visit**

Clinical care visit code	_____
Date of visit	_____
What is/are the reason(s) for this clinical care visit? Mark all that apply.	
Participant contacted site to report serious adverse event(s).	<input type="checkbox"/>
Update Serious Adverse Event log.	
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"/>
Medication management	<input type="checkbox"/>
Illness	<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 CLINICAL CARE 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"/>
Urine Dipstick Test	<input type="checkbox"/>

**Form: Antiretroviral Treatment Regimen**

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

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

Medication

Emtricitabine (FTC; Emtriva)

Lamivudine (3TC; Epivir)

Stavudine (d4T; Zerit)

Stavudine Extended Release Capsules (d4T XR; Zerit XR)

Tenofovir Disoproxil Fumarate (TDF; Viread)

Zidovudine (AZT, ZDV, Retrovir)

Delavirdine mesylate (DLV; Rescriptor)

Efavirenz (EFV; Sustiva; Stocrin)

Etravirine (Intelence)

Nevirapine (NVP; Viramune)

Rilpivirine (RPV; Edurant)

Doravirine (Pifeltro)

Amprenavir (APV; Agenerase)

Atazanavir (ATV; Reyataz)

Darunavir (DRV; Prezista)

Fosamprenavir (FPV; Lexiva; Telzir)

Indinavir (IDV; Crixivan)

Nelfinavir (NFV; Viracept)

Ritonavir (RTV; Norvir)

Saquinavir Hard-Gel Capsules (SQV; Invirase)

Saquinavir Soft-Gel Capsules (SQV; Fortovase)

Tipranavir (Aptivus)

Prezcobix (darunavir/cobicistat)

Evotaz (atazanavir/cobicistat)

Raltegravir (Isentress)

Dolutegravir (DTG; Tivicay)

Elvitegravir

Enfuvirtide (ENF; Fuzeon)

Maraviroc (Selzentry)

Fostemsavir (Rukobia)

Abacavir/Lamivudine (ABC/3TC; Epzicom; Kivexa)

**Form: Antiretroviral Treatment Regimen**

- 
- 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

Capsules

Drops

Puffs

Sachets

Suppository

Tablets

Units

Unknown

Other

If "Other", specify: \_\_\_\_\_

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Frequency  As needed

Daily

Twice per day

Three times per day

Four times per day

At hour of wake

At hour of sleep

ONCE

Other

If "Other", specify: \_\_\_\_\_

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Route  Oral

Intramuscular

Intravenous

Other

If "Other", specify: \_\_\_\_\_

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How was ART 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: 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

**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
- 2+ packs/day

**Form: Behavioral Questionnaire Part A**

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Refuse to answer

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**SUBSTANCE USE**

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In the last year [six months at 26 and 52 weeks], have you tried or taken cannabis (marijuana)? Yes   
No

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

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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

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

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

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In the last year [six months at 26 and 52 weeks], have you tried or taken cocaine? Yes   
No

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

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

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In the last year [six months at 26 and 52 weeks], have you tried or taken heroin? Yes   
No

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

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

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In the last year [six months at 26 and 52 weeks], have you tried or taken fentanyl? Yes   
No

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

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

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**Form: Behavioral Questionnaire Part A**

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   
No

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   
Snorting   
Smoked   
Injection

In the last year [six months at 26 and 52 weeks], have you tried or taken K2, Spice, or other synthetic marijuana? Yes   
No

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   
Vaping   
Smoked

In the last year [six months at 26 and 52 weeks], have you tried or taken buprenorphine (not prescribed for you)? Yes   
No

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   
Injection

In the last year [six months at 26 and 52 weeks], have you tried or taken methadone (not prescribed for you)? Yes   
No

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   
Injection

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   
No

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   
Snorting   
Smoked

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   
No

Drug names, specify: \_\_\_\_\_

In the past month, how many days did you use these drugs? \_\_\_\_\_

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

**Form: Behavioral Questionnaire Part A**

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Snorting

Smoked

Injection

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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

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Drug names, specify: \_\_\_\_\_

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

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

Snorting

Smoked

Injection

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**OVERDOSE HISTORY**

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

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

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What did you overdose on? Meth/stimulants

Cocaine

Opioids

Benzodiazepines (benzos)

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How many times have you overdosed in the past month? \_\_\_\_\_

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What did you overdose on? Meth/stimulants

Cocaine

Opioids

Benzodiazepines (benzos)

---

**Form: Behavioral Questionnaire Part B**

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**READINESS TO QUIT**

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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

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**MENTAL HEALTH**

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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"/>
<b>Add the mental health scores together.</b>	
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 Rarely or none of the time (Less than 1 day)

**Form: Behavioral Questionnaire Part B**

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

**Form: Behavioral Questionnaire Part B**

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

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"/>

**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

Months

Years

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

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"/>
<hr/>	
Pharmacy or drug store	<input type="checkbox"/>
<hr/>	
Doctor's office, clinic, or hospital	<input type="checkbox"/>
<hr/>	
HIV/AIDS-focused organization	<input type="checkbox"/>
<hr/>	
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.	
<hr/>	
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"/>

Participant ID: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**Form: CASI Tracking**

\_\_\_\_\_  
CASI collection date \_\_\_\_\_

\_\_\_\_\_  
CASI ID \_\_\_\_\_

Were there any problems or issues related to the administration or completion of the questionnaire? Yes

No

\_\_\_\_\_  
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/mm<sup>3</sup>

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: 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

\_\_\_\_\_  
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

\_\_\_\_\_  
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 IgG antibody (HAV IgG) 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

Hepatitis B DNA Test Not collected

Not done

Not detected/Negative

Positive/Reactive

Invalid

Indeterminate

**Form: Hepatitis Test Results**

HBV DNA quantitative results Fixed Unit: log IU/mL

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

HCV RNA Not collected   
Not done   
Not detected/Negative   
Positive/Reactive   
Invalid   
Indeterminate

HCV RNA quantitative results Fixed Unit: log IU/mL

Was the participant referred for Hepatitis C treatment? Yes   
No

Comments (max. 200 characters): \_\_\_\_\_

**Form: HIV Test Results**

Was HIV testing performed? Yes   
No

Specimen Collection Date \_\_\_\_\_

HIV Rapid 1 Non-reactive   
Reactive/Positive   
Not done

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 Qualitative Non-reactive   
Reactive/Positive   
Not done

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: \_\_\_\_\_

Participant ID: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**Form: Medical History Y/N**

Does the participant have any medical history to report?

Yes

No

If "Yes", update the Medical History log.

**Form: Medical History**

\_\_\_\_\_  
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**

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 (Vivitrol)

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**

\_\_\_\_\_ 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) \_\_\_\_\_

---

Participant ID: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**Form: Navigation Session Y/N**

Did the participant have any navigation sessions during the study?

Yes

No

If "Yes", update the Navigation Session log.

**Form: Navigation Session**

\_\_\_\_\_  
Date of navigation session \_\_\_\_\_

\_\_\_\_\_  
Navigator \_\_\_\_\_

Location of Session In Person   
Virtual

Length of session 0-5 min   
6-15 min   
16-30 min   
30-60 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

Opioids 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"/>
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	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: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**Form: Participant Identifier**

Participant ID: \_\_\_\_\_

Participant ID: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**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"/>

---

If "Care visit" or "Interim visit", specify visit code. \_\_\_\_\_

---

Date participant's records were sent to receiving study site \_\_\_\_\_

---

**Form: Pre-exposure Prophylaxis**

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

---

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 <input type="checkbox"/>
	No <input type="checkbox"/>
If no, specify reason not done.	Not of reproductive potential <input type="checkbox"/>
	Participant is pregnant <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify:	_____
Specimen date	_____
Collection time	_____
Pregnancy test result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>

Participant ID: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**Form: Protocol Deviations Y/N**

Have any protocol deviations been reported?

Yes

No

If "Yes", update the Protocol Deviations log.

**Form: Protocol Deviations**

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: Randomization**

Is the participant ready to be randomized? Yes

No

Randomization date and time \_\_\_\_\_

Randomization date \_\_\_\_\_

Randomization ID \_\_\_\_\_

Regime name \_\_\_\_\_

Regime ratio \_\_\_\_\_

Stratum name \_\_\_\_\_

Blinded \_\_\_\_\_

TSDV hidden variable \_\_\_\_\_

**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

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

Participant ID: \_\_\_\_\_

HPTN 094

Visit Code: \_\_\_\_\_

**Form: Serious Adverse Event Y/N**

Has the participant experienced a serious adverse event during the study?

Yes

No

If "Yes", update the Serious Adverse Event log.

**Form: Serious Adverse Event**

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 <input type="radio"/> Visit 2.0 - Enrollment <input type="radio"/> Visit 3.0 - 26 weeks <input type="radio"/> Visit 4.0 - 52 weeks <input type="radio"/> Care Visit <input type="radio"/> Interim Visit <input type="radio"/>
If "Care visit" or "Interim visit", specify visit code. _____	
Is the SAE still ongoing?	Yes <input type="radio"/> No <input type="radio"/>
If "No", outcome date _____	
Severity grade	Grade 1 (Mild) <input type="radio"/> Grade 2 (Moderate) <input type="radio"/> Grade 3 (Severe) <input type="radio"/> Grade 4 (Potentially life-threatening) <input type="radio"/> Grade 5 (Death) <input type="radio"/>
Action(s) taken:	<input type="checkbox"/>
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"/>
Other	<input type="checkbox"/>
If "Other", specify (max. 200 characters): _____	
Status/Outcome	Recovered/Resolved <input type="radio"/> Recovering/Resolving <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Not recovered/Not resolved <input type="radio"/> Fatal <input type="radio"/> Severity/Frequency increased <input type="radio"/>
If "Severity/Frequency increased" is selected, report as a new serious adverse event.	
If status or outcome is "Severity/Frequency increased", select serious adverse event. _____	

**Form: 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 MOUD   
Related to PrEP   
Related to ART and MOUD   
Related to MOUD and PrEP   
Not Related

Was this SAE reported as a SUSAR? Yes  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: 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). \_\_\_\_\_

---

**ALL 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"/>
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"/>
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"/>
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"/>
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"/>
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"/>
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

---

Medication(s)

---

Therapeutic procedure/surgery

---

Diagnostic procedure

---

Referral

---

Other

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 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. \_\_\_\_\_

---