HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Additional Study Procedures
Generated On: 04 Nov 2022 01:43:33

Select any additional forms completed at this visit.	
ACASI Tracking	☐
Chemistry Testing	☐
Counseling	☐
Fasting Lipid Test Results	☐
Hematology	☐
Hepatitis B Vaccination	☐
Hepatitis Test Results	☐
HIV Test Results	☐
Hormone Tests	☐
Participant Receipt	☐
Participant Transfer	☐
Patient Health Questionnaire	☐
Physical Exam	☐
PK Dose Time	☐
PK Specimen Collection	☐
Specimen Collection	☐
STI Tests	☐
Supplemental HIV Results	☐
Urinalysis	☐
Vital Signs	☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Date of Visit
Generated On: 04 Nov 2022 01:43:33

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date	_____
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Did participant have any changes or updates to their PrEP at this visit? If "Yes", please complete the Pre-exposure Prophylaxis Log.	Yes ☐ No ☐
Did participant have any changes or updates to their GAHT at this visit? If "Yes", please complete the Gender Affirming Hormone Therapy Log.	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Have any protocol deviations been reported at this visit?	Yes ☐ No ☐
Did the participant have any additional procedures at this visit?	Yes ☐ No ☐

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Date of Visit - Seroconverter Schedule
Generated On: 04 Nov 2022 01:43:33

Did the participant complete this visit?	Yes ☐ No ☐
Visit Date	_____
Were any new adverse events (AEs) reported at this visit?	Yes ☐ No ☐
Is the participant taking any concomitant medications that have not been previously reported?	Yes ☐ No ☐
Have any protocol deviations been reported at this visit?	Yes ☐ No ☐
Did the participant have any additional procedures at this visit?	Yes ☐ No ☐

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Enrollment
Generated On: 04 Nov 2022 01:43:33

Treatment arm	_____
Will this participant participate in DHI Sub-Study?	Yes ☐ No ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Interim Visit
Generated On: 04 Nov 2022 01:43:33

Interim visit date _____

Interim visit code _____

Was study product use permanently discontinued (scheduled or early) at this visit?
If "Yes", please complete the appropriate study product log CRF. Yes ☐ No ☐

Did the participant exit/terminate the study at this visit?
If "Yes", please complete the Study Termination CRF. Yes ☐ No ☐

Did participant have any changes or updates to their PrEP at this visit? Yes ☐ No ☐

If "Yes", please complete the Pre-exposure Prophylaxis Log.

Did participant have any changes or updates to their GAHT at this visit? Yes ☐ No ☐

If "Yes", please complete the Gender Affirming Hormone Therapy Log.

Were any new adverse events (AEs) reported at this visit?
If "Yes", please complete the Adverse Event Log. Yes ☐ No ☐

Is the participant taking any concomitant medications that have not been previously reported?
If "Yes", please complete the Concomitant Medications Log. Yes ☐ No ☐

Have any protocol deviations been reported at this visit?
If "Yes", please complete the Protocol Deviations Log. Yes ☐ No ☐

Reason for interim visit (Mark all that apply)

AE report or follow-up ☐

Report social harm ☐
If checked, please complete the Social Impact Log.

Additional laboratory testing ☐

Other ☐

If other, specify: _____

Were vital signs (such as weight) taken at this visit? Yes ☐ No ☐

Mark all forms completed at this visit.

ACASI Tracking ☐

Chemistry Panel ☐

Counseling ☐

Fasting Lipid Test Results ☐

Hematology ☐

Hepatitis B Vaccination ☐

Hepatitis Test Results ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Interim Visit
Generated On: 04 Nov 2022 01:43:33

HIV Test Results	☐
Hormone Tests	☐
Participant Receipt	☐
Participant Transfer	☐
Patient Health Questionnaire	☐
Physical Exam	☐
PK Dose Time	☐
PK Specimen Collection	☐
Specimen Collection and Storage	☐
STI Test Results	☐
Supplemental HIV Results	☐
Urinalysis	☐
Vital Signs	☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Missed Visit
Generated On: 04 Nov 2022 01:43:33

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:	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Identifier
Generated On: 04 Nov 2022 01:43:33

Participant ID: _____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Receipt
Generated On: 04 Nov 2022 01:43:33

Name of receiving study site	Bridge HIV CRS (764) ☐ Harlem Prevention Center CRS (745) ☐ Penn Prevention CRS (863) ☐ Houston AIDS Research Team (HART) CRS (853) ☐ Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721) ☐
Name of transferring study site	Bridge HIV CRS (764) ☐ Harlem Prevention Center CRS (745) ☐ Penn Prevention CRS (863) ☐ Houston AIDS Research Team (HART) CRS (853) ☐ Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721) ☐
Date informed consent signed at receiving site	_____
Date participant received at receiving site	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Participant Transfer
Generated On: 04 Nov 2022 01:43:33

Name of transferring study site	Bridge HIV CRS (764) ☐ Harlem Prevention Center CRS (745) ☐ Penn Prevention CRS (863) ☐ Houston AIDS Research Team (HART) CRS (853) ☐ Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721) ☐
Name of receiving study site	Bridge HIV CRS (764) ☐ Harlem Prevention Center CRS (745) ☐ Penn Prevention CRS (863) ☐ Houston AIDS Research Team (HART) CRS (853) ☐ Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS (721) ☐
Visit of last completed contact with participant	V1 - Screening ☐ V2 - Enrollment ☐ V3 - Week 13 ☐ V4 - Week 26 ☐ V5 - Week 39 ☐ V6 - Week 52 ☐ V7 - Week 65 ☐ V8 - Week 78 ☐ Interim Visit ☐ V201 - GAHT Initiation Visit ☐ V202 - DHI Day 8 Post Visit ☐ V301 - Seroconversion Termination Visit ☐ V401 - GAHT Safety Visit ☐
If "Interim visit", specify Interim visit code	_____
Date participant's records were sent to receiving study site	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Screening Date of Visit
Generated On: 04 Nov 2022 01:43:33

Screening visit date	

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Study Termination
Generated On: 04 Nov 2022 01:43:33

Date of study exit	_____
Primary reason for completion/discontinuation	☐ Scheduled exit visit/end of study ☐ Death ☐ Participant refused further participation ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up (remove for HVTN) ☐ Investigator decision ☐ Participant refused further study product use ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ One or more reactive HIV test results or acute HIV infection suspected ☐ Participant unable to adhere to visit schedule ☐ Other, specify
If "Other", specify (max. 200 characters):	_____
If "Death", enter date of death.	_____
If "Adverse event", select applicable adverse event.	_____
Does participant have a desire for future co-located Gender Affirming Hormone Therapy?	☐ Yes ☐ No ☐ Unable to contact participant

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: ACASI Tracking
Generated On: 04 Nov 2022 01:43:33

ACASI collection date	_____
ACASI ID	_____
Which questionnaire was completed?	Enrollment ☐ Week 13 ☐ Week 26 ☐ Week 39 ☐ Week 52 ☐ Week 65 ☐ Week 78/Termination ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If yes, please describe	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Counseling
Generated On: 04 Nov 2022 01:43:33

Date of completion	_____
Were any of the following topics discussed at this visit?	Yes ☐ No ☐
Mark all that apply.	
PrEP Adherence goal setting	☐
PrEP Adherence reminder strategies	☐
Barriers to PrEP adherence	☐
Planning for future PrEP use	☐
GAHT Adherence goal setting	☐
GAHT Adherence reminder strategies	☐
Barriers to GAHT adherence	☐
Planning for future GAHT	☐
Communication skills	☐
Product Storage	☐
Disclosing product use to others	☐
HIV prevention counseling	☐
Problem solving	☐
Other	☐
If other, please specify:	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Patient Health Questionnaire
Generated On: 04 Nov 2022 01:43:33

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

Little interest or pleasure in doing things	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Feeling down, depressed, or hopeless	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Trouble falling or staying asleep, or sleeping too much	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Feeling tired or having little energy	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Poor appetite or overeating	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Feeling bad about yourself - or that you are a failure or have let yourself or your family down	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Trouble concentrating on things, such as reading the newspaper or watching television	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Moving or speaking so slowly that other people could have noticed. Or the opposite - being so figety or restless that you have been moving around a lot more than usual	Not at all ☐ Several days ☐ More than half the days ☐ Nearly every day ☐
Thoughts that you would be better off dead, or of hurting yourself	Not at all ☐ Several days ☐ More than half the days ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Patient Health Questionnaire
Generated On: 04 Nov 2022 01:43:33

	Nearly every day ☐
PHQ Calculated Total	_____
If you mentioned any 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 ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐
In the past year, have you felt depressed or sad most days, even if you felt OK sometimes?	Yes ☐ No ☐
Has there been a time in the past month when you have had serious thoughts about ending your life?	Yes ☐ No ☐
Have you ever, in your whole life, tried to kill yourself or made a suicide attempt?	Yes ☐ No ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking
Generated On: 04 Nov 2022 01:43:33

Date of encounter _____

Visit Log completed at
- ☐ V1 - Screening
- ☐ V2 - Enrollment
- ☐ V3 - Week 13
- ☐ V4 - Week 26
- ☐ V5 - Week 39
- ☐ V6 - Week 52
- ☐ V7 - Week 65
- ☐ V8 - Week 78
- ☐ Interim Visit
- ☐ V201 - GAHT Initiation Visit
- ☐ V202 - DHI Day 8 Post Visit
- ☐ V301 - Seroconversion Termination Visit
- ☐ V401 - GAHT Safety Visit

If "Interim visit", specify Interim visit code _____

Was this encounter a PHN Session?
- ☐ Yes
- ☐ No

Type of Encounter
- ☐ In-person
- ☐ Email
- ☐ Text
- ☐ Phone
- ☐ Video Encounter

Duration of Encounter
- ☐ 10 minutes or less
- ☐ 11-30 minutes
- ☐ 31-60 minutes
- ☐ More than an hour

Number of Encounters (number of contacts on a given day) _____

Encounter initiated by
- ☐ Participant
- ☐ Peer Health Navigator

Content of Encounter
Mark all that apply

PrEP Adherence

PrEP Concerns ☐

GAHT Adherence ☐

GAHT Concerns ☐

Coordinating Care ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking
Generated On: 04 Nov 2022 01:43:33

Study Appointments	☐
Barriers to access	☐
Linkage to follow-up services	☐
Referral to gender-affirming social services	☐
Referral to gender-affirming health services	☐
Transgender community	☐
Housing	☐
Other	☐
If "Other", specify:	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Peer Health Navigation Tracking Y/N
Generated On: 04 Nov 2022 01:43:33

Is the participant engaging with Peer Health Navigation?	Yes ☐ No ☐

If "Yes", update the Peer Health Navigation Tracking log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Social Impact
Generated On: 04 Nov 2022 01:43:33

Date reported to site	
Concisely describe social impact (max. 200 characters).	
Onset date	
Reported at visit code	V1 - Screening ☐ V2 - Enrollment ☐ V3 - Week 13 ☐ V4 - Week 26 ☐ V5 - Week 39 ☐ V6 - Week 52 ☐ V7 - Week 65 ☐ V8 - Week 78 ☐ Interim Visit ☐ V201 - GAHT Initiation Visit ☐ V202 - DHI Day 8 Post Visit ☐ V301 - Seroconversion Termination Visit ☐ V401 - GAHT Safety Visit ☐
If "Interim visit", specify interim visit code.	
Social impact	Personal Relationships ☐ Travel/Immigration ☐ Employment ☐ Education ☐ Medical/Dental ☐ Health Insurance/Medical Aid/Hospital Plan ☐ Life Insurance/Funeral Coverage ☐ Housing ☐ Military/Other Government Agency ☐ Involuntary Disclosure of gender identity ☐ Other - Had other problems not covered in the list above. ☐
If "Other", specify (max. 200 characters):	

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Social Impact Y/N
Generated On: 04 Nov 2022 01:43:33

Has the participant experienced any social impacts related to study participation?	Yes ☐ No ☐

If "Yes", update the Social Impact log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Physical Exam
Generated On: 04 Nov 2022 01:43:33

Was a physical exam performed?	Yes ☐ No ☐
Date of exam	_____
BODY SYSTEM	
HEENT	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Neck	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Lymph Nodes	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Heart/Cardiovascular	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Lung/Respiratory	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Abdomen	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Genitourinary	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Extremities	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Neurological	Not done ☐ Normal ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Physical Exam
Generated On: 04 Nov 2022 01:43:33

	Abnormal ☐
If "Abnormal", specify:	_____
Skin	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
General appearance	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Other system finding	Not done ☐
	Normal ☐
	Abnormal ☐
If "Other system", specify system:	_____
If "Abnormal", specify:	_____
Comments (max. 200 characters):	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Vital Signs
Generated On: 04 Nov 2022 01:43:33

Were vital signs done?	Yes ☐ No ☐
Date of assessment	_____
Height	Fixed Unit: cm _____
Weight	Fixed Unit: kg _____
Body temperature	Fixed Unit: C _____
Systolic blood pressure	Fixed Unit: mmHg _____
Diastolic blood pressure	Fixed Unit: mmHg _____
Blood pressure severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Calculated Blood Pressure Severity Grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Blood Pressure adverse event, if applicable	_____
Not reportable as an adverse event	☐
Pulse	Fixed Unit: beats/min _____
Rate of respiration	Fixed Unit: breaths/min _____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: CD4 Test Results/Viral Load
Generated On: 04 Nov 2022 01:43:33
Lab Name: _____

CD4+

Was CD4+ specimen collected for testing? Yes ◯ No ◯

Specimen collection date _____

Unable to analyze ☐

Absolute CD4+ Fixed Unit: cells/mm3

_____

CD4 % _____

HIV RNA

Was HIV RNA PCR testing completed? Yes ◯ No ◯

Specimen collection date _____

Operator > ◯ < ◯ = ◯

HIV RNA PCR Fixed Unit: viral copies/mL

_____

HIV RNA PCR target not detected ☐

Detected, less than LLQ or LLD ☐

Detected, greater than the upper limit of quantification ☐

Additional CD4 Test Results or Viral Load data collected ☐

Check this box if another CD4 form is needed to capture additional testing data

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Chemistry Panel
Generated On: 04 Nov 2022 01:43:33
Lab Name: _____

Was a sample collected for serum chemistries?	Yes ☐ No ☐
Specimen collection date	_____
LIVER FUNCTION TESTS	
Alkaline Phosphatase result	_____
Alkaline Phosphatase severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Alkaline Phosphatase severity grade - calculated	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Alkaline Phosphatase adverse event	_____
Not reportable as an adverse event	☐
AST (SGOT) result	_____
AST (SGOT) severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
AST (SGOT) severity grade - calculated	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
AST (SGOT) adverse event	_____
Not reportable as an adverse event	☐
ALT (SGPT) result	_____
ALT (SGPT) severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Chemistry Panel
Generated On: 04 Nov 2022 01:43:33
Lab Name: _____

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

ALT (SGPT) adverse event _____

Not reportable as an adverse event ☐

Total Bilirubin result _____

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

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

Total Bilirubin adverse event _____

Not reportable as an adverse event ☐

RENAL FUNCTION TESTS

Creatinine result _____

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

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

Creatinine adverse event _____

Not reportable as an adverse event ☐

Creatinine Clearance result _____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Chemistry Panel
Generated On: 04 Nov 2022 01:43:33
Lab Name: _____

Creatinine Clearance severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Creatinine Clearance severity grade - calculated	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Creatinine Clearance adverse event	_____
Not reportable as an adverse event	☐
Urea result	_____
BUN result	_____
OTHER CHEMISTRIES	
Albumin result	_____
Albumin severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Albumin severity grade - calculated	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Albumin adverse event	_____
Not reportable as an adverse event	☐
Potassium result	_____
Potassium severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Potassium severity grade - calculated	Not gradable ☐ Grade 1 (Mild) ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Chemistry Panel
Generated On: 04 Nov 2022 01:43:33
Lab Name:

	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
Potassium adverse event	
Not reportable as an adverse event	☐
Comments (max. 200 characters):	

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Fasting Lipid Test Results
Generated On: 04 Nov 2022 01:43:33
Lab Name: _____

SERUM LIPID

Was a fasting sample collected for the lipid profile?
- Yes ☐
- No ☐

Did the participant fast for at least 8 hours prior to blood collection?
- Yes ☐
- No ☐

Date of collection: _____

Total Cholesterol result _____

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

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

Total Cholesterol adverse event _____

Not reportable as an adverse event ☐

HDL Cholesterol result _____

Triglycerides result _____

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

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

Triglycerides adverse event _____

Not reportable as an adverse event ☐

LDL Cholesterol result _____

LDL Cholesterol severity grade
- Not gradable ☐
- Grade 1 (Mild) ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Fasting Lipid Test Results
Generated On: 04 Nov 2022 01:43:33
Lab Name:

	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
LDL Cholesterol severity grade - calculated	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
LDL Cholesterol adverse event	
Not reportable as an adverse event	☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Hematology
Generated On: 04 Nov 2022 01:43:33
Lab Name: _____

HEMOGRAM

Was a hematology sample collected?
- Yes
- No

Hematology collection date: _____

Has this participant had 6+ consecutive months of GAHT? ☐

Hemoglobin: _____

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

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

Hemoglobin adverse event, if applicable: _____

Not reportable as an adverse event ☐

Hematocrit: _____

MCV: _____

Platelets: _____

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

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

Platelets adverse event, if applicable: _____

Not reportable as an adverse event ☐

WBC: _____

WBC severity grade
- Not gradable
- Grade 1 (Mild)

Staff initials/Date

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Form: Hematology
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Lab Name: _____

	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
WBC severity grade - calculated	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
WBC adverse event, if applicable	_____
Not reportable as an adverse event	☐
DIFFERENTIAL	
Was a differential done?	Yes ☐
	No ☐
Differential collection date	_____
Neutrophils	_____
Neutrophils severity grade	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
Neutrophils severity grade - calculated	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
Neutrophils adverse event, if applicable	_____
Not reportable as an adverse event	☐
Lymphocytes	_____
Lymphocytes severity grade	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
Lymphocytes severity grade - calculated	Not gradable ☐
	Grade 1 (Mild) ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Hematology
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Lab Name:

	Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Lymphocytes adverse event, if applicable	
Not reportable as an adverse event	☐
Monocytes	
Eosinophils	
Basophils	
Atypical lymphocytes	
Comments (max. 200 characters):	

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Hepatitis B Vaccination Tracking
Generated On: 04 Nov 2022 01:43:33

Is participant vaccinated for Hepatitis B?	Yes ☐
	No ☐
Date of vaccination	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Hepatitis Test Results
Generated On: 04 Nov 2022 01:43:33

Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Surface Antigen (HBsAG)	Positive ☐ Negative ☐ Indeterminate ☐
Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Surface Antibody (HBsAb)	Positive ☐ Negative ☐ Indeterminate ☐
Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis B Core Antibody (HBcAb)	Positive ☐ Negative ☐ Indeterminate ☐
Was a sample collected for Hepatitis C Antibody (HCAb) testing?	Yes ☐ No ☐
Date of collection	_____
Hepatitis C Antibody (HCAb)	Positive ☐ Negative ☐ Indeterminate ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: HIV Test Results
Generated On: 04 Nov 2022 01:43:33

Specimen Collection Date	_____
Was this sample collected for additional testing?	Yes ☐
	No ☐
HIV Rapid test result	Reactive/Positive ☐
	Non-Reactive/Negative ☐
	Invalid ☐
	Not Done ☐
HIV Laboratory based immunoassay test result	Reactive/Positive ☐
	Non-Reactive/Negative ☐
	Invalid ☐
	Not Done ☐
HIV RNA-1 Qualitative test result	Reactive/Positive ☐
	Non-Reactive/Negative ☐
	Invalid ☐
	Not Done ☐
Was a viral load done?	Yes ☐
	No ☐
Final HIV status	Reactive/Positive ☐
	Non-Reactive/Negative ☐
	Additional testing required ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Hormone Tests
Generated On: 04 Nov 2022 01:43:33

Was a serum total testosterone sample collected?	Yes ☐ No ☐
Date of collection:	_____
Total testosterone	Fixed Unit: ng/dL _____
Symbol	< ☐ = ☐
Was a serum estradiol sample collected?	Yes ☐ No ☐
Date of collection:	_____
Estradiol	Fixed Unit: pg/mL _____
Symbol	< ☐ = ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Dose Time
Generated On: 04 Nov 2022 01:43:33

DOT day
- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] PK Collection Day

Was dose observed?
- [ ] Yes
- [ ] No

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

Observed Dose date _____

Observed Dose time _____

DOT day
- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] PK Collection Day

Was dose observed?
- [ ] Yes
- [ ] No

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

Observed Dose date _____

Observed Dose time _____

DOT day
- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] PK Collection Day

Was dose observed?
- [ ] Yes
- [ ] No

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Dose Time
Generated On: 04 Nov 2022 01:43:33

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

Observed Dose date _____

Observed Dose time _____

DOT day
- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ■
- Day 5 ☐
- Day 6 ☐
- Day 7 ☐
- PK Collection Day ☐

Was dose observed?
- Yes ☐
- No ☐

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

Observed Dose date _____

Observed Dose time _____

DOT day
- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ■
- Day 6 ☐
- Day 7 ☐
- PK Collection Day ☐

Was dose observed?
- Yes ☐
- No ☐

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

Observed Dose date _____

Observed Dose time _____

DOT day
- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ■
- Day 7 ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Dose Time
Generated On: 04 Nov 2022 01:43:33

	PK Collection Day ☐
Was dose observed?	Yes ☐
	No ☐
If "No", record reason why dose was not observed (max. 200 characters).	_____
Observed Dose date	_____
Observed Dose time	_____
DOT day	Day 1 ☐
	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ■
	PK Collection Day ☐
Was dose observed?	Yes ☐
	No ☐
If "No", record reason why dose was not observed (max. 200 characters).	_____
Observed Dose date	_____
Observed Dose time	_____
DOT day	Day 1 ☐
	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ☐
	PK Collection Day ■
Was dose observed?	Yes ☐
	No ☐
If "No", record reason why dose was not observed (max. 200 characters).	_____
Observed Dose date	_____
Observed Dose time	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Specimen Collection
Generated On: 04 Nov 2022 01:43:33

PK Specimen type	Pre-dose Plasma storage ●
	Pre-dose DBS storage ○
	1 hour post-dose plasma ○
	1 hour post-dose PBMC ○
	4 hour post-dose plasma ○
	4 hour post-dose PBMC ○
	Pre-dose PBMC storage ○
	Serum storage ○
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 "No", record reason why sample was not stored (max. 200 characters).	_____

PK Specimen type	Pre-dose Plasma storage ○
	Pre-dose DBS storage ●
	1 hour post-dose plasma ○
	1 hour post-dose PBMC ○
	4 hour post-dose plasma ○
	4 hour post-dose PBMC ○
	Pre-dose PBMC storage ○
	Serum storage ○
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 "No", record reason why sample was not stored (max. 200 characters).	_____

PK Specimen type	Pre-dose Plasma storage ○
	Pre-dose DBS storage ○
	1 hour post-dose plasma ○

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Specimen Collection
Generated On: 04 Nov 2022 01:43:33

	1 hour post-dose PBMC ☐
	4 hour post-dose plasma ☐
	4 hour post-dose PBMC ☐
	Pre-dose PBMC storage ■
	Serum storage ☐
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 "No", record reason why sample was not stored (max. 200 characters).	
PK Specimen type	Pre-dose Plasma storage ☐
	Pre-dose DBS storage ☐
	1 hour post-dose plasma ☐
	1 hour post-dose PBMC ☐
	4 hour post-dose plasma ☐
	4 hour post-dose PBMC ☐
	Pre-dose PBMC storage ☐
	Serum storage ■
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 "No", record reason why sample was not stored (max. 200 characters).	
PK Specimen type	Pre-dose Plasma storage ☐
	Pre-dose DBS storage ☐
	1 hour post-dose plasma ■
	1 hour post-dose PBMC ☐
	4 hour post-dose plasma ☐
	4 hour post-dose PBMC ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Specimen Collection
Generated On: 04 Nov 2022 01:43:33

	Pre-dose PBMC storage ☐
	Serum storage ☐
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 "No", record reason why sample was not stored (max. 200 characters).	_____
PK Specimen type	Pre-dose Plasma storage ☐
	Pre-dose DBS storage ☐
	1 hour post-dose plasma ☐
	1 hour post-dose PBMC ■
	4 hour post-dose plasma ☐
	4 hour post-dose PBMC ☐
	Pre-dose PBMC storage ☐
	Serum storage ☐
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 "No", record reason why sample was not stored (max. 200 characters).	_____
PK Specimen type	Pre-dose Plasma storage ☐
	Pre-dose DBS storage ☐
	1 hour post-dose plasma ☐
	1 hour post-dose PBMC ☐
	4 hour post-dose plasma ■
	4 hour post-dose PBMC ☐
	Pre-dose PBMC storage ☐
	Serum storage ☐
Was specimen collected?	Yes ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: PK Specimen Collection
Generated On: 04 Nov 2022 01:43:33

	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 "No", record reason why sample was not stored (max. 200 characters).	_____
PK Specimen type	Pre-dose Plasma storage ☐
	Pre-dose DBS storage ☐
	1 hour post-dose plasma ☐
	1 hour post-dose PBMC ☐
	4 hour post-dose plasma ☐
	4 hour post-dose PBMC ■
	Pre-dose PBMC storage ☐
	Serum storage ☐
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 "No", record reason why sample was not stored (max. 200 characters).	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Specimen Collection
Generated On: 04 Nov 2022 01:43:33

Specimen type	Plasma ■
	Serum storage ☐
	DBS storage ☐
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 ☐
	Serum storage ■
	DBS storage ☐
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 ☐
	Serum storage ☐
	DBS storage ■
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).	

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: STI Tests
Generated On: 04 Nov 2022 01:43:33

Was a pharyngeal sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - Pharyngeal test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
C. trachomatis - Pharyngeal test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
Was a urine sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - URINE test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
C. trachomatis - URINE test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
Was a rectal swab sample collected for N. gonorrhea and C. trachomatis testing?	Yes ☐ No ☐
Collection date	_____
N. gonorrhea - RECTAL SWAB test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
C. trachomatis - RECTAL SWAB test result	Detected ☐ Non-detected ☐ Equivocal ☐ Invalid ☐
Was a sample collected for Syphilis testing?	Yes ☐ No ☐
Collection date	_____
Algorithm used	Traditional ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: STI Tests
Generated On: 04 Nov 2022 01:43:33

	Reverse ☐
Treponemal	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐
Non-Treponemal	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐
Syphilis titer if indicated	_____
Or	☐

N/A

Second Treponemal test	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐
Second Non-Treponemal test	Non-reactive ☐
	Reactive ☐
	Not reported ☐
	Not done ☐
Syphilis titer	_____
Third Treponemal test	Postive ☐
	Negative ☐
	Indeterminate ☐
	Not done ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Supplemental HIV Results
Generated On: 04 Nov 2022 01:43:33

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done ☐

OR

Specimen Collection Date _____

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
- ☐ Other

Other assay result: _____

Comments (max. 200 characters) _____

Laboratory Reported HIV Interpretation

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported ☐

OR

Interpretation

- ☐ HIV Negative
- ☐ HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.
- ☐ HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.
- ☐ HIV-1 Positive
- ☐ HIV-2 Positive
- ☐ HIV-2 Positive - This result is distinct from HIV Positive, Untypable.
- ☐ HIV Positive
- ☐ Acute HIV-1 Positive
- ☐ HIV-1 Negative, HIV-2 inconclusive
- ☐ Inconclusive
- ☐ Other

Other interpretation: _____

Comments (max. 200 characters) _____

HIV DNA

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Supplemental HIV Results
Generated On: 04 Nov 2022 01:43:33

Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:	
Not performed/Not reported by Lab (add comment)	☐
OR	
Specimen Collection Date	_____
DNA Result	Detectable DNA result (record below) ☐ Detectable DNA , but below limit of detection (<4.09 copies per million cells) ☐ Detectable DNA, above the reportable range of the assay (>100 copies per million cells) ☐ Undetectable DNA, below limit of detection (<4.09 copies per million cells) ☐
Detectable DNA result:	Fixed Unit: copies per million cells _____
Comments (max. 200 characters)	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Urinalysis
Generated On: 04 Nov 2022 01:43:33

Was a sample collected for urine tests?	Yes ☐ No ☐
Date of collection:	_____
Protein (Urine)	Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+ ☐ 30 mg/dL ☐ 100 mg/dL ☐ 300 mg/dL ☐ 2000 mg/dL or more ☐
Protein (Urine) Severity Grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Protein (Urine) severity grade - calculated	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Protein (Urine) Adverse Event	_____
Not reportable as an adverse event	☐
Glucose (Urine)	Negative ☐ Trace ☐ +1 ☐ +2 ☐ +3 ☐ +4 ☐ 250 mg/dL ☐ 500 mg/dL ☐ 1000 mg/dL ☐ 2000 mg/dL or more ☐ 1/10 g/dL (%) ☐ 1/4 g/dL (%) ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Urinalysis
Generated On: 04 Nov 2022 01:43:33

	1/2 g/dL (%) ☐
	1 g/dL (%) ☐
	2 g/dL (%) or more ☐
Glucose (Urine) Severity Grade	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
Glucose (Urine) severity grade - calculated	Not gradable ☐
	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
Glucose (Urine) Adverse Event	_____
Not reportable as an adverse event	☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:43:33

Therapy name	Estradiol Tablets ☐
	Estradiol Transdermal ☐
	Estradiol Injectable ☐
	Spironolactone ☐
	Cyproterone Acetate ☐
	Finasteride ☐
	Other ☐
If "Other", specify:	_____
Dose	_____
Dose units	Grams ☐
	Micrograms ☐
	Milligrams ☐
	Milliliters ☐
	Capsules ☐
	Drops ☐
	Puffs ☐
	Sachets ☐
	Suppository ☐
	Tablets ☐
	Units ☐
	Unknown ☐
	Other ☐
If "Other", specify:	_____
Frequency	PRN ☐
	QD ☐
	BID ☐
	TID ☐
	QID ☐
	QM ☐
	QH ☐
	ONCE ☐
	Other ☐
If "Other", specify:	_____
Route	Oral ☐
	Intramuscular ☐
	Intravenous ☐
	Topical ☐
	Inhalation ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:43:33

Vaginal ☐
Rectal ☐
Subcutaneous ☐
Other ☐

If "Other", specify: _____

How was GAHT obtained?

Study Clinic ☐
Private doctor ☐
Nonprescription ☐
Other ☐

If "Other", specify: _____

Date started _____

Ongoing ☐

What kind of product stoppage is being reported?

Product Hold ☐
Permanent Discontinuation ☐
Participant Reported ☐

Please complete the relevant section below

Participant Reported

Date of product stoppage as reported by participant : _____

Why was product stopped?

Lost product ☐
Product damaged ☐
Ran out of product ☐
Participant requested temporary "drug holiday" ☐
Other ☐

If "Other" is selected, please specify: _____

Date participant resumed study product: _____

Product Hold

Date when this study product hold was initiated: _____

Why is the study product being held?

Reported of use of prohibited concomitant medications ☐
One or more reactive HIV test results or expresses concern about having acute HIV infection ☐
Receiving PEP for potential HIV exposure ☐
Adverse Event ☐
Hepatitis B infection ☐
Participant unable/unwilling to comply with the required study procedures ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:43:33

	Might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee ☐ Other ☐
If "Other" is selected, please specify:	_____
If product hold was associated with an adverse event, select the applicable AE1:	_____
If product hold was associated with an adverse event, select the applicable AE2:	_____
If product hold was associated with a new or updated concomitant medication, select applicable medication(s):	_____
Date participant resumed study product:	_____
Is this a permanent discontinuation?	
Date stopped	_____
Primary reason for ending study product use	Scheduled study product use period completed ☐ Death ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Participant refused further study product use ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ One or more reactive HIV test results or acute HIV infection suspected ☐ Participant unable to adhere to visit schedule ☐ Participant switched to clinic-provided study product ☐ Change made to study product prescription ☐ Other, specify ☐
If "Other", specify:	_____
If "Investigator decision", specify:	_____
If "Adverse event", select applicable adverse event #1	_____
If "Adverse event", select applicable adverse event #2	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Log
Generated On: 04 Nov 2022 01:43:33

Is this a permanent discontinuation from study product?	Yes ☐
	No ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Gender Affirming Hormone Therapy Y/N
Generated On: 04 Nov 2022 01:43:33

Is the participant using GAHT?	Yes ☐
	No ☐

If "Yes", update the Gender Affirming Hormone Therapy log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:43:33

Medication name
- Descovy ☐
- Truvada ☐
- Cabotegravir ☐
- Other ☐

If "Other", specify: _____

How was PrEP obtained?
- Study Clinic ☐
- Private doctor ☐
- Nonprescription ☐
- Other ☐

If "Other", specify: _____

Date started _____

Ongoing ☐

What kind of product stoppage is being reported?
- Product Hold ☐
- Permanent Discontinuation ☐
- Participant Reported ☐

Please complete the relevant section below

Participant Reported

Date of product stoppage as reported by participant : _____

Why was product stopped?
- Lost product ☐
- Product damaged ☐
- Ran out of product ☐
- Participant requested temporary "drug holiday" ☐
- Other ☐

If "Other" is selected, please specify: _____

Date participant resumed study product: _____

Product Hold

Date when this study product hold was initiated: _____

Why is the study product being held?
- Reported of use of prohibited concomitant medications ☐
- One or more reactive HIV test results or expresses concern about having acute HIV infection ☐
- Receiving PEP for potential HIV exposure ☐
- Adverse Event ☐
- Hepatitis B infection ☐
- Participant unable/unwilling to comply with the required study procedures ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:43:33

	Might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee ☐ Other ☐
If "Other" is selected, please specify:	_____
If product hold was associated with an adverse event, select the applicable AE1:	_____
If product hold was associated with an adverse event, select the applicable AE2:	_____
If product hold was associated with a new or updated concomitant medication, select applicable medication(s):	_____
Date participant resumed study product:	_____
Is this a permanent discontinuation?	
Date stopped	_____
Primary reason for ending study product use	Scheduled study product use period completed ☐ Death ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Participant refused further study product use ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ One or more reactive HIV test results or acute HIV infection suspected ☐ Participant unable to adhere to visit schedule ☐ Participant switched to clinic-provided study product ☐ Change made to study product prescription ☐ Other, specify ☐
If "Other", specify:	_____
If "Investigator decision", specify:	_____
If "Adverse event", select applicable adverse event #1	_____
If "Adverse event", select applicable adverse event #2	_____

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Log
Generated On: 04 Nov 2022 01:43:33

Is this a permanent discontinuation from study product?	Yes ☐
	No ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Pre-exposure Prophylaxis Y/N
Generated On: 04 Nov 2022 01:43:33

Is the participant taking PrEP?	Yes ☐
	No ☐

If "Yes", update the Pre-exposure Prophylaxis log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Adverse Event
Generated On: 04 Nov 2022 01:43:33

Date AE reported to site	_____
Adverse event (AE)	_____
Onset date	_____
At which visit was this adverse event first reported?	V1 - Screening ☐ V2 - Enrollment ☐ V3 - Week 13 ☐ V4 - Week 26 ☐ V5 - Week 39 ☐ V6 - Week 52 ☐ V7 - Week 65 ☐ V8 - Week 78 ☐ Interim Visit ☐ V201 - GAHT Initiation Visit ☐ V202 - DHI Day 8 Post Visit ☐ V301 - Seroconversion Termination Visit ☐ V401 - GAHT Safety Visit ☐
If "Interim visit", specify interim visit code.	_____
Is the AE still ongoing?	Yes ☐ No ☐
If "No", outcome date	_____
Severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐ Grade 5 (Death) ☐
Relationship to study product Record pertinent details for relationship assessment in comments	Related to PrEP ☐ Related to GAHT ☐ Related to both PrEP and GAHT ☐ Not related ☐
Action taken with study product	Dose not changed ☐ Dose reduced ☐ Dose increased ☐ Drug withdrawn ☐ Drug interrupted ☐ Not applicable ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Adverse Event
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Other actions ☐

Mark "None" or all that apply.

None

Medication(s) ☐

Therapeutic procedure/surgery ☐

Diagnostic procedure ☐

Other ☐

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

Status/Outcome

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

- ◯ Recovered/Resolved
- ◯ Recovering/Resolving
- ◯ Recovered/Resolved with Sequelae
- ◯ Not recovered/Not resolved
- ◯ Fatal
- ◯ Severity/frequency increased

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

Is this a serious adverse event according to ICH/GCP or protocol guidelines?

If "No", go to "Has or will this AE be reported as an EAE?".
If "Yes", check all that apply.

- ◯ Yes
- ◯ No

Results in death ☐

Is life-threatening ☐

Requires inpatient hospitalization or prolongation of existing hospitalization ☐

Results in persistent or significant disability/incapacity ☐

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

Has or will this AE be reported as an EAE?

If "Yes", provide EAE number below.If "No", go to "Was this AE a worsening of a baseline medical condition?".

- ◯ Yes
- ◯ No

SAE/EAE number

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

SAE/EAE onset date _____

Comments (max. 450 characters): _____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Adverse Event Y/N
Generated On: 04 Nov 2022 01:43:33

Has the participant experienced an adverse event during the study? Yes ☐ No ☐

If "Yes", update the Adverse Event log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Concomitant Medications
Generated On: 04 Nov 2022 01:43:33

Medication name _____

Indication _____

Check if this medication a statin ☐

Check if this medication an anti-hypertensive ☐

Date started _____

Date stopped

Or _____

Ongoing ☐

Dose _____

Dose units

- Grams ☐
- Micrograms ☐
- Milligrams ☐
- Milliliters ☐
- Capsules ☐
- Drops ☐
- Puffs ☐
- Sachets ☐
- Suppository ☐
- Tablets ☐
- Units ☐
- Unknown ☐
- Other ☐

If "Other", specify: _____

Frequency

- PRN ☐
- QD ☐
- BID ☐
- TID ☐
- QID ☐
- QM ☐
- QH ☐
- ONCE ☐
- Other ☐

If "Other", specify: _____

Route

- Oral ☐
- Intramuscular ☐
- Intravenous ☐
- Topical ☐
- Inhalation ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Concomitant Medications
Generated On: 04 Nov 2022 01:43:33

	Vaginal ☐
	Rectal ☐
	Subcutaneous ☐
	Other ☐
If "Other", specify:	_____
Taken for a reported AE?	Yes ☐
	No ☐
If "Yes", select adverse event.	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Concomitant Medications Y/N
Generated On: 04 Nov 2022 01:43:33

Were any concomitant medications taken?	Yes ☐ No ☐

If "Yes", update the Concomitant Medications log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Demographics
Generated On: 04 Nov 2022 01:43:33

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	_____
If "Other", specify:	_____

Gender

Mark all that apply.

Female	☐
Transgender Female/Transgender Woman	☐
Gender nonbinary/Genderfluid/Gender Nonconforming	☐
Another gender identity	☐
If "Another gender identity", specify:	_____
Prefer not 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:	_____
What is the participant's current employment status?	full-time employment ☐
	part-time employment ☐
	not employed ☐
What is the participant's highest level of education?	No schooling ☐
	Primary school, not complete ☐
	Primary school, complete ☐
	Secondary school, not complete ☐
	Secondary school, complete ☐
	Technical training, not complete ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Demographics
Generated On: 04 Nov 2022 01:43:33

	Technical training, complete ☐ College/university or higher, not complete ☐ College/university or higher, complete ☐
In the last 6 months, did you have enough money to pay for rent, food, or utilities (gas, electric, phone, etc)?	Never ☐ Once in awhile ☐ Fairly often ☐ Very often ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Inclusion Exclusion Criteria
Generated On: 04 Nov 2022 01:43:33

Has the participant screened before?	Yes ☐ No ☐
If Yes, enter the first RAVE PTID assigned	_____
Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility status	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete screening ☐
Date "Eligible and Enrolled" or "Incomplete screening"	_____
If "Eligible and enrolled", or "Incomplete screening", end of form.	
Date "Eligible/Not Enrolled" or "Ineligible"	_____
Select reason(s) why participant is ineligible.	I1. Eighteen years or older at the time of screening. ☐ I2. Willing and able to provide informed consent for the study. ☐ I3. Interest in oral PrEP – as defined in the SSP Manual. ☐ I4. Non-reactive HIV test results at Screening and at least one non-reactive test result at Enrollment. ☐ I5. Available to return for all study visits and within site catchment area, as defined per site's Standard Operating Procedures (SOP). ☐ I6. At risk for sexually acquiring HIV infection based on self-report of at least one of the following: ☐ I6a. At risk for sexually acquiring HIV infection based on self-report of any anal or vaginal sex with one or more sexual partners in the previous 3 months, regardless of condom use. ☐ I6b. At risk for sexually acquiring HIV infection based on self-report of anal or vaginal sex in exchange for money, food, shelter, or other goods or favors in the previous 3 months. ☐ I6c. At risk for sexually acquiring HIV infection based on self-report of history of STI(s) in the past 6 months. ☐ I7. Willing to undergo all required study procedures. ☐ I8. General good health, as evidenced by the following laboratory values: ☐

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Inclusion Exclusion Criteria
Generated On: 04 Nov 2022 01:43:33

- [ ] I8a. Calculated creatinine clearance ≥ 60 mL/minute using the Cockcroft-Gault equation.
- [ ] I8b. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) and total bilirubin < 2.5 times the upper limit of normal (ULN) (with the exception of Gilbert's syndrome).
- [ ] I8c. HBV surface antigen (HBsAg) negative.
- [ ] E1. Any reactive or positive HIV test result at Screening or at least one reactive/positive HIV test result at Enrollment, even if HIV infection is not confirmed.
- [ ] E2. Plans to move away from the site area within the next 18 months.
- [ ] E3. Co-enrollment in any other research study that may interfere with this study (as provided by self-report or other available documentation). Exceptions may be made after consultation with the Clinical Management Committee (CMC).
- [ ] E4. Significant hepatic dysfunction or end-stage liver disease, per the opinion of the site investigator and in consultation with the CMC. For participants using cyproterone acetate, please consult the CMC for any evidence of liver abnormalities.
- [ ] E5. History of deep vein thrombosis, pulmonary embolism, and/or clotting disorder.
- [ ] E6. Active or planned use of medications with significant drug interactions as described in the Package Insert for Truvada® or Descovy®, per clinician's discretion (provided by self-report or obtained from medical history or medical records). See Section 5.8 for a full list of drug interactions.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Inclusion Exclusion Criteria
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	E7. Any other condition, including but not limited to alcohol or substance abuse and uncontrolled medical condition and/or allergies, that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives would make the patient unsuitable for the study or unable/unwilling to comply with the study requirements. ☐
If "Investigator decision", specify (max. 200 characters):	_____
If eligible, but participant declined enrollment, specify reason:	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Informed Consent
Generated On: 04 Nov 2022 01:43:33

Date informed consent signed	_____
Consent type	Screening and Enrollment ☐ Specimen Storage ☐ IDI Sub-study ☐ DHI Sub-study ☐ Other ☐
Consent version	_____
If "Other", specify	_____
Did the participant consent to long-term specimen storage and future testing?	Yes ☐ No ☐ Not applicable ☐
Did the participant consent to IDI Sub-study?	Yes ☐ No ☐ Not applicable ☐
Did the participant consent to DHI Sub-study?	Yes ☐ No ☐ Not applicable ☐

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Medical History
Generated On: 04 Nov 2022 01:43:33

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):	

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Medical History Y/N
Generated On: 04 Nov 2022 01:43:33

Does the participant have any medical history to report? Yes ☐ No ☐

If "Yes", update the Medical History log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Protocol Deviations
Generated On: 04 Nov 2022 01:43:33

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	Enrollment of an ineligible patient ☐ Informed consent not obtained prior to performing protocol-specified procedures ☐ Non-compliance with study randomization and blinding procedures ☐ Breach of participant confidentiality ☐ A protocol-specified laboratory assay consistently not being performed ☐ A site-specific laboratory assay is deliberately added to protocol requirements by the investigator to be conducted for all participants ☐ 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	_____

_____
Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Protocol Deviations Y/N
Generated On: 04 Nov 2022 01:43:33

Have any protocol deviations been reported?	Yes ☐
	No ☐

If "Yes", update the Protocol Deviations log.

Staff initials/Date

HPTN091_Version_4.0_PROD_02NOV2022: ALL
Form: Randomization
Generated On: 04 Nov 2022 01:43:33

Is the participant ready to be randomized?	Yes ☐ No ☐
Randomization date and time	_____

Staff initials/Date