

## **Enrollment (Day 0)**

### **Visit Code: 02.0**

#### **Required forms**

- Demographics (DEM-1)
- Pre-existing Conditions (PRE-1)
- Concomitant Medications Log (CM-1)
- Baseline Laboratory Results (BLR-1, BLR-2)
- Baseline Complete Blood Count (BCB-1)
- Hepatitis Test Results (HEP-1)
- Enrollment (ENR-1)
- DXA Scan (DXA-1)
- Specimen Storage–All Participants (SS-1)
- HIV Test Results (HTR-1)\*

#### ***Tissue Subset Only***

- Tissue Subset Specimen Storage (TSS-1)

***\* HIV Test Results (HTR-1) is no longer needed after HIV infection is confirmed.***

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## **Demographics (DEM-1)**

**Purpose:** This form is used to collect a participant's demographic information.

**General Information/Instructions:** This form is faxed to SCHARP DataFax only if a participant enrolls in the study.

**Item-specific Instructions:**

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of his/her age. Do not complete both answers.



HPTN 069 (109)

DEM-2 (002)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number						Chk	

Demographics

6. What is the participant's highest level of education?

- 8<sup>th</sup> grade or equivalent or less
- some high school
- high school graduate or equivalent
- vocational/trade/technical school
- some college or 2 year degree
- finished college
- masters or other advanced degree

7. Does the participant consider him/herself to be Latino/a or of Hispanic origin? .....  *yes*  *no*

8. What does the participant report as his/her race? *Mark all that apply.*

- 8a. American Indian or Alaskan Native
- 8b. Asian
- 8c. Black or African American
- 8d. Native Hawaiian or other Pacific Islander
- 8e. White
- 8f. other, specify: \_\_\_\_\_

Comments: \_\_\_\_\_

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## Demographics (DEM-2)

### Item-specific Instructions:

- **Item 6:** If home schooled, choose the option that is the closest equivalent to the level of education attained.
- **Item 7:** This item is based on self-definition. Per NIH policy, Latino/a or Hispanic includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
- **Item 8:** Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. Per NIH policy, Latino/a is considered an ethnic group and not a race and should not be entered in item 8f.



Note: Number pages sequentially (01, 02, 03) for each participant.

HPTN 069 (109)

PRE-1 (012)

Participant ID

-      -

Site Number      Participant Number      Chk

Pre-existing Conditions

No pre-existing conditions reported or observed. \_\_\_\_\_ → **End of form. Fax to SCHARP DataFax.**  
Staff Initials / Date

- |                       |  |   |
|-----------------------|--|---|
| <b>1. Description</b> | <i>MMM</i> <i>yy</i>   | <b>Date of Diagnosis/ Surgery</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <b>Comments</b>       | <b>Is condition ongoing?</b> <i>yes</i> <i>no</i><br><input type="checkbox"/> <input type="checkbox"/> | _____<br><small>Staff Initials / Date</small>   |
- |                       |  |   |
|-----------------------|--|---|
| <b>2. Description</b> | <i>MMM</i> <i>yy</i>   | <b>Date of Diagnosis/ Surgery</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <b>Comments</b>       | <b>Is condition ongoing?</b> <i>yes</i> <i>no</i><br><input type="checkbox"/> <input type="checkbox"/> | _____<br><small>Staff Initials / Date</small>   |
- |                       |  |   |
|-----------------------|--|---|
| <b>3. Description</b> | <i>MMM</i> <i>yy</i>   | <b>Date of Diagnosis/ Surgery</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <b>Comments</b>       | <b>Is condition ongoing?</b> <i>yes</i> <i>no</i><br><input type="checkbox"/> <input type="checkbox"/> | _____<br><small>Staff Initials / Date</small>   |
- |                       |  |   |
|-----------------------|--|---|
| <b>4. Description</b> | <i>MMM</i> <i>yy</i>   | <b>Date of Diagnosis/ Surgery</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <b>Comments</b>       | <b>Is condition ongoing?</b> <i>yes</i> <i>no</i><br><input type="checkbox"/> <input type="checkbox"/> | _____<br><small>Staff Initials / Date</small>   |
- |                       |  |   |
|-----------------------|--|---|
| <b>5. Description</b> | <i>MMM</i> <i>yy</i>   | <b>Date of Diagnosis/ Surgery</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <b>Comments</b>       | <b>Is condition ongoing?</b> <i>yes</i> <i>no</i><br><input type="checkbox"/> <input type="checkbox"/> | _____<br><small>Staff Initials / Date</small>   |
- |                       |  |   |
|-----------------------|--|---|
| <b>6. Description</b> | <i>MMM</i> <i>yy</i>   | <b>Date of Diagnosis/ Surgery</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| <b>Comments</b>       | <b>Is condition ongoing?</b> <i>yes</i> <i>no</i><br><input type="checkbox"/> <input type="checkbox"/> | _____<br><small>Staff Initials / Date</small>   |

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## Pre-existing Conditions (PRE-1)

**Purpose:** This form is used to document the participant's pre-existing medical conditions.

**General Information/Instructions:** Only medical conditions experienced up to study regimen initiation should be recorded unless otherwise specified in the protocol or Study Specific Procedures (SSPs). Include current medical conditions and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).

### Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
- **Description:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
- **Date of Diagnosis/Surgery:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.
- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.
- **Is condition ongoing?:** Mark the "yes" box if condition is ongoing at enrollment.
- **Pre-existing Conditions Revisions and Updates:** If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).



Note: Number pages sequentially (01, 02, 03) for each participant

HPTN 069 (109)

CM-1 (423)

Participant ID

Site Number      Participant Number      Chk

Concomitant Medications Log

No medications taken at Screening/Enrollment. Staff Initials/Date \_\_\_\_\_  
 ➔ Fax to SCHARP DataFax.

No medications taken throughout study. Staff Initials/Date \_\_\_\_\_  
 ➔ End of form. Fax to SCHARP DataFax.

**1. Medication (generic name)** **Staff Initials/Log Entry Date**

**Indication**

**Date Started**     
      
      

*dd                      MMM                      yy*

**Date Stopped**     
      
      
 OR  Continuing at end of study

*dd                      MMM                      yy*

**Frequency**     *prn*     *qd*     *tid*     *qhs*  
 Mark only one.     *once*     *bid*     *qid*     *other, specify:* \_\_\_\_\_

**Dose/Units**                      **Route**    *PO*    *IM*    *IV*    *TOP*    *IHL*    *VAG*    *REC*    *other, specify:*  
 Mark only one.                                     \_\_\_\_\_

**Taken for a reported AE?**  
 *yes*     *no*  
 ➔ Record AE Log page(s):  
      
      

**2. Medication (generic name)** **Staff Initials/Log Entry Date**

**Indication**

**Date Started**     
      
      

*dd                      MMM                      yy*

**Date Stopped**     
      
      
 OR  Continuing at end of study

*dd                      MMM                      yy*

**Frequency**     *prn*     *qd*     *tid*     *qhs*  
 Mark only one.     *once*     *bid*     *qid*     *other, specify:* \_\_\_\_\_

**Dose/Units**                      **Route**    *PO*    *IM*    *IV*    *TOP*    *IHL*    *VAG*    *REC*    *other, specify:*  
 Mark only one.                                     \_\_\_\_\_

**Taken for a reported AE?**  
 *yes*     *no*  
 ➔ Record AE Log page(s):  
      
      

**3. Medication (generic name)** **Staff Initials/Log Entry Date**

**Indication**

**Date Started**     
      
      

*dd                      MMM                      yy*

**Date Stopped**     
      
      
 OR  Continuing at end of study

*dd                      MMM                      yy*

**Frequency**     *prn*     *qd*     *tid*     *qhs*  
 Mark only one.     *once*     *bid*     *qid*     *other, specify:* \_\_\_\_\_

**Dose/Units**                      **Route**    *PO*    *IM*    *IV*    *TOP*    *IHL*    *VAG*    *REC*    *other, specify:*  
 Mark only one.                                     \_\_\_\_\_

**Taken for a reported AE?**  
 *yes*     *no*  
 ➔ Record AE Log page(s):

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## Concomitant Medications Log (CM-1)

**Purpose:** All medication(s) that are used by the participant during the study, other than study regimen, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

**General Information/Instructions:** When to fax this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

### Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
- **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.
- **Medication:** For combination medications, record the first three main active ingredients.
- **Indication:** For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”
- **Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year are required.
- **Frequency:** Below is a list of common frequency abbreviations:

<b>prn</b> as needed	<b>qd</b> every day	<b>tid</b> three times daily	<b>qhs</b> at bedtime
<b>once</b> one time	<b>bid</b> twice daily	<b>qid</b> four times daily	

- Use “other, specify” for alternate dosing schedules.

- **Route:** Below is a list of common route abbreviations:

<b>PO</b> oral	<b>IM</b> intramuscular	<b>IV</b> intravenous	<b>TOP</b> topical	<b>IHL</b> inhaled	<b>VAG</b> vaginal	<b>REC</b> rectal
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- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).



HPTN 069 (109)

BLR-1 (016)

**Participant ID**

Site Number			Participant Number						Chk		

**Baseline Laboratory Results**

**Initial Specimen Collection Date**

dd		MMM		yy	

**1. SERUM LIPIDS**

1a. Did the participant fast for at least 8 hours prior to blood collection? .....  *yes*  *no*

Not done/ Not collected	Alternate Collection Date		
	dd	MMM	yy
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

	mg/dL	Severity Grade
		If applicable
1b. Total cholesterol		
1c. Triglycerides		
1d. LDL .....		
1e. HDL .....		

Not done/ Not collected	Alternate Collection Date		
	dd	MMM	yy
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

**2. LIVER FUNCTION TESTS**

	U/L	Severity Grade
		If applicable
2a. Alkaline phosphatase		
2b. AST (SGOT)		
2c. ALT (SGPT)		
2d. Total bilirubin .....		

Not done/ Not collected	Alternate Collection Date		
	dd	MMM	yy
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

**3. ELECTROLYTES**

	mmol/L	Severity Grade
		If applicable
3a. Sodium .....		
3b. Potassium ....		
3c. Chloride .....		
3d. Phosphorus (Phosphate)		
3e. Bicarbonate		

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## Baseline Laboratory Results (BLR-1)

**General Information/Instructions:** Complete and submit this form only for enrolled participants. Results recorded on this form may come from either Screening or Enrollment samples. Refer to the protocol for further details.

**Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

**Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

### Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
  - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

### Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
  - Treat all missing digits in the lab value as zeros.
  - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table*.

### Item-specific Instructions:

- **Item 1a:** Participant should be fasting for at least 8 hours prior to blood collection. If fasting did not occur, mark "no" for item 1a.



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## Baseline Laboratory Results (BLR-2)

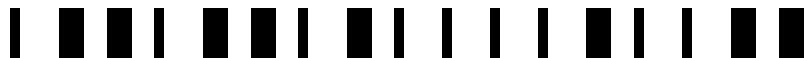
**Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

### Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
  - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

### Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
  - Treat all missing digits in the lab value as zeros.
  - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table*.



HPTN 069 (109)

BCB-1 (019)

**Participant ID**

-      -   
 Site Number      Participant Number      Chk

**Baseline Complete Blood Count**

**Specimen Collection Date**

/    /    
*dd                      MMM                      yy*

**1. HEMOGRAM**

	<b>Not reported</b>					<b>Severity Grade</b> <i>If applicable</i>
1a. Hemoglobin .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/> g/dL	<input type="checkbox"/>
1b. Hematocrit .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/> %	
1c. MCV .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/> fL	<b>Severity Grade</b> <i>If applicable</i>
1d. Platelets .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/> x10 <sup>3</sup> /mm <sup>3</sup>	<input type="checkbox"/>
1e. WBC .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/> x10 <sup>3</sup> /mm <sup>3</sup>	<input type="checkbox"/>

**DIFFERENTIAL**

	<b>Not reported</b>		<b>Absolute Count</b> <i>cells/mm<sup>3</sup></i>		<b>Severity Grade</b> <i>If applicable</i>
1f. Neutrophils .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/>
1g. Lymphocytes .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	<input type="text"/>
1h. Monocytes .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	
1i. Eosinophils .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	
1j. Basophils .....	<input type="checkbox"/>	.....	<input type="text"/>	<input type="text"/>	

Comments: \_\_\_\_\_

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## Baseline Complete Blood Count (BCB-1)

**General Information/Instructions:** Complete and submit this form only for enrolled participants. The results recorded on the Baseline Complete Blood Count are derived from Screening samples.

**Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

### Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
  - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

### Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
  - Treat all missing digits in the lab value as zeros.
  - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table*.



Visit Code

1

HPTN 069 (109)

HEP-1 (040)

Participant ID

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Site Number Participant Number Chk

Hepatitis Test Results

Initial Specimen Collection Date  
    
dd MMM yy

Not done/  
Not collected  Alternate Collection Date  
dd MMM yy

1. HEPATITIS C (required for Enrollment and as clinically indicated)

1a. Anti-Hepatitis C Antibody negative positive  
(anti-HCV): .....

Not done/  
Not collected  Alternate Collection Date  
dd MMM yy

2. HEPATITIS B (as clinically indicated)

2a. Hepatitis B Surface Antigen negative positive  
(HBsAg): .....

**If positive, complete Regimen Hold/  
Discontinuation Log and Adverse  
Experience Log.**

2b. Hepatitis B Surface Antibody negative positive  
(HBsAb): .....

2c. Hepatitis B Core Antibody negative positive  
(HBCoreAb): .....

3. Was the Hepatitis B vaccination series recommended? ..... yes no N/A

Comments: \_\_\_\_\_

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## Hepatitis Test Results (HEP-1)

**Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

**Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

### Item-specific Instructions:

- **Item 2:** Participants who are Hepatitis B surface antigen positive at Screening will not be enrolled in the study.



HPTN 069 (109)

ENR-1 (124)

**Participant ID**

-      -   
 Site Number      Participant Number      Chk

**Enrollment**

**Enrollment Date**

/    /    
*dd      MMM      yy*

1. Did the participant consent to specimen storage for future post-study testing? .....  *yes*       *no*
2. Did the participant consent to genetic testing? .....  *yes*       *no*
3. Did the participant consent to take part in the drug interaction substudy? .....  *yes*       *no*       *N/A (slots filled)*
4. Did the participant consent to take part in the tissue substudy? .....  *yes*       *no*       *N/A (slots filled) or site not participating*
5. Did the participant consent to a qualitative interview (PREMIS) that will be recorded? .....  *yes*       *no*       *N/A (site not participating)*
6. Record the number of the EDM device received at enrollment: .....    *device #*
7. Did the participant complete the CASI questionnaire for this visit? .....  *yes*       *no*      **→ If no, specify reason(s) in Comments.**

Comments: \_\_\_\_\_

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## **Enrollment (ENR-1)**

No additional instructions.



HPTN 069 (109)

DXA-1 (140)

Visit Code .

Participant ID

--  
Site Number Participant Number Chk

DXA Scan

1. Did the participant have a DXA scan for this visit? .....  <sup>yes</sup>  <sup>no</sup> **If no, end of form.**

1a. Date of DXA scan: .....  <sub>dd</sub>  <sub>MMM</sub>  <sub>yy</sub>

Comments: \_\_\_\_\_

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## **DXA Scan (DXA-1)**

**General Information/Instructions:** Do not fax this CRF to DataFax until the DXA scan has been completed.



Visit Code

1

HPTN 069 (109)

SS-1 (240)

Participant ID

--  
Site Number Participant Number Chk

Specimen Storage—  
All Participants

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min

:

1. Plasma for storage

stored not stored not collected

Reason not stored or not collected: \_\_\_\_\_



Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

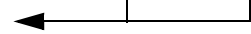
hr min

:

2. Viable PBMC  
(for immunological testing)

stored not stored not collected not required

Reason not stored or not collected: \_\_\_\_\_



Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min

:

3. PBMC for CCR5 genotyping

stored not stored not collected not required

Reason not stored or not collected: \_\_\_\_\_



Comments: \_\_\_\_\_

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## Specimen Storage—All Participants (SS-1)

**Purpose:** This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

**Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

**Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

### Item-specific Instructions:

- **Items 1–3:**
- Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
- Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.
- Mark the “not required” box if a specimen is not required to be collected and stored at this visit.



Visit Code

HPTN 069 (109)

HTR-1 (345)

Participant ID

-  -   
Site Number Participant Number Chk

HIV Test Results

Specimen #1 Collection Date

*dd* *MMM* *yy*

1. HIV Test Results:

Not done  *kit code*  
1a. HIV Rapid Test Kit Code .....   
*non-reactive* *reactive*  
1b. HIV Rapid: .....    
Not done  *kit code*  
1c. HIV EIA Test Kit Code: .....   
*non-reactive* *reactive*  
1d. HIV EIA: .....

Specimen #2 Collection Date

*dd* *MMM* *yy*

2. HIV Repeat Testing

Not done  *kit code*  
2a. HIV Rapid Test Kit Code: .....   
*non-reactive* *reactive*  
2b. HIV Rapid: .....    
Not done  *kit code*  
2c. HIV EIA Test Kit Code: .....   
*non-reactive* *reactive*  
2d. HIV EIA: .....

3. Final HIV Status from local confirmatory testing: .....

*negative* *positive* *indeterminate*

Comments: \_\_\_\_\_

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## HIV Test Results (HTR-1)

**General Information/Instructions:** Record test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when the final test results are available and recorded.

- **Specimen Collection Dates:** Record the date that the specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit.

### Item-specific Instructions:

- **Not Done:** For each test, mark either the “Not done” box or enter a test result. If the “Not done” box is marked at a visit where that test is required by the protocol, record the reason on the Comments line.
- **Items 1a and 2a:** Record the two-digit rapid test code from the table below.

Rapid Test Kit	Code
OraQuick ADVANCE Rapid HIV-1/2	02
Uni-Gold Recombigen HIV	03
Reveal G-3 Rapid HIV-1	08
MultiSpot HIV-1/2 Rapid Test	09
Clearview HIV-1/2 STAT-PAK	10
Clearview COMPLETE HIV-1/2	11
INSTI HIV-1 Antibody Test	13
SURE CHECK HIV 1/2 ASSAY	14

**Note:** Rapid tests on oral transudate are not allowed per protocol.

If a test kit being used at your site is not listed, contact the SCHARP Project Manager for a new code.

- **Items 1c and 2c:** Record the two-digit HIV EIA test code from the table below.

HIV EIA Test Kit	Code
ARCHITECT HIV Ag/Ab Combo <sup>35</sup>	50
Bio-Rad GS HIV Ag/Ab Combo EIA <sup>36</sup>	51
Avioq HIV-1 Microelisa System <sup>13</sup>	52
Abbott HIV AB HIV-1/HIV-2 (rDNA) EIA <sup>2</sup>	53
PRISM HIV O Plus assay <sup>27</sup>	54
GS HIV-1/HIV-2 Plus O EIA <sup>28</sup>	55
ADVIA Centaur HIV 1/O/2 Enhanced ReadyPack	56
Ortho VITROS HIV-1/HIV-2	57

If a test kit being used at your site is not listed, contact the SCHARP Project Manager for a new code.

If HIV infection is suspected or confirmed during follow-up, complete a Regimen Hold/Discontinuation Log.



Visit Code

1

HPTN 069 (109)

TSS-1 (230)

Participant ID

--  
Site Number Participant Number Chk

Tissue Subset Specimen Storage

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

:   
hr min

1. Plasma for PK

stored  not stored  not collected  not required

Reason not stored or not collected: \_\_\_\_\_

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

:   
hr min

2. PBMC for PK

stored  not stored  not collected  not required

Reason not stored or not collected: \_\_\_\_\_

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

:   
hr min

3. Rectal fluid (sponge) for PK

stored  not stored  not collected  not required

Reason not stored or not collected: \_\_\_\_\_

Alternate Collection Date

dd MMM yy

Time Collected (24-hr clock)

:   
hr min

4. Rectal Tissue

stored  not stored  not collected  not required

4a. Tissue for PK

stored  not stored  not collected  not required

Reason not stored or not collected: \_\_\_\_\_

4b. Tissue for ex-vivo HIV Challenge

stored  not stored  not collected  not required

Reason not stored or not collected: \_\_\_\_\_

4c. Tissue for GALT

stored  not stored  not collected  not required

Reason not stored or not collected: \_\_\_\_\_

Comments: \_\_\_\_\_

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## Tissue Subset Specimen Storage (TSS-1)

**Purpose:** This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

**Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

**Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

### Item-specific Instructions:

- **Items 1–4:**
  - Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
  - Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.
  - Mark the “not required” box if a specimen is not required to be collected and stored at this visit.