

***ADDITIONAL CRFs REQUIRED FOR PARTICIPANTS
WITH CONFIRMED HIV INFECTION***

Visit at time of diagnosis

- Seroconversion Testing and Sample Storage (STS-1)
- Specimen Storage–All Participants (SS-1)
- Tissue Subset Specimen Storage–Blood (TSB-1)

Week 49 or Last Study Visit

Visit Code: 11.0

- Seroconversion Testing and Sample Storage (STS-1)
- Specimen Storage–All Participants (SS-1)

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HPTN 069 (109)

STS-1 (330)

Visit Code

1

Participant ID

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Site Number Participant Number Chk

Seroconversion Testing and Sample Storage

Initial Collection Date

dd MMM yy

Not done/ Not collected Alternate Collection Date dd MMM yy

CD4/Viral Load Results

Unable to analyze cells/mm³

1. Absolute CD4+

not available

Not done/ Not collected Alternate Collection Date dd MMM yy

2. HIV-1 RNA PCR of Plasma

. % OR

viral copies/mL

> = <

Sample Storage for Participants with Confirmed HIV

Alternate Collection Date dd MMM yy

Time Collected hr min

3. Plasma for storage : (24-hr clock)

stored not stored not collected Reason not stored or not collected: _____

Alternate Collection Date dd MMM yy

Time Collected hr min

4. Plasma for PK : (24-hr clock)

stored not stored not collected Reason not stored or not collected: _____

Complete item 5 only for participants in the tissue subset.

Alternate Collection Date dd MMM yy

Time Collected hr min

5. PBMC for PK : (24-hr clock)

stored not stored not collected Reason not stored or not collected: _____

Comments: _____

Seroconversion Testing and Sample Storage (STS-1)

General Information/Instructions: This form is used only for participants with confirmed HIV infection.

- **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. Complete date required.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. 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. Complete date required.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results 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.
 - 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.

Item-specific Instructions:

- **Item 2:** One of the >, =, or < boxes must be marked in addition to the viral copies/mL.
- **Items 3–5:** Samples collected as a result of HIV infection should only be reported on this CRF. Do not record these samples on any other sample storage CRF (Tissue Subset Specimen Storage or Specimen Storage–All Participants).
 - Blood collection for plasma storage and for PK is completed for all participants with confirmed HIV infection.
 - PBMC storage for PK is only completed for those individuals participating in the Tissue Subset.



Visit Code

1

HPTN 069 (109)

SS-1 (240)

Participant ID

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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

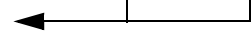
hr min

:

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: _____

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

1

HPTN 069 (109)

TSB-1 (220)

Participant ID

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Site Number Participant Number Chk

Tissue Subset Specimen Storage—Blood

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min

stored not stored not collected

: 1. Plasma for PK

Reason not stored or not collected: _____

↓ ↓ ↓
←

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min

stored not stored not collected

: 2. PBMC for PK

Reason not stored or not collected: _____

↓ ↓ ↓
←

Complete item 3 for Week 24 and 48 visits only. All other visits, end of form.

3. Date and time of last study dose: : (24-hr clock)

Comments: _____

Tissue Subset Specimen Storage—Blood (TSB-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 1–2:**
 - 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.