

Week 40 Visit

Visit Code: 09.0

Required forms

- Follow-up Visit (FUV-1)
- Follow-up Complete Blood Count (FCB-1)
- Follow-up Laboratory Results (FLR-1, FLR-2)
- Specimen Storage–All Participants (SS-1)
- HIV Test Results (HTR-1)*

Tissue Subset Only

- Tissue Subset Follow-up Laboratory Results (TSF-1)

As Needed

- Hepatitis Test Results (HEP-1)
- Social Impact Log (SIL-1)
- Regimen Hold/Discontinuation Log (RHD-1)
- Concomitant Medications Log (CM-1)
- Adverse Experience Log (AE-1)

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

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HPTN 069 (109)

FUV-1 (120)

Visit Code . 0

1

Participant ID

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Site Number Participant Number Chk

Visit Date

dd MMM yy

Follow-up Visit

1. At this visit, how many **new** Adverse Experiences (AEs) have been reported? → **Complete a separate AE Log page for each AE. If none, enter 00.**
new AEs
2. At this visit, how many **new** social impacts have been reported? → **Complete a separate Social Impact Log page for each event. If none, enter 00.**
new social impacts
3. At this visit, how many **new** regimen holds or discontinuations have been initiated? → **Complete a separate Regimen Hold/Discontinuation Log page for each hold or discontinuation. If none, enter 00.**
new regimen holds or discontinuations
4. Did the participant complete the CASI questionnaire for this visit?
yes no not required
→ **If no, specify reason in Comments.**
5. Did the participant receive a new EDM device at this visit?
yes no → **If no, go to item 6.**
device #
- 5a. New EDM device number:
6. Was the participant dispensed any pills at this visit?
yes no → **If no, end of form.**
pills dispensed
- 6a. Maraviroc (MVC)/placebo
- 6b. Emtricitabine (FTC)/placebo
- 6c. Tenofovir (TDF)/placebo

Comments: _____

Follow-up Visit (FUV-1)

Purpose: This form is used to document regularly scheduled follow-up visits.



Visit Code

HPTN 069 (109)

FCB-1 (142)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Complete Blood Count

Specimen Collection Date

dd MMM yy

Not done/
Not collected

1. HEMOGRAM

Not reported

1a. Hemoglobin g/dL

1b. Hematocrit %

1c. MCV fL

1d. Platelets $\times 10^3/mm^3$

1e. WBC $\times 10^3/mm^3$

Severity Grade <i>If applicable</i>	AE Log Page #	Not reportable as an AE
<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
Severity Grade <i>If applicable</i>	AE Log Page #	Not reportable as an AE
<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>

Not done

DIFFERENTIAL \rightarrow If not done, end of form.

Absolute Count
cells/mm³

1f. Neutrophils

1g. Lymphocytes

1h. Monocytes

1i. Eosinophils

1j. Basophils

Severity Grade <i>If applicable</i>	AE Log Page #	Not reportable as an AE
<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>

Comments: _____

Follow-up Complete Blood Count (FCB-1)

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*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.



Visit Code

1

HPTN 069 (109)

FLR-1 (143)

Participant ID

- -
Site Number Participant Number Chk

Initial Specimen Collection Date

dd MMM yy

Follow-up Laboratory Results

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

1b. Total cholesterol mg/dL Severity Grade If applicable AE Log Page # Not reportable as an AE OR

2. LIVER FUNCTION TESTS

Not done/Not collected Alternate Collection Date dd MMM yy

2a. Alkaline phosphatase U/L Severity Grade If applicable AE Log Page # Not reportable as an AE OR

3. ELECTROLYTES

Not done/Not collected Alternate Collection Date dd MMM yy

3a. Sodium mmol/L Severity Grade If applicable AE Log Page # Not reportable as an AE OR

Follow-up Laboratory Results (FLR-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.

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*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

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.



Visit Code

HPTN 069 (109)

FLR-2 (144)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Laboratory Results

Not done/ Not collected Alternate Collection Date dd MMM yy

4. OTHER LAB RESULTS

4a. Glucose mg/dL Severity Grade If applicable AE Log Page # Not reportable as an AE OR

4b. 25-OH-vit D ng/mL

4c. Parathyroid hormone (PTH) pg/mL

5. WEIGHT kg

Not done/ Not collected Alternate Collection Date dd MMM yy

6. RENAL FUNCTION TESTS

6a. Creatinine mg/dL Severity Grade If applicable AE Log Page # Not reportable as an AE OR

6a1. Calculated creatinine clearance mL/min

6b. BUN mg/dL

Not done/ Not collected

7. URINE TESTS

7a. Protein negative trace 1+ 2+ 3+ 4+ Severity Grade If applicable AE Log Page # Not reportable as an AE OR
7b. Glucose
7c. Phosphate: mg/dL
7d. Creatinine: mg/dL

Comments: _____

Follow-up Laboratory Results (FLR-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*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.



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

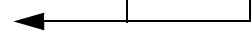
hr min

:

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)

HTR-1 (345)

Participant ID

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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: _____

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 ³⁵	50
Bio-Rad GS HIV Ag/Ab Combo EIA ³⁶	51
Avioq HIV-1 Microelisa System ¹³	52
Abbott HIV AB HIV-1/HIV-2 (rDNA) EIA ²	53
PRISM HIV O Plus assay ²⁷	54
GS HIV-1/HIV-2 Plus O EIA ²⁸	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

HPTN 069 (109)

TSF-1 (149)

Participant ID

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Site Number Participant Number Chk

Tissue Subset Follow-up Lab Results

Initial Specimen Collection Date

dd MMM yy

Not done/ Not collected Alternate Collection Date dd MMM yy

1. Syphilis screening test non-reactive reactive equivocal
If non-reactive, go to item 3. ←

1a. Syphilis titer 1: OR

2. Syphilis confirmatory test negative positive indeterminate

Not done/ Not collected Alternate Collection Date dd MMM yy

3. *N. gonorrhoea* negative positive

Not done/ Not collected Alternate Collection Date dd MMM yy

4. *C. trachomatis* negative positive

Comments: _____

Tissue Subset Follow-up Lab Results (TSF-1)

Item-specific Instructions:

- **Item 1a:** If the type of syphilis screening test does not yield a titer, mark the “N/A” box.
- **Items 3–4:** These tests are done using rectal swabs.