Week 16 Visit
Visit Code: 06.0

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)***
- Pregnancy Test Results (PTR-1) ** - ***Women only***

Tissue Subset Only

- Sexually Transmitted Infections (STI-1)

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

*****Pregnancy Test Results (PTR-1) is no longer required after pregnancy is confirmed or if participant is no longer of reproductive potential.***

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Visit Code ☐☐.0 1

HPTN 069 (109) FUV-1 (120)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Follow-up Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. At this visit, how many **new** Adverse Experiences (AEs) have been reported?

 # new AEs ☐☐ → ***Complete a separate AE Log page for each AE. If none, enter 00.***

2. At this visit, how many **new** social impacts have been reported? .....

 # new social impacts ☐☐ → ***Complete a separate Social Impact Log page for each event. If none, enter 00.***

3. At this visit, how many **new** regimen holds or discontinuations have been initiated? .....

 # new regimen holds or discontinuations ☐☐ → ***Complete a separate Regimen Hold/Discontinuation Log page for each hold or discontinuation. If none, enter 00.***

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.***

5a. New EDM device number: .....

device # ☐☐☐

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 ☐☐.☐ 1

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		Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
1a. Hemoglobin	☐	..... ☐☐.☐ *g/dL*	☐	☐☐☐	OR ☐
1b. Hematocrit	☐	..... ☐☐.☐ *%*			
1c. MCV	☐	..... ☐☐☐.☐ *fL*			
1d. Platelets	☐	..... ☐☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐
1e. WBC	☐	..... ☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐

Not done ☐ → ***If not done, end of form.***

DIFFERENTIAL

	Not reported		Absolute Count *cells/mm^3*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
1f. Neutrophils	☐		☐☐☐☐☐	☐	☐☐☐	OR ☐
1g. Lymphocytes	☐	.....	☐☐☐☐	☐	☐☐☐	OR ☐
1h. Monocytes	☐	.....	☐☐☐☐			
1i. Eosinophils	☐	.....	☐☐☐☐			
1j. Basophils	☐	.....	☐☐☐☐			

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

Follow-up 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		mg/dL	Severity Grade If applicable	AE Log Page #		Not reportable as an AE
☐				1b. Total cholesterol				OR	☐
☐				1c. Triglycerides				OR	☐
☐				1d. LDL				OR	☐
☐				1e. HDL				OR	☐

2. LIVER FUNCTION TESTS

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		U/L	Severity Grade If applicable	AE Log Page #		Not reportable as an AE
☐				2a. Alkaline phosphatase				OR	☐
☐				2b. AST (SGOT)				OR	☐
☐				2c. ALT (SGPT)				OR	☐
☐				2d. Total bilirubin	mg/dL ___.___			OR	☐

3. ELECTROLYTES

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		mmol/L	Severity Grade If applicable	AE Log Page #		Not reportable as an AE
☐				3a. Sodium				OR	☐
☐				3b. Potassium	___.___			OR	☐
☐				3c. Chloride					
☐				3d. Phosphorus (Phosphate)	mg/dL ___.___			OR	☐
☐				3e. Bicarbonate	mmol/L ___.___			OR	☐

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Staff Initials / Date

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 ☐☐.☐ 1

HPTN 069 (109) FLR-2 (144)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Follow-up Laboratory Results

4. OTHER LAB RESULTS

Not done/ Not collected	Alternate Collection Date dd MMM yy		mg/dL	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
☐	☐☐ ☐☐☐ ☐☐	4a. Glucose	☐☐☐	☐	☐☐☐	OR ☐
☐	☐☐ ☐☐☐ ☐☐	4b. 25-OH-vit D	☐☐ ng/mL			
☐	☐☐ ☐☐☐ ☐☐	4c. Parathyroid hormone (PTH)	☐☐ pg/mL			
☐	☐☐ ☐☐☐ ☐☐	**5. WEIGHT**	☐☐☐ kg			

6. RENAL FUNCTION TESTS

Not done/ Not collected	Alternate Collection Date dd MMM yy		mg/dL	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
☐	☐☐ ☐☐☐ ☐☐	6a. Creatinine	☐☐.☐	☐	☐☐☐	OR ☐
		6a1. Calculated creatinine clearance	☐☐☐ mL/min			
☐	☐☐ ☐☐☐ ☐☐	6b. BUN	☐☐☐ mg/dL			

7. URINE TESTS

Not done/ Not collected ☐

	negative	trace	1+	2+	3+	4+	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
7a. Protein	☐	☐	☐	☐	☐	☐	☐	☐☐☐	OR ☐
7b. Glucose	☐	☐	☐	☐	☐	☐			

7c. Phosphate: ..... ☐☐☐.☐ mg/dL

7d. Creatinine: ..... ☐☐☐.☐ mg/dL

Comments: _____

_____

_____

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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.

- **Item 6a1:** When calculating creatinine clearance, use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when blood was drawn for serum creatinine testing, weight from another date may be used for the calculation. Record the alternate collection date for item 5.
    - If weight and or serum creatinine are reported by the lab to a higher level of precision than is allowed on the CRF, round each result before calculating creatinine clearance.

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 *dd* *MMM* *yy* **Time Collected** *(24-hr clock)* *hr* *min*

1. Plasma for storage ☐ *stored* ☐ *not stored* ☐ *not collected*

Reason not stored or not collected: _____

Alternate Collection Date *dd* *MMM* *yy* **Time Collected** *(24-hr clock)* *hr* *min*

2. Viable PBMC (for immunological testing) ☐ *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. 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 ☐☐.☐ 1

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 ☐

1a. HIV Rapid Test Kit Code ..... *kit code* ☐☐

1b. HIV Rapid: ..... *non-reactive* ☐ *reactive* ☐

Not done ☐

1c. HIV EIA Test Kit Code: ..... *kit code* ☐☐

1d. HIV EIA: ..... *non-reactive* ☐ *reactive* ☐

Specimen #2 Collection Date

dd *MMM* *yy*

☐☐ ☐☐☐ ☐☐

2. HIV Repeat Testing

Not done ☐

2a. HIV Rapid Test Kit Code: ..... *kit code* ☐☐

2b. HIV Rapid: ..... *non-reactive* ☐ *reactive* ☐

Not done ☐

2c. HIV EIA Test Kit Code: ..... *kit code* ☐☐

2d. HIV EIA: ..... *non-reactive* ☐ *reactive* ☐

3. **Final HIV Status from local confirmatory testing:** ..... *negative* ☐ *positive* ☐ *indeterminate* ☐

Comments: _____

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Staff Initials / Date

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 ☐☐.☐ 1

HPTN 069 (109) PTR-1 (071)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pregnancy Test Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. PREGNANCY TEST

1a. Test result: ..... *negative* ☐ *positive* ☐ *not done/ not collected* ☐ → *If not done/not collected, specify reason below:*

If positive, complete Pregnancy Report and History CRF and Regimen Hold/ Discontinuation Log.

☐ no longer of reproductive potential

☐ other, specify: _____

Comments: _____

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Pregnancy Test Results (PTR-1)

General Information/Instructions: Complete at Enrollment and every follow-up visit, unless participant has previously been confirmed pregnant or is not of reproductive potential.

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.

Item-specific Instructions:

- **Item 1:** If the participant is not of reproductive potential (e.g., postmenopausal or post-surgery), the Pregnancy Test Results CRF is not required.

Visit Code ☐☐.☐ 1

HPTN 069 (109) STI-1 (148)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Sexually Transmitted Infections

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Not done/ Not collected	Alternate Collection Date *dd*	*MMM*	*yy*		*non-reactive*	*reactive*	*equivocal*
☐	☐☐	☐☐☐	☐☐	1. Syphilis screening test	☐	☐	☐

If non-reactive, go to item 3.

1a. Syphilis titer ..... **1:** ☐☐☐☐ **OR** N/A ☐

		negative	*positive*	*indeterminate*
2.	Syphilis confirmatory test	☐	☐	☐

Not done/ Not collected	Alternate Collection Date *dd*	*MMM*	*yy*		*negative*	*positive*
☐	☐☐	☐☐☐	☐☐	3. *N. gonorrhea*–URINE	☐	☐
☐	☐☐	☐☐☐	☐☐	4. *C. trachomatis*–URINE	☐	☐
☐	☐☐	☐☐☐	☐☐	5. *N. gonorrhea*–RECTAL	☐	☐
☐	☐☐	☐☐☐	☐☐	6. *C. trachomatis*–RECTAL	☐	☐
☐	☐☐	☐☐☐	☐☐	7. *N. gonorrhea*–CERVICOVAGINAL	☐	☐
☐	☐☐	☐☐☐	☐☐	8. *C. trachomatis*–CERVICOVAGINAL	☐	☐

Comments: _____

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Sexually Transmitted Infections (STI-1)

General Information/Instructions:

- All participants: Test results from samples collected at the Screening or Enrollment visit may be reported as baseline using visit code “2.0” on the CRF.
- Main study participants: Complete this form at baseline, Week 24, and Week 48.
  - Rectal swabs and urine are collected in all men.
  - Rectal swabs are collected in women who report having had anal sex in the last year (from the time the swab is collected).
  - At sites that have the clinical and laboratory capacity to collect and test cervical or vaginal swabs for GC/CT, this swab should be collected.
  - A woman may opt to self-collect a vaginal swab specimen; if she does, this must be done at the study clinic.
  - For sites that cannot collect and test vaginal or cervical swabs for GC/CT testing, urine should be collected for this purpose.
- Tissue subset participants: Complete this form at baseline, Week 16, and Week 40.

Item-specific Instructions:

- **Item 1a:** If the type of syphilis screening test does not yield a titer, mark the “N/A” box.