

## Non-ART Visits

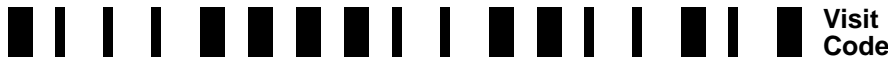
### Required forms

- Non-ART Study Visit (NSV-1)
- Specimen Storage (SS-1)
- Laboratory Results–Revised–Version 2 (LAB-1)
- Social Harms Assessment (SH-1~SH-5)—*Required at 3, 12, and 24 months*
- Sexually Transmitted Diseases Results (STR-1)

### If Applicable:

- Non-ART Concomitant Medications Log (NCM-1)
- ART Enrollment (AEN-1)
- ART Initiation Information–Revised (AIN-1)
- HIV/AIDS-associated Events Log (HA-1)
- Pregnancy Report and History (PR-1)
- Pregnancy Outcome (PO-1)
- Missed Visit (MV-1)
- Participant Transfer (PT-1)
- Participant Receipt (PRC-1)
- Protocol Deviation Log (PDL-1)
- Family Planning (FP-1)
- ACASI Tracking (ACT-1)
- Follow-up Behavioral Questionnaire (FBQ-1~FBQ-10)
- Follow-up Behavioral Questionnaire–Version 2 (FQ-1~FQ-3)

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MTN 015 (143)

NSV-1 (101)

Visit Code

0

1

Participant ID

Site Number - Participant Number - Chk

Non-ART Study Visit

Visit Date

dd MMM yy

1. Has the participant initiated ART since her last study visit? yes no

If yes, complete ART Enrollment, ART Initiation Information, Antiretroviral Treatment Regimen Log, and ART Study Visit forms. End of form.

1a. Reason why the participant reports not having started ART:

- participant is not receiving medical care for HIV
ART not recommended by the participant's health care provider/clinic
ART recommended but not started because of cost
ART recommended but not started because participant does not want to take it
other reason, specify:

2. Is the participant completing a parent protocol visit at this MTN 015 visit? yes no If no, end of form.

2a. Visit code of parent protocol visit completed today: visit code

Comments:

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## Non-ART Study Visit (NSV-1)

**Purpose:** This form is used to document non-ART follow-up visits.

**General Information/Instructions:** Complete this form **once** at each required non-ART follow-up visit. Do **not** complete this form at the Screening/Enrollment visit or at interim study visits. For interim study visits, complete the Interim Visit form.

**Item-specific Instructions:**

- **Visit Code:** Only visit codes assigned to non-ART visits should be recorded. Non-ART visits are assigned visit codes ranging from 02.0 through 28.0.
- **Item 1:** Mark “yes” if the participant reported initiation of ART use for the very first time at this visit. Once this item is marked “yes”, end the form. This form should not be completed any more for the participant, as a “yes” response indicates the participant is now being followed per the ART visit schedule.
- **Item 1a:** Mark the reason that best explains why the participant has never used ART.
- **Items 2 and 2a:** If the participant is completing a parent protocol visit (regular visit or interim visit) on this same day, mark item 2 “yes” and in 2a, record the visit code (regular or interim) of the parent protocol visit completed on this date.



MTN 015 (143)

SS-1 (161)

Visit Code

□□.□□

Participant ID

□□□-□□□□□□-□  
Site Number Participant Number Chk

Specimen Storage

Initial Collection Date

□□ □□□ □□  
dd MMM yy

Alternate Collection Date

dd MMM yy  
□□ □□□ □□

□□ □□□ □□

□□ □□□ □□

□□ □□□ □□

□□ □□□ □□

		<i>not required</i>	<i>stored</i>	<i>not stored</i>	<i>Reason:</i>
1. Plasma .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
2. PBMC .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
3. Serum .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
4. Vaginal swab .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____
5. Cervicovaginal lavage .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____

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

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## Specimen Storage (SS-1)

**Purpose:** This form is used to document collection and storage of MTN 015 specimens that will be tested at a lab other than the local site laboratory.

**General Information/Instructions:** Only record specimens collected for MTN 015 on this form. Do not record specimens collected for the participant's parent study. Check the information on this form against the MTN 015 LDMS Specimen Tracking Sheet completed for this visit to make sure the information is the same.

**Initial Collection Date:** Record the date that the first specimen(s) was *collected* 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 Initial Collection Date. 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.

### Item-specific Instructions:

- **Items 1–5:** If the specimen is not required to be collected and stored at this visit, mark “not required.” If the specimen is required to be stored, but for some reason it is not stored at this visit, mark “not stored” and record the reason why on the line provided.



<b>Laboratory Results—Revised--Version 2 (LAB-1)</b>	
<b>Purpose:</b>	This form is used to document absolute CD4+, HIV plasma RNA, and pregnancy test results obtained during the study.
<b>General Information/ Instructions:</b>	<p>Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.</p> <p><b>Initial Specimen Collection Date:</b> 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.</p> <p><b>Alternate Collection Date:</b> This date is to be completed ONLY if the specimen was collected on a day after the Initial Collection Date. A specimen collected for the same visit but on a later date should be recorded on the same form only when obtained within the same visit window. A complete date is required.</p> <p><b>Not done/Not collected:</b> For every test, mark either the "Not done/Not collected" box or enter a test result. If a result is not available, mark the "Not done/Not collected" box.</p>
<b>Item-specific Instructions:</b>	
<b>Item 1a:</b>	If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 1a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.
<b>Item 2a:</b>	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation. If result is "target not detected", mark the "target not detected" box and do not enter any numbers in the "viral copies/mL" boxes. If the result is "<20 Below Range" or "<40Detected", leave the "Target not detected" box blank, and mark the "<" box and the number "00000020" or "00000040" in the "viral copies/mL" boxes. Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
<b>Item 2b:</b>	If a second HIV RNA PCR result was obtained for the specimen, record the result here (refer to instructions for item 2a above) and complete item 2b. If a second HIV RNA PCR result was not obtained for the specimen, mark the "Not done" box and go to item 3.
<b>Item 3:</b>	Note that a Pregnancy Report and History form is required to be completed once for each pregnancy, not for each positive pregnancy test result.

MTN 015 (143) SH-1 (371) Visit Code

Visit Code input boxes

Participant ID

Participant ID input boxes: Site Number, Participant Number, Chk

Social Harms Assessment

Visit Date

Visit Date input boxes: dd, MMM, yy

1. Since your last interview, have you had any problems with the following people as a result of being in the study: Read each response option aloud.

yes no

- 1a. your husband or partner?
1b. people at home/family?
1c. your friends/personal relationships?
1d. people at work?
1e. people at school?
1f. your doctor, nurse, midwife, or other health care provider?
1g. your landlord or property owner?
1h. other people, specify:

Local Language:
English:

If all are marked no, go to item 5 on page 3.

2. Please describe the problem:

Local Language:
English:

NOTE: Item 3 is not read aloud.

3. Clinic Staff: Was this problem assessed to be possibly, probably, or definitely related to MTN 015 study participation or procedures?

possibly related, probably related, definitely related checkboxes

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## Social Harms Assessment (SH-1)

Items 1–3 ask about problems the participant may have encountered as a result of being **in the study**.

### Item-specific Instructions:

- **Item 1:** Emphasize “in the study.” If “yes” is marked for item 1h, record the participant’s verbatim response. Also provide the English translation in the space provided.
- **Item 2:** Describe the problem. Do **not** record the participant’s verbatim response - describe the problem in your own words so that the nature of the problem is clear. Provide the English translation in the space provided.
- **Item 3:** This is not an interviewer-administered item. If the participant reports more than one social harm, mark this item based on the social harm that relates most strongly to MTN015 study participation or procedures.



MTN 015 (143)

SH-2 (372)

Visit Code

□□□

1

Participant ID

□□□-□□□□□□-□  
Site Number Participant Number Chk

Social Harms Assessment

No data recorded on this page

4. Has this problem/any of these problems resulted in...

4a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem. ....  yes  no

4a1. Please describe the problem:

Local Language:

\_\_\_\_\_  
\_\_\_\_\_

English:

\_\_\_\_\_  
\_\_\_\_\_

If no, go to item 4b.

4b. physical harm to you? For example, has anyone physically hurt you as a result of this problem. ....  yes  no

4b1. Please describe the problem:

Local Language:

\_\_\_\_\_  
\_\_\_\_\_

English:

\_\_\_\_\_  
\_\_\_\_\_

If no, go to item 4c.

4c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn an income. ....  yes  no

4c1. Please describe the problem:

Local Language:

\_\_\_\_\_  
\_\_\_\_\_

English:

\_\_\_\_\_  
\_\_\_\_\_

If no, go to item 4d on page 3.

□ □ □  29-FEB-08

01

Language

Staff Initials / Date

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## Social Harms Assessment (SH-2)

### Item-specific Instructions:

- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.
- **Items 4a1–4c1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

MTN 015 (143)

SH-3 (373)

Visit Code

□□.□

Participant ID

□□□-□□□□□□-□  
Site Number Participant Number Chk

Social Harms Assessment

4d. physical or other harm to your children? .....  yes  no

4d1. Please describe the problem:  
Local Language:

\_\_\_\_\_

English:

\_\_\_\_\_

If no, go to item 5.

5. Since your last interview, have you had any problems with the following people as a result of being HIV positive: **Read each response option aloud.**

yes

no

5a. your husband or partner?

5b. people at home/family?

5c. your friends/personal relationships?

5d. people at work?

5e. people at school?

5f. your doctor, nurse, midwife, or other health care provider?

5g. your landlord or property owner?

5h. other people, specify:

If all are marked no, end of form. Do not fax pages 4-5.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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## Social Harms Assessment (SH-3)

### Item-specific Instructions:

- **Item 4d1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 5** asks about problems the participant may have encountered as a result of being **HIV-positive**.
  - Emphasize "HIV-positive." If "yes" is marked for item 5h, be sure to record the participant's verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

SH-4 (374)

Visit Code

□□.□

Participant ID

□□□-□□□□□-□

Site Number

Participant Number

Chk

Social Harms Assessment

6. Please describe the problem:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

7. Has this problem/any of these problems resulted in...

7a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem. ....  yes  no

7a1. Please describe the problem:

Local Language:

\_\_\_\_\_  
\_\_\_\_\_

English:

\_\_\_\_\_  
\_\_\_\_\_

If no, go to item 7b.

7b. physical harm to you? For example, has anyone physically hurt you as a result of this problem. ....  yes  no

7b1. Please describe the problem:

Local Language:

\_\_\_\_\_  
\_\_\_\_\_

English:

\_\_\_\_\_  
\_\_\_\_\_

If no, go to item 7c on page 5.

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## Social Harms Assessment (SH-4)

### Item-specific Instructions:

Items 6–7 ask about problems the participant may have encountered as a result of being **HIV-positive**.

- **Item 6:** Describe the problem. Do **not** record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. Provide the English translation in the space provided.
- **Items 7a1 and 7b1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

MTN 015 (143) SH-5 (375)

Visit Code

1

Participant ID

Site Number Participant Number Chk

Social Harms Assessment

7c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn an income. .... yes no

7c1. Please describe the problem: Local Language:

Horizontal lines for local language description

English:

Horizontal lines for English description

If no, go to item 7d.

7d. physical or other harm to your children? ..... yes no

7d1. Please describe the problem: Local Language:

Horizontal lines for local language description

English:

Horizontal lines for English description

If no, end of form.

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## Social Harms Assessment (SH-5)

### Item-specific Instructions:

- **Items 7c1 and 7d1:** Briefly describe the problem. Do not record the participant's verbatim response. Describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.



Visit Code

□□.□□

MTN 015 (143)

STR-1 (131)

Participant ID

□□□-□□□□□□-□  
Site Number Participant Number Chk

Initial Collection Date

□□ □□□□ □□  
dd MMM yy

Sexually Transmitted Diseases Results

Not done/ Not collected   
Alternate Collection Date dd MMM yy  
□□ □□□□ □□

1. VAGINAL WET PREP

Not done   
1a. Homogeneous vaginal discharge  negative  positive  
1b. pH ..... □□ → If > 4.5 mark as positive. →   
1c. Whiff test .....  negative  positive  
1d. Clue cells ≥ 20% .....  negative  positive  
1e. Trichomonads .....  negative  positive  
1f. Buds and/or hyphae (yeast) .....  negative  positive

Not done/ Not collected   
Alternate Collection Date dd MMM yy  
□□ □□□□ □□

2. STD SEROLOGY

2a. Syphilis screening test .....  non-reactive  reactive  
2a1. Titer 1: □□□□ → If non-reactive, go to item 3a.  
2b. Syphilis confirmatory test .....  negative  positive

Not done/ Not collected   
Alternate Collection Date dd MMM yy  
□□ □□□□ □□  
  
□□ □□□□ □□

3. OTHER STD TESTS

3a. N. gonorrhea .....  negative  positive  
3b. C. trachomatis .....  negative  positive

Not done/ Not collected   
Alternate Collection Date dd MMM yy  
□□ □□□□ □□  
  
□□ □□□□ □□

4. Trichomonas Rapid Test .....  negative  positive  
5. ~~NO LONGER APPLICABLE FOR THIS PROTOCOL~~ .....  negative  positive

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

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## Sexually Transmitted Diseases Results (STR-1)

**Purpose:** This form is used to document sexually transmitted disease test results obtained during the study.

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

**Initial 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 Initial Collection Date. 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.

**Not done/Not collected:** For each item, mark *either* the “Not done/Not collected” box *or* enter a test result(s). For items 1a–1f, mark the “Not done” box if a particular test is not done.

### Item-specific Instructions:

- **Item 1a:** Only mark “negative” or “positive” if a clinical work-up for BV is performed. If homogenous vaginal discharge is observed but BV work-up is not done, mark this item as “Not done” and record the abnormal discharge on the Pelvic Exam Diagrams and Medical History Log non-DataFax forms.
- **Item 2a1:** Remember to use leading zeros when recording syphilis titer level. For example, a titer level of 1:4 is recorded as “1:0004.”
- **Items 3a and 3b:** If a result of “indeterminate” is received, do not record this result. Repeat the testing and/or specimen collection until a result of “positive” or “negative” is received, and record that result on the form. Also record “Alternate Collection Date” if additional specimens are collected for this testing.