

ART Visits

Required forms

- ART Study Visit (ASV-1)
- Specimen Storage (SS-1)
- Laboratory Results–Revised–Version 2 (LAB-1)
- Social Harms Assessment (SH-1~SH-5)
- Antiretroviral Therapy Adherence (ATA-1~ATA-5)
- ART Enrollment (AEN-1)

If Applicable:

- Non-ART Concomitant Medications Log (NCM-1)
- Antiretroviral Treatment Regimen Log (TXR-1)
- HIV/AIDS-associated Events Log (HA-1)
- Sexually Transmitted Diseases Results (STR-1)
- Pregnancy Report and History (PR-1)
- Pregnancy Outcome (PO-1)
- Non-ART Study Visit (NSV-1)—*Required if the participant switched to the ART Follow-up Visit schedule at this visit*
- ACASI Tracking (ACT-1)
- Follow-up Behavioral Questionnaire (FBQ-1~FBQ-10)
- Follow-up Behavioral Questionnaire–Version 2 (FQ-1~FQ-3)
- Protocol Deviation Log (PDL-1)
- Missed Visit (MV-1)
- Participant Transfer (PT-1)
- Participant Receipt (PRC-1)

This page intentionally left blank.



MTN 015 (143)

ASV-1 (110)

Visit Code

. 0

1

Participant ID

- -

Site Number

Participant Number

Chk

ART Study Visit

Visit Date

dd

MMM

yy

1. Is the participant completing a parent protocol visit at this MTN 015 visit?

yes

no

→ **If no, end of form.**

1a. Visit code of parent protocol visit completed today:

visit code

.

Comments: _____

29-FEB-08

0 1

Language

Staff Initials / Date

ART Study Visit (ASV-1)

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

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

Item-specific Instructions:

- **Visit Code:** Only visit codes assigned to ART visits should be recorded. ART visits are assigned visit codes ranging from 30.0 through 57.0.
- **Items 1 and 1a:** If the participant is completing a parent protocol visit (regular visit or interim visit) on this same day, mark item 1 “yes” and in 1a, record the visit code (regular or interim) of the parent protocol visit completed on this date.



Visit Code

□□.□□

MTN 015 (143)

SS-1 (161)

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: _____

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.

Laboratory Results—Revised--Version 2 (LAB-1)	
Purpose:	This form is used to document absolute CD4+, HIV plasma RNA, and pregnancy test results obtained during the study.
General Information/ Instructions:	<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>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.</p> <p>Alternate Collection Date: 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>Not done/Not collected: 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>
Item-specific Instructions:	
Item 1a:	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.
Item 2a:	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."
Item 2b:	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.
Item 3:	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

□□.□□

1

Participant ID

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

Social Harms Assessment

Visit Date

□□ □□□□ □□
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?

<i>possibly related</i>	<i>probably related</i>	<i>definitely related</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

□□□ 29-FEB-08

01

Language

Staff Initials / Date

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.

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

□□.□

1

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:

Local Language: _____

English: _____

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

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.

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

Participant ID form with Site Number, Participant Number, and Chk fields.

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 If no, go to item 7d.

7c1. Please describe the problem: Local Language:

Blank line for Local Language description.

English:

Blank line for English description.

7d. physical or other harm to your children?

yes no If no, end of form.

7d1. Please describe the problem: Local Language:

Blank line for Local Language description.

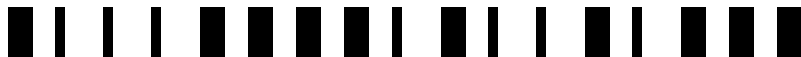
English:

Blank line for English description.

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.



MTN 015 (143)

ATA-1 (151)

Visit Code .

1

Participant ID

- -

Site Number

Participant Number

Chk

Antiretroviral Therapy Adherence

Visit Date

dd

MMM

yy

1. Have you been prescribed any HIV medication (ARVs) today or since the last visit?.....

yes

no

If no, end of form. Do not fax pages 2-4.

2. ~~NO LONGER APPLICABLE FOR THIS PROTOCOL~~ Have you missed any of your HIV medication (ARVs)?

- within the past week
- 1-2 weeks ago → *If 1-2 weeks ago, go to item 5 on page 2.*
- 2-4 weeks ago → *If 2-4 weeks ago, go to item 5 on page 2.*
- 1-3 months ago → *If 1-3 months ago, go to item 5 on page 2.*
- more than 3 months ago → *If more than 3 months ago, end of form. Do not fax pages 2-4.*
- never miss taking HIV medication (ARVs) → *If never miss taking medicine, end of form. Do not fax pages 2-4.*
- don't know

NO LONGER APPLICABLE FOR THIS PROTOCOL

3. During the past 4 days, **for how many days** have you missed taking **all your HIV medication (ARVs)**?

none

1 day

2 days

3 days

4 days

Go to item 7 on page 2.

4. ~~NO LONGER APPLICABLE FOR THIS PROTOCOL~~ Some people find that they forget to take their HIV medication (ARVs) on weekend days. Did you miss any of your HIV medication (ARVs) last Saturday or Sunday?

yes

NO LONGER APPLICABLE FOR THIS PROTOCOL

Antiretroviral Therapy Adherence (ATA-1)

The intent of items 1 and 3 is to assess the participant's access to and uptake of HIV care and treatment. The questions measure adherence to medication/ARVs and factors that influence adherence to ARVs.



MTN 015 (143)

ATA-2 (152)

Visit Code .

Participant ID

- -
 Site Number Participant Number Chk

Antiretroviral Therapy Adherence

5. ~~Now I'm going to ask you about the HIV medication (ARVs) you have been prescribed and if you have missed taking any of the HIV medication (ARVs) in the past 2 weeks, and in the past 30 days. If you only took a portion of a dose on one or more of these days, report the dose as being missed.~~

	Med code	Abbreviation/Name of your drugs	# of prescribed doses missed (past 2 weeks)	# of prescribed doses missed (past 30 days)
5a.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5b.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5c.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5d.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
5e.	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

NO LONGER APPLICABLE FOR THIS PROTOCOL

6. ~~How many days have you not been able to take your HIV medication (ARVs) in the past 30 days because you did not have pills and could not get more?~~

of days

yes no

7. Have you **taken any HIV medication (ARVs) in the past month?**

8. In the **past month**, how often have you **missed taking your HIV medication (ARVs)** because you:

Read each response option aloud.

	never	rarely	sometimes	often
8a. wanted to avoid side effects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8b. could not follow dietary instructions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8c. were sharing ART with other family members and friends?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8d. religious beliefs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Antiretroviral Therapy Adherence (ATA-2)

The intent of items 7 and 8 is to assess the participant's access to and uptake of HIV care and treatment. The questions measure adherence to medication/ARVs and factors that influence adherence to ARVs.



MTN 015 (143)

ATA-3 (153)

Visit Code

1

Participant ID

- -

Site Number Participant Number Chk

Antiretroviral Therapy Adherence

Read each response option aloud.

- | | <i>never</i> | <i>rarely</i> | <i>sometimes</i> | <i>often</i> |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 8e. do not fully understanding the regimen and its requirements? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8f. were traveling away from home? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8g. had transportation problems getting to the clinic? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8h. lost pills? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8i. had too many pills? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8j. had a bad event happen that you felt was related to taking the pills? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8k. forgot? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8l. ran out of pills? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8m. were busy doing other things? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8n. tired of taking too many pills? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8o. other illness or health problems got in the way? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8p. stigmatization (what others may say or discover about my disease)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8q. fear of stigmatization within the home (e.g., not wanting the husband to know)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

29-FEB-08

Language

Staff Initials / Date

Antiretroviral Therapy Adherence (ATA-3)

Item-specific Instructions:

- **Item 8p:** This question refers to stigmatization from people outside one's family.



MTN 015 (143)

ATA-4 (154)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Antiretroviral Therapy Adherence

Read each response option aloud.

- | | <i>never</i> | <i>rarely</i> | <i>sometimes</i> | <i>often</i> |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 8r. pills got damaged from heat or getting wet? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8s. were too ill to attend clinic to collect drugs? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8t. pills getting stolen (e.g., while in transit in a taxi/
bus station)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8u. having to wake up very early to commute and no time
to eat? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8v. didn't think they would really work? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8w. were bothered by your dreams? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8x. clinic or doctor did not have pills for you? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8y. other, specify below: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Local Language: _____ | | | | |
| English: _____ | | | | |

Antiretroviral Therapy Adherence (ATA-4)

Item-specific Instructions:

- **Item 8y:** If “other, specify” is marked, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.



MTN 015 (143)

AEN-1 (075)

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

ART Enrollment

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>dd</i>		<i>MMM</i>			<i>yy</i>

1. Date of ART initiation:

dd *MMM* *yy*

1a. Is this date known or estimated?.....

<i>known</i>	<i>estimated</i>
<input type="checkbox"/>	<input type="checkbox"/>

2. Is the date of ART initiation within 24 months of date of seroconversion?

<i>yes</i>	<i>no</i>
<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

05-MAY-17

ART Enrollment (AEN-1)

Purpose: This form is used to document those participants who enroll in the study after initiation of ART or who initiate ART during the study. Completion of this form indicates the participant is being followed using the ART visit schedule/visit calendar.

General Information/Instructions: This form is completed only once for each participant, and is completed at the visit where it is determined the participant will be followed using the ART visit schedule/visit calendar.

Item-specific Instructions:

- **Item 1:** Record the date the participant first used ART. A complete date (day, month, and year) is required. If the exact day is not known, use “15” as the day and mark item 1a as “estimated.”