

Plate 001 DM-1: Mother's Demographics (page 1)

Visit Code

HPTN 046 Ext NVP Mother (089) DM-1 (001)

Page 1 of 2

Participant ID

Mother's Demographics

- - -
Site Number Participant Number Chk Cohort

Mother's Demographics

Form Completion Date

dd MMM yy

1. Mark the appropriate racial category for this participant:

DMrace
 White
 Indian
 other, specify: DMracex

2. What is the participant's date of birth?

dd MMM yy → If unknown, record age: years

3. How many years of education has the mother had (excluding kindergarten, pre-school, and repeated years)?

years

yes no

4. Does the mother earn income by working outside the home?

DMwork

5. What kind of housing does the mother live in?

DMhou house
 rent room
 own house
 staff quarters
 stay with relatives
 other, specify: DMhoux

Plate 002 DM-2: Mother's Demographics (page 2)

Visit Code

HPTN 046 Ext NVP Mother (089) DM-2 (002)

Page 2 of 2

Participant ID

ptid - - -
Site Number Participant Number Chk Cohort

Mother's Demographics

6. What is the mother's current marital status?

- ~~DMmar~~ er married / not living with partner
- married
- living with partner
- separated
- divorced
- widowed

7. What utilities does the mother have on her premises?

yes no

7a. electricity ~~DMelec~~

7b. running water ~~DMwatr~~

8. What does the mother use for cooking each day? *Mark all that apply.*

~~DMcooke~~ stove

~~DMcookg~~ ove

~~DMcookp~~ n stove

~~DMcookc~~ al stove

~~DMcookf~~ od

Plate 005 MSO-1: Mother's Screening Outcome

Visit Code

HPTN 046 Ext NVP Mother (089) MSO-1 (005)

Page 1 of 1

Participant ID

Mother's Screening Outcome

Form Completion Date

ptid - - -
 Site Number Participant Number Chk Cohort

Mother's Screening Outcome

MSfcdt
 dd MMM yy

1. Date mother provided informed consent:

MSconsdt
 dd MMM yy

yes no

2. Was this mother's infant randomized?

MSirand

If yes, end of form. Submit all mother and infant forms for screening, enrollment, birth, and randomization.

3. Reason infant(s) not randomized:

MSnrme not eligible: Mark all that apply.

- MSnrmage 18 years old
- MSnrmcon sign informed consent
- MSnrmpg pregnant
- MSnrmhiv HIV infected
- MSnrmill illness or condition that prohibits participation in the study
- MSnrmbfd intend to breastfeed
- MSnrmsit does not intend to deliver at study site

MSnrine (Infant(s)) not eligible: Mark all that apply.

- MSnrribld HIV DNA PCR, CBC, and ALT not collected within 3 days of birth
- MSnrribwt weight less than 2000 grams
- MSnrriubf infant unable to breastfeed
- MSnrriidbf mother decided against breastfeeding
- MSnrrirsh 2, 3, or 4 rash
- MSnrrihep exposed or suspected hepatitis
- MSnrriill illness or condition that prohibits participation in the study
- MSnrrialt ALT Grade 2 or above
- MSnrrihem hemoglobin, absolute neutrophil count, or platelet count Grade 2 or above

- MSnrstil /infant death
- MSnrnsit mother did not deliver at site and did not return within 3 days
- MSnrnret infant did not return for randomization
- MSnrref mother refused
- MSnrrifaf infant on rifampin or oral ketaconazole
- MSnrroth other specify: MSnrrothx

Comments: MScomm

Plate 006 MSO-1: Protocol 3 Mother's Screening Outcome

Visit Code

HPTN 046 Ext NVP Mother (089) MSO-1 (006)

Page 1 of 1

Participant ID

- - -
 Site Number Participant Number Chk Cohort

Mother's Screening Outcome

Protocol Version 3.0
 Mother's Screening Outcome

Form Completion Date

dd MMM yy

1. Date mother provided informed consent:

dd MMM yy

2. Was this mother's infant enrolled?

yes no

If yes, end of form. Submit all mother and infant forms for screening and enrollment.

3. Indicate the reason the infant(s) was not enrolled. *Mark only one.*

MSnotenr mother not eligible *Go to item 3a1.*

3b. infant(s) not eligible *Go to item 3b1.*

3c. stillbirth/infant death

3d. mother did not deliver at site and did not return within 7 days

3e. mother/infant did not return for enrollment

3f. mother refused

3g. infant on rifampin or oral ketaconazole

3h. other, specify:

End of form.

3a1. Indicate the reason(s) the mother is not eligible. *Mark all that apply.*

less than 18 years old

serious illness or condition that prohibits participation in the study

did not sign informed consent

does not intend to breastfeed

not pregnant

does not intend to deliver at study site

not HIV-infected

End of form.

3b1. Indicate the reason(s) the infant is not eligible. *Mark all that apply.*

HIV, CBC, and ALT not available within 7 days of birth

serious illness or condition that prohibits participation in the study

birthweight less than 2000 grams

ALT Grade 2 or above

mother/infant unable to breastfeed

hemoglobin, absolute neutrophil count, or platelet count Grade 2 or above

mother decided against breastfeeding

Grade 2b, 3, or 4 rash

positive HIV test results

confirmed or suspected hepatitis

Plate 007 ENR-1: Mother's Enrollment (page 1)

Visit Code

HPTN 046 Ext NVP Mother (089) ENR-1 (007)

Page 1 of 4

Participant ID

Mother's Enrollment

ptid - - -
 Site Number Participant Number Chk Cohort

Mother's Enrollment

Infant Enrollment Date

MEirdt
 dd MMM yy

Eligibility Checklist (at Time of Informed Consent)

1. Is the mother 18 years of age or older? **MEage** *yes no*
2. Is the mother willing and able to provide study informed consent?..... **MEcons**
3. Is the mother in the third trimester of pregnancy or on or before day 3 after delivery?..... **MEpreg**
4. Is the mother HIV-infected by WHO acceptable diagnostic HIV-1 infection criteria for adults (two positive EIAs, or one positive EIA and one positive Western Blot, or two separate rapid tests)? **MEhiv**
5. Does the mother intend to breastfeed?..... **MEbfd** *N/A*
6. If not already delivered, does the mother intend to deliver at your study site? ... **MEsite**
7. Has the mother been judged by the on site clinician to have no serious medical condition that would interfere with participation in the study (e.g., a condition that would prevent breastfeeding or adherence to the follow-up schedule)? **MEinill**

NOT APPLICABLE TO VERSION 3.0 OF PROTOCOL

History

8. Total number of pregnancies, including this pregnancy:..... **MEtpreg**
9. Total number of prior live births:..... **MElive**
10. Has the mother taken nevirapine for prevention of mother-to-child transmission of HIV in previous pregnancies? **MEpnv** *yes no* **→ If no, go to item 11.**

10a. Dates of previous nevirapine doses by mother's self-report:

MMM yy MMM yy MMM yy
MEpnv1my **MEpnv2my** **MEpnv3my**

MEpnv1dt **MEpnv2dt** **MEpnv3dt**

11. Did the mother take any antiretroviral medications, other than standard-of-care nevirapine, during this pregnancy?..... **MEart** **→ If no, go to item 12 on page 2.**
- 11a. Antiretroviral medications as treatment?..... **MEarttx** **→ If yes to either, complete Mother's Antiretroviral Medication Log.**
- 11b. Antiretroviral medications other than nevirapine for prevention of mother-to-child transmission of HIV?..... **MEartmc** **→**

Comments: **ME1comm**

05-OCT-07

formlang **sfdt_007**

Participant ID

ptid - - -
 Site Number Participant Number Chk Cohort

Mother's Enrollment

Delivery Information **MEdelqc**

12. Did participant deliver at your study site? **MEdeliv** yes no ▶ *If no, complete as many of items 13-17 as possible.*

13. Onset of labor: **MElabdt** **MElabtm** 24-hour clock
dd MMM yy hr min

14. Membranes ruptured: **MErupdt** **MEruptm** 24-hour clock
dd MMM yy hr min

15. Date of delivery: **MEdlvdt**
dd MMM yy

16. Type of amniotic fluid: *Mark all that apply.*

MEafcler **MEafpuru**
 MEafmeco **MEafoth** specify: MEafothx
 MEafbldy

17. Was an episiotomy performed, or were there any primary vaginal/cervical tears?..... **MEepiter** yes no

Instruction: Items 18-19 must be completed for all participants, even if mother does not deliver at study clinic or hospital.

18. Birth was: *singleton* **MEbhtyp** *twin* *triplet*

19. Outcome of pregnancy:

stillbirth **MEoutcma** *liveborn infant* *infant's PTID (liveborn infants only)*

19a. first born **MEptida** - - -

19b. second born **MEptidb** - - -

19c. third born **MEptidc** - - -

Comments: **ME2comm**

Participant ID

ptid - - -
Site Number Participant Number Chk Cohort

Mother's Enrollment

Nevirapine Dosing

Instruction: Items 20–21 must be completed for all participants, even if mother does not deliver at study clinic or hospital.

20. Was the mother dosed with standard-of-care nevirapine during this delivery?... **ME1nvp** **no**
If yes, go to item 20b.

20a. Reason not dosed:

ME1nonvp refused
 arrived in second stage or after delivery
 other, specify: **ME1nonvpx**
Go to item 22 on page 4.

ME1nqc 20b. First dose:

Date:
dd MMM yy Time: 24-hour clock **ME1nsrc** ward
 self-report/estimate

21. Was the mother redosed with nevirapine due to false labor, vomiting, or other causes?..... **ME1redos** **no**
If no, go to item 22 on page 4.

21a. What was the reason for redosing? Mark all that apply.

ME1nreaf labor
 ME1nreav vomiting
 ME1nreao other, specify: **ME1nreaox**

ME2nqc 21b. Second dose:

Date:
dd MMM yy Time: 24-hour clock **ME2nsrc** ward
 self-report/estimate

Comments: **ME3comm**

Plate 010 ENR-4: Mother's Enrollment (page 4)

Visit Code

HPTN 046 Ext NVP Mother (089) ENR-4 (010)

Page 4 of 4

Participant ID

- - -
Site Number Participant Number Chk Cohort

Mother's Enrollment

Breast Exam

22. Right breast: normal abnormal

If abnormal, record below. Mark all that apply.
 MEbercs **MEberu**s **MEberp**ent/bloody discharge
 MEbermtitis **MEbero**, specify:

23. Left breast: normal abnormal

If abnormal, record below. Mark all that apply.
 MEbelcs **MEbelu**s **MEbelp**ent/bloody discharge
 MEbelmtitis **MEbelo**, specify:

Comments:

05-OCT-07

Language Staff Initials / Date

Plate 022 MLR-2: Mother's Laboratory Results (page 2)

Visit Code **visit**

HPTN 046 Ext NVP Mother (089) MLR-2 (022)

Page 2 of 2

Participant ID

ptid [] - [] - [] - []
Site Number Participant Number Chk Cohort

Mother's Laboratory Results

p22v8

Alternate Collection Date

Not done/ Not collected dd MMM yy
MRdif MRdifdt [] [] [] []

5. DIFFERENTIAL

	Not reported	percentage	OR	Absolute Count cells/mm ³
5a. Neutrophils	MRneum	MRneup	[]	MRneu
5b. Lymphocytes	MRlym	MRlymp	[]	MRlym
5c. Monocytes	MRmon	MRmonp	[]	MRmon
5d. Eosinophils	MReos	MReosp	[]	MReos
5e. Basophils	MRbas	MRbasp	[]	MRbas
5f. Other, specify: <u>MRodx</u>	MRodn	MRodp	[]	MRod

Alternate Collection Date

Not done/ Not collected dd MMM yy
MRtcl MRtcldt [] [] [] []

6. T CELL SUBSETS

	Unable to analyze	cells/mm ³
6a. Absolute CD4+	MRcd4	MRcd4

Alternate Collection Date

Not done/ Not collected dd MMM yy
MRhrp MRhrpdt [] [] [] []

7. HIV TEST RESULTS

	>	=	<	viral copies/mL
7a. HIV RNA PCR (plasma)	MRhrpo			MRhrp

Comments: MR2comm

[] [] [] [] 30-NOV-05

formlang sfdt_022

Plate 031 CS-1: Mother's WHO Clinical Stage Assessment (page 1) **visit**

HPTN 046 Ext NVP Mother (089) CS-1 (031) Page 1 of 3

Participant ID

ptid - - -
 Site Number Participant Number Chk Cohort

Mother's WHO Clinical Stage Assessment

Mother's WHO Clinical Stage Assessment

Assessment Date

CSadt
 dd MMM yy

1. Current visit:

CScurvis baseline assessment → **Go to item 2.**

follow-up assessment

1a. Has mother's WHO Clinical Stage increased since the last WHO Clinical Assessment form was submitted? **CSincrs** yes no → **If no, end of form.**

2. WHO Clinical Stage I **CS1yn** yes no → **If no, go to item 3.** CS1qc

2a. Which of the following symptoms indicate that the mother is Clinical Stage I?
 Mark all that apply

CS1asy symptomatic

CS1pgl persistent generalized lymphadenopathy

3. WHO Clinical Stage II **CS2yn** yes no → **If no, go to item 4 on page 2.** CS2qc

3a. Which of the following symptoms indicate that the mother is Clinical Stage II?
 Mark all that apply

CS2wt1 weight loss, < 10 percent of body weight

CS2muc mucocutaneous manifestations (e.g., seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilitis)

CS2hzs herpes zoster within the last 5 years

CS2uri recurrent upper respiratory tract infections (e.g., bacterial sinusitis)

CS2sna performance scale 2: symptomatic, normal activity

Comments: **CS1comm**

Plate 032 CS-2: Mother's WHO Clinical Stage Assessment (page 2) Visit

HPTN 046 Ext NVP Mother (089) CS-2 (032)

Participant ID

ptid - - -
 Site Number Participant Number Chk Cohort

Mother's WHO Clinical Stage Assessment

4. WHO Clinical Stage III ^{yes} ^{no} **CS3yn** **CS3qc**
 If no, go to item 5 on page 3.

4a. Which of the following symptoms indicate that the mother is Clinical Stage III?
 Mark all that apply

- CS3wt1** Weight loss, > 10 percent of body weight
- CS3ucd** Unexplained chronic diarrhea, > 1 month
- CS3fev** Unexplained prolonged fever (intermittent or constant), > 1 month
- CS3thr** Candidiasis (thrush)
- CS3ohl** Oral hairy leukoplakia
- CS3ptb** Pulmonary tuberculosis within the past year
- CS3inf** Frequent bacterial infections (e.g., pneumonia, pyomyositis)
- CS3bdr** Barthel's performance scale 3: bedridden < 50 percent of the day during the last month
- CS3ant** Unexplained anemia, neutropenia, and/or chronic thrombocytopenia
- CS3nec** Necrotizing ulcerative stomatitis, gingivitis, or periodontitis

Plate 033 CS-3: Mother's WHO Clinical Stage Assessment (page 3) **visit**

HPTN 046 Ext NVP Mother (089) CS-3 (033)

Participant ID

ptid - - -
 Site Number Participant Number Chk Cohort

Mother's WHO Clinical Stage Assessment

5. WHO Clinical Stage IV **CS4yn** **no** **yes** **If no, end of form.** **CS4qc**

5a. Which of the following symptoms indicate that the mother is Clinical Stage IV?
 Mark all that apply

- CS4wst** Wasting syndrome, as defined by the CDC: weight loss of > 10 percent of body weight, plus either unexplained chronic diarrhea (> 1 month) or chronic weakness and unexplained prolonged fever (> 1 month)
- CS4pcp** *Pneumocystis carinii* pneumonia
- CS4tox** Toxoplasmosis of the brain
- CS4crd** Cryptosporidiosis with diarrhea > 1 month
- CS4cre** Cryptococcosis, extrapulmonary
- CS4cyt** Cytomegalovirus disease of an organ other than the liver, spleen, or lymph nodes
- CS4hsv** Herpes simplex virus infection, mucocutaneous > 1 month, or visceral any duration
- CS4pml** Progressive multifocal leukoencephalopathy
- CS4dis** Disseminated endemic mycosis (e.g., histoplasmosis, coccidioidomycosis)
- CS4cnd** Candidiasis of the esophagus, trachea, bronchi, or lungs
- CS4icc** Invasive cervical carcinoma
- CS4atm** Atypical mycobacteriosis, disseminated
- CS4hiv** Asymptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy
- CS4sal** Typhoid Salmonella septicaemia
- CS4adl** Atypical disseminated leishmaniasis
- CS4etb** Extrapulmonary tuberculosis
- CS4bpn** Bacteremic severe bacterial pneumonia
- CS4lym** Lymphoma
- CS4iso** Isosporiasis
- CS4kap** Kaposi's sarcoma
- CS4enc** Encephalopathy, as defined by the CDC: clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection which could explain the findings
- CS4bdr** Barthel's performance scale 4: bedridden > 50 percent of the day during the last month

Plate 041 MFU-1: Mother's Follow-up Visit

Visit Code

HPTN 046 Ext NVP Mother (089) MFU-1 (041)

Page 1 of 1

Participant ID

Mother's Follow-up Visit

- - -
 Site Number Participant Number Chk Cohort

Mother's Follow-up Visit

Visit Date

dd MMM yy

1. Weight: kilograms

2. Physical exam and history since last scheduled visit:
 normal abnormal
 If normal, go to item 3.

2a. Specify diagnoses or exam findings: Mark all that apply.

- ralized wasting
- regaly
- ralized lymphadenopathy
- monia
- osi's sarcoma
- spiratory infection
- regaly
- specify:

3. Breast exam:

3a. Right breast:
 normal abnormal
 If abnormal, record below. Mark all that apply.

ent/bloody discharge

specify:

3b. Left breast:
 normal abnormal
 If abnormal, record below. Mark all that apply.

ent/bloody discharge

specify:

4. Was breast milk collected at this visit?
 yes no
 If no, go to item 5.

4a. From which breast was breast milk collected?
 right left both

5. Has the mother taken any new antiretroviral medications or changed therapy since the last visit, or at this visit?
 yes no
 If yes, update Mother's Antiretroviral Medication Log.

Comments:

30-NOV-05

Plate 411 MAM-1: Mother's Antiretroviral Medication Log

visit

Page

HPTN 046 Ext NVP Mother (089) MAM-1 (411)

Participant ID Mother's Antiretroviral

ptid - - -
Site Number Participant Number Chk Cohort

Mother's Antiretroviral Medication Log

ARrefax at participant termination.

ARmedqc

		Date started			Date stopped			Continuing at end of study
		dd	MMM	yy	dd	MMM	yy	
1.	<input type="checkbox"/> ARazt (zidovudine; Retrovir)	<input type="checkbox"/> ARaztrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARaztpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARaztcor
2.	<input type="checkbox"/> AR3TC (Lamivudine; Epivir)	<input type="checkbox"/> AR3TCrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> AR3TCpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> AR3TCcor
3.	<input type="checkbox"/> ARcom bivir (AZT + 3TC)	<input type="checkbox"/> ARcomrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARcompdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARcomcor
4.	<input type="checkbox"/> ARddI didanosine; Videx)	<input type="checkbox"/> ARddIrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARddIpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARddIcor
5.	<input type="checkbox"/> ARd4T (Stavudine; Zerit)	<input type="checkbox"/> ARd4Trdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARd4Tpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARd4Tcor
6.	<input type="checkbox"/> ARaba cavir	<input type="checkbox"/> ARabardt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARabapdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARabacor
7.	<input type="checkbox"/> ARNvp rapine (Viramune)	<input type="checkbox"/> ARNvprdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARNvppdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARNvpcor
8.	<input type="checkbox"/> AREfa irenz (Sustiva)	<input type="checkbox"/> AREfardt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> AREfapdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> AREfacor
9.	<input type="checkbox"/> ARind avir (Crixivan)	<input type="checkbox"/> ARindrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARindpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARindcor
10.	<input type="checkbox"/> ARsaq uinavir (Invirase; Fortovase)	<input type="checkbox"/> ARsaqrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARsaqpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARsaqcor
11.	<input type="checkbox"/> ARnel navir (Viracept)	<input type="checkbox"/> ARnelrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARnelpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARnelcor
12.	<input type="checkbox"/> ARrit navir (Norvir)	<input type="checkbox"/> ARritrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARritpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARritcor
13.	<input type="checkbox"/> ARten fovir (Viread)	<input type="checkbox"/> ARtenrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARtenpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARtencor
14.	<input type="checkbox"/> ARtrv o/Triomune (d4T + 3TC + NVP)	<input type="checkbox"/> ARtrvrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARtrvpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARtrvcor
15.	<input type="checkbox"/> ARcov ro (d4T + 3TC)	<input type="checkbox"/> ARcovrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARcovpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARcovcor
16.	<input type="checkbox"/> ARtrz vir (AZT + 3TC + Abacavir)	<input type="checkbox"/> ARtrzrdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARtrzpdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARtrzcor
17.	<input type="checkbox"/> ARot1 r, specify: <u>ARot1x</u>	<input type="checkbox"/> ARot1rdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARot1pdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARot1cor
18.	<input type="checkbox"/> ARot2 r, specify: <u>ARot2x</u>	<input type="checkbox"/> ARot2rdt	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> ARot2pdt	<input type="text"/>	<input type="text"/>	OR <input type="checkbox"/> ARot2cor

Comments: **ARcomm**

30-NOV-05

formlang **sfdt_411**

Plate 463 MV-1: Mother's Missed Visit

Visit Code

visit

HPTN 046 Ext NVP Mother (089) MV-1 (463)

Participant ID

Mother's Missed

Form Completion Date

ptid - - - -

Mother's Missed Visit

MVfcdt - - - -

Site Number

Participant Number

Chk

Cohort

dd

MMM

yy

Instructions: Record the Visit Code of the scheduled visit that was missed.

Comments: **MVcomm**

Plate 489 MEI-1: Mother's End of Study Inventory

Visit Code

HPTN 046 Ext NVP Mother (089) MEI-1 (489)

Page 1 of 1

Participant ID

Mother's End of Study

- - -
Site Number Participant Number Chk Cohort

Mother's End of Study Inventory

Form Completion Date

dd MMM yy

Instructions: Complete this form whenever a participant terminates from the study.

1. What is the last visit code for which data has been submitted (not including Missed Visit or Comments forms)?

Visit Code

2. What was the last Mother's Antiretroviral Medication Log page number submitted for this participant?.....

page # OR

30-NOV-05

Language Staff Initials / Date

Plate 490 TM-1: Mother's Termination

Visit Code

visit			
-------	--	--	--

HPTN 046 Ext NVP Mother (089) TM-1 (490)

Participant ID

Termination

ptid

--	--	--	--

 -

--	--	--	--

 -

--

 -

--

Mother's Termination

1. Termination Date:

TMtmdt			
--------	--	--	--

--	--	--	--

--	--

Date the site determined that the participant was no longer in the study.

2. Reason for termination. Mark only one.

2a. Scheduled exit visit/end of study. ———▶ End of form.

2b. Death. Indicate date and cause if known.

2b1. Date of death

TMddt			
-------	--	--	--

--	--	--	--

--	--

 OR

TMddun

 unknown
2b2. Cause of death

TMdcau

 OR

TMdcun

 e unknown

2c. Participant refused further participation, specify:

TMrefrx

2d. Participant unable to adhere to visit schedule.
NOT APPLICABLE FOR THIS PROTOCOL.

2e. Participant relocated, no follow-up planned.

2f. Investigator decision, specify:

TMinvdx

2g. Unable to contact participant.

2h. HIV infection.
 2i. Inappropriate enrollment.
NOT APPLICABLE FOR THIS PROTOCOL.

2j. Invalid ID due to duplicate screening/enrollment.

2k. Other, specify:

TMtrmox

2l. Early study closure.

2m. Death of infant.

2n. Infant not randomized.

Comments:

TMcomm

--	--	--	--

 05-OCT-07

formlang	sfdt_490
----------	----------