

Plate 007 IB-1: Infant Birth (page 1)

Visit Code

HPTN 046 Ext NVP Infant (090) IB-1 (007)

Page 1 of 3

Participant ID Infant Birth
 - - -
Site Number Participant Number Chk Cohort

IB1qc
Infant Birth

Birth Date

dd MMM yy

yes no

1. Was infant delivered at the study site clinic or hospital?

vaginal caesarian

2. Type of delivery: **►** *If caesarian, go to item 2b.*

2a. Vaginal birth: *Mark all that apply.*

IBvbspon eous vertex delivery
|
 IBvbbrch
|
 IBvbforc
|
 IBvbvacu extraction
|
 IBvboth specify:
|
► Go to item 3.

elective emergency

2b. Caesarian section:

Identification

24-hour clock

3. Time of birth:
hr min

male female

4. Sex:

4a. Date of enrollment:
dd MMM yy

Comments:

Plate 008 IB-2: Infant Birth (page 2)

Visit Code

HPTN 046 Ext NVP Infant (090) IB-2 (008)

Page 2 of 3

Participant ID

- - -
Site Number Participant Number Chk Cohort

Infant Birth

Physical Exam

5. Birthweight: kilograms

6. Pre-existing conditions and illnesses: *Mark all that apply.*

IBprenon *If none, mark only this response. Go to item 7 on page 3.*

IBskinab *skin abnormality: Mark all that apply.*

IBjaunde, specify:

IBmilia

IBthrush

IBpeelborn peeling skin

IBcnganital anomaly, specify:

IBerthyea toxicum

IBhptmgyegaly (> 2 cm below costal margin)

IBmelant pustular melanosis

IBsepsis sepsis

IBhrashash (miliaria)

IBtachyptachypnea

IBdermatcific dermatitis

IBmeconmm aspiration

IBbmarkark

IBconjunivitis

IBskininfection, specify:

IBopthalia neonatorum

IBskinoskin condition, specify:

IBpeothspecify:

IBpreqc

Comments:

31-OCT-07

Language Staff Initials / Date

Plate 009 IB-3: Infant Birth (page 3)

Visit Code

HPTN 046 Ext NVP Infant (090) IB-3 (009)

Page 3 of 3

Participant ID

- - -
 Site Number Participant Number Chk Cohort

Infant Birth
 IB3qc

7. Has the infant been given any antibiotic, antifungal, or antimicrobial medications since birth?

yes no

 IBmeds

If yes, update the Infant's Concomitant Medications Log.

8. Was infant dosed with standard-of-care nevirapine?

IBnvp

If yes, go to item 8b.

8a. Reason not dosed:

IBnonvp refused
 other, specify: IBnonvpx
 Go to item 10.

Time: 24-hour clock

IB1nsrc staff
 self-report/estimate

8b. First dose given:

Dose: ml
 Date:
 dd MMM yy hr min
 IB1ndose IB1ndt IB1ntm

9. Was the infant redosed due to vomiting or other causes?

yes no

 IBredos

If no, go to item 10.

9a. Why was infant redosed?

IBnreas
 other, specify: IBnreasx

Time: 24-hour clock

IB2nsrc staff
 self-report/estimate

9b. Second dose given:

Dose: ml
 Date:
 dd MMM yy hr min
 IB2ndose IB2ndt IB2ntm

10. Was infant given any other antiretroviral medications?

yes no

 IBart

If yes, complete Infant's Antiretroviral Medication Log.

Comments: IB3comm

Plate 018 IR-1: Infant's Randomization

Visit Code

HPTN 046 Ext NVP Infant (090) IR-1 (018)

Page 1 of 1

Participant ID Infant's Randomization

ptid - - - Infant's Randomization
Site Number Participant Number Chk Cohort

1. Was infant randomized? **IRrand** *yes no* **IRrand** *If no, end of form.*

2. Date randomized: **IRranddt**
dd MMM yy

3. Infant randomized within:
 IRstrata A: mother currently on ART for treatment
 Stratum C: mother not currently on ART for treatment

Immediately fax to SCHARP DataFax after completing items 1-3.

4. Was study drug dosing started? **IRsdds** *yes no* **IRsdds** *If no, complete the Infant Permanent Study Drug Discontinuation form. End of form.*

4a. Date study drug started: **IRsddsdt**
dd MMM yy

4b. Time study drug started: **IRsddstm** *24-hour clock* **IRsddsrc** *self-report/estimate*
hr min

Refax to SCHARP DataFax at the next visit (scheduled or interim)—when item 4 is completed.

Comments: _____

31-OCT-07

formlang **sfdt_018**

Plate 021 ILR-1: Infant's Laboratory Results (page 1)

Visit Code

HPTN 046 Ext NVP Infant (090) ILR-1 (021)

Page 1 of 2

Participant ID Infant's Laboratory Results
 ptid - - -
 Site Number Participant Number Chk Cohort

Initial Specimen Collection Date
 IRcoldt
 dd MMM yy

Infant's Laboratory Results

Specimen Collection for Storage

	stored	N/A	not stored	reason not stored
1. Plasma	<input type="checkbox"/> IRplstr <input type="checkbox"/>		<input type="checkbox"/> →	IRplstrx
2. Dried blood spot	<input type="checkbox"/> IRdbstr <input type="checkbox"/>		<input type="checkbox"/> →	IRdbstrx
3. Cell pellet	<input type="checkbox"/> IRcpstr <input type="checkbox"/>		<input type="checkbox"/> →	IRcpstrx

Not done/
 Not collected Alternate Collection Date
 dd MMM yy
 IRhem IRhemdt

4. HEMOGRAM

Not reported

				AE Severity Grade If applicable	AE Log Page #
<input type="checkbox"/> IRwbcn 1a. WBC	<input type="checkbox"/> IRwbc <input type="text"/>	<input type="text"/>	$\times 10^3/mm^3$	<input type="checkbox"/> IRwbcg <input type="text"/>	<input type="text"/> IRwbcp
<input type="checkbox"/> IRhgbn 1b. Hemoglobin	<input type="checkbox"/> IRhgb <input type="text"/>	<input type="text"/>	g/dL	<input type="checkbox"/> IRhgbg <input type="text"/>	<input type="text"/> IRhgbp
<input type="checkbox"/> IRhctn 1c. Hematocrit	<input type="checkbox"/> IRhct <input type="text"/>	<input type="text"/>	%		<input type="text"/> IRhctp
<input type="checkbox"/> IRmcvn 1d. MCV	<input type="checkbox"/> IRmcv <input type="text"/>	<input type="text"/>	fL		<input type="text"/> IRmcvp
<input type="checkbox"/> IRpltn 1e. Platelets	<input type="checkbox"/> IRplt <input type="text"/>	<input type="text"/>	$cells/mm^3$	<input type="checkbox"/> IRpltg <input type="text"/>	<input type="text"/> IRpltgp

Not done/
 Not collected Alternate Collection Date
 dd MMM yy
 IRtcln IRtcldt

5. T CELL SUBSETS

Unable to analyze $cells/mm^3$

5a. Absolute CD4+ IRcd4n IRcd4

IRcd4p

Not done/
 Not collected Alternate Collection Date
 dd MMM yy
 IRaltn IRaltdt

6. LIVER FUNCTION TESTS

6a. ALT (SGPT) IRalt U/L IRaltg IRaltgp

Comments: IR1comm

06-JUN-06

formlang sfdt_021

Language Staff Initials / Date

Plate 022 ILR-2: Infant's Laboratory Results (page 2)

Visit Code **visit**

HPTN 046 Ext NVP Infant (090) ILR-2 (022)

Page 2 of 2

Participant ID

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

Infant's Laboratory Results

Not done/ Not collected
 Alternate Collection Date
 dd MMM yy
 IRdif IRdifdt [] [] [] []

7. DIFFERENTIAL

	Not reported	percentage	OR	Absolute Count cells/mm ³	AE Severity Grade If applicable	AE Log Page #
7a. Neutrophils	IRneut	IRneup []	OR	IRneu [] [] []	IRneug	IRneupg
7b. Lymphocytes	IRlym	IRlymp []	OR	IRlym [] [] []		
7c. Monocytes	IRmon	IRmonp []	OR	IRmon [] [] []		
7d. Eosinophils	IREost	IREosp []	OR	IREos [] [] []		
7e. Basophils	IRbas	IRbasp []	OR	IRbas [] [] []		
7f. Other, specify: <u>IRodx</u>	IRodn	IRodp []	OR	IRod [] [] []		

Not done/ Not collected
 Alternate Collection Date
 dd MMM yy
 IReia IReiadt [] [] [] []

8. HIV TEST RESULTS

8a. HIV EIA	negative	positive	IHO-1 Log Page #		
IReia	[]	IReia	IReia		
8b. HIV Rapid	negative	positive	IHO-1 Log Page #		
IRrap	[]	IRrap	IRrap		
8c. HIV Qualitative DNA ...	negative	positive	invalid	IHU-1 Log Page #	
IRhqd	[]	IRhqp	[]	IRhqd	
8d. HIV RNA PCR (plasma)	>	=	<	viral copies/mL	IHU-1 Log Page #
IRhrp	[]	IRhrp	[] [] [] [] [] []	IRhrp	
				If ≥ 400 copies/mL:	IRhrp

Comments: IR2comm

[] [] [] [] 06-JUN-06

formlang sfdt_022

Language Staff Initials / Date

HPTN 046 Ext NVP Infant (090) IHU-1 (025)

Participant ID Infant's Confirmatory HIV

ptid - - -
 Site Number Participant Number Chk Cohort

Infant's Confirmatory HIV Results—15 Months and Under

Sample #2 Collection Date

dd MMM yy
 IUs2dt

Visit Code IUs2vis

1. Confirmatory testing (HIV Qualitative DNA or HIV RNA PCR)

Not Done

IUs2hqdn HIV Qualitative DNA..... IUs2hqdn

negative positive invalid

If both sample #1 and #2 are positive, go to item 4.

IUs2hrpn HIV RNA PCR (plasma).....

IUs2hrpo IUs2hrp

> = < viral copies/mL

If both sample #1 and #2 are ≥ 400 copies/mL, go to item 4.

Sample #3 Collection Date

dd MMM yy
 IUs3dt

Visit Code IUs3vis

2. Confirmatory testing (HIV Qualitative DNA or HIV RNA PCR)

Not Done

IUs3hqdn HIV Qualitative DNA..... IUs3hqdn

negative positive invalid

If both sample #2 and #3 are positive or both are negative, go to item 4.

IUs3hrpn HIV RNA PCR (plasma).....

IUs3hrpo IUs3hrp

> = < viral copies/mL

If both sample #2 and #3 are ≥ 400 copies/mL or both are < 400 copies/mL, go to item 4.

Sample #4 Collection Date

dd MMM yy
 IUs4dt

Visit Code IUs4vis

3. Confirmatory testing (HIV Qualitative DNA or HIV RNA PCR)

Not Done

IUs4hqdn HIV Qualitative DNA..... IUs4hqdn

negative positive invalid

IUs4hrpn HIV RNA PCR (plasma).....

IUs4hrpo IUs4hrp

> = < viral copies/mL

negative positive

4. Final test results..... IUhiv

Comments: IUcomm

Plate 027 IHO-1: Infant's Confirmatory HIV Results—Over 15 Months Visit

Page

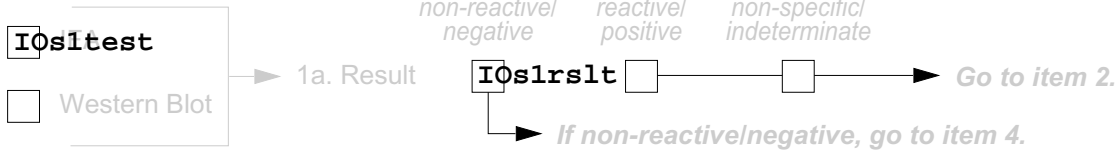
HPTN 046 Ext NVP Infant (090) IHO-1 (027)

Participant ID Infant's Confirmatory HIV

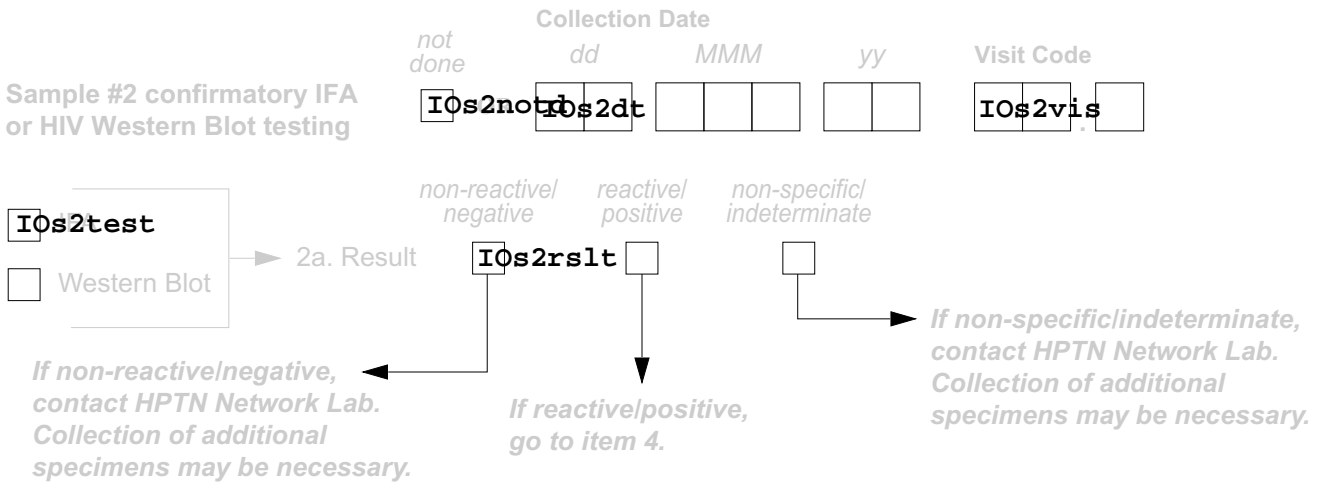
ptid - - - - -
 Site Number Participant Number Chk Cohort

Infant's Confirmatory HIV Results—
 Over 15 Months

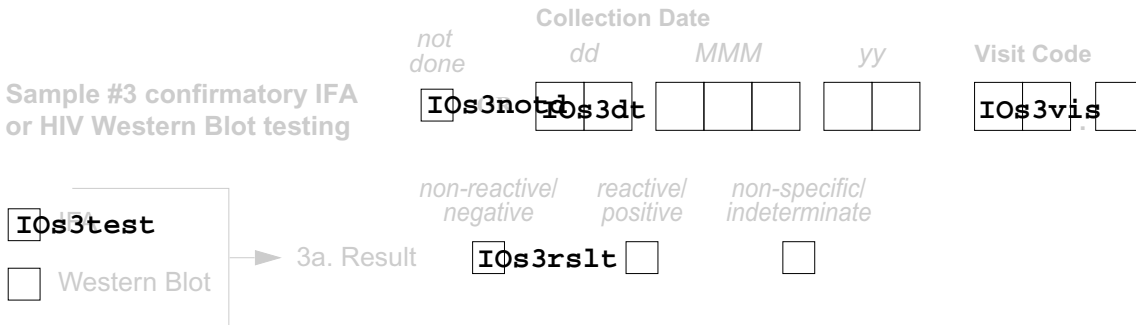
1. Initial sample IFA or HIV Western Blot testing



2. Sample #2 confirmatory IFA or HIV Western Blot testing



3. Sample #3 confirmatory IFA or HIV Western Blot testing



4. Final test results IOhiv

Comments: IOcomm

08-NOV-07

formlang sfdt_027

Language Staff Initials / Date

Plate 033 IDD-1: Infant's Study Drug Dosing (page 1)

Visit Code

HPTN 046 Ext NVP Infant (090) IDD-1 (033)

Page 1 of 2

Participant ID Infant's Study Drug Dosing

- - -
 Site Number Participant Number Chk Cohort

Infant's Study Drug Dosing

Visit Date

dd MMM yy

ISaddqc Since the last visit (scheduled or interim), has the infant been given any open-label NVP/study drug?

2. Since the last visit (scheduled or interim), has a new clinical hold been initiated? → *If no, go to item 3.*

2a. Reason for temporary clinical drug hold: *Mark all that apply.*

toconazole

AE Log page #(s)

verse experience (AE) →

specify:

2b. Date hold started:
(first day open-label NVPI study drug not given)
 dd MMM yy

3. Was dosing on hold at the last visit (scheduled or interim)?
 → *If no, go to item 4.*

3a. If held, has dosing been resumed or will it be resumed at this visit? → *If no, go to item 4.*

3b. Date dosing resumed: → *Go to item 5 on page 2.*
 dd MMM yy

4. Has open-label NVP/study drug been permanently discontinued?.....

If pre-randomization, complete the Open-label NVP Permanent Discontinuation form.

If post-randomization, complete the Permanent Study Drug Discontinuation form.

Comments:

Plate 036 IOD-1: Infant's Open-label NVP Permanent Discontinuation Visit

HPTN 046 Ext NVP Infant (090) IOD-1 (036)

Participant ID

Infant's Open-label NVP

IDsubsum

ptid - - -
Site Number Participant Number Chk Cohort

Infant's Open-label NVP
Permanent Discontinuation

1. Infant enrolled but open-label NVP never started: yes no
IDnosd *If yes, go to item 3.*

2. Date open-label NVP use stopped:
(first day open-label NVP not given) dd MMM yy

3. Reason open-label NVP not started or discontinued:

IDstoprsvisit

AE Log page #(s)

infant death IDdae1p IDdae2p IDdae3p IDdae4p

adverse experience (AE) IDaae1p IDaae2p IDaae3p IDaae4p

HIV infection

breastfeeding never initiated

breastfeeding discontinued early

parental refusal

other, specify: IDstoprx _____

Comments: IDcomm _____

Plate 037 IPD-1: Infant's Permanent Study Drug Discontinuation Visit Code

HPTN 046 Ext NVP Infant (090) IPD-1 (037)

Participant ID

Infant's Permanent Study

IPsubsum

Form Completion Date

ptid - - -
 Site Number Participant Number Chk Cohort

Infant's Permanent Study Drug Discontinuation

IPfcdt
 dd MMM yy

1. Infant randomized but study drug never started: IPnosd
 yes no
 If yes, go to item 3.
2. Date study drug use stopped:
 (first day study drug not given) dd MMM yy
3. Reason study drug not started or discontinued:

IPstoprs visit

AE Log page #(s)

- infant death → IPdae1p IPdae2p IPdae3p IPdae4p
- adverse experience (AE) → IPaae1p IPaae2p IPaae3p IPaae4p
- HIV infection
- breastfeeding never initiated
- breastfeeding discontinued early
- parental refusal
- other, specify: IPstoprx

Comments: IPcomm

Plate 041 IFU-1: Infant's Follow-up Visit (page 1)

Visit Code

HPTN 046 Ext NVP Infant (090) IFU-1 (041)

Page 1 of 2

Participant ID Infant's Follow-up Visit
 - - -
Site Number Participant Number Chk Cohort

Infant's Follow-up Visit

Visit Date

dd MMM yy

Medical History Since Last Study Visit

1. Has the infant been given any antiretroviral medications other than study drug since the last visit, or at this visit?
yes no
 If yes, update Infant's Antiretroviral Medication Log.
2. Has the infant been given any antibiotic, antifungal, or antimicrobial medications since the last visit, or at this visit?.....
 If yes, update Infant's Concomitant Medications Log.
3. Has the infant had any new Adverse Experiences, or increases in severity, since the last visit (scheduled or interim) including this visit?
 If no, go to item 4.
- 3a. How many of these Adverse Experiences are non-serious?
 Update Infant's Adverse Experience Log if 8 months of age or younger.
- 3b. How many of these Adverse Experiences are Serious?
 Update Infant's Adverse Experience Log.
- 3c. How many of these Adverse Experiences were reported to the DAIDS Safety Office as an EAE?

Measurements

4. Current weight:..... kilograms
5. Crown-heel length: centimeters
6. Head circumference: centimeters

General Exam

7. Physical exam and current assessment:
normal abnormal
 If normal, go to item 8 on page 2.
- 7a. Specify diagnoses or exam findings: *Mark all that apply.*

<input type="text" value="IFnothr"/> thrive <input type="text" value="IFthrush"/> thrush <input type="text" value="IFgenlym"/> generalized lymphadenopathy (lymph nodes > 1.5 cm) <input type="text" value="IFsknab"/> abnormality, specify: <input type="text" value="IFsknab"/> <input type="text" value="IFhptmgy"/> hepatomegaly (> 2 cm below costal margin) → <input type="text" value="IFhptcm"/> <input type="text" value="IFsplmgy"/> splenomegaly (> 1 cm below costal margin) → <input type="text" value="IFsplcm"/> <input type="text" value="IFpeoth"/> specify: <input type="text" value="IFpeothx"/>	<input type="text" value="IFdrash"/> (napkin) rash <input type="text" value="IFotitis"/> otitis media <input type="text" value="IFrti"/> irritable upper or lower respiratory tract infection (including bronchiolitis) → <i>Do not report as AE unless meets criteria for expedited reporting.</i> <input type="text" value="IFhptcm"/> <input type="text" value="IFsplcm"/> <input type="text" value="IFpeqc"/>
---	--

Update Infant's Adverse Experience Log if 8 months of age or younger. If older than 8 months of age, update AE Log if serious or meets criteria for expedited reporting.

Comments:

30-NOV-05

Language Staff Initials / Date

Plate 042 IFU-2: Infant's Follow-up Visit (page 2)

Visit Code

HPTN 046 Ext NVP Infant (090) IFU-2 (042)

Page 2 of 2

Participant ID

- - -

Infant's Follow-up Visit

Breastfeeding IFbfdqc

8. Has the infant received any breastmilk since the last scheduled visit?.....

9. Has the infant's breastfeeding status changed since the last scheduled visit?.....

Note: Infant's breastfeeding status has changed if:

- 1. infant has not received any breastmilk for at least 30 days, OR
- 2. infant has restarted breastfeeding after stopping for at least 30 days.

If yes, update Infant's Breastfeeding Log.

10. Since the last visit, has the infant been given anything besides breast milk? **If no, end of form.**

10a. Has the infant received any of the following?

10a1. water

10a2. juice

10a3. formula.....

10a4. cow's milk (fresh or powdered)

10a5. tea.....

10a6. herbs or traditional medicine.....

10a7. cereal or porridge

10a8. other, specify:

Comments:

30-NOV-05

Language Staff Initials / Date

Plate 350 IV-1: Infant's Interim Visit

Visit Code

HPTN 046 Ext NVP Infant (090) IV-1 (350)

Page 1 of 1

Participant ID Infant's Interim Visit

ptid - - -
Site Number Participant Number Chk Cohort

Infant's Interim Visit

Visit Date

ivdt
dd MMM yy

1. Reason for interim visit: *Mark all that apply.*

AE Log page #(s)

IVrae reverse experience (AE) → IVrae1p IVrae2p IVrae3p IVrae4p

IVrholdr hold started → *Complete Infant's Study Drug Dosing form.*

IVrholdp hold ended → *Complete Infant's Study Drug Dosing form.*

IVrdisc permanent dosing discontinuation → *Complete Infant's Open-label NVP Permanent Discontinuation or Infant's Permanent Study Drug Discontinuation and Infant's Study Drug Dosing forms.*

IVrresup open-label NVP/study drug resupply → *Complete Infant's Study Drug Dosing form.*

IVrhiv confirmatory HIV testing → *Complete Infant's Confirmatory HIV Results—15 Months and Under or Infant's Confirmatory HIV Results—Over 15 Months form.*

IVroth, specify: IVrothx

2. Has the infant been given any antiretroviral medications other than open-label NV/study drug since the last visit?

yes no
 IVart

→ *If yes, update Infant's Antiretroviral Medication Log.*

3. Has the infant been given any antibiotic, antifungal, or antimicrobial medications since the last visit, or at this visit?

IVmeds

→ *If yes, update Infant's Concomitant Medications Log.*

Comments:

31-OCT-07

Language Staff Initials / Date

Plate 401 IBL-1: Infant's Breastfeeding Log

visit

Page

HPTN 046 Ext NVP Infant (090) IBL-1 (401)

Participant ID Infant's Breastfeeding Log

ptid - - - -
Site Number Participant Number Chk Cohort

Infant's Breastfeeding Log

Date Breastfeeding Stopped

Date Breastfeeding Re-started

	dd	MMM	yy	Reported at Visit	dd	MMM	yy	Reported at Visit
1.	IGsp1dt			IGsp1vis	IGrs1dt			IGrs1vis
2.	IGsp2dt			IGsp2vis	IGrs2dt			IGrs2vis
3.	IGsp3dt			IGsp3vis	IGrs3dt			IGrs3vis
4.	IGsp4dt			IGsp4vis	IGrs4dt			IGrs4vis
5.	IGsp5dt			IGsp5vis	IGrs5dt			IGrs5vis
6.	IGsp6dt			IGsp6vis	IGrs6dt			IGrs6vis

Comments: IGcomm

30-NOV-05

formlang sfdt_401

Plate 411 IAM-1: Infant's Antiretroviral Medication Log

visit

Page

HPTN 046 Ext NVP Infant (090) IAM-1 (411)

Participant ID

Infant's Antiretroviral Medi-

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

Infant's Antiretroviral Medication Log

ARrefax at participant termination.

ARclinqc

		Date started			Date stopped			Continuing at end of study
		dd	MMM	yy	dd	MMM	yy	
1.	ARazt (zidovudine; Retrovir)	ARaztrdt	[]	[]	ARaztpdt	[]	[]	OR ARaztcor
2.	AR3TC (Lamivudine; Epivir)	AR3TCrdt	[]	[]	AR3TCpdt	[]	[]	OR AR3TCcor
3.	ARcombivir (AZT + 3TC)	ARcomrdt	[]	[]	ARcompdt	[]	[]	OR ARcomcor
4.	ARddI (didanosine; Videx)	ARddIrdt	[]	[]	ARddIpdt	[]	[]	OR ARddIcor
5.	ARd4T (Stavudine; Zerit)	ARd4Trdt	[]	[]	ARd4Tpdt	[]	[]	OR ARd4Tcor
6.	ARabacavir	ARabardt	[]	[]	ARabapdt	[]	[]	OR ARabacor
7.	ARnvpapine (Viramune)	ARnvprdt	[]	[]	ARnvpdpdt	[]	[]	OR ARnvpcor
8.	AREfairenz (Sustiva)	AREfardt	[]	[]	AREfapdt	[]	[]	OR AREfacor
9.	ARindavir (Crixivan)	ARindrdt	[]	[]	ARindpdt	[]	[]	OR ARindcor
10.	ARsaquinavir (Invirase; Fortovase)	ARsaqrdt	[]	[]	ARsaqpdt	[]	[]	OR ARsaqcor
11.	ARnelnavir (Viracept)	ARnelrdt	[]	[]	ARnelpdt	[]	[]	OR ARnelcor
12.	ARritnavir (Norvir)	ARritrdt	[]	[]	ARritpdt	[]	[]	OR ARritcor
13.	ARtenfovir (Viread)	ARtenrdt	[]	[]	ARtenpdt	[]	[]	OR ARtencor
14.	ARtrv or Triomune (d4T + 3TC + NVP)	ARtrvrdt	[]	[]	ARtrvpdt	[]	[]	OR ARtrvcor
15.	ARcovro (d4T + 3TC)	ARcovrdt	[]	[]	ARcovpdt	[]	[]	OR ARcovcor
16.	ARtrzarvir (AZT + 3TC + Abacavir)	ARtrzrdt	[]	[]	ARtrzpdt	[]	[]	OR ARtrzcor
17.	ARot1r, specify: ARot1x	ARot1rdt	[]	[]	ARot1pdt	[]	[]	OR ARot1cor
18.	ARot2r, specify: ARot2x	ARot2rdt	[]	[]	ARot2pdt	[]	[]	OR ARot2cor

Comments: ARcomm

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

formlang sfdt_411

Plate 420 AE-1: Infant's Adverse Experience Log

visit

Page

HPTN 046 Ext NVP Infant (090) AE-1 (420)

EAE # AEsaeo

Participant ID

Infant's

AEsubsum

Date Reported to Site

ptid - - - -
Site Number Participant Number Chk Cohort

Infant's Adverse Experience Log

AErptdt - - - -
dd MMM yy

Flag/Version Aefver MedDRA AEmdra

1. Adverse Experience (AE)

2. Onset Date

AEcodeq AEdiag

AEondt - - - -
dd MMM yy

Record diagnosis if available. Include anatomical location, if applicable.

3. Severity

4. Relationship to Study Product

5. Study Product Administration

AEsleve
 Grade 1 - Mild
 Grade 2 - Moderate
 Grade 3 - Severe AEsleveqc
 Grade 4 - Life-threatening
 Grade 5 - Death

AERelpro
 Definitely related
 Probably related
 Possibly related
 Probably not related
 Not related
Record reason why AE is "not related" in Comments below.

AEdrad
 Change
 Held
 Permanently discontinued
 N/A
 Change in administration
Comment below.

6. Status/Outcome

7. Treatment Mark "None" or all that apply.

AEoutc
 Continuing
 Resolved
 Death
 Severity/frequency increased
Report as new AE.
 Continuing at end of study participation

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

AEocdt - - - -
dd MMM yy

AETrno
AETrrx
AETrho Prolonged hospitalization
Comment below.
AETrpr Procedure/Surgery
Comment below.
AETrot
Comment below.

8. Is this AE serious according to ICH guidelines?
yes no
AEich

9. Has/will this AE be reported as an EAE?
AEdaids

10. This AE was first reported at visit:
Visit code required (regular or interim).
AEvisit
iDreturn holdprevalid

Comments: _____

AEcomm

Plate 423 CM-1: Infant's Con Meds Log

visit

Page

HPTN 046 Ext NVP Infant (090) CM-1 (423)

Participant ID

ptid - - -
 Site Number Participant Number Chk Cohort

Infant's
 Concomitant
 Medications Log

CMnomeds Medications taken throughout study.
 CMsfdtno Staff Initials/Date
 End of form. Fax to SCHARP DataFax.

Infant's Concomitant Medications Log

Medication (generic name) CM1med		<input type="checkbox"/> CM1ndsce <small>clinically significant</small>	Staff Initials/Log Entry Date CM1init
Indication CM1ind		Taken for a reported AE? CM1ae <input type="checkbox"/> no	
Date Started CM1stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped CM1spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM1cont <small>Continuing of study</small>	
		Record AE Log page(s): CM1ae1p CM1ae2p CM1ae3p CM1ae4p	

Medication (generic name) CM2med		<input type="checkbox"/> CM2ndsce <small>clinically significant</small>	Staff Initials/Log Entry Date CM2init
Indication CM2ind		Taken for a reported AE? CM2ae <input type="checkbox"/> no	
Date Started CM2stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped CM2spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM2cont <small>Continuing of study</small>	
		Record AE Log page(s): CM2ae1p CM2ae2p CM2ae3p CM2ae4p	

Medication (generic name) CM3med		<input type="checkbox"/> CM3ndsce <small>clinically significant</small>	Staff Initials/Log Entry Date CM3init
Indication CM3ind		Taken for a reported AE? CM3ae <input type="checkbox"/> no	
Date Started CM3stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped CM3spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM3cont <small>Continuing of study</small>	
		Record AE Log page(s): CM3ae1p CM3ae2p CM3ae3p CM3ae4p	

Medication (generic name) CM4med		<input type="checkbox"/> CM4ndsce <small>clinically significant</small>	Staff Initials/Log Entry Date CM4init
Indication CM4ind		Taken for a reported AE? CM4ae <input type="checkbox"/> no	
Date Started CM4stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped CM4spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM4cont <small>Continuing of study</small>	
		Record AE Log page(s): CM4ae1p CM4ae2p CM4ae3p CM4ae4p	

30-NOV-05

formlang
 Language

Plate 463 MV-1: Infant's Missed Visit

Visit Code

visit

HPTN 046 Ext NVP Infant (090) MV-1 (463)

Participant ID

Infant's Missed Visit

Form Completion Date

ptid - - - -

Infant'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 490 TM-1: Infant's Termination

Visit Code

	visit		
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HPTN 046 Ext NVP Infant (090) TM-1 (490)

Termination

Participant ID

ptid

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Site Number Participant Number Chk Cohort

Infant's Termination

1. Termination Date:

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^{dd}

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^{MMM}

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^{yy} *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

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^{dd}

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^{MMM}

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^{yy} OR 2b1. **TMddun** unknown

2b2. Cause of death **TMdcau** OR 2b2. **TMdcun**e unknown

Complete or update Adverse Experience Log.

2c. Parent(s) refused further participation, specify: **TMrefrx**

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

2e. Parent(s) relocated, no follow-up planned.

2f. Investigator decision, specify: **TMinvdx**

2g. Unable to contact parent(s).

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. Infant not randomized, 3-month visit completed.

3. Was termination associated with...

3a. Adverse Experience?

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^{yes}

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^{no}

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^{don't know} **Record Adverse Experience Log page:**

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^{page #} **TMaelp**

Comments: **TMcomm**

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 31-OCT-07

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formlang

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