

Index ID

secret1

Form fields for Index ID: iid, Index Number, pid, Chk

Index Demographics

Form Completion Date

Form fields for Form Completion Date: IDmfcdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

- 1. What is the participant's date of birth? (IDMbdtt, OR Age: IDMage years)
2. What is the participant's biological sex? (IDMsex, male, female)
3. What is the participant's current marital status? (IDMstat, married, living with partner but not married, separated/married but living separately, divorced, widowed)
4. During the past 12 months, what was the participant's average household monthly income? (IDMhinc, OR IDMhhinc)
5. During the past 12 months, what was the participant's average personal monthly income? (IDMpinc, OR IDMppinc)
6. What is the highest level of education the participant has reached? (IDMedu, schooling, some primary school, completed primary school, some secondary school, completed secondary school, attended college or university, graduate/professional school)

Index ID

Site Number iid Index Number pid Partner Chk

Index Demographics-United States

Form Completion Date

IDUfcdt dd MMM yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's race? Mark all that apply.

IDUatam American Indian or Alaska Native

IDUasian

IDUblack Black American or Black

IDUhawpi Native Hawaiian or other Pacific Islander

IDUwhite

IDUrace other, specify: IDUracox (Note: Latino is not a race.)

2. Does the participant consider themselves to be Latino/a or of Hispanic origin? yes no IDUhispp

3. What is the participant's sexual orientation? Mark only one.

IDUsexo Straight/heterosexual

Gay/homosexual

Bisexual

Not sure

other, specify: IDUsexox

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Demographics—Zimbabwe

Form Completion Date

Form fields for Form Completion Date: IDZfcdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group or tribe? Mark all that apply.

IDZshona

IDZndebele

IDZwhite

IDZtribe: Other African tribe, specify: Local Language English IDZtribx

IDZoeth, specify: Local Language English IDZoethx

2. How many children does the participant have?

of children

IDZchild

3. How did the participant hear of this study? Mark all that apply.

IDZcommunity

IDZfrnds

IDZmedia

IDZpubls health sector

IDZstaff staff

IDZosrc, specify: Local Language English IDZosrcx

Index ID

Site ID: iid - Index Number - Partner: pid - Chk

Index Demographics-India

Form Completion Date

Form Completion Date: IDIfcddt (dd MMM yy)

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group? Mark all that apply.

IDIAsian, including Indian

IDIwhite

IDIoethr, specify: Local Language English IDIoethx

Pune only

2. What is the participant's mother tongue or native language? Mark all that apply.

IDIMarathi

IDIhindi

IDIkanna

IDItelegu

IDIolan, specify: Local Language English IDIolanx

Index ID

Form for Index ID with fields: iid, Index Number, pid, Chk

Index Demographics—Malawi

Form Completion Date

Form for Form Completion Date with fields: IDWfcdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group or tribe? Mark all that apply.

Form for question 1 with checkboxes for ethnic groups: Chewa, Ngoni, Yao, Umbuka, Other African tribe, and Other.

2. What is the participant's current form of employment? Mark all that apply.

Form for question 2 with checkboxes for employment types: unemployed, technical, domestic worker, accounting, housewife, health care, student, religion, business, teacher, military/police, skilled labor, farming, government, driver, unskilled labor.

3. How many children does the participant have? # of children

Form for question 3 with field: IDWchild

4. Does the participant have electricity in their home? yes no

Form for question 4 with field: IDWelect

5. What is the participant's main source of drinking water? Mark only one.

Form for question 5 with checkboxes for water sources: piped water, unprotected well, protected well, borehole, surface water (spring, river/stream, pond/lake, dam)

Index ID

Form for Index ID with fields: iid, Index Number, pid, Chk

Index Demographics-Thailand

Form Completion Date

Form for Form Completion Date with fields: IDTfcdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group or tribe? Mark all that apply.

- List of checkboxes for ethnic groups: IDThai, IDYao, IDKaren, IDLisu, IDTaiyai, IDLahu, IDakha, IDLua, IDHmong, IDToeth

Other, specify: Local Language _____

English IDToethx _____

Plate Number: 007 IDB-1: Index Demographics-Brazil

HPTN 052 (096)

IDB-1 (007)

Visit Code visit

Page 1 of 1

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Demographics-Brazil

Form Completion Date

Form fields for Form Completion Date: IDBfcdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group? Mark all that apply.

IDBlack

IDAsian

IDMixed Race

IDNative

IDWhite

IDBoeth, specify: Local Language _____ English IDBoethx _____

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formlang Language

sfdt_007 Staff Initials / Date

Index ID

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Site Number Index Number Partner Chk

Index Demographics—
Johannesburg/Soweto

Form Completion Date

dd MMM yy

Instructions: Complete this form at Enrollment only.

1. In which race classification does the participant belong? *Mark all that apply.*

IDJwhite White

IDJblack Black *Identify ethnic group or home language.*

1b1. **IDJbkeh** Sotho Other, specify: **IDJbkoex**

IDJmixed Coloured (i.e., mixed race)

IDJasian Asian

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Demographics-Botswana

Form Completion Date

Form fields for Form Completion Date: IDOfcdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

1. How long has the participant been in his/her primary relationship? IDOrelyr years IDOrelmo months

2. How often does this couple stay together?

- IDOstay of the time
most of the time
often
not so often
do not stay together

3. What is the participant's ethnic group?

- IDOtswan
IDOkalanga
IDOeth Other, African tribe; specify: Local Language English IDOoethx

4. How many children does the participant have? IDOkids total # of children

4a. How many children does the participant have with his/her current partner? IDOkidsp total # of children with partner

5. How did the participant hear of this study? Mark all that apply.

- IDOscmm Community
IDOsfrnd Friends
IDOsmed Media; specify: Local Language English IDOSmedx
IDOspubh Public Health Sector
IDOsrec Recruitment Campaign by project staff at (specify): local clinic VCT Centre other venue
IDOsrlc IDOsrcvc IDOsarco
IDOsOTH Other, specify: Local Language English IDOsothx

Index ID

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 Site Number Index Number Partner Chk

Index Pre-existing Conditions

Form Completion Date

dd MMM yy

No pre-existing conditions reported or observed. — End of form. Fax to SCHARP DataFax.

1. Description PRE1desc	Date of Diagnosis/ Surgery MMM yy mm yy PRE1dsmy PRE1dsdt	Comments PRE1com	Is condition ongoing?
			yes no <input type="checkbox"/> PRE1ongo <input type="checkbox"/>

You should keep the year for these diagnoses dates, in addition to the calculated dates on study, which will probably be -xx days for pre-existing conditions

2. Description PRE2desc	Date of Diagnosis/ Surgery MMM yy mm yy PRE2dsmy PRE2dsdt	Comments PRE2com	Is condition ongoing?
			yes no <input type="checkbox"/> PRE2ongo <input type="checkbox"/>

3. Description PRE3desc	Date of Diagnosis/ Surgery MMM yy mm yy PRE3dsmy PRE3dsdt	Comments PRE3com	Is condition ongoing?
			yes no <input type="checkbox"/> PRE3ongo <input type="checkbox"/>

4. Description PRE4desc	Date of Diagnosis/ Surgery MMM yy mm yy PRE4dsmy PRE4dsdt	Comments PRE4com	Is condition ongoing?
			yes no <input type="checkbox"/> PRE4ongo <input type="checkbox"/>

5. Description PRE5desc	Date of Diagnosis/ Surgery MMM yy mm yy PRE5dsmy PRE5dsdt	Comments PRE5com	Is condition ongoing?
			yes no <input type="checkbox"/> PRE5ongo <input type="checkbox"/>

6. Description PRE6desc	Date of Diagnosis/ Surgery MMM yy mm yy PRE6dsmy PRE6dsdt	Comments PRE6com	Is condition ongoing?
			yes no <input type="checkbox"/> PRE6ongo <input type="checkbox"/>

Index ID

Site Number iid, Index Number, Partner pid, Chk

Include this year, in addition to calculated days on study

Initial Collection Date

Initial Collection Date ICHicdt dd MMM yy

Instructions: This form is completed at Enrollment for all index cases. For index cases assigned to the delayed arm, it is also completed at the first visit at which ART is initiated.

Specimen Collection Date

If different from Initial Collection Date

Specimen Collection Date dd MMM yy

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

ICHhemf ICHhemdt

1. H

AE Severity Grade

If applicable

AE Severity Grade 1 2 3 4

Not done

ICHhbnd

1a. H

g/dl

ICHhbgr

ICHhb

ICHhctnd

1b. H

%

ICHhc

ICHmcvnd

1c. H

MCV.....

ICHmcv

fl

ICHmc

ICHpltnd

1d. H

Platelets

ICHplt

cells/mm³

ICHpltgr

ICHpl

Specimen Collection Date

If different from Initial Collection Date

Specimen Collection Date dd MMM yy

ICHwbctnd ICHwbctdt

2. WHITE BLOOD CELLS

AE Severity Grade

If applicable

AE Severity Grade 1 2 3 4

2a. WBC.....

ICHwbctn

x10³/mm³

ICHwbctgr

ICHwb

OR ICHwbcc1

cells/mm³

2b. Differential

Not reported percentage

cells/mm³

AE Severity Grade

If applicable

AE Severity Grade 1 2 3 4

2b1. Neutrophils.....

ICHneupc

OR

ICHneuc1

ICHneugr

ICHne

2b2. Lymphocytes.....

ICHlympc

OR

ICHlymc1

ICHlymgr

ICHly

2b3. Monocytes.....

ICHmonpc

OR

ICHmonc1

ICHmo

2b4. Eosinophils.....

ICHEospc

OR

ICHEosc1

ICHEos

2b5. Basophils.....

ICHbaspc

OR

ICHbascl

ICHba

2b6. Bands.....

ICHbanpc

OR

ICHbancl

ICHba

2b7. Atypical lymphocytes.....

ICHatypc

OR

ICHatycl

ICHat

Comments:

ICHcomm

Include this year, in addition to calculated days on study

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Complete Chemistries

Initial Collection Date

Form fields for Initial Collection Date: ICCicdt, dd, MMM, yy

Instructions: This form is completed at Enrollment for all index cases. For index cases assigned to the delayed arm, it is also completed at the first visit at which ART is initiated.

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected dd MMM yy

Form fields for Specimen Collection Date 1

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

AE Severity Grade If applicable

1 2 3 4

Form fields for AE Severity Grade 1

Form fields for Specimen Collection Date 1a

U/L

Form fields for AE Severity Grade 1a

ICCa1

Form fields for Specimen Collection Date 1b

U/L

Form fields for AE Severity Grade 1b

ICCa2

Form fields for Specimen Collection Date 1c

U/L

Form fields for AE Severity Grade 1c

ICCa3

Form fields for Specimen Collection Date 1d

1d. Total bilirubin

Form fields for Total bilirubin

mg/dL

Form fields for AE Severity Grade 1d

ICCa4

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected dd MMM yy

Form fields for Specimen Collection Date 2

2. ELECTROLYTES

AE Severity Grade If applicable

1 2 3 4

Form fields for AE Severity Grade 2

Form fields for Specimen Collection Date 2a

2a. Sodium.....

Form fields for Sodium

mEq/L

Form fields for AE Severity Grade 2a

ICCa5

Form fields for Specimen Collection Date 2b

2b. Potassium.....

Form fields for Potassium

mEq/L

Form fields for AE Severity Grade 2b

ICCa6

Form fields for Specimen Collection Date 2c

2c. Chloride

Form fields for Chloride

mEq/L

Form fields for AE Severity Grade 2c

ICCa7

Form fields for Specimen Collection Date 2d

2d. Phosphate.....

Form fields for Phosphate

mg/dL

Form fields for AE Severity Grade 2d

ICCa8

Form fields for Specimen Collection Date 2e

2e. CO2/bicarbonate

Form fields for CO2/bicarbonate

mEq/L

Form fields for AE Severity Grade 2e

ICCa9

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected dd MMM yy

Form fields for Specimen Collection Date 3

3. RENAL FUNCTION TESTS

AE Severity Grade If applicable

1 2 3 4

Form fields for AE Severity Grade 3

Form fields for Specimen Collection Date 3a

3a. Creatinine

Form fields for Creatinine

mg/dL

Form fields for AE Severity Grade 3a

ICCa10

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected dd MMM yy

Form fields for Specimen Collection Date 4

4. OTHER CHEMISTRIES

AE Severity Grade If applicable

1 2 3 4

Form fields for AE Severity Grade 4

Form fields for Specimen Collection Date 4a

4a. Albumin.....

Form fields for Albumin

g/dL

Form fields for AE Severity Grade 4a

ICCa11

Comments:

ICCcomm

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Complete Chemistries

Initial Collection Date

Form fields for Initial Collection Date: ICCicdt, dd, MMM, yy

Include this year, in addition to calculated days on study

Instructions: For all index participants: Complete form for Enrollment, Quarterly, Post-ART Initiation (Week 2), and Yearly visits and for the two scheduled monthly visits following ART initiation. For delayed arm participants: Complete this form also at the ART initiation visit.

Form section 1: Alternate Collection Date (dd, MMM, yy) and specimen collection dates (ICCalbk, ICCastk, ICCaltk, ICCtbi)

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

1. 1a. 1b. 1c. 1d. Total bilirubin

Form section 1: Laboratory results (U/L, mg/dL) and AE Severity Grade/Log Page #

Form section 2: Alternate Collection Date (dd, MMM, yy) and specimen collection dates (ICCsdm, ICCpsm, ICCchl, ICCpht, ICCbic)

2. ELECTROLYTES

Form section 2: Laboratory results (mEq/L, mg/dL) for Sodium, Potassium, Chloride, Phosphorus, Bicarbonate

Form section 2: AE Severity Grade/Log Page #

Form section 3: Alternate Collection Date (dd, MMM, yy) and specimen collection date (ICCcre)

3. RENAL FUNCTION TESTS

Form section 3: Laboratory result (mg/dL) for Creatinine

Form section 3: AE Severity Grade/Log Page #

Form section 4: Alternate Collection Date (dd, MMM, yy) and specimen collection date (ICCalb)

4. OTHER CHEMISTRIES

Form section 4: Laboratory result (g/dL) for Albumin

Form section 4: AE Severity Grade/Log Page #

Comments:

ICCcomm

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Screening/Enrollment CD4/Viral Load Results

Initial Collection Date

Form fields for Initial Collection Date: IEVidct, dd, MMM, yy

Include this year, in addition to calculated days on study

Instructions: Complete this form for enrolled participants only.

Form fields for Alternate Collection Date: Not done/Not collected, dd, MMM, yy

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

Form fields for IEVcd4dt

Form fields for lcc1 cells/mm³

IEVt1cq

Form fields for i4cl cells/mm³

IEVcd4c

not available

Form fields for i4pc % OR IEVcd4pn

Form fields for Alternate Collection Date: Not done/Not collected, dd, MMM, yy

Form fields for IEVrnaadt

3. RNA PCR of Plasma

IEVrna

< (less than) = (equal to) > (greater than)

Form fields for IEVrnaeq

Form fields for IEVrna

copies/mL OR IEVrnaun undetectable

Specimen Collection Date

Form fields for Specimen Collection Date: dd, MMM, yy

Screening Results

4. Absolute CD4+

Form fields for IEVcdscl cells/mm³

IEVcdsc

not available

Form fields for 4a. IEVcdspc % OR IEVcdspn

Comments: _____

IEVcomm

Visit Code

Form completion date fields: dd, MMM, yy

Index ID

Index ID fields: iid, Site Number, Index Number, pid, Partner, Chk

Index Enrollment Pregnancy Report and History

Form Completion Date

Form completion date fields: IPRfcddt, dd, MMM, yy

Instructions: Complete this form for all female participants for Enrollment.

PREGNANCY REPORT

1. Date of Enrollment pregnancy test: IPRprgdt (dd, MMM)
2. Result of pregnancy test: IPRprg (negative, positive)

Because this is for enrollment only no need to include a year for this date or dates below. Just calculated days on study

If pregnancy is confirmed, complete Pregnancy Report form.

3. Date of last menstrual period: IPRlmpdt
4. Estimated date of delivery: IPReddt

NO LONGER APPLICABLE FOR THIS PROTOCOL

PREGNANCY HISTORY

5. Has the participant ever been pregnant before? IPRreprg (yes, no)
5a. Number of full term live births (>= 37 weeks): IPRftmbt
5b. Number of premature live births (< 37 weeks): IPRprmbt
5c. Number of spontaneous fetal deaths or stillbirths (>= 20 weeks): IPRstlbt
5d. Number of spontaneous abortions (miscarriages) (< 20 weeks): IPRmscrg
5e. Number of therapeutic/elective abortions: IPRabort
5f. Number of ectopic pregnancies: IPRectpg
6. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? IPRhxcom (yes, no)

If no and participant is currently pregnant, go to item 7 on page 2. If no and participant is not pregnant, end of form and fax only page 1 to SCHARP DataFax.

Index ID

Site Number Index Number Partner Chk

Include year

Index Enrollment

Enrollment Date

dd MMM yy

Instructions: Complete this form for Enrollment only.

IENcqc

Item 2 is for female participants only. Male participants go to item 3.

1. Did the participant take ART for prevention of peripartum transmission for her most recent pregnancy prior to enrolling in this study?

yes no IENartpt

If no, go to item 2.

NO LONGER APPLICABLE FOR THIS PROTOCOL

1a. Record the medication code for each ART medication taken for prevention of peripartum transmission.

1a1. IEN1art 1a2. IEN2art 1a3. IEN3art 1a4. IEN4art 1a5. IEN5art

1b. Date of last ART medication received:

dd MMM yy IENldrtd days

Include year if we have these data

2. Is the participant currently breast feeding?

yes no IENbfeed

3a. Does the participant agree to genetic testing on long-term storage specimens?

yes no IENgents

3. Did the participant provide informed consent for specimen storage?

yes no IENinfc

If no, go to item 4.

4. To which cohort is the participant assigned?

immediate ART therapy (arm 1) delayed ART therapy (arm 2) IENarm

4a. What time did randomization occur?

hr min IENrtine 24-hr clock

5. Did the participant receive HIV counseling?

yes no IENhivc

6. Did the participant receive ART adherence counseling?

yes no N/A (Index not on ART) IENadhc

Index ID

Site Number iid, Index Number, Partner pid, Chk

Index Abnormal Hematology Results

Collection Date IAHicdt dd, MMM, yy

Include this year, in addition to calculated days on study

Instructions: This form is completed at follow-up visits when the value of a test is abnormal according to your laboratory ranges.

Specimen Collection Date

If different from Initial Collection Date

dd, MMM, yy IAHhemdt

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

AE Severity Grade If applicable

1 2 3 4 IAHhbgr

Specimen Collection Date

If different from Initial Collection Date

dd, MMM, yy IAHwbcdt

1d. Platelets IAHplt cells/mm3 IAHpltgr

2. WHITE BLOOD CELLS

AE Severity Grade If applicable

1 2 3 4 IAHwbcgr

2a. WBC IAHwbctn x103/mm3 IAHwbccr

OR IAHwbcc1 cells/mm3

2b. Differential

AE Severity Grade If applicable

1 2 3 4 IAHneugr

2b1. Neutrophils IAHneupc OR IAHneuc1 IAHneugr
2b2. Lymphocytes IAHlympc OR IAHlymc1 IAHlymgr
2b3. Monocytes IAHmonpc OR IAHmonc1 IAHmongr
2b4. Eosinophils IAHeospc OR IAHeoscl1 IAHeosgr
2b5. Basophils IAHbaspc OR IAHbascl1 IAHbasgr
2b6. Bands IAHbanpc OR IAHbancl1 IAHbangr
2b7. Atypical lymphocytes IAHatypc OR IAHatycl1 IAHatygr

Comments: IAHcomm

Include this year, in addition to calculated days on study

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Abnormal Chemistries

Form fields for Collection Date: IACicdt, dd, MMM, yy

Instructions: This form is completed at follow-up visits when the value of a test is abnormal according to your laboratory ranges.

Specimen Collection Date

If different from Initial Collection Date

Form fields for Specimen Collection Date: IACalkdt, IACastdt, IACaltdt, IACTbidtd

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

AE Severity Grade

Form fields for AE Severity Grade: IACalkgr, IACastgr, IACaltgr, IACTbigr

Specimen Collection Date

If different from Initial Collection Date

Form fields for Specimen Collection Date: IACsdmtdt, IACpsmtdt, IACchldtd, IACphttdt, IACbicddt

2. ELECTROLYTES

Form fields for Electrolytes: 2a. Sodium, 2b. Potassium, 2c. Chloride, 2d. Phosphate, 2e. CO2/bicarbonate

AE Severity Grade

Form fields for AE Severity Grade: IACsdmgr, IACpsmgr, IACchldgr, IACphtgr, IACbicgr

Specimen Collection Date

If different from Initial Collection Date

Form fields for Specimen Collection Date: IACcredtdt

3. RENAL FUNCTION TESTS

Form fields for Renal Function Tests: 3a. Creatinine

AE Severity Grade

Form fields for AE Severity Grade: IACcregr

Specimen Collection Date

If different from Initial Collection Date

Form fields for Specimen Collection Date: IACalbdtdt

4. OTHER CHEMISTRIES

Form fields for Other Chemistries: 4a. Albumin

AE Severity Grade

Form fields for AE Severity Grade: IACalbdgr

Comments: IACcomm

Index ID

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Site Number Index Number Partner Chk

Index Virologic Failure Assessment

Form Completion Date

dd MMM yy

Instruction: Complete this form any time virologic failure has been confirmed.

1. Date virologic failure was confirmed:

← OK to include year

2. What new regimen did the participant begin as a result of failure?

- ~~new~~ regimen
- secondary regimen
- salvage regimen
- no change

Comments:

Index ID
iid - pid - Chk
Site Number Index Number Partner Chk

Index Diseases

Initial Collection Date
ISTicdt
dd MMM yy

Include this year, in addition to calculated days on study

Instructions: Complete form for Enrollment and Yearly visits, partner seroconversion, and as clinically needed.

Alternate Collection Date
Not done/ Not collected
ISThepnd ISThepdt
dd MMM

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

SCREENING VISIT ONLY:
ISThep
ISTswb
swab collected?

Not done/ Not collected
ISTvagnd ISTvagdt
dd MMM yy

3. VAGINAL WET PREP STUDIES

Not done
ISTvnda. Homogeneous vaginal discharge...
ISTrphnd b. pH
ISTrwhfnd. Whiff test
ISTrclund. Clue cells ≥ 20%
ISTtrind. Trichomonads
ISTrystnd. Buds and/or hyphae (yeast)

Not done/ Not collected
ISTsernd ISTserdt
dd MMM yy

4. STD SEROLOGY

4a. Syphilis screening test (RPR, VDRL)
4a1. Titer 1:
4b. Syphilis confirmatory test (FTA-ABS, MHA-TP, TP-PA)

Not done/ Not collected
ISTgonnd ISTgondt
ISTtrand ISTtradt
dd MMM yy

5. OTHER STD TESTS

5a. N. Gonorrhea
5b. C. Trachomatis

Index ID

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 Site Number Index Number Partner Chk

Index Treatment Adherence

Visit Date

ITAvdt dd MMM yy

Instructions: This is an interviewer-administered form. Complete form at every follow-up visit for index participants on ART. Prior to the participant's arrival, record all medications and medication code(s) in the participant's current regimen.

1. Now I'm going to ask you about the study medication(s) you have been prescribed and if you have missed taking any of the doses yesterday, 2 days ago, 3 days ago, and in the past 2 weeks. If you only took a portion of a dose on one or more of these days, report the dose(s) as being missed.

	Med code	Abbreviation/ Name of your drugs	# of prescribed doses (per day)	# of prescribed doses missed (yesterday)	# of prescribed doses missed (2 days ago)	# of prescribed doses missed (3 days ago)	# of prescribed doses missed (past 2 weeks)
1a.	<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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
1b.	<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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
1c.	<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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
1d.	<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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
1e.	<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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

2. In the past 30 days, when was the last time you missed taking any of your medications?

Show Card #11.

- within the past week
 1-2 weeks ago
 2-4 weeks ago
 1-3 months ago
 more than 3 months ago
 never skip medications or not applicable

Index ID

- - -

Site Number Index Number Partner Chk

Index Quality of Life

Visit Date

dd MMM yy

Instructions: This is an interviewer-administered form. Complete form for Enrollment, Quarterly, and Yearly visits.

I am now going to ask you some questions about your health, how you've been feeling and the support you get from family and friends. I will first ask the question and then show you a card with the answer choices. Select the choice that best describes how you feel. Remember that there are no right or wrong answers.

1. During the **past 4 weeks**, has your health kept you from working at a job, doing work around the house, or going to school? **IQLwork** *yes, for all of the time* *yes, for some of the time* *no*
Show Card #1.

2. During the **past 4 weeks**, how much pain have you had (for example, headache, muscle pain, back pain, stomach ache)?
Show Card #2.

- IQLpain**
- very mild
 - mild
 - moderate
 - severe
 - very severe

3. During the **past 4 weeks**, how much has your physical health or emotional problems interfered with your normal social activities (for example, socializing with friends or family)?
Show Card #3.

- IQLsoc1**
- not at all
 - a little bit
 - moderately
 - quite a bit
 - extremely

4. During the **past 4 weeks**, have you been unable to do certain kinds or amounts of work, housework or schoolwork because of your health? **IQLcert** *yes, for all of the time* *yes, for some of the time* *no*
Show Card #1.

Index ID
 iid - - pid - Chk Index **Include year for this date** →
 Site Number Index Number Partner Chk

Visit Date
 IFUvdt - - -
 dd MMM yy

Instructions: Complete this form at every follow-up and interim visit.
 Items 1–3 are for females only. Male participants go to item 4.

1. Result of pregnancy test: negative positive not done → If not done, specify reason: Pregnant Other, specify: _____
 IFUprg IFUptnd

If pregnancy is confirmed, complete Pregnancy Report form.

1a. Date of last menstrual period: dd MMM yy IFUmpdt
 1b. Estimated date of delivery: dd MMM yy IFUeddt
 IFUptndx

Do not include year for these dates ←

NO LONGER APPLICABLE FOR THIS PROTOCOL.

2. Since the last visit, were any pregnancy outcomes reported? yes no IFUipo
 Complete Index Pregnancy Outcome form.

3. Is the participant currently breast feeding? yes no IFUbfeed

4. Since the participant's last visit, ...
 4a. have any previously reported Adverse Events Grade 3 or above resolved or have any new adverse events started? ... yes no IFUae
 Complete or update Index Adverse Event Log.

4b. have any previously reported HIV/AIDS associated events or other targeted medical conditions resolved or have any new events started? ... IFUhae
 Complete or update Index When to Start form.

4c. were any previously reported antiretrovirals stopped or modified, or were any new antiretrovirals started? ... IFUart
 Complete or update Index Antiretroviral Treatment Log.

4d. were any other non-ART medications stopped or were any new medications started? ... IFUmed
 Complete or update Index Concomitant Medications Log.

Index ID

iid [] [] - [] [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Index Follow-up Visit IFU2cqc

CMC decision IFUacmc
previous out-of-study ART use IFUaprev
clinician decision IFUaclin
LOA#5 to V3.0 IFUaloe

5. For this visit,...

5a. **NO LONGER APPLICABLE FOR THIS PROTOCOL.** was a laboratory ordered exam performed?

yes no
IFUexam []

5b. did the participant receive HIV counseling?

yes no
IFUhivc []

N/A (Index not on ART)

5c. did the participant receive ART adherence counseling?

IFUadhc []

5d. did the participant report symptoms of a sexually transmitted disease without being tested?

IFUstd []

Complete Index Symptomatic STD form.

5d1. was the participant tested for STDs?

yes no
IFUtstd []

Complete Index Sexually Transmitted Diseases form.

5e. was a CD4/Viral Load test performed?.....

IFUcd4vl []

Complete Index CD4/Viral Load Results form.

5f. was ART dispensed or returned?

IFUartad []

If no, go to item 5g.

5f1. If yes, is this the first visit at which pills were dispensed (delay arm initiation)?

IFUartst []

If no, complete Index Pill Count and Index Treatment Adherence form.

5f2. If yes to 5f1, indicate the reason(s) for ART initiation. Mark only primary reason.

IFUacd4+ ≤ 250 cells/mm³
IFUaids defining illness
IFUapreg pregnancy

Go to item 6.

If yes, complete Index Pill Count, Index Complete Chemistries, and Index Complete Hematology forms.

5g. was this the Post-ART Initiation visit?

yes no
IFUparti []

5h. were any abnormal hematology results reported?

IFUabhcn []

5i. were any abnormal chemistries or LFTs reported?

IFUabchn []

NO LONGER APPLICABLE FOR THIS PROTOCOL

6. Was this the partner seroconversion visit?

yes no
IFUpsero []

Index ID

- - -

Site Number Index Number Partner Chk

Index Altruism Questionnaire

Visit Date

dd MMM yy

Instructions: This is an interviewer-administered form. Complete this survey one time for each Index participant.

1. For each item, indicate how often you have performed the following activities:
 Mark one box for each item.

Show Card #13.

	<i>never</i>	<i>once</i>	<i>more than once</i>	<i>often</i>	<i>very often</i>
1a. I have helped push or restart a stranger's vehicle when it was stalled.	<input type="checkbox"/> IAQspuve	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1b. I have given directions to a stranger.	<input type="checkbox"/> IAQsdir	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1c. I have made change for a stranger.	<input type="checkbox"/> IAQschg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1d. I have given money to a charity.	<input type="checkbox"/> IAQcharm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1e. I have given money to a stranger who needed it (or asked me for it).	<input type="checkbox"/> IAQsmon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1f. I have donated goods or clothes to a charity, a school or a church.	<input type="checkbox"/> IAQcharg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1g. I have done volunteer work for a charity or my church.	<input type="checkbox"/> IAQcharv	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1h. I have donated blood.	<input type="checkbox"/> IAQdonbl	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1i. I have helped carry a stranger's belongings (books, parcels, etc.).	<input type="checkbox"/> IAQscrry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1j. I have helped an acquaintance obtain something important that he or she needed (e.g., a job, a place to live, etc.).	<input type="checkbox"/> IAQaobtn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1k. I have allowed someone to go ahead of me in a line or queue.	<input type="checkbox"/> IAQqyeue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Index ID

- - -

Site Number Index Number Partner Chk

Index Altruism Questionnaire

1. **Continued:** For each item, indicate how often you have performed the following activities:

Mark one box for each item.

Show Card #13.

	<i>never</i>	<i>once</i>	<i>more than once</i>	<i>often</i>	<i>very often</i>
1l. As part of a group of people, I have done menial jobs that needed doing without being asked, even though they were not part of my responsibilities.	IAQmnlwo <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1m. I have pointed out a clerk's error (in a bank, at the market, etc.) in undercharging me for an item.	IAQclerr <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1n. I have let a neighbor whom I didn't know too well borrow an item of some value to me (e.g., a dish, tools, etc.).	IAQnborr <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1o. I have paid a little more to buy an item from a merchant who I felt deserved my support.	IAQmnrch <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1p. I have helped a classmate whom I did not know that well with a homework assignment when my knowledge was greater than his or hers.	IAQtutor <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1q. I have looked after a neighbor's pets without being asked and without being paid for it.	IAQnpets <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1r. I have offered to help an elderly or handicapped stranger across the street.	IAQscrss <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1s. I have offered my seat on a bus or train to a stranger who was standing.	IAQsbuss <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1t. I have helped someone I know move households.	IAQamove <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1u. I have done some work without payment on a friend's farm or in his/her business when he/she was sick or was unable to work for some other reason.	IAQfwork <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Index ID

- - -

Site Number Index Number Partner Chk

Index Altruism Questionnaire

I am now going to ask you some questions about your primary sexual partner. If you do not currently have one, please refer to your most recent primary sexual partner.

2. Do you have a primary sexual partner? **IAQppart** *yes* *no* *If no, go to item 4.*
- 2a. Is he/she HIV infected? **IAQpphiv** *yes* *no*
3. How long have you and your primary sexual partner been together?
- | | | | | | |
|---------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|
| | <i>less than
1 month</i> | <i>1-12
months</i> | <i>1-5
years</i> | <i>5-10
years</i> | <i>more than
10 years</i> |
| 3. How long have you and your primary sexual partner been together? | <input type="checkbox"/> IAQpplen <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
4. For each of the items below, indicate how much you agree with the statement.
Mark one box for each item.
Show Card #14.
- | | | | | | |
|------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------|---------------------------------------|--------------------------|---------------------------|
| | <i>strongly
disagree</i> | <i>disagree</i> | <i>neither agree
nor disagree</i> | <i>agree</i> | <i>strongly
agree</i> |
| 4a. If I take my medications it will help my sexual partner(s) not get HIV infected. | <input type="checkbox"/> IAQmedpp <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4b. If my partner gets infected with HIV, I would be devastated. | <input type="checkbox"/> IAQipdev <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4c. Whether my partner gets infected is up to fate. | <input type="checkbox"/> IAQipfa <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4d. If my partner gets infected, it is because of the weakness of his/her physical body. | <input type="checkbox"/> IAQipwea <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4e. Whether my partner gets infected, is up to him/her. | <input type="checkbox"/> IAQipupp <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4f. Whether my partner gets infected is up to me. | <input type="checkbox"/> IAQipupm <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4g. Since I found out I had HIV, my relationship has had more problems. | <input type="checkbox"/> IAQrprbs <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4h. Taking my medications is not easy because they have side effects. | <input type="checkbox"/> IAQmedse <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Index ID

- - -

Site Number Index Number Partner Chk

Index Altruism Questionnaire

4. **Continued:** For each of the items below, indicate how much you agree with the statement.
 Mark one box for each item.

Show Card #14.

	<i>strongly disagree</i>	<i>disagree</i>	<i>neither agree nor disagree</i>	<i>agree</i>	<i>strongly agree</i>
4i. I take my medications to help myself.	<input type="checkbox"/> IAQmed4m <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4j. I take my medications to help my partner not get HIV infected.	<input type="checkbox"/> IAQmed4p <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4k. If my partner became infected, I would feel guilty.	<input type="checkbox"/> IAQipglt <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4l. If my partner became infected, others would blame me.	<input type="checkbox"/> IAQipobm <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4m. If my partner became infected, I would feel I did something wrong.	<input type="checkbox"/> IAQipflw <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4n. I take my medications to prevent my partner from getting infected because he/she will then be there to help me in the future.	<input type="checkbox"/> IAQmedfu <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4o. My religion tells me to help others.	<input type="checkbox"/> IAQrelho <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<i>more than once a day</i>	<i>once a day</i>	<i>once a week</i>	<i>once every 2 weeks</i>	<i>once a month</i>
5. I help my partner do daily household activities.	<input type="checkbox"/> IAQdlyhh <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Show Card #15.

Index ID

iid - - pid -

Site Number

Index Number

Partner

Chk

Index Interim Visit

Visit Date

IIVvdt . .

dd

MMM

yy

1. What CRFs were completed at this visit? Mark all that apply. Note: The Follow-up Visit form must be completed at every interim visit.

- IIVife. Index CD4/Viral Load Results (IFV-1)
IIVist. Index Sexually Transmitted Diseases (IST-1)
IIViss. Index Symptomatic Sexually Transmitted Diseases (ISS-1)
IIVisc. Index Specimen Collection (ISC-1)
IIVipe. Index Pill Count (IPC-1)
IIVich. Index Complete Hematology (ICH-1)
IIVicc. Index Complete Chemistries (ICC-1)
IIVicm. Index Concomitant Medications Log (ICM-1)
IIVitx. Index Antiretroviral Treatment Regimen Log (ITX-1)
IIViwt. Index When to Start (IWT-1-4)
IIViae. Index Adverse Event Log (IAE-1)
IIVipo. Index Pregnancy Outcome (IPO-1)
IIVipr. Index Pregnancy Report (IP-1)
IIVitm. Index Termination (ITM-1)
IIVptm. Partner Termination (PTM-1)
IIVida. Index Delay Arm Participant ART Initiation (IDA-1)

Comments: IIVcomm

Index ID

- - -
 Site Number Index Number Partner Chk

Index Delay Arm Participant ART Initiation

Visit Date

IDAvdt dd MMM yy

Instructions: Complete this form any time a participant on the delay arm is offered antiretroviral treatment (ART) in response to LOA #5 to version 3.0 of the protocol.

1. Did the participant agree to start ART at this visit? **IDAart** yes no
 End of form.

1a. Reason(s) participant did not agree to start ART. Mark all that apply.

- IDAnotr** not ready
- IDAcd4** CD4 is too high
- IDAfeel** feeling healthy
- IDAfear** afraid of side effects
- IDAwait** waiting to discuss with partner
- IDAoubt** doubts ability to adhere to the prescribed regimen
- IDAoth** other reason(s), specify: **IDArothx**

Comments: **IDAcomm**

Partner ID

secret1

iid [] [] - [] [] [] [] - pid [] [] - [] []

Site Number Index Number Partner Chk

Partner Demographics

Form Completion Date

PDMfcdt [] [] [] [] [] []

dd MMM yy

Instructions: Complete this form for Enrollment only.

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

PDMbdt [] [] [] [] [] []

OR Age: PDMage [] [] years

2. What is the participant's biological sex?

PDMsex [] []

3. What is the participant's current marital status? Mark only one.

PDMstat [] [] [] []

- married
living with partner but not married
separated/married but living separately
divorced
widowed

4. During the past 12 months, what was the participant's average household monthly income?

PDMhinc [] [] [] [] [] []

OR PDMhhinc [] [] [] [] [] []

5. During the past 12 months, what was the participant's average personal monthly income?

PDMpinc [] [] [] [] [] []

OR PDMppinc [] [] [] [] [] []

6. What is the highest level of education the participant has reached? Mark only one.

- PDMedu schooling
some primary school
completed primary school
some secondary school
completed secondary school
attended college or university (includes vocational or trade school)
graduate/professional school

Partner ID

- - -
 Site Number Index Number Partner Chk

Partner Demographics—
United States

Form Completion Date

dd MMM yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's race? *Mark all that apply.*

- PDUnatam** Native American or Alaska Native
- PDUsian** Asian
- PDUblack** African American or Black
- PDUhawi** Native Hawaiian or other Pacific Islander
- PDUwhite** White
- PDUrace** other, specify: PDUracox (**Note:** Latino is not a race.)

2. Does the participant consider themselves to be Latino/a or of Hispanic origin? yes no
 PDUhispp

3. What is the participant's sexual orientation? *Mark only one.*

- PDUsexo** Straight/heterosexual
- Gay/homosexual
- Bisexual
- Not sure
- other, specify: PDUsexox

Partner ID

iid [] [] - [] [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Partner Demographics—
Malawi

Form Completion Date

PDWfcdt [] [] [] [] [] []
dd MMM yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group or tribe? Mark all that apply.

PDWchewa

PDWngoni

PDWyaO

PDWTumbuka

PDWtrib Other African tribe, specify: Local Language _____ English PDWtribx _____

PDWoeth Other, specify: Local Language _____ English PDWoethx _____

2. What is the participant's current form of employment? Mark all that apply.

PDWunemp unemployed

PDWtech technical

PDWdomw domestic worker

PDWaccou accounting

PDWhousew housewife

PDWhealth health care

PDWstud student

PDWrelig religion

PDWbusn business

PDWteach teacher

PDWmilpo military/police

PDWsklab skilled labor

PDWfarm farming

PDWgover government

PDWdrive driver

PDWunlab unskilled labor

3. How many children does the participant have?

of children

PDWchild [] []

4. Does the participant have electricity in their home? yes no

PDWelect

5. What is the participant's main source of drinking water? Mark only one.

PDWwater water

unprotected well

protected well

borehole

surface water (spring, river/stream, pond/lake, dam)

Partner ID

iid [] [] - [] [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Partner Demographics—
Thailand

Form Completion Date

PDTfcdt [] [] [] [] [] []
dd MMM yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group or tribe? *Mark all that apply.*

PDThai

PDYao

PDKaren

PDTlisu

PDTaiyai

PDTlahu

PDakha

PDTlua

PDHmong

PDToeth, specify: *Local Language* _____

English PDToethx _____

Partner ID

iid [] [] - [] [] [] [] - pid [] [] - [] []

Site Number Index Number Partner Chk

Partner Demographics—Brazil

Form Completion Date

PDBfcdt [] [] [] [] [] [] [] []

dd MMM yy

Instructions: Complete this form for Enrollment only.

1. What is the participant's ethnic group? Mark all that apply.

PDBblack

PDBasian

PDBmixed Race

PDBnative

PDBwhite

PDBother, specify: Local Language _____ English PDBoethx _____

Partner ID

iid [] [] - [] [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Partner Demographics—
Botswana

Form Completion Date

PDOfc [] [] [] [] [] [] [] []
dd MMM yy

Instructions: Complete this form for Enrollment only.

1. How long has the participant been in his/her primary relationship?

PDorelyr [] [] years

PDorelmo [] [] months

2. How often does this couple stay together?

- PDostay of the time
- most of the time
- often
- not so often
- do not stay together

3. What is the participant's ethnic group?

PDotswan

PDokalan

PDooethr, African tribe; specify: Local Language _____ English PDooethx _____

4. How many children does the participant have?

PDokids [] [] total # of children

4a. How many children does the participant have with his/her current partner?

PDokids [] [] total # of children with partner

5. How did the participant hear of this study? Mark all that apply.

PDoscomm Community

PDosfrnd Friends

PDosmed Media; specify: Local Language _____ English PDosmedx _____

PDospubh Public Health Sector

PDosrc Recruitment Campaign by project staff at (specify):
local clinic VCT Centre other venue

PDosrc lc

PDosrc vc

PDosrc o

PDosothr Other, specify: Local Language _____ English PDosothx _____

Partner ID

Form for Partner ID: iid, Index Number, pid, Chk

Partner Enrollment

Enrollment Date

Form for Enrollment Date: PENenrdt, dd, MMM, yy

Instructions: Complete this form for Enrollment only.

- 1. Did the participant provide informed consent for specimen storage?.....
2. Did the participant receive ART adherence counseling for this visit?.....
3. Did the participant receive HIV counseling for this visit?
4. Was the participant previously enrolled in the study under a different ID number?

4a. If yes, previous Partner ID: PENpiid - [] - PENppid - []

- 5. Did the participant agree to genetic testing on long term storage specimens?.....
6. Prior to enrolling in this study, did the participant take ART as post-exposure prophylaxis?

6a. For the most recent exposure, record the medication code for each ART medication taken as post-exposure prophylaxis.

6a1. PEN1art, 6a2. PEN2art, 6a3. PEN3art, 6a4. PEN4art, 6a5. PEN5art

6b. Date of last dose of ART medication received: PENldrdt, dd, MMM, yy

Partner ID

Site Number iid, Index Number, Partner pid, Chk

Partner Hematology Results

Initial Collection Date

Initial Collection Date PCHicdt dd, MMM, yy

Include this year, in addition to calculated days on study

Instructions: Complete this form at partner seroconversion only.

Alternate Collection Date

Not done/ Not collected dd, MMM, yy

Alternate Collection Date PCHhem, PCHhemdt

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

PCHhb g/dl

PCHhct %

PCHmcv fL

PCHplt Platelets PCHplt cells/mm3

Alternate Collection Date

Not done/ Not collected dd, MMM, yy

Alternate Collection Date PCHwbc, PCHwbcdt

2. WHITE BLOOD CELLS

2a. WBC PCHwbctn x10^3/mm^3

OR PCHwbcc1 cells/mm^3

2b. Differential

Not reported percentage

Absolute Count cells/mm^3

2b1. Neutrophils, 2b2. Lymphocytes, 2b3. Monocytes, 2b4. Eosinophils, 2b5. Basophils, 2b6. Bands, 2b7. Atypical lymphocytes

Comments: PCHcomm

Partner ID

Form fields for Partner ID: iid, Index Number, pid, Chk

Partner Chemistries

Initial Collection Date

Form fields for Initial Collection Date: PCCicdt, dd, MMM, yy

Include this year, in addition to calculated days on study

Instructions: Complete this form at partner seroconversion only.

Alternate Collection Date

Form fields for Alternate Collection Date: PCCalk, PCCast, PCCalt, PCCtbi

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

RENAL FUNCTION TESTS

Form fields for Renal Function Tests: PCCalk, PCCast, PCCalt, PCCtbi

Alternate Collection Date

Form fields for Alternate Collection Date: PCCsdm, PCCpsm, PCCchl, PCCpht, PCCbic

2. ELECTROLYTES

Form fields for Electrolytes: PCCsdm, PCCpsm, PCCchl, PCCpht, PCCbic

Alternate Collection Date

Form fields for Alternate Collection Date: PCCcre

3. RENAL FUNCTION TESTS

Form fields for Renal Function Tests: PCCcre

Alternate Collection Date

Form fields for Alternate Collection Date: PCCalb

4. OTHER CHEMISTRIES

Form fields for Other Chemistries: PCCalb

Comments: PCCcomm

Plate Number: 325 PVL-1: Partner CD4/Viral Load Results

visit

HPTN 052 (096)

PVL-1 (325)

Page 1 of 1

Partner ID

Site Number iid - Index Number - Partner pid - Chk

Partner Results

Initial Collection Date

PVLicdt dd MMM yy

Include this year, in addition to calculated days on study

Instructions: Complete this form at partner seroconversion only.

Not done/ Not collected Alternate Collection Date dd MM

PVLcd4 PVLcd4dt

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

PVLt1ccl cells/mm³

PVLcd4c1 cells/mm³

not available

2a. PVLcd4pc % OR PVLcd4pn

Not done/ Not collected Alternate Collection Date dd MMM yy

PVLrna PVLrnadt

3. RNA PCR of Plasma

< (less than) = (equal to) > (greater than)

PVLrnaeq

PVLrna

copies/mL

undetectable

PVLrnaun

Comments: PVLcomm

bit 4b 325 325 325 325 JAN-13

formlang Language

sfdt_325 Staff Initials / Date

Partner ID

iid [] [] - [] [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Partner Circumcision Assessment

Visit Date

PCAvdt [] [] [] [] [] []
dd MMM yy

Instructions: Complete this form for all male participants at enrollment and yearly visits.

ENROLLMENT VISIT ONLY

1. Circumcision Status

PCAcrcst participant refused exam → End of form.
 not circumcised
 circumcised → Go to item 3.

YEARLY FOLLOW-UP VISITS ONLY

2. Has the participant been circumcised since his last exam?

PCAcrcmlle circumcision previously reported → End of form.
 participant refused exam
 no
 yes

3. Circumcision

PCAcrcm circumcised
 partial circumcised

4. Date of Circumcision:

PCAcrcm dt [] [] [] [] [] []
dd MMM yy

OK to include the year for this date

Include this year, in addition to calculated days on study

Partner ID

Site Number iid, Index Number, Partner pid, Chk

Partner Sexually Transmitted Diseases

Collection Date

PSTicdt dd, MMM, yy

Instructions: Complete this form for Enrollment and yearly visits, partner seroconversion, and as clinically needed.

Alternate Collection Date

Not done/ Not collected

PSThepnd, PSThepdt dd

Do not include years for these additional specimen collection dates as it will be no more than a few days different than the initial collection date. If present do include calculated days on study

Alternate Collection Date

PSTiswbdt dd

Not done/ Not collected

PSTvagnnd, PSTvagndt dd, MMM, yy

3. VAGINAL WET PREP STUDIES

Not done

Form for Vaginal Wet Prep Studies including items a through f with checkboxes for negative/positive results.

Not done/ Not collected

PSTsernd, PSTserdt dd, MMM, yy

4. STD SEROLOGY

4a. Syphilis screening test (RPR, VDRL) PSTsypsc

4a1. Titer 1: PSTsypti

4b. Syphilis confirmatory test (FTA-ABS, MHA-TP, TP-PA) PSTsyperc

5. OTHER STD TESTS

Not done/ Not collected

PSTgonnd, PSTgondt dd, MMM, yy; PSTtrand, PSTtradt dd, MMM, yy

5a. N. Gonorrhea PSTgon

5b. C. Trachomatis PSTtra

Index ID

Form for Index ID with fields: iid, Site Number, Index Number, pid, Partner, Chk

Partner Symptomatic Sexually Transmitted Diseases

Visit Date

Form for Visit Date with fields: PSSvdt, dd, MMM, yy

Instructions: Complete this form when a participant is treated for symptoms of a sexually transmitted disease.

1. Indicate if the participant was treated for symptoms of any of the following sexually transmitted diseases.

- 1a. chlamydia... PSSchla
1b. gonorrhea... PSSgon
1c. syphilis... PSSsyp
1d. BV (bacterial vaginosis)... PSSbv
1e. TV (trichomonas vaginalis)... PSStv
1f. candida... PSScan
1g. genital ulcer disease... PSSgulc
1h. other, specify: PSS1othx
1i. other, specify: PSS2othx

Comments: PSScomm

Partner ID

Form fields for Partner ID: iid, Index Number, pid, Chk

Partner HIV Test Results

Instructions: Complete this form at each quarterly and yearly visit, and as clinically needed.

Specimen #1 Collection Date

Form fields for Specimen #1 Collection Date: PHT1cdt, dd, MMM, yy

1a.

No need to include the years for these dates as this was testing as part of the study, calculated days on study is enough

1a2.

Form fields for 1a2: rapid, standard, PHTeiat, negative, positive

PHTeia

If negative, go to item 4.

PHT2eia

If both 1a2 and 1a3 are negative, go to item 4.

1a3. Second EIA Rapid Result Complete 1a3 only if required by in-country regulations.

1b. Confirmatory HIV Western Blot or IFA

1b1. Type of test:

Form fields for 1b1: WB, IFA, PHT1cont

1b2. Result:

Form fields for 1b2: negative, positive, indeterminate, PHT1con

If negative, go to item 4.

Specimen #2 Collection Date

Form fields for Specimen #2 Collection Date: PHT2cdt, dd, MMM, yy

2. HIV Western Blot or IFA

2a. Type of test:

Form fields for 2a: WB, IFA, PHT2cont

2b. Result:

Form fields for 2b: negative, positive, indeterminate, PHT2con

If positive, go to item 4.

Specimen #3 Collection Date

Form fields for Specimen #3 Collection Date: PHT3cdt, dd, MMM, yy

3. HIV Western Blot or IFA

3a. Type of test:

Form fields for 3a: WB, IFA, PHT3cont

3b. Result:

Form fields for 3b: negative, positive, indeterminate, PHT3con

4. Final test results

4a. Was test result determined by Central Lab?

Form fields for 4a: yes, no, PHTfinal, PHTclab

If negative or indeterminate, consult the HPTN Central Lab and record Central Lab decision in item 4.

Comments: PHTcomm

Include this year, in addition to calculated days on study

Partner ID

Form for Partner ID with fields iid, Index Number, pid, and Chk.

Partner Specimen Collection

Initial Collection Date

Form for Initial Collection Date with fields PSCicdt, dd, MMM, and yy.

Instructions: Complete this form for Enrollment and yearly visits, partner seroconversion, and as clinically needed.

For each of the following, indicate if specimen was collected.

Do not include years for these dates

1. Whole blood for plasma HIV genotyping: PSCpls [yes/no checkboxes]

Alternate Collection Date for PSCpls: PSCplsdt [dd/MMM/yy]

2. Blood for storage: PSCblld [yes/no checkboxes]

Alternate Collection Date for PSCblld: PSCblldt [dd/MMM/yy]

2a. Mark each component to be stored for this visit.

- PSCwblld Whole blood
PSCpls Plasma
PSCserum Serum
PSCpbmc PBMCs

Alternate Collection Date for 2a: PSCswbdt, PSCspldt, PSCssrdt, PSCspbdt [dd/MMM/yy]

3. Cervical sample for HIV-1 RNA: PSCcer [yes/no checkboxes]

Alternate Collection Date for PSCcer: PSCcerdt [dd/MMM/yy]

4. Semen sample for HIV-1 RNA: PSCsem [yes/no checkboxes]

Alternate Collection Date for PSCsem: PSCsemdt [dd/MMM/yy]

5. Genital secretions for storage: PSCgen [yes/no checkboxes]

Alternate Collection Date for PSCgen: PSCgendt [dd/MMM/yy]

Partner ID

Site Number Index Number Partner Chk

Partner Follow-up Visit

Visit Date

dd MMM yy

Instructions: Complete at all follow-up and interim visits.

1. Is this the Post-ART Initiation visit? PFUparti

2. For this visit, 2a. was a symptom-detected exam performed? PFUexam

NOT APPLICABLE FOR THIS PROTOCOL.

N/A (Index not on ART)

2b. did the participant receive ART adherence counseling? PFUadhc

Complete Partner Symptomatic STD form.

2c. did the participant report symptoms of a sexually transmitted disease without being tested? PFUstd

Complete Partner Sexually Transmitted Diseases form.

2c1. was the participant tested for STDs? PFUtstd

3. For this visit, did the participant... 3a. receive HIV counseling? PFUhivc

Complete Partner HIV Test Results form.

3b. receive pre-HIV test counseling? PFUpre

3c. receive HIV testing? PFUhiv

3d. receive post-HIV test counseling? PFUpost

4. Was this the partner seroconversion visit? PFUpsero

5. Since the last visit, did the participant take ART as post-exposure prophylaxis? PFUpep If no, end of form.

5a. For the most recent exposure, record the medication code for each ART medication taken as post-exposure prophylaxis.

5a1. 5a2. 5a3. 5a4. 5a5. PFU1art PFU2art PFU3art PFU4art PFU5art

5b. Date of last dose of ART medication received: PFUldrdt

Partner ID

Site Number Index Number Partner Chk

Partner Interim Visit

Visit Date

dd MMM yy

1. Did the participant miss all of his/her last monthly, quarterly, or yearly study visit and is he/she outside of any visit window?.....

yes no PIVmakup If no, go to item 2.

1a. What visit is this replacing? PIVvisit End of form.

2. What is the reason for this visit? Mark all that apply.

PIVproc To complete a procedure(s) missed at a previous visit. (Mark this box only if the participant is outside of any visit window.)

PIVstd STD symptoms/treatment

PIVhiw HIV testing/results

PIVorsn or, specify: PIVorsnx

Comments: PIVcomm

Partner ID

iid [] [] - [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Partner Termination

Instructions: Complete this form when a partner terminates from the study.

1. Termination Date: PTMtdt [] [] [] [] [] [] [] []
dd MMM 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 PTMddt [] [] [] [] [] [] [] [] OR PTMdat unknown
dd MMM yy

2b2. Cause of death PTMdcou _____ OR PTMdcun _____

2c. Participant refused further participation, specify: PTMrefrx _____

2d. Participant unable to adhere to visit schedule.

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

2f. Investigator decision, please specify: PTMinvdx _____

2g. Unable to contact participant.

2h. HIV infection.

2i. Inappropriate enrollment.

2j. Invalid ID due to duplicate screening/enrollment

2k. Other reason, please specify: PTMtrmox _____

2l. Early study closure.

2m. Relationship ended.

2n. Death of index.

PTMcommx

Comments: _____

HPTN 052 (096)

ITX-1 (400)

Index ID

- - -
 Site Number Index Number Partner Chk

Index Antiretroviral Treatment Regimen Log

Instructions: When starting a new or modified regimen, complete Part A and fax to SCHARP DataFax. When stopping or modifying this regimen, complete Part B, refax to SCHARP DataFax, and complete Part A of a new Index Antiretroviral Treatment Regimen Log with the new or modified regimen and fax to SCHARP DataFax.

PART A	PART B																																
1. Regimen Start Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small> ITXstdt	6. Regimen Stop/Modification Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>dd MMM yy</small> ITXspdt																																
2. Visit Code at which regimen was started: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>peripartum initial/primary secondary salvage</small> ITXstvis	7. Visit Code at which regimen was stopped or modified: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ITXspvis																																
3. This regimen is: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> ITXreg	ITXregqc																																
4. REGIMEN MEDICATIONS: Record codes for all medications in the regimen.																																	
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Med Code</th> <th>Dose (mg)</th> <th>Frequency</th> </tr> </thead> <tbody> <tr> <td>ITX1med</td> <td>ITX1dose</td> <td> <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid </td> </tr> <tr> <td>ITX2med</td> <td>ITX2dose</td> <td> <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid </td> </tr> <tr> <td>ITX3med</td> <td>ITX3dose</td> <td> <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid </td> </tr> <tr> <td>ITX4med</td> <td>ITX4dose</td> <td> <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid </td> </tr> <tr> <td>ITX5med</td> <td>ITX5dose</td> <td> <input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid </td> </tr> </tbody> </table>	Med Code	Dose (mg)	Frequency	ITX1med	ITX1dose	<input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid	ITX2med	ITX2dose	<input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid	ITX3med	ITX3dose	<input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid	ITX4med	ITX4dose	<input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid	ITX5med	ITX5dose	<input type="checkbox"/> qd <input type="checkbox"/> bid <input type="checkbox"/> tid <input type="checkbox"/> qid	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Medication Status</th> <th>Stop/Mod Codes</th> </tr> </thead> <tbody> <tr> <td> <input type="checkbox"/> no change <input type="checkbox"/> dose / freq. change <input type="checkbox"/> stopped <input type="checkbox"/> held </td> <td> <input type="checkbox"/> primary <input type="checkbox"/> secondary </td> </tr> <tr> <td>ITX1stat</td> <td>ITX1pri ITX1sec</td> </tr> <tr> <td>ITX2stat</td> <td>ITX2pri ITX2sec</td> </tr> <tr> <td>ITX3stat</td> <td>ITX3pri ITX3sec</td> </tr> <tr> <td>ITX4stat</td> <td>ITX4pri ITX4sec</td> </tr> <tr> <td>ITX5stat</td> <td>ITX5pri ITX5sec</td> </tr> </tbody> </table>	Medication Status	Stop/Mod Codes	<input type="checkbox"/> no change <input type="checkbox"/> dose / freq. change <input type="checkbox"/> stopped <input type="checkbox"/> held	<input type="checkbox"/> primary <input type="checkbox"/> secondary	ITX1stat	ITX1pri ITX1sec	ITX2stat	ITX2pri ITX2sec	ITX3stat	ITX3pri ITX3sec	ITX4stat	ITX4pri ITX4sec	ITX5stat	ITX5pri ITX5sec
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ITX4stat	ITX4pri ITX4sec																																
ITX5stat	ITX5pri ITX5sec																																
5. Initials and date of staff member completing Part A: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Staff Initials / Date</small> sfdt_400	8. Were any of the above stop/modification codes reported as an AE? <input type="checkbox"/> yes <input type="checkbox"/> no ITXae <input type="checkbox"/> If no, go to item 9. 8a. Record AE Log page(s). <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ITX1page ITX2page ITX3page																																
	9. Initials and date of staff member completing Part B: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Staff Initials / Date</small> ITXstpsf																																

HPTN 052 (096)

IHA-1 (410)

Index ID

 Site Number Index Number Partner Chk

Index HIV/AIDS Associated Events Log

Instructions: Record HIV-related illnesses and/or AIDS-defining conditions experienced by the participant. Record only illnesses considered to be related to HIV or AIDS and that appear on the HIV/AIDS Associated Event Code list. Other illnesses and conditions should be recorded on the Index Adverse Event Log if Grade 3 or above. Refer to the back of this form for additional instructions and the HIV/AIDS Associated Events Code list.

Fax this form to SCHARP DataFax each time a new event starts or an event resolves.

1.	HIV/AIDS Event Code: <input type="text"/> IHA1code	Visit Code at which this event was first reported: <input type="text"/> IHA1vis . <input type="text"/>	Clinical Diagnosis: confirmed probable <input type="text"/> IHA1cdx <input type="text"/>	IHA1qc
	Date Started <input type="text"/> IHA1stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> IHA1spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="text"/> IHA1long <input type="text"/> dd MMM yy Ongoing of study	Staff Initials/Log Entry Date <input type="text"/> IHA1init	
	1a. Is this an AIDS-defining illness? <input type="text"/> IHA1adil <input type="text"/> no			

2.	HIV/AIDS Event Code: <input type="text"/> IHA2code	Visit Code at which this event was first reported: <input type="text"/> IHA2vis . <input type="text"/>	Clinical Diagnosis: confirmed probable <input type="text"/> IHA2cdx <input type="text"/>	IHA2qc
	Date Started <input type="text"/> IHA2stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> IHA2spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="text"/> IHA2long <input type="text"/> dd MMM yy Ongoing of study	Staff Initials/Log Entry Date <input type="text"/> IHA2init	
	2a. Is this an AIDS-defining illness? <input type="text"/> IHA2adil <input type="text"/> no			

3.	HIV/AIDS Event Code: <input type="text"/> IHA3code	Visit Code at which this event was first reported: <input type="text"/> IHA3vis . <input type="text"/>	Clinical Diagnosis: confirmed probable <input type="text"/> IHA3cdx <input type="text"/>	IHA3qc
	Date Started <input type="text"/> IHA3stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> IHA3spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="text"/> IHA3long <input type="text"/> dd MMM yy Ongoing of study	Staff Initials/Log Entry Date <input type="text"/> IHA3init	
	3a. Is this an AIDS-defining illness? <input type="text"/> IHA3adil <input type="text"/> no			

4.	HIV/AIDS Event Code: <input type="text"/> IHA4code	Visit Code at which this event was first reported: <input type="text"/> IHA4vis . <input type="text"/>	Clinical Diagnosis: confirmed probable <input type="text"/> IHA4cdx <input type="text"/>	IHA4qc
	Date Started <input type="text"/> IHA4stdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	Date Stopped <input type="text"/> IHA4spdt <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="text"/> IHA4long <input type="text"/> dd MMM yy Ongoing of study	Staff Initials/Log Entry Date <input type="text"/> IHA4init	
	4a. Is this an AIDS-defining illness? <input type="text"/> IHA4adil <input type="text"/> no			

Index ID

Site Number Index Number Partner Chk

Index When to Start

IWTdelte

diagnosis code

1. Record diagnosis code for this event: IWTcode IWTqc

1a. Specify diagnosis: IWTdiag

1b. Indicate if diagnosis is confirmed or probable: IWTcldx

1c. Is this an AIDS-defining illness? IWTadil

1d. Indicate the Visit Code at which this event was first reported: IWTvis

1e. Was this event recorded on the Index Adverse Events Log? IWTae IWTaepg

1f. Diagnosis status: IWTdxst

1g. Date event started: IWTstdt

1h. Date of diagnosis: IWTdxdt

1i. Outcome: IWToutc 1i1. Date of outcome: IWTocdt

2. Is diagnosis a clinical event with a code of 30-44? IWTsubst If yes, end of form. Fax only page 1 to SCHARP DataFax.

Comments: IWTcomm

Index ID

Form for Index ID: iid, Index Number, pid, Chk

WTS Diagnosis Review

WDRsubs

diagnosis code

1. Diagnosis code for this event provided by site: WDRcode

Reviewed by:

1a. Date of initial review: WDRidt, dd, MMM, yy

WDRirvw

yes no more information needed

2. Diagnosis accepted? WDRdxac

If yes, end of form.

2a. Record additional information needed from site:

WDRiinfo

yes no

2b. Additional information from site received? WDRiinfo

Reviewed by:

3. Date of subsequent review: WDRsdt, dd, MMM, yy

WDRsrvw

yes no

3a. Additional information needed? WDRsinfo

3b. Record additional information needed from site:

WDRsinfo

yes no

3c. Additional information received? WDRsinfo

yes no

4. Is the site's diagnosis accepted? WDRsdxac

If yes, end of form.

4a. Record final diagnosis code and specify diagnosis: WDRfcode

Specify diagnosis:

WDRfcodx

4b. Indicate if diagnosis is confirmed or probable: WDRdxcon

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IAE-1 (421)

AESubsum

Index ID

Date Reported to Site

Form for Index ID: iid, Index Number, pid, Chk

Index Adverse Event Log

Form for Date Reported to Site: AErptdt, IAEhae, dd, MMM, yy

SAE # AEsaeo

Flag/Version AEFver, MedDRA AEMdra, med in com

1. Adverse Event

IAEmedcm

2. Onset Date

AEcoded, AEdiag

Form for Onset Date: AEondt, dd, MMM, yy

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

1a. Indicate if diagnosis is confirmed or probable: AEdiagcp Confirmed Probable

3. Severity

4. Relationship to ART Study Product

5. ART Study Product Administration

Form for Severity: AEseve, AEseveqc, Grade 3-5 options

Form for Relationship to ART Study Product: AERelpro, Definitely, Probably, Possibly, Probably not, Not related

Form for ART Study Product Administration: No change, Held, Permanently discontinued, N/A

3a. Is this AE serious according to ICH guidelines? AEich, yes, no

Record related study medications in item 10.

AEdrad, Change in administration, Comment below.

6. Status/Outcome

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

Form for Status/Outcome: IAEoutc, Continuing, Resolved, Death, Severity/frequency increased, Status changed to reportable, Continuing at end of study participation

6a. Status/Outcome Date: AEocdt, dd, MMM, yy

Form for Treatment: AETrt, None, Medication(s), Prolonged hospitalization, Procedure/Surgery, Other

8. Has/will this AE be reported as an EAE? AEdaids, yes, no

9. This AE was first reported at visit: AEvisit, Visit code required

10. Record the medication and relationship codes for each study medication that is definitely, probably, or possibly related to the AE (see item 4 above): Medication codes (Med Code), Relationship to ART Study Product (Rel Code)

Table with 8 columns: 10a. Med Code, 10a1. Rel Code, 10b. Med Code, 10b1. Rel Code, 10c. Med Code, 10c1. Rel Code, 10d. Med Code, 10d1. Rel Code

Comments:

AEcomm

HPTN 052 (096)

ICM-1 (423)

Index ID

- - -
 Site Number Index Number Partner Chk

Index Concomitant Medications Log

CMnone No medications taken throughout study. **CMninit** Staff Initials/Date
 End of form. Fax to SCHARP DataFax.

Medication (generic name) CM1med		<input type="checkbox"/> CM1clsig clinically significant	Staff Initials/Log Entry Date <input type="text" value="CM1init"/>
Indication CM1ind		Taken for a reported AE? <input type="checkbox"/> CM1ae <input type="checkbox"/> no	
Date Started <input type="text" value="CM1stdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text" value="CM1spdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM1cont Continuing of study	
		Record AE Log page(s): <input type="text" value="CM1ae1pg"/> <input type="text" value="CM1ae2pg"/> <input type="text" value="CM1ae3pg"/> <input type="text" value="CM1ae4pg"/>	

CM1me

Medication (generic name) CM2med		<input type="checkbox"/> CM2clsig clinically significant	Staff Initials/Log Entry Date <input type="text" value="CM2init"/>
Indication CM2ind		Taken for a reported AE? <input type="checkbox"/> CM2ae <input type="checkbox"/> no	
Date Started <input type="text" value="CM2stdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text" value="CM2spdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM2cont Continuing of study	
		Record AE Log page(s): <input type="text" value="CM2ae1pg"/> <input type="text" value="CM2ae2pg"/> <input type="text" value="CM2ae3pg"/> <input type="text" value="CM2ae4pg"/>	

CM2me

Medication (generic name) CM3med		<input type="checkbox"/> CM3clsig clinically significant	Staff Initials/Log Entry Date <input type="text" value="CM3init"/>
Indication CM3ind		Taken for a reported AE? <input type="checkbox"/> CM3ae <input type="checkbox"/> no	
Date Started <input type="text" value="CM3stdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text" value="CM3spdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM3cont Continuing of study	
		Record AE Log page(s): <input type="text" value="CM3ae1pg"/> <input type="text" value="CM3ae2pg"/> <input type="text" value="CM3ae3pg"/> <input type="text" value="CM3ae4pg"/>	

CM3me

Medication (generic name) CM4med		<input type="checkbox"/> CM4clsig clinically significant	Staff Initials/Log Entry Date <input type="text" value="CM4init"/>
Indication CM4ind		Taken for a reported AE? <input type="checkbox"/> CM4ae <input type="checkbox"/> no	
Date Started <input type="text" value="CM4stdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Date Stopped <input type="text" value="CM4spdt"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> CM4cont Continuing of study	
		Record AE Log page(s): <input type="text" value="CM4ae1pg"/> <input type="text" value="CM4ae2pg"/> <input type="text" value="CM4ae3pg"/> <input type="text" value="CM4ae4pg"/>	

CM4me

bit 4 1 2 3 4 2 5 4 2 3 4 2 3 4 2 3 4 2 3 NOV-11

formlang
Language

Index ID

Form fields for Index ID: iid, Index Number, pid, Chk

Index Pregnancy Outcome POqc

POunk Outcome unknown at end of study. POinit Staff Initials/Date. End of form. Fax to SCHARP DataFax.

1. How many pregnancy outcomes resulted from the reported pregnancy? POoutcm

2. OUTCOME #1

2a. Outcome Date PO1outdt dd MMM yy

2b. Specify Outcome: Mark only one.

PO1outcm full term live birth (>= 37 weeks) PO1mthd C-section vaginal
premature live birth (< 37 weeks)
spontaneous fetal death and/or still birth (>= 20 weeks)
spontaneous abortion (< 20 weeks) Complete AE Log. Refer to the protocol and SSP to determine whether an EAE is submitted.
ectopic pregnancy
therapeutic/elective abortion

2c. Were any fetal/infant congenital anomalies identified? PO1anom yes no not assessed

If only one outcome, end of form.

3. OUTCOME #2

3a. Outcome Date PO2outdt dd MMM yy

3b. Specify Outcome: Mark only one.

PO2outcm full term live birth (>= 37 weeks) PO2mthd C-section vaginal
premature live birth (< 37 weeks)
spontaneous fetal death and/or still birth (>= 20 weeks)
spontaneous abortion (< 20 weeks) Complete AE Log. Refer to the protocol and SSP to determine whether an EAE is submitted.
ectopic pregnancy
therapeutic/elective abortion

3c. Were any fetal/infant congenital anomalies identified? PO2anom yes no not assessed

Comments: IPOcomm

Plate Number: 463 CMV-1: Couples Missed Visit

HPTN 052 (096)

CMV-1 (463)

visit [] [] []

Visit Code

Index ID

iid [] [] - [] [] [] - pid [] [] - []

Site Number

Index Number

Partner

Chk

Couples Missed Visit

Form Completion Date

CMVfcdt [] [] [] [] [] []

dd

MMM

yy

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

Comments: CMVcomm

Horizontal lines for additional comments.

Index ID

iid - - pid - Chk

Couples Transfer

Form Completion Date

CTdt dd MMM yy

Instructions: The transferring study site completes this form when a couple transfers to another study site.

1. Name of transferring study site: CTtsite CTtuid Unit ID

2. Name of receiving study site: CTrsite CTruid Unit ID

3. Visit Code of last completed contact with index and/or partner: CTvisit

4. Date index and partner records were sent to receiving study site: CTsentdt dd MMM yy

Do not include year for this date

Comments: CTcomm

Index ID

Form for Index ID with fields iid, Index Number, pid, and Chk.

Couples Receipt

Form Completion Date

Form for Form Completion Date with fields CRdt, dd, MMM, and yy.

Instructions: The receiving study site completes this form when a couple transfers from another study site. Record above the index ID assigned by the transferring study site (i.e., keep original index ID). Do not assign new IDs to the index or partner.

1. Name of receiving study site: CRrsite [CRruid] Unit ID

2. Name of transferring study site: CRtsite [CRTuid] Unit ID

3. Date index signed informed consent at receiving study site: [CRIicdt] dd MMM yy. Includes red box: Do not include years for these dates.

4. Date partner signed informed consent at receiving study site: [CRpicdt] dd MMM yy

5. Did index provide informed consent for specimen storage at receiving study site? [CRiconsn] yes no. Includes note: If no, go to item 6.

5a. Date informed consent for specimen storage signed: [CRicondt] dd MMM yy. Includes red box: Do not include year for this date.

6. Did partner provide informed consent for specimen storage at receiving study site? [CRpconsn] yes no. Includes note: If no, end of form.

6a. Date informed consent for partner specimen storage signed: [CRpcondt] dd MMM yy. Includes red box: Do not include year for this date.

Comments: CRcomm

HPTN 052 (096)

PDV-1 (488)

Page 1 of 1

PDVsite

Participant

Not included in de-identified datasets

Study: HPTN 052

Site: Site Name, City, State/Country

I verify that as of dd-MMM-yy:

- The participant ID numbers listed below are all of the participants from this site for whom data were faxed to SCHARP.
- To the best of my knowledge, the data faxed to SCHARP are complete and accurate.

PDVpsig

Principal Investigator Signature

dd MMM yy

PDVsigdt

Today's Date

Principal Investigator Name (printed)

Please fax all pages to SCHARP DataFax by dd-MMM-yy.

bit 4 168 488 488 488 AN-13

Index ID

Form for Index ID with fields: iid, Index Number, pid, Chk

Couples End of Study Inventory

Not included in de-identified datasets

Form Completion Date

Form for Form Completion Date with fields: CESfcdt, dd, MMM, yy

Instructions: Complete this form only when both the index and partner terminate from the study.

- 1. What is the page number of the last Index Adverse Event Log?
2. What is the page number of the last Index Concomitant Medications Log?
3. What is the event number of the last Index When to Start form?
4. What is the page number of the last Index Antiretroviral Treatment Regimen Log?
5. What is the page number of the last Index Pre-existing Conditions Log?
6. Record the participant's identification number for each partner that enrolled with this index:
6a. CESp1iid - CESp1pid
6b. CESp2iid - CESp2pid
6c. CESp3iid - CESp3pid
7. How many interim visits were conducted for the Index during the study and recorded on a form submitted via DataFax?
8. How many interim visits were conducted for the partner(s) during the study and recorded on a form submitted via DataFax?

Index ID

iid [] [] - [] [] [] - pid [] [] - [] []
Site Number Index Number Partner Chk

Index Termination

1. Termination Date: ITMtdt [] [] [] [] [] [] [] []
dd MMM yy

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

2. Reason for termination. Mark only one.

ITMtrsn Scheduled exit visit/end of study. —> End of form.

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

2b1. Date of death ITMddt [] [] [] [] [] [] OR ITMdun unknown
dd MMM yy

2b2. Cause of death ITMdcou _____ OR ITMdcun unknown

Complete or update Index Adverse Event Log.

2c. Participant refused further participation, specify: ITMrefrx _____

2d. Participant unable to adhere to visit schedule.

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

2f. Investigator decision, specify: ITMinvdx _____

2g. Unable to contact participant.

2h. NOT APPLICABLE FOR THIS PROTOCOL.

2i. Inappropriate enrollment.

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

2k. Other, specify: ITMtrmox _____

2l. Early study closure.

3. Was termination associated with...

Adverse Event? yes ITMaef no don't know
Record Index Adverse Event Log page: ITMaelp [] [] [] page #

Comments: ITMcommx _____

Index ID

iid						pid	
Site Number		Index Number		Partner		Chk	

Couples Termination

1. Termination Date: *dd* *MMM* *yy*

CTMtdt					
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Date the site determined that the couple was no longer in the study.

Comments: **CTMcommx**
