



Participant ID

ptid									
------	--	--	--	--	--	--	--	--	--

  
Site Number      Participant Number      Chk

Demographics

country code

6. In which country were you born? .....

DEMcount		
----------	--	--

→ If born in the U.S., go to item 7.

6a. What is the total number of years you have been living in the U.S.? .....

# years  

DEMinUS		
---------	--	--

7. What is the highest grade or year of schooling you have completed? *Do not read response categories aloud.*

DEMeduc	
---------	--

 grade or equivalent or less  
DEMEDUC\*

- some high school
- high school graduate or equivalent
- vocational/trade/technical school
- some college or 2 year degree
- finished college
- masters or other advanced degree

yes      no

8. Are you currently a student? .....

DEMstud	
YESNO	

→ If no, go to item 9.

full-time      part-time

8a. Are you a full-time or part-time student? .....

DEMftpt	
DEMFTPT*	

9. Are you currently working? *Mark only one.*

DEMwork	
---------	--

 working full-time  
DEMWORK\*

- yes, working part-time or occasionally
- no, unemployed
- no, retired
- no, unable to work (disabled)

Plate 003 DEM-3: Demographics, page 3

Visit Code

HPTN 061 (162)

DEM-3 (003)

Page 3 of 4

Participant ID

-  -   
Site Number Participant Number Chk

Demographics

10. Which of the following best describes your household?

- DEMhouse**  by myself  
**DEMHOUSE\***
- I live with a partner or spouse (with or without children)
- I live with a roommate or roommates (who are not partners)
- I live with relatives (parents, grandparents, siblings, etc.)
- I live with members of my house (such as house ball community)
- I do not have a stable home
- other, specify: **DEMhouox** \_\_\_\_\_

11. What was the total yearly income of your household before taxes were taken out?  
*Do not read response categories aloud.*

- DEMincom**  an \$5,000  
**DEMINCOM\***
- \$5,000–\$9,999
- \$10,000–\$19,999
- \$20,000–\$29,999
- \$30,000–\$39,999
- \$40,000–\$49,999
- \$50,000–\$59,999
- \$60,000–\$69,999
- \$70,000–\$79,999
- \$80,000 or more

12. How many people does this income support?

- one, only myself*      *two*      *three*      *four or more*
- DEMpeop**     
**DEMPEOP\***

10-JUN-09

**LANGUAG** **CHECKBOX**  
Language Staff Initials / Date

Plate 004 DEM-4: Demographics, page 4

Visit Code visit

HPTN 061 (162)

DEM-4 (004)

Page 4 of 4

Participant ID

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

Demographics

13. In the last 6 months, how often was there not enough money in the household for rent, food, or utilities (e.g., gas, electric, phone)?

never once in a while fairly often very often  
DEMnomon [ ] [ ] [ ] [ ]  
DEMNONOMON\*

14. Do you currently have any health care coverage, including health insurance, a health plan such as HMO, or government plan such as Medicaid?.....

yes no  
DEHcov [ ]  
YESNO

Plate 071 ENR-1: Enrollment, page 1

Visit Code

HPTN 061 (162)

ENR-1 (071)

Page 1 of 2

Participant ID

-  -   
Site Number Participant Number Chk

Enrollment

Enrollment Date

DDMMYY8 dd MMM yy

1. Has the participant signed the informed consent for long-term specimen storage? .....  yes  no  
 YESNO

2. Did the participant complete the ACASI Enrollment Questionnaire? .....  yes  no  
 YESNO

3. Did the participant complete the Social and Sexual Network Survey? .....  yes  no  
 YESNO

4. Enrollment categories:

Participant refused HIV testing

4b. Participant is HIV-negative

Index

4b2. non-Index

4c. Participant is HIV-positive – new diagnosis (Index)

4d. Participant previously diagnosed as HIV-positive

in care/treatment

4d2. not in care/treatment and reports having unprotected anal intercourse with HIV-negative or unknown serostatus partners (Index)

4d3. not in care/treatment and reports having unprotected anal intercourse **only** with HIV-positive partners

5. Was the participant referred by an Index participant? .....  yes  no  
 YESNO  *If no, go to item 6.*

5a. Index Participant ID: .....  -  -   
Site Number Participant Number Chk

6. Is the participant eligible for follow-up visits? .....  yes  no  
 YESNO  *If no, go to item 8 on page 2.*

Participant ID

ptid									
------	--	--	--	--	--	--	--	--	--

  
Site Number      Participant Number      Chk

Enrollment

7. Did the participant accept Peer Health Navigation services at this visit? .....

yes      no  

ENRphn	
YESNO	

→ If yes, go to item 8.

7a. Why did the participant choose to not work with Peer Health Navigation services?  
Mark the one explanation that best matches the participant's response.

- I can access the services I need on my own.
- I do not need the services that a PHN could connect me with.
- I do not have the time to meet with a PHN.
- Now is not a good time for me to work with a PHN. I hope to work with a PHN later.
- I am concerned that my participation in this study will not be confidential if I participate in the PHN component.
- other, specify: **ENRnopox** \_\_\_\_\_

8. Has the participant ever taken antiretroviral medication for treatment? .....

yes      no      N/A—not HIV-positive  

ENRearv		
ENREARV*		

→ If no or N/A, go to item 9.

8a. Is the participant currently taking antiretroviral medications for treatment? .....

yes      no  

ENRcarv	
YESNO	

8b. Date of last dose: .....

ENRarvdt				
DDMMYY8				

  
dd      MMM      yy

CIRCUMCISION ASSESSMENT

9. Status: .....

circumcised      partially circumcised      uncircumcised      not applicable  

ENRcircu			
ENRCIRCU*			

9a. Method of determination: .....

self-report      clinical exam  

ENRcird	
ENRCIRD*	

**ENRcomm**

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

Plate 075 ELR-1: Enrollment STI Laboratory Results

Visit Code

HPTN 061 (162)

ELR-1 (075)

Page 1 of 1

Participant ID

ptid  -  -   
Site Number Participant Number Chk

Specimen Collection Date

ELRdt     
DDMMYY8 dd MMM yy

Enrollment STI Laboratory Results

Alternate Collection Date  
Not done/ Not collected dd MMM yy  
ELRsyndt     
CHECKBOX DDMMYY8

1. SYPHILIS SEROLOGY *non-reactive reactive*

1a. Screening test (RPR) ..... ELRsyyps   
NONRCT  
If non-reactive, go to item 4.

1a1. Syphilis titer ..... 1: ELRsyyst

1b. Confirmatory test (TPHA, MHA-TP, FTA, or TPPA) *negative positive*  
ELRsyypc   
NEGPOS  
If negative, go to item 4.

2. Has the participant ever been treated for syphilis? ..... *yes no don't know*  
ELRsyptr     
YESNODK  
If no or don't know, go to item 3.

2a. How was this treatment reported? ..... *self-report documentation*  
ELRsyprp   
ELRSYPRP\*

3. Diagnosis:

ELRsyidx      
ELRSYIDX\*  
 *active infection*  
 *treated infection*  
 *indeterminate response*

Alternate Collection Date  
Not done/ Not collected dd MMM yy  
ELRrgondt     
CHECKBOX DDMMYY8  
ELRrctdt     
CHECKBOX DDMMYY8

4. URINE NAAT *negative positive*

4a. *N. gonorrhea* ..... ELRrgon   
NEGPOS  
4b. *C. trachomatis* ..... ELRrct   
NEGPOS

ELRrsdt     
CHECKBOX DDMMYY8

5. Rectal Swabs

*self-collected clinician-collected*  
5a. ELRrsco   
ELRRSCO\*  
*stored not stored Reason:*  
5b. ELRrsst  → ELRrsx

10-JUN-09

formlang  sfdt\_075  
LANGUAG CHECKBOX

Plate 076 RSR-1: Rectal Swab Results

Visit Code

HPTN 061 (162)

RSR-1 (076)

Page 1 of 1

Participant ID

-  -   
Site Number Participant Number Chk

Rectal Swab Results

Specimen Collection Date

DDMMYY8      
dd MMM yy

Not done/  
Not collected **Alternate Collection Date**  
dd MMM yy  
  
CHECKBOX DDMMYY8

1. RECTAL SWABS

negative positive equivocal/  
re-collect required  
1a. *N. gonorrhoea* .....   
CHECKBOX RSRGON\*

CHECKBOX DDMMYY8

negative positive equivocal/  
re-collect required  
1b. *C. trachomatis* .....   
CHECKBOX RSRCT\*

RSRcomm

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

12-OCT-09

LANGUAGE CHECKBOX

Language Staff Initials / Date



Plate 085 MRR-1: Medical Records Review

Visit Code

visit

HPTN 061 (162)

MRR-1 (085)

Participant ID

Form Completion Date

ptid  -  -

Site Number Participant Number Chk

Medical Records Review

MRRdt

DDMMYY8 dd MMM yy

1. ARV start date for treatment: .....

MRRstxdt

DDMMYY8

2. HIV RNA PCR prior to ARV initiation:

Specimen Collection Date

dd MMM yy

MRRarvdt

DDMMYY8

> = <

MRRarvo

GTEQLT

viral copies/mL

MRRarv

MRRcomm

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

10-JUN-09

formlang sfdt\_085  
LANGUAGE CHECKBOX

Language Staff Initials / Date





Plate 093 HCU-3: Health Care Utilization, page 3

Visit Code

HPTN 061 (162)

HCU-3 (093)

Page 3 of 4

Participant ID

-     -   
Site Number Participant Number Chk

Health Care Utilization

6. In the last 6 months, did you ever need health care but could not get it? .....

yes no  
HCUprev  
YESNO

If no, go to item 7 on page 4.

6a. What prevented you from getting health care?  
*Do not read response categories aloud. Mark all that apply.*

HCU<sup>exp</sup><sub>CHECKBOX</sub> it was too expensive or not covered by insurance

HCU<sup>appt</sup><sub>CHECKBOX</sub> I couldn't get an appointment

HCU<sup>plac</sup><sub>CHECKBOX</sub> I didn't know any place to go

HCU<sup>call</sup><sub>CHECKBOX</sub> I didn't know who to call

HCU<sup>tran</sup><sub>CHECKBOX</sub> I had no way to get there

HCU<sup>kids</sup><sub>CHECKBOX</sub> I couldn't get child care

HCU<sup>jail</sup><sub>CHECKBOX</sub> I was in jail, prison, or juvenile detention center

HCU<sup>race</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because of my race/ethnicity

HCU<sup>comf</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because of my HIV status

HCU<sup>sexm</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because I have sex with men

HCU<sup>home</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because I am homeless

HCU<sup>idu</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because I use needles to inject drugs

HCU<sup>drug</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because I use other drugs to get high

HCU<sup>high</sup><sub>CHECKBOX</sub> there was no place I felt comfortable because I was high/drunk

HCU<sup>oth</sup><sub>CHECKBOX</sub> other, specify:

10-JUN-09

LANGUAG <sub>CHECKBOX</sub>  
Language Staff Initials / Date



Plate 121 FUV-1: Follow-up Visit, page 1

Visit Code

HPTN 061 (162)

FUV-1 (121)

Page 1 of 2

Participant ID

ptid  -  -   
Site Number Participant Number Chk

Follow-up Visit

Visit Date

FUVdt     
DDMMYY8 dd MMM yy

- 1. Did the participant complete the ACASI Follow-up Questionnaire? .....   YESNO  YESNO
- 2. Did the participant complete the Social and Sexual Network Survey? ...   YESNO  YESNO
- 3. Since the last visit, has the participant been diagnosed with a sexually transmitted infection (STI)? .....   YESNO  YESNO ➔ If no, go to item 4 on page 2.

Indicate which of the following STIs with which the participant has been diagnosed:

	yes	no	self-report	documentation	pharyngeal	rectal	urethral	yes	no
3a. gonorrhea	<input type="text" value="FUVgon"/>	<input type="checkbox"/> YESNO	<input type="text" value="FUVgonr"/>	<input type="checkbox"/> FUVGONR*	<input type="text" value="FUVgonl"/>	<input type="checkbox"/> FUVGONL*	<input type="checkbox"/>	<input type="text" value="FUVgont"/>	<input type="checkbox"/> YESNO
<i>If no, go to item 3b.</i> ←									
3b. chlamydia	<input type="text" value="FUVchl"/>	<input type="checkbox"/> YESNO	<input type="text" value="FUVchlr"/>	<input type="checkbox"/> FUVCHLR*	<input type="text" value="FUVchll"/>	<input type="checkbox"/> FUVCHLL*	<input type="checkbox"/>	<input type="text" value="FUVchlt"/>	<input type="checkbox"/> YESNO
<i>If no, go to item 3c.</i> ←									
3c. Herpes simplex	<input type="text" value="FUVher"/>	<input type="checkbox"/> YESNO	<input type="text" value="FUVherr"/>	<input type="checkbox"/> FUVHERR*	<input type="text" value="FUVherl"/>	<input type="checkbox"/> FUVHERL*		<input type="text" value="FUVhert"/>	<input type="checkbox"/> YESNO
					Infection status:				
					new infection		recurring outbreak		
					<input type="text" value="FUVherli"/>		<input type="checkbox"/> FUVHERLI*		

3d. other STI   YESNO  YESNO

If yes, specify:

Plate 122 FUV-2: Follow-up Visit, page 2

Visit Code

HPTN 061 (162)

FUV-2 (122)

Page 2 of 2

Participant ID

-  -   
Site Number Participant Number Chk

Follow-up Visit

4. Since the last visit, has the participant been circumcised?

**FUVcirc** was already circumcised  
**FUVCIRC\***

no, he remains uncircumcised

yes →         
circumcision date  
MMM yy

not applicable

5. Since the last visit, has the participant initiated taking any antiretroviral medications for treatment?

yes no N/A (not HIV-positive)  
 **FUVarv**    
**FUVARV\***

If yes, complete Medical Records Review. ←

6. Since the last visit, has the participant reported any social impacts? .....

yes no  
 **FUVsi**   
**YESNO**

If yes, complete a Social Impact Log for each impact. ←

WEEK 26 VISIT ONLY:

7. Since the last visit, has the participant used or accepted Peer Health Navigation services (including at this visit)? .....

yes no  
 **FUVphn**   
**YESNO**

→ If yes, end of form.

7a. Why did the participant choose to not work with Peer Health Navigation services? Mark the one explanation that best matches the participant's response.

**FUVphnn** I already can access the services I need on my own.  
**FUVPHNN\***

I do not need the services that a PHN could connect me with.

I do not have the time to meet with a PHN.

Now is not a good time for me to work with a PHN. I hope to work with a PHN later.

I am concerned that my participation in this study will not be confidential if I participate in the PHN component.

other, specify: **FUVphnnx** \_\_\_\_\_

**FUVcomm**

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

10-JUN-09

**LANGUAG** **CHECKBOX**

Language Staff Initials / Date

Plate 131 FLR-1: Follow-up STI Laboratory Results

Visit Code

HPTN 061 (162)

FLR-1 (131)

Participant ID

-  -   
Site Number Participant Number Chk

Specimen Collection Date

DDMMYY8 dd MMM yy

Follow-up STI Laboratory Results

Alternate Collection Date

Not done/ Not collected dd MMM yy  
     
FLRsyptdt CHECKBOX DDMMYY8

1. SYPHILIS SEROLOGY *non-reactive reactive*

1a. Screening test (RPR) .....   
FLRsypts NONRCT

If non-reactive, go to item 4.

1a1. Syphilis titer ..... 1:   
FLRsypt

1b. Confirmatory test (TPHA, MHA-TP, FTA, or TPPA)

*negative positive*

FLRsyptc NEGPOS

If negative, go to item 4.

2. Since the last visit, has the participant been treated for syphilis? .....

*yes no don't know*

FLRsypttr YESNODK

If no or don't know, go to item 3.

*self-report documentation*

2a. How was this treatment reported? .....   
FLRsyprp FLRSYPRP\*

3. Diagnosis:

FLRsyptdx FLRSYPTDX\*  
active infection

treated infection

indeterminate response

Alternate Collection Date

Not done/ Not collected dd MMM yy

FLRgondt CHECKBOX DDMMYY8

4. URINE NAAT *negative positive*

4a. N. gonorrhea .....   
FLRgon NEGPOS

FLRctdt CHECKBOX DDMMYY8

4b. C. trachomatis .....   
FLRct NEGPOS

FLRrsdt CHECKBOX DDMMYY8

5. Rectal Swabs (required at Week 52 only)

*self-collected clinician-collected*

5a.    
FLRrsco FLRRSCO\*

*stored not stored Reason:*

5b.     
FLRrsst FLRRSST\* FLRrsx

10-JUN-09

formlang sfidt\_131  
LANGUAG CHECKBOX

Language Staff Initials / Date

Plate 152 SIL-1: Social Impact Log

Page visit

HPTN 061 (162)

SIL-1 (152)

Page 1 of 1

Participant ID

ptid  -  -

Site Number Participant Number Chk

Social Impact Log

**Instructions:** Fax this form to SCHARP DataFax whenever a new Social Impact is recorded or information on this form is updated. Fax only pages with new entries or revisions.

1. Concisely describe social impact:

**SILsumx**

---



---



---



---

2. Onset date: .....

dd MMM yy

**SILondt**  
DDMMYY8

3. Reported at visit: .....

**SILatvis**

4. Social impact code:

**SILcode**

**Social Impact Codes:** See back for definitions.

01 Personal Relationships	05 Medical/Dental	09 Military/Other
02 Travel/Immigration	06 Health Insurance	Government Agency
03 Employment	07 Life Insurance	10 Other
04 Education	08 Housing	

**SILcomm**

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

10-JUN-09

**formlang** **sfdt\_152**  
**LANGUAGE** **CHECKBOX**

Language Staff Initials / Date

HPTN 061 (162)

FPR-1 (181)

Page 1 of 3

Participant ID

ptid  -  -

Site Number

Participant Number

Chk

Follow-up Prevention Research Questionnaire

Form Completion Date

FPRdt      
DDMMYY8

dd

MMM

yy

FPRlnone  
CHECKBOX and recorded on this page (participant is HIV-positive)

We will now ask you a few questions about other ways that people try to prevent infection with HIV. PEP (post-exposure prophylaxis) is when a person is given medicine right after getting exposed to HIV (like after unprotected sex with an infected partner) to prevent becoming infected.

1. Since your last visit, have you used PEP? .....  yes  no  don't know  
FPRupep  
YESNODK  
*If no or don't know, go to statement above item 2.*

1a. When you used PEP, was it part of a research study? .....  yes  no  
FPRpeprs  
YESNO

PrEP (pre-exposure prophylaxis) is when a person is given medicine before being exposed to HIV (like when they expect they will be having unprotected sex with an infected partner) to prevent becoming infected.

2. Since your last visit, have you used PrEP? .....  yes  no  don't know  
FPRuprep  
YESNODK  
*If no or don't know, go to statement above item 3.  
If this is the participant's 26-week visit, end of form.*

2a. When you used PrEP, was it part of a research study? .....  yes  no  
FPRprepr  
YESNO  
*If this is the participant's 26-week visit, end of form.*

Research is also being done to develop an HIV vaccine, that is, a shot or series of shots that would prevent someone from being infected if they were exposed to HIV or that would keep them healthy longer if they were infected with HIV. It would be like vaccines people already get to prevent measles or polio.

3. Before today, had you ever heard of an HIV vaccine? .....  yes  no  don't know  
FPRhivva  
YESNODK  
*If no or don't know, go to statement above item 5 on page 2.*

3a. Have you ever been in an HIV vaccine research study? .....  yes  no  don't know  
FPRvaccr  
YESNODK  
*If yes, go to statement above item 5 on page 2.*

Plate 182 FPR-2: Follow-up Prevention Research Questionnaire, page 2

HPTN 061 (162)

FPR-2 (182)

Page 2 of 3

Participant ID

ptid							
Site Number	Participant Number				Chk		

Follow-up Prevention Research Questionnaire

FPR2none  
CHECKBOX data recorded on this page

We would like to know how likely people would be to participate in a vaccine study, based on the following facts:

- You cannot get HIV from an HIV vaccine
- Half the participants in a study would get vaccine and half would get an inactive substance (placebo)
- Study participants would still need to use condoms to be protected when they have sex
- Participants who get the vaccine may test positive on regular HIV tests after the study is over, even if they are HIV negative

4. How likely do you think you would be to participate in an HIV vaccine research study? We are not asking you to volunteer for an actual vaccine study. We just want to know how likely you would be to participate in one.

FPRparh  
FPRPARH\* likely to participate

- somewhat likely to participate
- somewhat unlikely to participate
- very unlikely to participate

Some researchers believe that treating sexually transmitted infections (STI) may lower an individual's risk of getting HIV. Research so far, has not shown this to be effective.

5. How likely do you think you would be to participate in a study where you would be treated for STIs to see if it lowered the risk of getting HIV? We are not asking you to volunteer for an actual study. We just want to know how likely you would be to participate in one.

FPRpars  
FPRPARS\* likely to participate

- somewhat likely to participate
- somewhat unlikely to participate
- very unlikely to participate

Some recent studies have shown that men who are circumcised ("cut") have a lower chance of getting HIV from vaginal sex with women than uncircumcised (or "uncut") men. We don't know if this is true for anal sex between men.

6. Before today, had you ever heard that circumcision can lower the risk of HIV for some men? .....

yes    no    don't know

FPRcirc  
YESNODK

10-JUN-09

formlang sfdt\_182  
LANGUAGE CHECKBOX  
Language Staff Initials / Date

Plate 183 FPR-3: Follow-up Prevention Research Questionnaire

visit

HPTN 061 (162)

FPR-3 (183)

Participant ID

ptid								
Site Number	Participant Number						Chk	

Follow-up Prevention Research Questionnaire

FPR3none  
CHECKBOX data recorded on this page

Only complete item 7 if participant is uncircumcised.

We would like to know how likely people would be to participate in a study of circumcision among men who have sex with men, knowing the following facts:

- Study participants would still need to use condoms to be protected when they have sex
- Half the men would be circumcised by a doctor and half would not be circumcised
- Men who were circumcised would be told to not have sex for 6–8 weeks to allow healing of the surgery site

7. How likely do you think you would be to participate in a circumcision research study? Again, we are not asking you to volunteer for an actual study. We just want to know how likely you would be to participate in one.

FPRparc  
FPRPARC\* likely to participate

- somewhat likely to participate
- somewhat unlikely to participate
- very unlikely to participate

FPRcomm

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

10-JUN-09

formlang sfdt\_183  
LANGUAGE CHECKBOX  
Language Staff Initials / Date

Plate 191 PHE-1: Peer Health Navigation Encounter, page 1

Encounter #: visit

HPTN 061 (162)

PHE-1 (191)

Page 1 of 3

Participant ID

ptid - -  
Site Number Participant Number Chk

Peer Health Navigation Encounter

Date of Encounter

PHEdt  
DDMMYY8  
dd MMM yy

Peer Health Navigator: \_\_\_\_\_

1. Type of Encounter:

PHEtype to-face  
PHEtype\*

PHEf2f  
PHEf2F\*y site

- other social service agency
- other medical setting (clinic, hospital)
- streets, parks, open spaces
- mobile van
- residential treatment program
- other community setting (bar, club, drop-in center, coffee shop, etc.)

PHEf2fox

other, specify: \_\_\_\_\_

telephone

letter

e-mail/internet

other, specify: PHEtypex \_\_\_\_\_

▶ If type of contact is letter, e-mail/internet, or other, go to item 2 on page 2.

1a. Duration of contact: PHEhrs # of hours

PHEmin # of minutes

Participant ID

ptid  -  -   
Site Number Participant Number Chk

Peer Health Navigation  
Encounter

2. Service provided: Mark all that apply.

Education/Assessment:

PHEintro Participant introduction

PHEintak Intake assessment/discussion

2b1. Was the information collected during the initial interview adequate for making an informed referral?  yes  no  
 PHEadeq YESNO

PHErela Relationship-building

PHEghed General health education

PHEhived Focused HIV education

PHEcomu Training on communication with medical or service providers (including appointment scheduling)

PHEappt Appointment reminder

PHEremin Reminder for follow-up study visit

PHErrc HIV or STI risk reduction counseling

PHEinfo HIV treatment/care information

Other services:

PHEcondm Condoms

PHEbene Assistance with benefits/entitlements

PHElegal Assistance with legal services

PHEcris Immediate crisis response

PHEadvo Advocated for client

PHEsuba Accompanied client to substance abuse treatment appointment

PHEhiva Accompanied client to HIV treatment and care appointment

PHEment Accompanied client to mental health appointment

PHEmedi Accompanied client to medical appointment

PHEoappt Accompanied client to other appointment

PHEother Other specify: \_\_\_\_\_ PHEothex

Participant ID

-  -   
 Site Number      Participant Number      Chk

Peer Health Navigation Encounter

3. Was a referral made at this encounter? .....  **PHErefer**   
YESNO  yes no  
 → *If yes, complete a Referral Log.*
4. Was a social impact reported at this encounter? ....  **PHEsi**   
YESNO  yes no  
 → *If yes, complete a Social Impact Log for each impact. If this is an interim visit, also complete an Interim Visit form.*
5. Did the participant report initiating any antiretroviral medications for treatment at this encounter? .....  **PHEarv**   
PHEARV\*  yes no      *N/A (not HIV-positive)*  
 → *If yes, complete a Medical Records Review.*

**PHEcomm**

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

10-JUN-09

LANGUAGE CHECKBOX  
Language Staff Initials / Date

Plate 201 HTR-1: HIV Test Results, page 1

Visit Code

HPTN 061 (162)

HTR-1 (201)

Page 1 of 2

Participant ID

ptid  -  -   
Site Number Participant Number Chk

Initial Specimen Collection Date

HTRdt      
DDMMYY8 dd MMM yy

HIV Test Results

Not done/  
Not collected  
1. Plasma Storage .....

stored not stored Reason not stored:  
HTRplas  → HTRplasx

Not done/  
Not collected

HTRrapn   
CHECKBOX HIV Rapid Kit Code .....

HTRrapk

2a. HIV Rapid Test Results

negative positive  
HTRrap   
NEGPOS

If negative, go to item 7 on page 2.

Not done/  
Not collected

HTRcd4n   
CHECKBOX Absolute CD4+ .....

cells/mm<sup>3</sup>  
HTRcd4

Not done/  
Not collected

HTR1wbn   
CHECKBOX HIV Western Blot Results .....

negative positive indeterminate  
HTR1wb    
NEGPOSIN

Not done/  
Not collected

HTR1hrpn   
CHECKBOX 4a. HIV RNA PCR (plasma) ....

> = < viral copies/mL  
HTR1hrpo  HTR1hrp

Not done/  
Not collected

HTR2n   
CHECKBOX 5. Sample #2 .....

Specimen Collection Date  
dd MMM yy  
HTR2dt      
DDMMYY8

5a. Plasma Storage .....

stored not stored Reason not stored:  
HTR2s  → HTR2sx

Not done/  
Not collected

HTR2wbn   
CHECKBOX 5b. HIV Western Blot Results

negative positive indeterminate  
HTR2wb    
NEGPOSIN

Not done/  
Not collected

HTR2hrpn   
CHECKBOX 5c. HIV RNA PCR (plasma) .....

> = < viral copies/mL  
HTR2hrpo  HTR2hrp

Plate 202 HTR-2: HIV Test Results, page 2

Visit Code

HPTN 061 (162)

HTR-2 (202)

Page 2 of 2

Participant ID

ptid  -  -   
Site Number Participant Number Chk

HIV Test Results

Not done/  
Not collected

HTR3n  
CHECKBOX Sample #3 .....

Specimen Collection Date

dd MMM yy  
HTR3dt      
DDMMYY8

stored not stored Reason not stored:

6a. Plasma Storage .....

HTR3s  → HTR3sx  
HTR3S\*

Not done/  
Not collected

HTR3wbn  
CHECKBOX 6b. HIV Western Blot Results .....

negative positive indeterminate

HTR3wb    
NEGPOSIN

Not done/  
Not collected

HTR3hrpn  
CHECKBOX 6c. HIV RNA PCR (plasma) .....

> = < viral copies/mL  
HTR3hrpo  HTR3hrp        
GTEOLT

negative positive indeterminate additional testing needed unknown/  
HIV test refused

7. Final HIV Status .....

HTRfinal   OR    
HTRFINAL\*

Complete Additional HIV Test Results form.

End of form.

7a. How was this HIV-status determined?

HTRstde  
HTRSTDE\* test(s) performed by study staff

Endpoint Adjudication Committee

External Medical Records

▶ Mark one of the following types of External Medical Records.

HTRext  
HTREXT\* letter from physician, provider, or agency

AIDS Drug Assistance Program (ADAP) documentation

a positive test result

evidence that the participant has been prescribed anti-retroviral medications for treatment of HIV infection

HTRcomm

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

12-OCT-09

formlang   
LANGUAG sfdt\_202  
CHECKBOX

Language Staff Initials / Date

Plate 251 AHT-1: Additional HIV Test Results, page 1

Visit Code

visit

HPTN 061 (162)

AHT-1 (251)

Page 1 of 2

Participant ID

ptid  -  -

Site Number Participant Number Chk

Additional HIV Test Results

Form Completion Date

AHTdt

DDMMYY8 dd MMM yy

Not done/  
Not collected

AHT4n  
CHECKBOX 1. Sample #4 .....

Specimen Collection Date  
dd MMM yy

AHT4dt

DDMMYY8

stored not stored Reason not stored:

1a. Plasma Storage .....

AHT4s  → AHT4sx

AHT4S\*

Not done/  
Not collected

AHT4wbn  
CHECKBOX 1b. HIV Western Blot Results .....

negative positive indeterminate

AHT4wb

NEGPOSIN

Not done/  
Not collected

AHT4hrpn  
CHECKBOX 1c. HIV RNA PCR (plasma) .....

viral copies/mL

> = < AHT4hrp

GTEQLT

Not done/  
Not collected

AHT5n  
CHECKBOX 2. Sample #5

Specimen Collection Date  
dd MMM yy

AHT5dt

DDMMYY8

stored not stored Reason not stored:

2a. Plasma Storage.....

AHT5s  → AHT5sx

AHT5S\*

Not done/  
Not collected

AHT5wbn  
CHECKBOX 2b. HIV Western Blot Results .....

negative positive indeterminate

AHT5wb

NEGPOSIN

Not done/  
Not collected

AHT5hrpn  
CHECKBOX 2c. HIV RNA PCR (plasma) .....

viral copies/mL

> = < AHT5hrp

GTEQLT

10-JUN-09

formlang  sfdt\_251  
LANGUAGE CHECKBOX

Language Staff Initials / Date

Plate 252 AHT-2: Additional HIV Test Results, page 2

Visit Code

visit

HPTN 061 (162)

AHT-2 (252)

Page 2 of 2

Participant ID

ptid							
Site Number	Participant Number				Chk		

Additional HIV Test Results

Not done/  
Not collected

AHT6n 3. Sample #6 .....  
CHECKBOX

Specimen Collection Date

dd MMM yy

AHT6dt .....  
DDMMYY8

stored not stored Reason not stored:

3a. Plasma Storage.....

AHT6s .....  
AHT6S\* → AHT6sx

Not done/  
Not collected

AHT6wbn 3b. HIV Western Blot Results .....  
CHECKBOX

negative positive indeterminate

AHT6wb .....  
NEGPOSIN

Not done/  
Not collected

AHT6hrpn 3c. HIV RNA PCR (plasma) .....  
CHECKBOX

viral copies/mL

> = <  
 AHT6hrpo .....  
GTEQLT AHT6hrp

negative positive indeterminate unknown

4. Final HIV Status .....

AHTfinal .....  
AHTFINAL\*

AHTcomm

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

10-JUN-09

formlang sfdt\_252  
LANGUAGE CHECKBOX

Language Staff Initials / Date





Plate 463 MV-1: Missed Visit

Visit Code

visit

HPTN 061 (162)

MV-1 (463)

Participant ID

Form Completion Date

ptid [ ] - [ ] [ ] [ ] [ ] [ ] - [ ]

Missed Visit

MVfcdt [ ] [ ] [ ] [ ] [ ] [ ]  
DDMMYY8

Site Number

Participant Number

Chk

dd

MMM

yy

dd

MMM

yy

1. Target Visit Date: MVtdt [ ] [ ] [ ] [ ] [ ] [ ]  
DDMMYY8

2. Reason visit was missed. *Mark only one.*

MVreasn  
MVREASN\*

unable to contact participant

2b. unable to schedule appointment(s) within allowable window

2c. participant refused visit

2d. participant incarcerated

2e. participant admitted to a health care facility

2f. participant withdrew from the study —————> **Complete a Termination form.**

2g. participant deceased —————> **Complete a Termination form.**

2h. other, specify:

MVotrex

Comments:

MVcomm

[ ] [ ] [ ] [ ] 10-JUN-09

formlang sfdt\_463  
LANGUAGE CHECKBOX

Language

Staff Initials / Date

Plate 465 PT-1: Participant Transfer

Visit Code

HPTN 061 (162)

PT-1 (465)

Page 1 of 1

Participant ID

-  -   
Site Number Participant Number Chk

Participant Transfer

Form Completion Date

DDMMYY8 dd MMM yy

- Name of transferring study site:   Site #
- Name of receiving study site:   Site #
- Visit Code of last completed contact with participant:
- Date participant records were sent to receiving study site:      
DDMMYY8 dd MMM yy

Comments:

10-JUN-09

LANGUAGE CHECKBOX  
Language Staff Initials / Date

Plate 466 PRC-1: Participant Receipt

Visit Code

HPTN 061 (162)

PRC-1 (466)

Page 1 of 1

Participant ID

-  -   
Site Number Participant Number Chk

Participant Receipt

Form Completion Date

DDMMYY8 dd MMM yy

Note: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.

1. Name of receiving study site:   Site #

2. Name of transferring study site:   Site #

3. Date informed consent signed at receiving study site:      
DDMMYY8 dd MMM yy

4. Did participant provide informed consent for specimen storage at receiving study site?  yes  no  
 YES  NO  If no, end of form.

4a. Date informed consent for specimen storage signed:      
DDMMYY8 dd MMM yy

Comments:

10-JUN-09

LANGUAGE CHECKBOX  
Language Staff Initials / Date

Plate 487 PIL-1: Participant Incident Log

Page 

visit
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HPTN 061 (162)

PIL-1 (487)

Participant ID

ptid 

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Site Number Participant Number Chk

Participant Incident Log  
For Internal Use Only

dd MMM yy

Form Completion Date: PILfcdt 

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 DMMYY8

SC Staff Name: PILstaff \_\_\_\_\_

Source of Information: PILsourc \_\_\_\_\_

If applicable:

Plate #: PILplate 

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Visit: PILvisit 

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Subject: Mark all that apply.

PILforms  
CHECKBOX

PILprot  
CHECKBOX

PILdata  
CHECKBOX

PILlab  
CHECKBOX

PILenrol  
CHECKBOX

PILrand  
CHECKBOX

PILsubo  
CHECKBOX, specify: \_\_\_\_\_

PILsubox

Event and resolution details:

PILevnt

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
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 10-JUN-09

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Language

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Staff Initials / Date

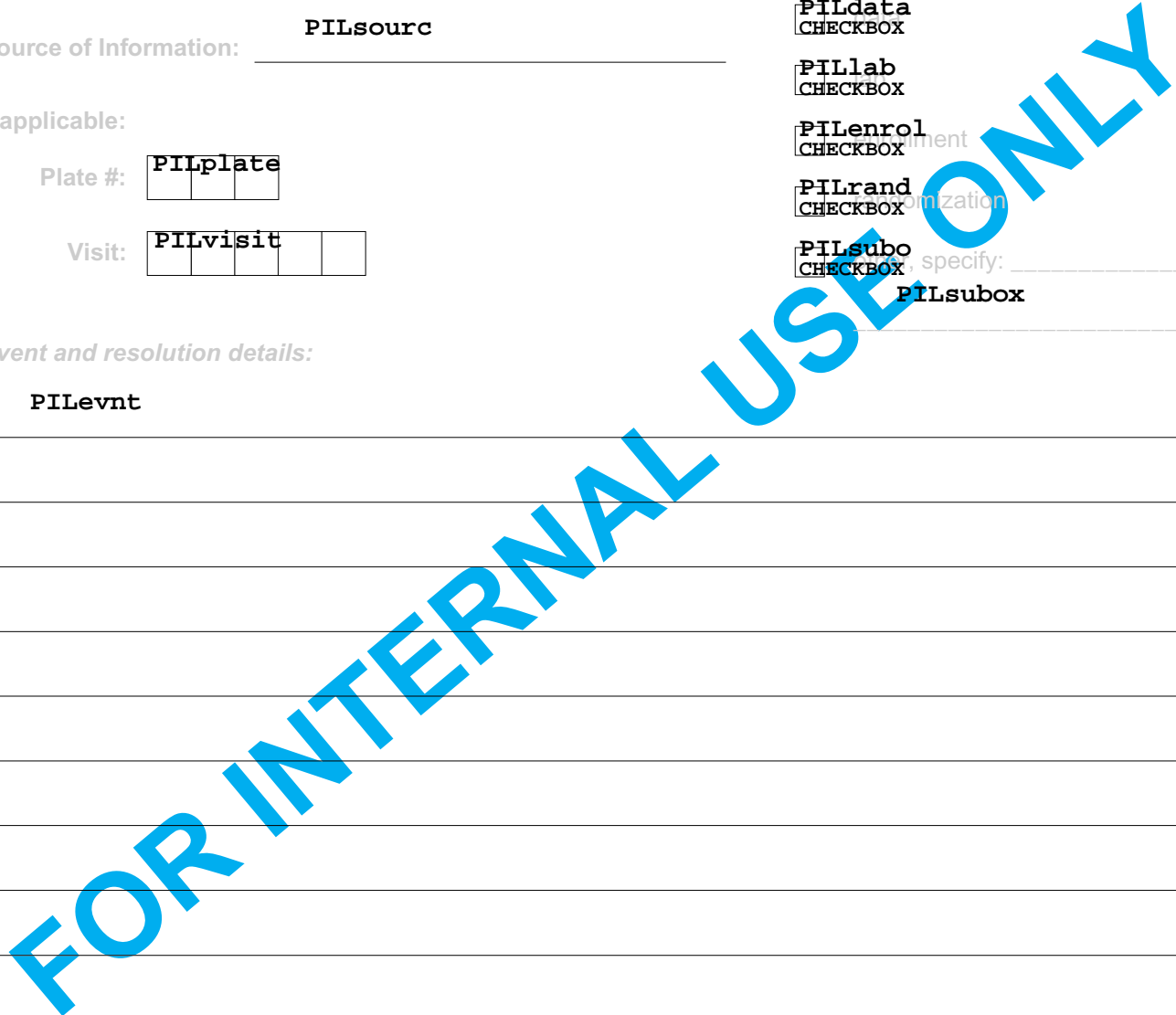


Plate 489 ESI-1: End of Study Inventory

Visit Code

HPTN 061 (162)

ESI-1 (489)

Page 1 of 1

Participant ID

Form Completion Date

ptid  -  -   
Site Number Participant Number Chk

End of Study Inventory

ESIdt      
DDMMYY8 dd MMM yy

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax?.....

visit code  
ESlvis

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?.....

# of interim visits  
ESlvis

3. Indicate the **highest** page number submitted for this participant for each of the following forms:

3a. Social Impact Log (SIL-1) .....  page # OR  no pages submitted

ESlvispg  
CHECKBOX

3b. Peer Health Navigation Encounter (PHE-1) .....  encounter # OR  no encounters submitted

ESlphnpg  
CHECKBOX

3c. Referral Log (RL-1) .....  page #

ESlrefpg

ESlcomm

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

10-JUN-09

formlang   
LANGUAGE CHECKBOX  
Language Staff Initials / Date

Plate 490 TM-1: Termination

Visit Code

HPTN 061 (162)

TM-1 (490)

Page 1 of 1

Participant ID

-  -   
Site Number Participant Number Chk

Termination

1. Termination Date:   
DDMMYY8          
Date the site determined that the participant was no longer in the study.

2. Reason for termination. Mark only one.

**TMtrmrnsn** Scheduled exit visit/end of study

2b. death, indicate date and cause if known

2b1. date of death   
DDMMYY8       OR  unknown

2b2. cause of death  OR  unknown

2c. participant refused further participation, specify:

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

2e. participant relocated, no follow-up planned

2f. investigator decision, specify:

2g. unable to contact participant

2h. HIV infection  
**NOT APPLICABLE FOR THIS PROTOCOL.**

2i. inappropriate enrollment

2j. invalid ID due to duplicate screening/enrollment

2k. other, specify:

2l. early study closure

Comments:

10-JUN-09

LANGUAGE CHECKBOX  
Language Staff Initials / Date