

Plate 001 ECF-1: Screening Eligibility Criteria—Female

Visit Code 6 visit

HPTN 039 (093)

ECF-1 (001)

Page 1 of 1

## Participant ID

7 ptid - - - - -  
Site Number Participant Number ChkScreening Eligibility Crite-  
ria—FemaleScreening Eligibility Criteria—  
Female

## Form Completion Date

8 ECFdt - - - - -  
dd MMM yy**Instructions:** Answer items 1–4 before interviewing participant.

1. Is the participant of legal age to provide independent informed consent per local regulations and guidelines? .. yes no  
9 ECFage ☐ → If no, participant is ineligible. End of form.
2. Was the participant willing and able to provide independent, written informed consent for screening? .... yes no  
10 ECFsic ☐ → If no, participant is ineligible. End of form.
- 2a. When was the informed consent for screening marked or signed? ..... dd MMM yy  
11 ECFsicdt
3. Was the participant willing and able to provide adequate locator information? ..... yes no  
12 ECFloc ☐ → If no, participant is ineligible. End of form.
4. Is the participant willing and able to undergo clinical evaluations, take study drug as directed, and adhere to the follow-up schedule? ..... yes no  
13 ECFadher ☐ → If no, participant is ineligible. End of form.
5. Are you currently participating in any other HIV vaccine or prevention study? ..... yes no  
14 ECFostdy ☐ → If yes, participant is ineligible. End of form.
6. Have you ever had a known bad (adverse) reaction to acyclovir? ..... yes no  
15 ECFreac ☐ → If yes, participant is ineligible. End of form.
7. Do you currently use or plan to use famciclovir, valacyclovir, or acyclovir for genital herpes? ..... yes no  
16 ECFcyclo ☐ → If yes, participant is ineligible. End of form.
8. Do you plan to permanently move away from this area in the next 12 months (1 year)? ..... yes no don't know  
17 ECFmove ☐ ☐ → If yes, participant is ineligible. End of form.
9. Do you plan to be away from this area for more than 2 months in a row (this includes seasonal travel) in the next 12 months (1 year)? ..... yes no don't know  
18 ECFaway ☐ ☐ → If yes, participant is ineligible. End of form.
10. Have you had unprotected vaginal sex (without a condom) at least once in the past 6 months? ..... yes no  
19 ECFvsex ☐ → If no, participant is ineligible. End of form.

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formlang  
Language25  
sfdt\_001  
Staff Initials / Date

Plate 002 ECF-1: Screening Eligibility Criteria-Female

Visit Code 6 visit

HPTN 039 (093)

ECF-1 (002)

Page 1 of 1

## Participant ID

7 ptid - - - - -  
Site Number Participant Number ChkScreening Eligibility Crite-  
ria—FemaleScreening Eligibility Criteria—  
Female

## Form Completion Date

8 ECFdt - - - - -  
dd MMM yy**Instructions:** Answer items 1–3 before interviewing participant.

1. Is the participant of legal age to provide independent informed consent per local regulations and guidelines? .. yes no  
9 ECFage ☐ → If no, participant is ineligible. End of form.
2. Was the participant willing and able to provide independent, written informed consent for screening? .... yes no  
10 ECFsic ☐ → If no, participant is ineligible. End of form.
- 2a. When was the informed consent for screening marked or signed? ..... dd MMM yy  
11 ECFsicdt
3. Was the participant willing and able to provide adequate locator information? ..... yes no  
12 ECFloc ☐ → If no, participant is ineligible. End of form.
4. Are you currently participating in any other HIV vaccine or prevention study? ..... yes no  
13 ECFostdy ☐ → If yes, participant is ineligible. End of form.
5. Have you ever had a known bad (adverse) reaction to acyclovir? ..... yes no  
14 ECFreac ☐ → If yes, participant is ineligible. End of form.
6. Do you currently use or plan to use famciclovir, valacyclovir, or acyclovir for genital herpes? ..... yes no  
15 ECFcyclo ☐ → If yes, participant must discontinue medication by the Enrollment visit to be eligible.
7. Do you plan to permanently move out of this area at any time during your study participation? ..... yes no don't know  
16 ECFmove ☐ ☐ → If yes, participant is ineligible. End of form.
8. Do you plan to be away from this area for more than 2 months in a row (this includes seasonal travel) at any time during your study participation? ..... yes no don't know  
17 ECFaway ☐ ☐ → If yes, participant is ineligible. End of form.
9. Have you had unprotected vaginal sex (without a condom) at least once in the past 6 months? ..... yes no  
18 ECFvsex ☐ → If no, participant is ineligible. End of form.

19 20 21 22  
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formlang  
Language24  
sfdt\_002  
Staff Initials / Date

Plate 003 ECM-1: Screening Eligibility Criteria-Male Page 1

Visit Code 

6	visit		
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HPTN 039 (093)

ECM-1 (003)

Page 1 of 2

## Participant ID

7							
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Site Number Participant Number ChkScreening Eligibility Crite-  
ria—MaleScreening Eligibility Criteria—  
Male

## Form Completion Date

8					
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ECMdt dd MMM yy**Instructions:** Answer items 1–5 before interviewing participant.

1. Is the participant of legal age to provide independent informed consent per local regulations and guidelines? .. yes no  
9 ECMage ☐ → If no, participant is ineligible. End of form.
2. Was the participant willing and able to provide independent, written informed consent for screening? .... yes no  
10 ECMsic ☐ → If no, participant is ineligible. End of form.
- 2a. When was the informed consent for screening marked or signed? ..... dd MMM yy  
11 ECMsicdt 

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3. Was the participant willing and able to provide adequate locator information? ..... yes no  
12 ECMloc ☐ → If no, participant is ineligible. End of form.
4. Is the participant willing and able to undergo clinical evaluations, take study drug as directed, and adhere to the follow-up schedule? ..... yes no  
13 ECMadher ☐ → If no, participant is ineligible. End of form.
5. Is the participant's sex at birth male?..... yes no  
14 ECMmale ☐ → If no, participant is ineligible. End of form.
6. Are you currently participating in any other HIV vaccine or prevention study? ..... yes no  
15 ECMstdy ☐ → If yes, participant is ineligible. End of form.
7. Have you ever had a known bad (adverse) reaction to acyclovir? ..... yes no  
16 ECMreac ☐ → If yes, participant is ineligible. End of form.
8. Do you currently use or plan to use famciclovir, valacyclovir, or acyclovir for genital herpes? ..... yes no  
17 ECMcyclo ☐ → If yes, participant is ineligible. End of form.
9. Do you plan to permanently move away from this area in the next 12 months (1 year)? ..... yes no don't know  
18 ECMmove ☐ ☐ → If yes, participant is ineligible. End of form.

19 20 21 22  
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formlang  
Language24  
sfdt\_003  
Staff Initials / Date

Plate 004 ECM-2: Screening Eligibility Criteria-Male Page 2

Visit Code 

6	visit		
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HPTN 039 (093)

ECM-2 (004)

Page 2 of 2

Participant ID

7							
ptid						chk	
Site Number		Participant Number				Chk	

Screening Eligibility Criteria—Male

10. Do you plan to be away from this area for more than 2 months in a row (this includes seasonal travel) in the next 12 months (1 year)? .....

yes no don't know

8		
ECMaway	<input type="checkbox"/>	<input type="checkbox"/>

If yes, participant is ineligible. End of form.

11. Have you been in a mutually monogamous relationship with an HIV-negative partner for the past 2 years (meaning you only had sex with each other and no one else)? .....

yes no

9	
ECMmrel	<input type="checkbox"/>

If yes, participant is ineligible. End of form.

12. Have you had anal intercourse with another man at least once within the past 6 months? .....

yes no

10	
ECMasex	<input type="checkbox"/>

If no, participant is ineligible. End of form.

Plate 005 ECM-1: Screening Eligibility Criteria-Male Page 1

Visit Code 6 visit

HPTN 039 (093)

ECM-1 (005)

Page 1 of 2

## Participant ID

7 ptid - - - - -  
Site Number Participant Number ChkScreening Eligibility Crite-  
ria—MaleScreening Eligibility Criteria—  
Male

## Form Completion Date

8 ECMdt - - - - -  
dd MMM yy**Instructions:** Answer items 1–4 before interviewing participant.

1. Is the participant of legal age to provide independent informed consent per local regulations and guidelines? .. yes no  
9 ECMage ☐ → If no, participant is ineligible. End of form.
2. Was the participant willing and able to provide independent, written informed consent for screening? .... yes no  
10 ECMsic ☐ → If no, participant is ineligible. End of form.
- 2a. When was the informed consent for screening marked or signed? ..... dd MMM yy  
11 ECMsicdt
3. Was the participant willing and able to provide adequate locator information? ..... yes no  
12 ECMloc ☐ → If no, participant is ineligible. End of form.
4. Is the participant's sex at birth male? ..... yes no  
13 ECMmale ☐ → If no, participant is ineligible. End of form.
5. Are you currently participating in any other HIV vaccine or prevention study? ..... yes no  
14 ECMostdy ☐ → If yes, participant is ineligible. End of form.
6. Have you ever had a known bad (adverse) reaction to acyclovir? ..... yes no  
15 ECMreac ☐ → If yes, participant is ineligible. End of form.
7. Do you currently use or plan to use famciclovir, valacyclovir, or acyclovir for genital herpes? ..... yes no  
16 ECMcyclo ☐ → If yes, participant must discontinue medication by the Enrollment visit to be eligible.
8. Do you plan to permanently move out of this area at any time during your study participation? ..... yes no don't know  
17 ECMmove ☐ ☐ → If yes, participant is ineligible. End of form.

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formlang  
Language23  
sfdt\_005  
Staff Initials / Date

Plate 006 ECM-2: Screening Eligibility Criteria-Male Page 2

Visit Code 

6	visit		
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HPTN 039 (093)

ECM-2 (006)

Page 2 of 2

Participant ID

7							
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Site Number Participant Number Chk

Screening Eligibility Criteria—Male

9. Do you plan to be away from this area for more than 2 months in a row (this includes seasonal travel) at any time during your study participation? .....

yes no don't know

8  
ECMaway ☐

If yes, participant is ineligible. End of form.

10. Have you been in a mutually monogamous relationship with an HIV-negative partner for the past 2 years (meaning you only had sex with each other and no one else)? .....

yes no

9  
ECMmrel ☐

If yes, participant is ineligible. End of form.

11. Have you had anal intercourse with another man at least once within the past 6 months? .....

yes no

10  
ECMasex ☐

If no, participant is ineligible. End of form.

Plate 010 DMF-1: Demographics-Female Page 1

Visit Code 6 visit

HPTN 039 (093)

DMF-1 (010)

Page 1 of 2

Participant ID

Demographics—Female

Visit Date

7 ptid - - Chk  
Site Number Participant Number

Demographics—Female

8 DMFdt - -  
dd MMM yy

1. What is your date of birth (if available)?..... 9 DMFdobdt - -  
dd MMM yy

OR

How old are you (completed years)? ..... 10 DMFage years

2. What is your current marital status? *Read aloud.* 11 DMFmstat married

If never married, divorced or widowed, go to item 4.

- ☐ never married  
☐ divorced  
☐ widowed

3. Does your husband currently have more than 1 wife? ..... yes no 12 DMFwife

4. With whom do you primarily live? 13 DMFlive alone  
*Read aloud.*

- ☐ with male partner  
☐ other

5. What is your highest level of education? *Read aloud.* 14 DMFedu no schooling

- ☐ some primary school, but not complete  
☐ completed primary school  
☐ some secondary school, but not complete  
☐ completed secondary school  
☐ attended college or university  
☐ graduate/professional school

15 16 17 18  
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19 formlang  
Language

20 sfdt\_010  
Staff Initials / Date

Plate 011 DMF-2: Demographics-Female Page 2

Visit  
Code 6 visit

HPTN 039 (093)

DMF-2 (011)

Page 2 of 2

## Participant ID

Demographics—Female

7 ptid - - - - -  
Site Number Participant Number Chk

## Demographics—Female

1. Do you earn an income of your own? ..... ☐ yes ☐ no  
8 DMFinc ☐ If no, go to statement before item 7.

1a. What is your monthly income? .....  
9 DMFamt

10 DMFcur Kwacha  
☐ Zimbabwe Dollars

Items 7 and 7a are for married participants or participants living with partners only. Otherwise, go to item 8.

2. Does your husband or partner earn an income? ..... ☐ yes ☐ no ☐ don't know  
11 DMFpinc ☐ If no or don't know, go to item 8.

2a. What is his monthly income? .....  
12 DMFpamt OR 13 DMFpdk

14 DMFpcur Kwacha  
☐ Zimbabwe Dollars

3. What is your ethnic group or tribe? Read aloud. Mark all that apply.

## ZIMBABWE

15 DMFshona Shona

16 DMFndeb Ndebele

17 DMFziot other, specify:

18

DMFziotx

## ZAMBIA

19 DMFbemba Bemba

20 DMFnyan Nyanja

21 DMFtonga Tonga

22 DMFlozi Lozi

23 DMFwhite White

24 DMFzaot other, specify:

25

DMFzaotx

26 27 28 29  
bit4b011b011b011 18 AUG-03

30 formlang  
Language

31 sfdt\_011  
Staff Initials / Date



Plate 012 PRE-1: Pre-Existing Conditions

Page 6  
visit

HPTN 039 (093)

PRE-1 (012)

Note: Number pages sequentially  
(01, 02, 03) for each participant.

## Participant ID

Pre-existing Conditions

## Form Completion Date

7  
ptid - -  
Site Number Participant Number Chk

## Pre-existing Conditions

8  
PREdt - -  
dd MMM yy9  
PREnpre No pre-existing conditions reported or observed. —▶ End of form. Fax to SCHARP DataFax.

1. Description 10 PRE1desc	Date of Diagnosis/ Surgery 11 PRE1dsmy	MMM yy mm yy 12 PRE1dsdt	13 PRE1qc
Comments 14 PRE1com	Is condition ongoing? yes no 15 PRE1ongo		

2. Description 16 PRE2desc	Date of Diagnosis/ Surgery 17 PRE2dsmy	MMM yy mm yy 18 PRE2dsdt	19 PRE2qc
Comments 20 PRE2com	Is condition ongoing? yes no 21 PRE2ongo		

3. Description 22 PRE3desc	Date of Diagnosis/ Surgery 23 PRE3dsmy	MMM yy mm yy 24 PRE3dsdt	25 PRE3qc
Comments 26 PRE3com	Is condition ongoing? yes no 27 PRE3ongo		

4. Description 28 PRE4desc	Date of Diagnosis/ Surgery 29 PRE4dsmy	MMM yy mm yy 30 PRE4dsdt	31 PRE4qc
Comments 32 PRE4com	Is condition ongoing? yes no 33 PRE4ongo		

5. Description 34 PRE5desc	Date of Diagnosis/ Surgery 35 PRE5dsmy	MMM yy mm yy 36 PRE5dsdt	37 PRE5qc
Comments 38 PRE5com	Is condition ongoing? yes no 39 PRE5ongo		

6. Description 40 PRE6desc	Date of Diagnosis/ Surgery 41 PRE6dsmy	MMM yy mm yy 42 PRE6dsdt	43 PRE6qc
Comments 44 PRE6com	Is condition ongoing? yes no 45 PRE6ongo		

46 47 48 49  
bit4b0113b012012 18 AUG-0350  
formlang51  
sfdt\_012

Plate 013 DMM-1: Demographics-Male Page 1

Visit Code 6 visit

HPTN 039 (093)

DMM-1 (013)

Page 1 of 2

Participant ID

Demographics—Male

Visit Date

7 ptid - - - - -  
Site Number Participant Number Chk

Demographics—Male

8 DMMdt - - - - -  
dd MMM yy

1. What is your date of birth (if available)?..... 9 DMMdobdt - - - - -  
dd MMM yy

OR

How old are you (completed years)? ..... 10 DMMage years

2. What was your sex at birth? ..... 11 DMMsex ☐ male ☐ female  
If female, participant is ineligible. End of form.

3. What is your current marital status? Read aloud. 12 DMMstat  
☐ married  
☐ with partner but not married  
☐ single, meaning not married and not with partner  
☐ divorced/separated  
☐ widowed

4. With whom do you primarily live? Read aloud. 13 DMMlive  
☐ alone  
☐ with male partner  
☐ with female partner  
☐ other

5. What is your highest level of education? Read aloud. 14 DMMedu  
☐ no schooling  
☐ some primary school, but not complete  
☐ completed primary school  
☐ some secondary school, but not complete  
☐ completed secondary school  
☐ attended college or university  
☐ graduate/professional school

15 16 17 18  
bit4b013b012b013\_013 AUG-03

19 20  
formlang sfdt\_013  
Language Staff Initials / Date

Plate 014 DMM-2: Demographics-Male Page 2

Visit Code 6 visit

HPTN 039 (093)

DMM-2 (014)

Page 2 of 2

## Participant ID

Demographics—Male

7 ptid - - - - - Chk  
Site Number Participant Number

## Demographics—Male

6. Do you earn an income of your own? ..... ☐ yes ☐ no  
8 DMMinc ☐ If no, go to statement before item 7.

6a. What is your monthly income? .....  
9 DMMamt   
10 DMMcur   
☐ U.S. Dollars

Items 7 and 7a are for married participants or participants living with partners only. Otherwise, go to item 8.

7. Does your partner earn an income? ..... ☐ yes ☐ no ☐ don't know  
11 DMMpinc ☐ If no or don't know, go to item 8.

7a. What is your partner's monthly income? .....   
12 DMMpamt   
13 DMMpdk   
14 DMMpcur   
☐ U.S. Dollars

8. What is your race or ethnic group? Read aloud. Mark all that apply.

## U.S.

15 DMMunatv American Indian or Alaska Native  
16 DMMuasiasia Asian  
17 DMMublick Black or African American  
18 DMMupac Native Hawaiian or Other Pacific Islander  
19 DMMuwwhite White  
20 DMMuoth other, specify: 21 DMMuothx

## PERU

22 DMMpind Indigenous  
23 DMMpmix Mixed  
24 DMMpwhite White  
25 DMMpasia Asian  
26 DMMpblack Black  
27 DMMpother other, specify: 28 DMMpothx

9. U.S. only: Do you consider yourself to be Latino or Hispanic? ..... ☐ yes ☐ no  
29 DMMhisp ☐

30 31 32 33  
bit 4b01 4b01 4b01 4b01 014

18 AUG-03

34 formlang  
Language35 sfdt\_014  
Staff Initials / Date

Plate 015 LRF-1: Laboratory Results—Female

Visit Code 6 visit

HPTN 039 (093)

LRF-1 (015)

Page 1 of 1

Participant ID

Laboratory Results—Female

Specimen Collection Date

7 ptid - - - - -  
 Site Number Participant Number Chk

Laboratory Results—Female

8 LRFdt - - - - -  
 dd MMM yy

1. Vaginal gram stain collected ..... yes no not done/  
 LRFgram not collected
2. Vaginal pH ..... LRFphnd
3. Wet mount negative positive not done/  
 not collected
  - 3a. Whiff test ..... LRFwhiff
  - 3b. Clue cells ..... LRFclue
  - 3c. T. vaginalis ..... LRFtvag
4. Trichomonas In-Pouch Culture ..... LRFtrich
5. Chlamydia NAAT or rapid test ..... LRFchlam
6. Cervical gonorrhea NAAT or culture ..... LRFcgon

Comments: 18  
 LRFcomm

19 20 21 22  
 bit 4b013b012-015 26 DEC-03

23 24  
 formlang sfdt\_015  
 Language Staff Initials / Date

Plate 016 DMF-2: Demographics—Female Page 2

Visit Code 6 visit

HPTN 039 (093)

DMF-2 (016)

Page 2 of 2

## Participant ID

Demographics—Female

7  
ptid - - - - -  
Site Number Participant Number Chk

## Demographics—Female

6. Do you earn an income of your own? ..... ☐ yes ☐ no  
8 DMFinc ☐ If no, go to statement before item 7.

6a. What is your monthly income? .....  
9 DMFamt

10 DMFcur Kwacha  
☐ Zimbabwe Dollars  
☐ Rand

Items 7 and 7a are for married participants or participants living with partners only. Otherwise, go to item 8.

7. Does your husband or partner earn an income? ..... ☐ yes ☐ no ☐ don't know  
11 DMFpinc ☐ If no or don't know, go to item 8.

7a. What is his monthly income? .....  
12 DMFpamt OR 13 DMFpdk don't know  
14 DMFpcur Kwacha  
☐ Zimbabwe Dollars  
☐ Rand

8. What is your ethnic group or tribe? Read aloud. Mark all that apply.

## ZIMBABWE

15 DMFshona Shona  
16 DMFndeb Ndebele  
17 DMFziot other, specify:  
18 DMFziotx

## ZAMBIA

19 DMFbemba Bemba  
20 DMFnyan Nyanja  
21 DMFtonga Tonga  
22 DMFlozi Lozi  
23 DMFzawht White  
24 DMFzaot other, specify:  
25 DMFzaotx

## SOUTH AFRICA

26 DMFblack Black  
27 DMFsawht White  
28 DMFindn Indian  
29 DMFcolrd Colored  
30 DMFsaot other, specify:  
31 DMFsaotx

32 33 34 35  
bit 4b018b011b015\_016 26 APR-04

36 formlang Language  
37 sfdt\_016 Staff Initials / Date

Plate 017 LRM-1: Laboratory Results-Male

Visit Code 6 visit

HPTN 039 (093)

LRM-1 (017)

Page 1 of 1

Participant ID

Laboratory Results—Male

Specimen Collection Date

7 ptid - - - - -  
 Site Number Participant Number Chk

Laboratory Results—Male

8 LRMdt - - - - -  
 dd MMM yy

1. Rectal gonorrhea culture.....  
 negative positive not done/  
 not collected  
 9 LRMrgon ☐ ☐
2. Urine LE .....  
 negative or trace positive (> trace) not done/  
 not collected  
 10 LRMule ☐ ☐ → If not done/  
 not collected,  
 end of form.  
 → If negative or trace, end of form.
- 2a. > Trace results .....  
 1+ 2+ 3+ 4+  
 11 LRMtrace ☐ ☐ ☐
- 2b. Urine gonorrhea NAAT or  
 urethral GC culture .....  
 negative positive  
 12 LRMgon ☐
- 2c. Urine chlamydia .....  
 negative positive  
 13 LRMchlam ☐

Comments: 14  
 LRMcomm

15 16 17 18  
 bit 4b013b012b017 18 AUG-03

19  
 formlang  
 Language

20  
 sfdt\_017  
 Staff Initials / Date

Plate 020 EN-1: Enrollment Page 1

Visit Code	6	visit		
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HPTN 039 (093)

EN-1 (020)

Page 1 of 2

Participant ID

Visit Date

<b>7</b>			-					-	
<b>ptid</b>									
Site Number				Participant Number					Chk

## Enrollment

8	
ENdt	

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*dd*
*MMM*
*yy*

- |     |  |           |  |   |   |
|-----|--|-----------|--|---|---|
| 1.  | Is the visit being conducted within 60 days of when the participant provided informed consent for screening? ..... | yes<br>no | <div><div>9</div><div>EN60days</div></div> <div><input type="checkbox"/></div>   | ➔ | <i>If no, recommence screening, participant is ineligible.<br/>End of form.</i> |
| 2.  | Did the participant meet all Screening Visit clinical, behavioral, and lab eligibility criteria? .....             | yes<br>no | <div><div>10</div><div>ENscrit</div></div> <div><input type="checkbox"/></div>   | ➔ | <i>If no, participant is ineligible. End of form.</i>                           |
| 3.  | Was the participant willing and able to provide independent, written informed consent for enrollment? .....        | yes<br>no | <div><div>11</div><div>ENeic</div></div> <div><input type="checkbox"/></div>   | ➔ | <i>If no, participant is ineligible. End of form.</i>                           |
| 3a. | When was the informed consent for enrollment marked or signed? .....   | ddMMMyy   | <div><div>12</div><div>ENeicdt</div></div> <div><div><div><div></div><div></div></div><div><div></div><div></div></div><div><div></div><div></div></div></div><div><div><div></div><div></div></div><div><div></div><div></div></div></div></div>  |   |   |
| 4.  | Was the participant willing and able to provide independent, written informed consent for specimen storage?.....   | yes<br>no | <div><div>13</div><div>ENspic</div></div> <div><input type="checkbox"/></div>  | ➔ | <i>If no, go to statement before item 5.</i>                                    |
| 4a. | When was the informed consent for specimen storage marked or signed?.....  | ddMMMyy   | <div><div>14</div><div>ENspicdt</div></div> <div><div><div><div></div><div></div></div><div><div></div><div></div></div><div><div></div><div></div></div></div><div><div><div></div><div></div></div><div><div></div><div></div></div></div></div> |   |   |

*Item 5 for female participants only. Male participants go to item 6.*

5. Is the participant's pregnancy test negative at this visit? ..... yes no  
☒ 15 ☐ ENpreg → *If no, participant is ineligible. End of form.*

Plate 021 EN-2: Enrollment Page 2

Visit  
Code6  
visit

HPTN 039 (093)

EN-2 (021)

Page 2 of 2

## Participant ID

7  
ptid

Site Number

Participant Number

Chk

## Enrollment

6. Does the participant have any condition that, in the opinion of the Site Investigator or designee, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?.....

yes no

8  
ENocndIf yes, participant is  
ineligible. End of form.

7. Was the participant randomized? .....

yes no

9  
ENrandIf no, participant is  
ineligible. End of form.

- 7a. What is the participant's study drug  
number?.....

10  
ENsdrug

8. Which bottles of the study medication were  
dispensed at this visit?.....

11  
EN1bott1

bottle #

12  
EN2bott1

bottle #

13  
EN3bott1

bottle #

Comments: 14  
ENcomm15 16 17 18  
bit4b021b021b021 18 AUG-0319  
formlang  
Language20  
sfdt\_021  
Staff Initials / Date



Plate 022 EN-1: Enrollment Page 1

Visit Code 6 visit

HPTN 039 (093)

EN-1 (022)

Page 1 of 2

Participant ID

7 ptid - - - - - Chk

Enrollment

Enrollment

Visit Date

8 ENdt - - - - - dd MMM yy

**Instructions:** Do not complete this form if the participant was determined to be ineligible prior to the Enrollment Visit.

1. Is the visit being conducted within 60 days of when the participant provided informed consent for screening? ..... yes no  
 9 EN60days - - - - - If no, recommence screening, participant is ineligible. End of form.

2. Did the participant meet all Screening Visit clinical, behavioral, and lab eligibility criteria? ..... yes no  
 10 ENScrit - - - - - If no, participant is ineligible. End of form.

3. Was the participant willing and able to provide independent, written informed consent for enrollment? ..... yes no  
 11 ENeic - - - - - If no, participant is ineligible. End of form.

3a. When was the informed consent for enrollment marked or signed? ..... dd MMM yy  
 12 ENeicdt - - - - -

4. Was the participant willing and able to provide independent, written informed consent for specimen storage? ..... yes no  
 13 ENspic - - - - - If no, go to item 5.

4a. When was the informed consent for specimen storage marked or signed? ..... dd MMM yy  
 14 ENspicdt - - - - -

5. Is the participant willing and able to undergo clinical evaluations, take study drug as indicated, and adhere to the follow-up schedule? ..... yes no  
 15 ENadher - - - - - If no, participant is ineligible. End of form.

6. Does the participant currently use or plan to use famciclovir, valacyclovir, or acyclovir for genital herpes? ..... yes no  
 16 ENcyclo - - - - - If yes, participant is ineligible. End of form.

Item 7 for female participants only. Male participants go to item 8.

7. Is the participant's pregnancy test negative at this visit? ..... yes no  
 17 ENpreg - - - - - If no, participant is ineligible. End of form.

18 19 20 21  
 bit 4b022b022b022 JAN-04

22 formlang  
 Language

23 sfdt\_022  
 Staff Initials / Date

Plate 023 EN-2: Enrollment Page 2

Visit Code 6 visit

HPTN 039 (093)

EN-2 (023)

Page 2 of 2

Participant ID

7 ptid - - - - -

Site Number Participant Number Chk

Enrollment

8. Does the participant have any condition that, in the opinion of the Site Investigator or designee, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?.....

yes no

8 ENocnd

If yes, participant is ineligible. End of form.

9. Was the participant randomized? .....

yes no

9 ENrand

If no, participant is ineligible. End of form.

9a. What is the participant's study drug number?.....

10 ENsdrug

10. Which bottles of the study medication were dispensed at this visit?.....

11 EN1bott1

bottle #

12 EN2bott1

bottle #

Comments: 13 ENcomm

## Plate 025 SLR-1: Screening Laboratory Results

Visit Code	6	visit		
------------	---	-------	--	--

HPTN 039 (093)

SLR-1 (025)

Page 1 of 1

## Participant ID

7			-					-	
ptid									

Participant Number

Chk

## Screening Laboratory Results

Specimen Collection Date

8					
SLRdt					

*dd*

MMM

yy

*negative*

*positive*

1. Final HIV status.....

9  
SLRhiv

--	--

***If positive, participant is ineligible. End of form.***

2. HSV-2 index .....

10		
SLRhsv		

7

*If < 3.5, participant is ineligible.  
End of form.*

*Item 3 for female participants only. Male participants, end of form.*

*negative*

*positive*

3. Pregnancy test .....

```
11 SLRpreg
```

1

*If positive, participant is ineligible.*

Comments: 12  
SLRcomm

13 14 15 16  
bit4b025b025b025 025

17	
formlang	
Language	

18  
sfdt\_025

---

Staff Initials / Date

Plate 026 SLR-1: Screening Laboratory Results

Visit Code 6 visit

HPTN 039 (093)

SLR-1 (026)

Page 1 of 1

Participant ID

7 ptid - - - - -  
 Site Number Participant Number Chk

Screening Laboratory  
 Results

Screening Laboratory Results

Specimen Collection Date

8 SLRdt - - - - -  
 dd MMM yy

1. Final HIV status..... 9 SLRhiv ☐ *negative* ☐ *positive* → If positive, participant is ineligible. End of form.
2. HSV-2 index..... 10 SLRhsy ☐ → If ≥ 3.5, go to instructions above item 3.
- 2a. HSV-2 WB test ..... 11 SLRhsvwb ☐ *negative* ☐ *positive* ☐ *not done/ not collected* → If negative or not done/ not collected, participant is ineligible. End of form.

Item 3 for female participants only. Male participants, end of form.

3. Pregnancy test..... 12 SLRpreg ☐ *negative* ☐ *positive* → If positive, participant is ineligible.

Comments: 13 SLRcomm

Plate 030 MSF-1: Monthly Sexual Behavior-Female

Visit  
Code6  
visit

HPTN 039 (093)

MSF-1 (030)

Page 1 of 1

## Participant ID

7  
ptid - - - - -  
Site Number Participant Number ChkMonthly Sexual Behavior—  
FemaleMonthly Sexual Behavior—  
Female

## Visit Date

8  
MSFdt - - - - -  
dd MMM yy

Now I'm going to ask you about your sexual practices. While some of this information may be embarrassing or difficult to remember, we do need to have you give us your best answers. In some cases, these questions may sound repetitive, but we need to ask all questions of all participants.

For these questions, sex is defined as any vaginal or anal sex (but not oral sex). By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus. A sexual partner is someone with whom you have had vaginal or anal sex, either regularly or only once.

## Sexual Behavior—Last 12 Months

1. **Ask at Enrollment visit only:** During the **last 12 months**, how many sexual partners have you had? ..... 9  
MSFp12mo # of partners

## Sexual Behavior—Last Month

2. During the **last month** (30 days), how many sexual partners have you had?..... 10  
MSFp1mo # of partners

If 0, end of form.

3. How many of your sex partners were HIV-positive? Only include those whom you know are positive..... 11  
MSFhivp # of partners

4. How many of your sex partners told you they were HIV-negative and you had no reason to doubt it? ..... 12  
MSFhivn # of partners

5. How many of your sex partners never told you their HIV status, or told you they were negative and you had reason to doubt it, or you don't know the status? ..... 13  
MSFhivu # of partners

14 15 16 17  
bit4b083b082b060\_030 18 AUG-0318  
formlang  
Language19  
sfdt\_030  
Staff Initials / Date

Plate 032 MSM-1: Monthly Sexual Behavior-Male

Visit  
Code6  
visit

HPTN 039 (093)

MSM-1 (032)

Page 1 of 1

## Participant ID

7  
ptid

Site Number

Participant Number

Chk

Monthly Sexual Behavior—  
MaleMonthly Sexual Behavior—  
Male

## Visit Date

8  
MSMdt

dd

MMM

yy

Now I'm going to ask you about your sexual practices. While some of this information may be embarrassing or difficult to remember, we do need to have you give us your best answers. In some cases, these questions may sound repetitive, but we need to ask all questions of all participants.

For these questions, sex is defined as any anal or vaginal sex (but not oral sex). By anal sex, I mean when a man puts his penis inside your anus, or when you put your penis inside a man's or woman's anus. By vaginal sex, I mean when you put your penis inside a woman's vagina. A sexual partner is someone with whom you have had anal or vaginal sex, either regularly or only once.

## Sexual Behavior—Last 12 Months

1. **Ask at Enrollment visit only:** During the **last 12 months**, how many sexual partners have you had? ..... 9  
MSMp12mo # of partners

## Sexual Behavior—Last Month

2. During the **last month** (30 days), how many male sexual partners have you had? ..... 10  
MSMpm1mo # of partners
3. During the **last month** (30 days), how many female sexual partners have you had? ..... 11  
MSMpf1mo # of partners
- If both items 2 and 3 are 0, end of form.
4. How many of your sex partners were HIV-positive? Only include those whom you know are positive. .... 12  
MSMhivp # of partners
5. How many of your sex partners told you they were HIV-negative and you had no reason to doubt it? ..... 13  
MSMhivn # of partners
6. How many of your sex partners never told you their HIV status, or told you they were negative and you had reason to doubt it, or you don't know the status? ..... 14  
MSMhivu # of partners

15 16 17 18  
bit4b082b082b082\_032 18 AUG-0319  
formlang  
Language20  
sfdt\_032  
Staff Initials / Date

Plate 040 QSF-1: Quarterly Sexual Behavior—Female Page 1

Visit  
Code6  
visit

HPTN 039 (093)

QSF-1 (040)

Page 1 of 3

## Participant ID

7  
ptid - - - - -  
Site Number Participant Number ChkQuarterly Sexual Behav-  
ior—FemaleQuarterly Sexual Behavior—  
Female

## Visit Date

8  
QSFdt - - - - -  
dd MMM yy

## Sexual Behavior—3 Most Recent Male Partners: Partner-specific Questions

You will now be asked more detailed questions about your most recent male sexual partner(s) in the last 90 days, up to a maximum of 3 partners. For these questions, sex is defined as any vaginal sex (but not oral sex). By vaginal sex, I mean when a man puts his penis inside your vagina. A sexual partner is someone with whom you have had sex, either regularly or only once.

1. Did you have sex with any partners in the **last 3 months** (90 days)? ..... **9** **QSFp13mo** ☐ *If no, end of form.*
2. Which of the following best describes \_\_\_\_\_, the person you had sex with last? ..... **10** **QSFp1dsc** ☐ *steady non-steady*
- 2a. Is this a new partner (someone you had sex with for the first time in the **last 3 months** [90 days])? ..... **11** **QSFp1new** ☐ *yes no*
- 2b. Has this partner ever tested positive for HIV? ..... **12** **QSFp1hiv** ☐ *yes no don't know*
- 2c. How long did you know this partner before you first had sex?
- 13** **QSFp1lmg** ☐ *enter number* **14** **QSFp1msr** ☐ *minutes* ☐ *weeks*  
☐ *hours* ☐ *months*  
☐ *days* ☐ *years*
- 2d. During the **last 3 months** (90 days), how many times did you have vaginal sex with this partner? ..... **15** **QSFp1vsx** ☐ *# of times*
- 2d1. How many of these times was a condom used? ..... **16** **QSFp1cnd** ☐ *# of times*
- 2e. Did you drink alcohol the last time you had sex with this partner, either during sex or up to 2 hours before you had sex? ..... **17** **QSFp1alc** ☐ *yes no don't know*
- 2f. Did this partner give you or receive from you money, drugs, food, or a place to stay, in exchange for sex the last time you had sex? ..... **18** **QSFp1exc** ☐ *yes no*
3. Did you have sex with any other partners in the **last 3 months** (90 days)? ..... **19** **QSFp23mo** ☐ *If no, end of form.*

20 21 22 23  
bit 4b043b0412-040 21 JAN-0424  
formlang  
Language25  
sfdt\_040  
Staff Initials / Date

Plate 041 QSF-2: Quarterly Sexual Behavior-Female Page 2 Visit Code

6  
visit

HPTN 039 (093)

QSF-2 (041)

Page 2 of 3

## Participant ID

7  
ptid - - - - -  
Site Number Participant Number ChkQuarterly Sexual Behavior—  
Female

4. Which of the following best describes \_\_\_\_\_, your next most recent partner?.....

steady non-steady

8  
QSFp2dsc

4a. Is this a new partner (someone you had sex with for the first time in the last 3 months [90 days])? .....

yes no

9  
QSFp2new

4b. Has this partner ever tested positive for HIV? .....

yes no don't know

10  
QSFp2hiv

4c. How long did you know this partner before you first had sex?

Mark only one measure of time.

11  
QSFp2lmg  
enter number → 12  
QSFp2msr minutes weeks  
hours months  
days years

4d. During the last 3 months (90 days), how many times did you have vaginal sex with this partner? .....

13  
QSFp2vsx # of times

4d1. How many of these times was a condom used? .....

14  
QSFp2cnd # of times

4e. Did you drink alcohol the last time you had sex with this partner, either during sex or up to 2 hours before you had sex? .....

yes no don't know

15  
QSFp2alc

4f. Did this partner give you or receive from you money, drugs, food, or a place to stay, in exchange for sex the last time you had sex? .....

yes no

16  
QSFp2exc

5. Did you have sex with any other partners in the last 3 months (90 days)? .....

yes no

17  
QSFp33moIf no,  
end of form.18 19 20 21  
bit4b041b041b041 JAN-0422  
formlang  
Language23  
sfdt\_041  
Staff Initials / Date



Plate 042 QSF-3: Quarterly Sexual Behavior-Female Page 3

Visit  
Code6  
visit

HPTN 039 (093)

QSF-3 (042)

Page 3 of 3

## Participant ID

7  
ptid

Site Number

Participant Number

Chk

Quarterly Sexual Behavior—  
Female

6. Which of the following best describes \_\_\_\_\_, your next  
most recent partner? .....

steady non-steady

8  
QSFp3dsc

6a. Is this a new partner (someone you had sex with for the first time  
in the **last 3 months** [90 days])? .....

yes no

9  
QSFp3new

6b. Has this partner ever tested positive for HIV? .....

yes no don't know

10  
QSFp3hiv

6c. How long did you know this partner before you first had sex?

Mark only one measure of time.

11  
QSFp3lmg

enter number

12  
QSFp3msr

minutes

weeks

hours

months

days

years

6d. During the **last 3 months** (90 days), how many times did you have  
vaginal sex with this partner? .....

13  
QSFp3vsx # of times

6d1. How many of these times was a condom used? .....

14  
QSFp3cnd # of times

6e. Did you drink alcohol the last time you had sex with this partner,  
either during sex or up to 2 hours before you had sex? .....

yes no don't know

15  
QSFp3alc

6f. Did this partner give you or receive from you money, drugs, food, or a  
place to stay, in exchange for sex the last time you had sex? .....

yes no

16  
QSFp3exc

Plate 046 QSM-1: Quarterly Sexual Behavior-Male Page 1

Visit  
Code6  
visit

HPTN 039 (093)

QSM-1 (046)

Page 1 of 6

## Participant ID

7  
ptid

Site Number

Participant Number

Chk

Quarterly Sexual Behav-  
ior—MaleQuarterly Sexual Behavior—  
Male

## Visit Date

8  
QSMdt

dd

MMM

yy

Sexual Behavior—3 Most Recent Male Partners: Partner-specific Questions

You will now be asked more detailed questions about your most recent **male** sexual partner(s) in the last 90 days, up to a maximum of 3 partners. For these questions, sex is defined as any anal sex (but not oral sex). By anal sex, I mean when a man puts his penis inside your anus, or when you put your penis inside another man's anus.

1. Did you have any sex partners in the **last 3 months** (90 days)? .....

yes

no

9  
QSMp13mo**If no,  
end of form.**

2. Which of the following best describes \_\_\_\_\_, the person you had sex with last? .....

steady non-steady

10  
QSMp1dsc2a. Is this a new partner (someone you had sex with for the first time in the **last 3 months** [90 days])? .....

yes

no

11  
QSMp1new

2b. Has this partner ever tested positive for HIV? .....

yes

no

don't know

12  
QSMp1hiv

2c. How long did you know this partner before you first had sex?

Mark only one measure of time.

13  
QSMp1lmg

enter number

14  
QSMp1msr

minutes

hours

days

weeks

months

years

2d. During the **last 3 months** (90 days), how many times did you have anal insertive sex with this partner (were a "top")? .....15  
QSMp1isx

# of times

**If 0, go to item 2e.**

2d1. How many of these times was a condom used? .....

16  
QSMp1icn

# of times

17 18 19 20  
bit4b045b045b045 18 AUG-03

/hivnet/forms/PTN\_039/forms/sex\_behavior\_male\_quarterly.fm

Schema Last Modified: Thu May 6 13:55:33 2004

21  
formlang

Language

22  
sfdt\_046

Staff Initials / Date

Plate 047 QSM-2: Quarterly Sexual Behavior-Male Page 2

Visit  
Code6  
visit

HPTN 039 (093)

QSM-2 (047)

Page 2 of 6

## Participant ID

7						
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Site Number - Participant Number - ChkQuarterly Sexual Behavior—  
Male

- 2e. During the **last 3 months** (90 days), how many times did you have anal receptive sex with this partner (were a “bottom”)?

8			
---	--	--	--

  
QSMp1rsx # of times

If 0, go to item 2f.

- 2e1. How many of these times was a condom used?

9			
---	--	--	--

  
QSMp1rcn # of times

- 2f. Did you drink alcohol the last time you had sex with this partner, either during sex or up to 2 hours before you had sex?

yes	no	don't know
10		

  
QSMp1alc

- 2g. Did you use any of the following the last time you had sex with this partner, either during sex or up to 2 hours before you had sex: Viagra, poppers, crystal methamphetamines, cocaine, crack cocaine, heroin, speedball (heroin and cocaine), MDMA (ecstasy), or other drugs?

yes	no	don't know
11		

  
QSMp1drg

- 2h. Did this partner give you or receive from you money, drugs, food, or a place to stay, in exchange for sex the last time you had sex?

yes	no
12	

  
QSMp1exc

3. Did you have sex with any other male partners in the **last 3 months** (90 days)?

yes	no
13	

  
QSMp23moIf no,  
end of form.

14	15	16	17
----	----	----	----

  
bit4b003b0042b047 18 AUG-03

18	
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formlang  
Language

19	
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sfdt\_047  
Staff Initials / Date

Plate 048 QSM-3: Quarterly Sexual Behavior-Male Page 3

Visit  
Code

6  
visit

HPTN 039 (093)

QSM-3 (048)

Page 3 of 6

Participant ID

7  
ptid - - - - -  
Site Number Participant Number Chk

Quarterly Sexual Behavior—  
Male

4. Which of the following best describes \_\_\_\_\_, your next  
most recent partner? .....

steady non-steady

8  
QSMp2dsc

4a. Is this a new partner (someone you had sex with for the first time  
in the **last 3 months** [90 days])? .....

yes no

9  
QSMp2new

4b. Has this partner ever tested positive for HIV? .....

yes no don't know

10  
QSMp2hiv

4c. How long did you know this partner before you first had sex?

Mark only one measure of time.

11  
QSMp2lmg  
enter number → 12  
QSMp2msr minutes  
hours months  
days years

4d. During the **last 3 months** (90 days), how many times did you have  
anal insertive sex with this partner (were a "top")? .....

13  
QSMp2isx # of times

If 0, go to item 4e.

4d1. How many of these times was a condom used? .....

14  
QSMp2icn # of times

4e. During the **last 3 months** (90 days), how many times did you have  
anal receptive sex with this partner (were a "bottom")? .....

15  
QSMp2rsx # of times

If 0, go to item 4f  
on page 4.

4e1. How many of these times was a condom used? .....

16  
QSMp2rcn # of times

17 18 19 20  
bit 4b043b043b043 18 AUG-03

21  
formlang

22  
sfdt\_048

7		
ptid		

-

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-

--

Chk

8  
QSMp2a1c

9 QMp2drg

10 QMp2exc

11 QSMp3 3mo

*If no,  
end of form.*

Plate 050 QSM-5: Quarterly Sexual Behavior-Male Page 5

Visit  
Code6  
visit

HPTN 039 (093)

QSM-5 (050)

Page 5 of 6

## Participant ID

7  
ptid

Site Number - Participant Number - Chk

Quarterly Sexual Behavior—  
Male

6. Which of the following best describes \_\_\_\_\_, your next  
most recent partner? .....

steady non-steady

8  
QSMp3dsc

6a. Is this a new partner (someone you had sex with for the first time  
in the **last 3 months** [90 days])? .....

yes no

9  
QSMp3new

6b. Has this partner ever tested positive for HIV? .....

yes no don't know

10  
QSMp3hiv

6c. How long did you know this partner before you first had sex?

Mark only one measure of time.

11  
QSMp3lmg

enter number

12  
QSMp3msr

minutes

hours

days

weeks

months

years

6d. During the **last 3 months** (90 days), how many times did you have  
anal insertive sex with this partner (were a "top")? .....

13  
QSMp3isx

# of times

If 0, go to item 6e.

6d1. How many of these times was a condom used? .....

14  
QSMp3icn

# of times

6e. During the **last 3 months** (90 days), how many times did you have  
anal receptive sex with this partner (were a "bottom")? .....

15  
QSMp3rsx

# of times

If 0, go to item 6f  
on page 6.

6e1. How many of these times was a condom used? .....

16  
QSMp3rcn

# of times

17 18 19 20  
bit4b053b052b050 18 AUG-0321  
formlang

Language

22  
sfdt\_050

Staff Initials / Date

Plate 051 QSM-6: Quarterly Sexual Behavior-Male Page 6

Visit  
Code

6  
visit

HPTN 039 (093)

QSM-6 (051)

Page 6 of 6

Participant ID

7  
ptid - - - - -  
 Site Number Participant Number Chk

Quarterly Sexual Behavior—  
Male

6f. Did you drink alcohol the last time you had sex with this partner,  
 either during sex or up to 2 hours before you had sex? .....

yes no don't know

8  
QSMp3alc

6g. Did you use any of the following the last time you had sex with this  
 partner, either during sex or up to 2 hours before you had sex:  
 Viagra, poppers, crystal methamphetamines, cocaine, crack cocaine,  
 heroin, speedball (heroin and cocaine), MDMA (ecstasy), or other  
 drugs? .....

yes no don't know

9  
QSMp3drg

6h. Did this partner give you or receive from you money, drugs, food, or a  
 place to stay, in exchange for sex the last time you had sex? .....

yes no

10  
QSMp3exc

Plate 070 FSC-1: Current Symptoms-Female

Visit  
Code

6  
visit

HPTN 039 (093)

FSC-1 (070)

Page 1 of 1

Participant ID

Current Symptoms—Female

Visit Date

7  
ptid

Current Symptoms—Female

8  
FSCdt

dd

MMM

yy

1. In the last 7 days, have you experienced...

1a. burning when urinating? .....

yes no  
9  
FSCburn

1b. sores on your genital and/or anal area  
(including buttocks)? .....

10  
FSCsores

1c. abnormal discharge from your vagina? .....

11  
FSCdsch

1d. lower abdominal pain and/or abnormal bleeding? .....

12  
FSCpnbl

If yes to any,  
complete Female  
Genital Exam form.

2. Since your last visit, how many times have you been  
hospitalized? .....

13  
FSChosp # of times

If hospitalized,  
report each  
hospitalization on a  
separate SAE form.

3. Pregnancy test: .....

negative positive not done/  
not collected  
14  
FSCpreg

If positive, complete  
Pregnancy Report form.

Comments: 15  
FSCcomm

16 17 18 19  
bit 4b073b072070 18 AUG-03

20  
formlang  
Language

21  
sfdt\_070  
Staff Initials / Date



Plate 072 MSC-1: Current Symptoms-Male

Visit  
Code

6  
visit

HPTN 039 (093)

MSC-1 (072)

Page 1 of 1

Participant ID

Current Symptoms—Male

Visit Date

7  
ptid

Current Symptoms—Male

8  
MSCdt

1. In the **last 7 days**, have you experienced...

1a. burning when urinating or a discharge from your penis? .....

yes no  
9  
MSCburn

1b. sores on your penis or scrotum? .....

10  
MSCpsore

1c. sores in or around your anus (including buttocks)? .....

11  
MSCasore

1d. pain in your testicles? .....

12  
MSCpain

1e. other rectal symptoms? .....

13  
MSCrsymp

If yes to any,  
complete Male  
Genital Exam form.

2. Since your **last visit**, how many times have you been hospitalized?

14  
MSChosp # of times

If hospitalized,  
report each  
hospitalization on a  
separate SAE form.

Comments: 15  
MSCcomm

16 17 18 19  
bit4b072b072b072b072 18 AUG-03

20  
formlang  
Language

21  
sfdt\_072  
Staff Initials / Date

Plate 074 FSQ-1: Quarterly Symptoms-Female Page 1

Visit  
Code6  
visit

HPTN 039 (093)

FSQ-1 (074)

Page 1 of 2

## Participant ID

7  
ptid

Site Number

Participant Number

Chk

Quarterly Symptoms—  
Female

## Quarterly Symptoms—Female

## Visit Date

8  
FSQdt

dd

MMM

yy

1. In the **last 3 months** (90 days), have you had any of the following symptoms:

yes no

1a. burning when urinating? .....

9  
FSQburn1b. sores on your genital and/or anal area  
(including buttocks)? .....10  
FSQsores

1c. abnormal discharge from your vagina? .....

11  
FSQdsch

1d. lower abdominal pain and/or abnormal bleeding? .....

12  
FSQpnbl

2. In the **last 3 months** (90 days), has a health care provider diagnosed you with or treated you for any of the following sexually-transmitted or genital infections:

yes no don't know

2a. vaginitis or vaginal discharge.....

13  
FSQvag

2b. chlamydia or cervicitis.....

14  
FSQchlam

2c. gonorrhea .....

15  
FSQgon

2d. PID.....

16  
FSQpid

2e. syphilis .....

17  
FSQsyph

→ If no or  
don't know,  
go to item 2f.

2e1. Titer (if known).....

1: 18  
FSQtiter

2e2. Did you receive treatment for syphilis? .....

yes no  
19  
FSQstrt

2f. chancroid .....

yes no don't know  
20  
FSQchanc2g. Were you diagnosed with a sexually-transmitted infection  
but don't know the name or it isn't listed above? .....yes no  
21  
FSQsti2h. Were you given treatment as a contact to a sexually-  
transmitted infection (because your partner had a  
sexually-transmitted infection)? .....yes no don't know  
22  
FSQsttrt23 24 25 26  
bit 4b07 4b07 4b07 4b07

18 AUG-03

27  
formlang  
Language28  
sfdt\_074  
Staff Initials / Date

Plate 075 FSQ-2: Quarterly Symptoms-Female Page 2

Visit  
Code

6  
visit

HPTN 039 (093)

FSQ-2 (075)

Page 2 of 2

Participant ID

7  
ptid

Site Number

Participant Number

Chk

Quarterly Symptoms—Female

3. In the **last 3 months** (90 days), have you had a recurrent episode of anogenital herpes? .....

yes no don't know

8  
FSQhrpes

3a. Where did you have the herpes? *Mark all that apply.*

9  
FSQhvag

10  
FSQhanus

11  
FSQhbutt

12  
FSQhothr

13

FSQhothx

*If no or don't know, go to item 4.*

4. In the **last 3 months** (90 days), have you experienced any unusual weight gain (5 pounds [lbs.] or more)? .....

yes no

14  
FSQwgt

5. In the **last 3 months** (90 days), have you experienced a decrease in your urine output? .....

15  
FSQdecur

*If yes to both items 4 and 5, please see the SSP for further instructions.*

16 17 18 19  
bit4b075b075b075b075 18-AUG-03

20  
formlang  
Language

21  
sfdt\_075  
Staff Initials / Date



Plate 077 MSQ-2: Quarterly Symptoms-Male Page 2

Visit  
Code

6  
visit

HPTN 039 (093)

MSQ-2 (077)

Page 2 of 2

Participant ID

7  
ptid - - - - -  
Site Number Participant Number Chk

Quarterly Symptoms—Male

2e. Were you diagnosed with a sexually-transmitted infection but don't know the name? .....

yes no  
8  
MSQsti

2f. Were you given treatment as a contact to a sexually-transmitted infection (because your partner had a sexually-transmitted infection)? .....

yes no don't know  
9  
MSQsttrt

3. In the last 3 months (90 days), have you had a recurrent episode of anogenital herpes? .....

yes no don't know  
10  
MSQhrpes

3a. Where did you have the herpes? Mark all that apply.

11  
MSQhpnis

12  
MSQhanus

13  
MSQhbutt

14  
MSQhothr other specify: 15  
MSQhothx

If no or  
don't know,  
go to item 4.

4. In the last 3 months (90 days), have you experienced any unusual weight gain (5 pounds [lbs.] or more)? .....

yes no  
16  
MSQwgt

5. In the last 3 months (90 days), have you experienced a decrease in your urine output? .....

17  
MSQdecur

If yes to both items 4 and 5,  
please see the SSP for  
further instructions.

18 19 20 21  
bit 4b073b072b071 18 AUG-03

22  
formlang  
Language

23  
sfdt\_077  
Staff Initials / Date

Plate 080 MA-1: Medication Adherence

Visit  
Code6  
visit

HPTN 039 (093)

MA-1 (080)

Page 1 of 1

Participant ID

Medication Adherence

Visit Date

7  
ptid - - - - -  
Site Number Participant Number Chk

Medication Adherence

8  
MA dt - - - - -  
dd MMM yy

1. Number of tablets returned at this visit: .....

9  
MAr1tab

# of tablets

10  
MAr1bttl

bottle #

11  
MAr2tab

# of tablets

12  
MAr2bttl

bottle #

13  
MAr3tab

# of tablets

14  
MAr3bttl

bottle #

2. Did you miss taking any doses since the last visit? .....

yes no don't know

15  
MAmisdos

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

2a. Did you ever miss 2 or more doses in a row (1 day or more)?

16  
MAm2dos

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

2b. What was the largest number of doses in a row you missed?

17  
MAnummis # of doses

2c. For the period described in Item 2b, why did you miss taking tablets? Read categories. Mark all that apply.

18  
MAforgot22  
MAaway from home19  
MAill23  
MAhad a change in daily routine20  
MAproblems taking number of tablets24  
MAbelieve there were side effects21  
MAlost tablets25  
MAother, specify:

26

MAothrx

3. Since your last visit, have you given any of your study tablets to another person? .....

yes no

27  
MAgive

If no, go to item 4.

3a. How many of your tablets did you give to another person? ....

28  
MAgvtab # of tablets

4. Since your last visit, did you take acyclovir, valacyclovir, or famciclovir in addition to your study medication for treatment of herpes? .....

yes no don't know

29  
MAhtreat

5. Bottles dispensed at this visit: .....

30  
MAad1bttl bottle #31  
MAad2bttl bottle #32  
MAad3bttl bottle #33 34 35 36  
bit4b080b080b080b080 JAN-0437  
formlang38  
sfdt\_080

Plate 090 FGE-1: Female Genital Exam

Visit  
Code6  
visit

HPTN 039 (093)

FGE-1 (090)

Page 1 of 1

## Participant ID

Female Genital Exam

## Examination Date

7  
ptid - - - - -  
Site Number Participant Number Chk

## Female Genital Exam

8  
FGE dt - - - - -  
dd MMM yy

## 1. Were any of the following abnormalities noted?

- |   | yes            | no                       | not done/<br>not collected |
|---|----------------|--------------------------|----------------------------|
| 1a. abnormal vaginal discharge .....                    | 9<br>FGEvdsch  | <input type="checkbox"/> | <input type="checkbox"/>   |
| 1b. cervical mucopus .....                              | 10<br>FGEcmuc  | <input type="checkbox"/> | <input type="checkbox"/>   |
| 1c. cervical friability .....                           | 11<br>FGEcfri  | <input type="checkbox"/> | <input type="checkbox"/>   |
| 1d. adnexal, cervical, or uterine tenderness .....      | 12<br>FGEtendr | <input type="checkbox"/> | <input type="checkbox"/>   |
| 1e. vulvar, perineal, perianal, or gluteal ulcers ..... | 13<br>FGEulcer | <input type="checkbox"/> | <input type="checkbox"/>   |
| 1f. other, specify below .....                          | 14<br>FGEothr  | <input type="checkbox"/> | <input type="checkbox"/>   |
| 15<br>FGEothrx  |                |                          |                            |

## 2. Did you make a presumptive or clinical diagnosis of a sexually-transmitted infection? .....

yes no  
16  
FGEsti ☐ If no, end of form.

## 2a. Which diagnosis(es) was made? Mark all that apply.

- |                |              |
|----------------|--------------|
| 17<br>FGEhulcr | 20<br>FGEvag |
| 18<br>FGEoulcr | 21<br>FGEpid |
| 19<br>FGEcerv  | 22<br>FGEodx |
| 23<br>FGEodxx  |              |

## 2b. Was episodic acyclovir provided for this diagnosis? .....

yes no  
24  
FGEacyc ☐

## 3. How many swab(s) were collected for anogenital ulcers? .....

25  
FGEswabs # of swab(s)

## 3a. Please indicate the location of ulcers for which a swab(s) was collected. Mark all that apply.

- |                 |                |
|-----------------|----------------|
| 26<br>FGEvswab  | 30<br>FGEoswbx |
| 27<br>FGEpswab  |                |
| 28<br>FGEbsswab |                |
| 29<br>FGEoswab  |                |

If 0, end of form.

31 32 33 34  
bit 4b093b092090 18 AUG-0335  
formlang  
Language36  
sfdt\_090  
Staff Initials / Date

Plate 092 MGE-1: Male Genital Exam

Visit  
Code6  
visit

HPTN 039 (093)

MGE-1 (092)

Page 1 of 1

## Participant ID

Male Genital Exam

## Examination Date

7  
ptid - - - - -  
Site Number Participant Number Chk

## Male Genital Exam

8  
MGE dt - - - - -  
dd MMM yy

yes no not done

- 1.
- Required at Enrollment visit only:**
- Is the participant circumcised? .....

9  
MGEcirc ☐ ☐

2. Penile Region:
- 
- (including scrotum
- 
- and including
- 
- foreskin, if present)

not done normal abnormal

10  
MGEpenrg ☐☐If abnormal, please specify type of finding.  
Mark all that apply.11  
MGEprves14  
MGEprcrs12  
MGEprud15  
MGEprery13  
MGEprulc16  
MGEproth

17

MGEprotx

3. Perianal area:
- 
- (including buttocks)

not done normal abnormal

18  
MGEperi ☐☐If abnormal, please specify type of finding.  
Mark all that apply.19  
MGEpaves22  
MGEpacrs20  
MGEpard23  
MGEpaery21  
MGEpaulc24  
MGEpaoth

25

MGEpaotx

4. Did you make a presumptive or clinical diagnosis of a
- 
- sexually-transmitted infection?.....

yes no

26  
MGEsti ☐

If no, end of form.

- 4a. Which diagnosis(es) was made? Mark all that apply.

27  
MGEhulcr30  
MGEproct28  
MGEoulcr31  
MGEodx

32

MGEodxx

29  
MGEureth

yes no

- 4b. Was episodic acyclovir provided for this diagnosis?.....

33  
MGEacyc ☐

5. How many swab(s) were collected for anogenital ulcers? .....

34  
MGEswabs

# of swab(s) → If 0, end of form.

- 5a. Please indicate the location of ulcers for which a swab(s) was collected. Mark all that apply.

35  
MGEpswab38  
MGEaswab36  
MGEbswab39  
MGEoswab

40

MGEoswbx

37  
MGEsswab41 42 43 44  
bit 4b 092 092 092 092

18 AUG-03

45  
formlang

Language

46  
sfdt\_092

Staff Initials / Date



Visit  
Code

6	visit	
---	-------	--

IV-1 (350)

Page 1 of 1

Visit Date

## Interim Visit

8					
IVdt					

Participant Number

Chk

 $dd$ 

MMM

yy

- 9** **IVmiss** participant missed his/her last regularly scheduled study visit and is outside of any visit window.

10 IVsti 1b. STI symptom(s)

11 1cprob other gynecological or genital problem(s), specify:

12

~~IVgnprbx~~

**Perform necessary clinical and laboratory procedures. Complete Genital Exam if applicable.**

13 1d confirmatory HIV test blood draw

**Complete HIV Rapid or Non-rapid Test Result form.**

14  
IVlost 1e. lost study drug

**Complete Medication Adherence form.**

15 ☐ TV ☐ other, specify: 1f

16

~~IVvothrx~~

- 17 No other DataFax forms were completed at this visit

18 IVsae SAE

19 IV adhere

## 20 HIV Rapid Test Results or HIV Non-rapid Test Results

21 Genital Exam

22  
IVqbehav

23 Monthly Behavioral form

24 Concomitant Medications Log

25  
IVpreg

26 IVfothr

27

~~IVfothrx~~

28 29 30 31  
bit4b350b350b350 350

32	
formlang	
Language	

33  
sfdt\_350

---

Staff Initials / Date

Plate 351 HTR-1: HIV Rapid Test Results

Visit  
Code6  
visit

1

HPTN 039 (093)

HTR-1 (351)

Page 1 of 1

## Participant ID

HIV Rapid Test Results

7  
ptid

Site Number Participant Number Chk

## HIV Rapid Test Results

## SAMPLE 1

## Specimen Collection Date

8  
HTRs1dt

dd MMM yy

not done/  
not collected

negative

positive

1. HIV rapid EIA: .....

9  
HTRs1eia

☐☐

If negative, go to item 5.

not done/  
not collected

negative

positive

indeterminate

1a. HIV WB or IFA: .....

10  
HTRs1wb

☐☐☐

If negative, go to item 5.

## SAMPLE 2

## Specimen Collection Date

11  
HTRs2dt

dd MMM yy

not done/  
not collected

negative

positive

indeterminate

2. HIV WB or IFA: .....

12  
HTRs2wb

☐☐☐

If positive, go to item 5.

## SAMPLE 3

## Specimen Collection Date

13  
HTRs3dt

dd MMM yy

not done/  
not collected

negative

positive

indeterminate

3. HIV WB or IFA: .....

14  
HTRs3wb

☐☐☐

If positive, go to item 5.

## SAMPLE 4

## Specimen Collection Date

15  
HTRs4dt

dd MMM yy

not done/  
not collected

negative

positive

indeterminate

4. HIV WB or IFA: .....

16  
HTRs4wb

☐☐☐

## FINAL HIV STATUS

negative

positive

5. Final HIV status: .....

17  
HTRhiv

☐

18  
Comments: HTRcomm

19 20 21 22  
bit4b151b352b351\_351

18 AUG-03

23  
formlang

Language

24  
sfdt\_351

Staff Initials / Date

Plate 352 HNR-1: HIV Non-rapid Test Results

Visit  
Code6  
visit

1

HPTN 039 (093)

HNR-1 (352)

Page 1 of 1

## Participant ID

HIV Non-rapid Test  
Results

7  
ptid

Site Number Participant Number Chk

## HIV Non-rapid Test Results

## SAMPLE 1

## Specimen Collection Date

8  
HNRs1dt

dd MMM yy

not done/  
not collected

negative

positive

1. HIV EIA: .....

9  
HNRs1eia

☐☐

If negative, go to item 5.

not done/  
not collected

negative

positive

indeterminate

1a. HIV WB or IFA: .....

10  
HNRs1wb

☐☐☐

If negative, go to item 5.

## SAMPLE 2

## Specimen Collection Date

11  
HNRs2dt

dd MMM yy

not done/  
not collected

negative

positive

indeterminate

2. HIV WB or IFA: .....

12  
HNRs2wb

☐☐☐If negative or positive,  
go to item 5.

## SAMPLE 3

## Specimen Collection Date

13  
HNRs3dt

dd MMM yy

not done/  
not collected

negative

positive

indeterminate

3. HIV WB or IFA: .....

14  
HNRs3wb

☐☐☐If negative or positive,  
go to item 5.

## SAMPLE 4

## Specimen Collection Date

15  
HNRs4dt

dd MMM yy

not done/  
not collected

negative

positive

indeterminate

4. HIV WB or IFA: .....

16  
HNRs4wb

☐☐☐

## FINAL HIV STATUS

negative

positive

5. Final HIV status:.....

17  
HNRhiv

☐Comments: 18  
HNRcomm19 20 21 22  
bit 4b152b352b352 18 AUG-0323  
formlang  
Language24  
sfdt\_352  
Staff Initials / Date

Plate 353 STR-1: Syphilis Test Results

Visit  
Code

6  
visit

HPTN 039 (093)

STR-1 (353)

Page 1 of 1

Participant ID

Syphilis Test Results

Specimen Collection Date

7  
ptid  
Site Number - Participant Number - Chk

Syphilis Test Results

8  
STRdt  
dd MMM yy

1. Syphilis RPR.....

negative weakly reactive reactive not done/  
not collected

9  
STRrpr

If negative, weakly reactive, or not  
done/not collected, end of form.

1a. Titer.....

1: 10  
STRtiter

1b. Syphilis confirmatory test.....

negative positive

11  
STRconf

Comments: 12  
STRcomm

13 14 15 16  
bit4b153b152b153\_353 18-AUG-03

17  
formlang  
Language

18  
sfdt\_353  
Staff Initials / Date

Plate 354 IV-1: Interim Visit

Visit  
Code6  
visit

HPTN 039 (093)

IV-1 (354)

Page 1 of 1

Participant ID

7  
ptid - - - - -  
Site Number Participant Number Chk

Interim Visit

Interim Visit

Visit Date

8  
IVdt - - - - -  
dd MMM yy1. What is the reason for this visit? *Mark all that apply.*9  
IVmiss 1a. participant missed his/her last regularly scheduled  
study visit and is outside of any visit window.10  
IVsti 1b. STI symptom(s)11  
IVgnprob 1c. other gynecological or genital problem(s), specify:12  
IVgnprbxPerform necessary clinical and  
laboratory procedures. Complete  
Genital Exam if applicable.13  
IVhivdrw 1d. confirmatory HIV test blood drawComplete HIV Rapid or Non-rapid Test  
Result form.14  
IVlost 1e. lost study drug

Complete Medication Adherence form.

15  
IVprtvtst 1f. participant completed part of a visit, and is outside  
of any visit window.16  
IVvothr 1g. other, specify:17  
IVvothrx2. Besides this Interim Visit form, what other DataFax study forms were completed at this visit? *Mark all that apply.*18  
IVsae SAE19  
IVadhere Medication Adherence20  
IVhivtr HIV Rapid Test Results or HIV Non-rapid Test Results21  
IVgenexm Genital Exam22  
IVqbehav Quarterly Behavioral form23  
IVmbehav Monthly Behavioral form24  
IVcsymp Current Symptoms25  
IVqsymp Quarterly Symptoms26  
IVconmed Concomitant Medications Log27  
IVpreg Pregnancy Report28  
IVfothr other, specify:

29

IVfothrx

30 31 32 33  
bit4b154b154b154b154 JAN-0434  
formlang  
Language35  
sfdt\_354  
Staff Initials / Date

Plate 421 SAE-1: Serious Adverse Experience Log (PTN)

6  
Page  
visit

HPTN 039 (093)

SAE-1 (421)

8  
AEsubsum

Date Reported to Site

Participant ID

7  
ptid

Site Number

Participant Number

Chk

Serious Adverse Experi-

Serious Adverse Experience Log

SAE #

10  
AEsaeno9  
AErptdt

dd

MMM

yy

11  
AEfver12  
AEmdra

Flag/Version

MedDRA

## 1. Serious Adverse Experience (SAE)

## 2. Onset Date

13

AEdiag

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

TDS/DC: If translated; show line below on site copy.

English (if above is in Local Language):

## 3. Severity

## 4. Relationship to Study Product

## 5. Study Product Administration

15

AEseve

Not applicable  
to this study.

Grade 2 - Moderate

☐

Grade 3 - Severe

☐

Grade 4 - Life-threatening

☐

Grade 5 - Death

16

AEseveqc

17

AERelpro

Definitely related

☐

Probably related

☐

Possibly related

☐

Not related

Record reason why SAE is "not related"  
in Comments below.

18

AEdrad

No change

☐

Held

☐

Permanently discontinued

☐

N/A

☐Change in administration  
Comment below.

## 6. Status/Outcome

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

19

AEoutc

☐

Resolved

☐

Death

☐Severity/frequency increased  
Report as new SAE.☐

Continuing at end of study participation

## 6a. Status/Outcome Date

Leave blank if status/outcome  
is "Continuing."20  
AEocdt

dd

MMM

yy

21

AETrno

22

AETrrx

Medication(s)

Report on Concomitant Medications Log.  
New/Prolonged hospitalization  
Comment below.

23

AETrho

Procedure/Surgery

Comment below.

24

AETrpr

25

AETrot

Other  
Comment below.8. Has this SAE been reported to all  
appropriate regulatory authorities as  
a Serious Adverse Experience (SAE)?

yes

no

26  
AESae☐9. This SAE was first  
reported at visit:27  
AEvisit☐

Comments:

28

AEcomm

TDS/DC: If translated; show line below on site copy.

English (if Comments above are in Local Language):

29 30 31 32  
bit4b123b123b121\_421

08 OCT-03

/hivnet/forms/PTN\_039/forms/sae\_log.fm

33  
formlang

Language

34  
sfdt\_421

Staff Initials / Date

Plate 423 CM-1: Concomitant Medications Log

6  
Page  
visit

HPTN 039 (093)

CM-1 (423)

## Participant ID

7  
ptid  
Site Number - Participant Number - ChkConcomitant  
Medications LogConcomitant Medications  
Log8  
CMnoneNo medications taken  
throughout study.9  
CMnoinit

Staff Initials/Date

End of form. Fax to SCHARP DataFax.

Medication (generic name) 10 CM1med		Staff Initials/Log Entry Date 11 CM1init	
Indication 13 CM1ind		Taken for a reported SAE? 14 CM1sae <input type="checkbox"/>	
Date Started 18 CM1stdt dd MMM yy		Date Stopped 19 CM1spdt dd MMM yy OR 20 CM1cont Continuing at end of study	
		Record SAE Log page(s): page # page # page # 15 CM1sae1p 16 CM1sae2p 17 CM1sae3p	

12  
CM1me

Medication (generic name) 21 CM2med		Staff Initials/Log Entry Date 22 CM2init	
Indication 24 CM2ind		Taken for a reported SAE? 25 CM2sae <input type="checkbox"/>	
Date Started 29 CM2stdt dd MMM yy		Date Stopped 30 CM2spdt dd MMM yy OR 31 CM2cont Continuing at end of study	
		Record SAE Log page(s): page # page # page # 26 CM2sae1p 27 CM2sae2p 28 CM2sae3p	

23  
CM2me

Medication (generic name) 32 CM3med		Staff Initials/Log Entry Date 33 CM3init	
Indication 35 CM3ind		Taken for a reported SAE? 36 CM3sae <input type="checkbox"/>	
Date Started 40 CM3stdt dd MMM yy		Date Stopped 41 CM3spdt dd MMM yy OR 42 CM3cont Continuing at end of study	
		Record SAE Log page(s): page # page # page # 37 CM3sae1p 38 CM3sae2p 39 CM3sae3p	

34  
CM3me

Medication (generic name) 43 CM4med		Staff Initials/Log Entry Date 44 CM4init	
Indication 46 CM4ind		Taken for a reported SAE? 47 CM4sae <input type="checkbox"/>	
Date Started 51 CM4stdt dd MMM yy		Date Stopped 52 CM4spdt dd MMM yy OR 53 CM4cont Continuing at end of study	
		Record SAE Log page(s): page # page # page # 48 CM4sae1p 49 CM4sae2p 50 CM4sae3p	

45  
CM4me54 55 56 57  
bit4b123b123b123 423

18 AUG-03

58  
formlang  
Language

Plate 451 PR-1: Pregnancy Report Page 1

6  
visit

HPTN 039 (093)

PR-1 (451)

Page 1 of 2

## Participant ID

7  
ptid

Site Number

Participant Number

Chk

Pregnancy Report

## Pregnancy Report

## Form Completion Date

8  
PRdt

dd

MMM

yy

**Instructions:** Upon notification of pregnancy, complete items 1–4 and fax to SCHARP DataFax. At pregnancy outcome, update item 4 and complete items 5–7 on page 2. Fax the form again to SCHARP DataFax.

## PREGNANCY NOTIFICATION

1. Date of first day of last menstrual period:

dd MMM yy  
9  
PRmdldt

2. Date of last negative pregnancy result obtained by site:

dd MMM yy  
10  
PRnegdt

3. Estimated date of delivery:

dd MMM yy  
11  
PRestdt3a. How was this date determined? *Mark all that apply.*

ultrasound	fundal height	LMP	other, specify:	16	don't know
12	13	14	15	PRomthdx	17
PRultras	PRfundal	PRlmp	PRomthd		PRdk

4. Briefly comment on participant's condition, clinical history of pregnancy, therapeutic management, and hospitalizations relevant to this pregnancy.

18  
PRcommx19 20 21 22  
bit4b151b152b151\_451 JAN-04

/hivnet/forms/PTN\_039/forms/pregnancy\_report.fm

Schema Last Modified: Thu May 6 13:55:33 2004

23  
formlang  
Language24  
sfdt\_451  
Staff Initials / Date



PR-2 (452)

Page 2 of 2

## Pregnancy Report

7									
ptid									
Site Number			Participant Number				Chk		

5. Number of fetuses:  $\frac{8}{PR_{fetus}}$  *#fetuses*

9 PRlive live birth(s).

yes      no      don't know

6a1. Was the delivery premature (< 37 weeks)? .....

10  
PRprem

**11** ☐ PRanom ☐ ☐

12 PRdth30d

13 PRmiscarr miscarriage (gestational age  $\leq$  20 weeks)

14 PRabort elective abortion

15  
PRectopc ectopic pregnancy

16 PRstlbt still birth(s)/fetal death (gestational age > 20 weeks)

yes      no      don't know

6e1. Were any congenital anomalies or birth defects present?.....

17 PRsbanom

18  
PRunk unknown/lost to follow-up

*Complete SAE form for all hospitalizations except normal live births and elective cesareans.*

7. Date of delivery or termination of pregnancy: ..... **dd** **MMM** **yy**

**19** **PRdlyrdr** **yrdr**

Plate 461 COM-1: Comments

Visit  
Code

6  
visit

HPTN 039 (093)

COM-1 (461)

Page 1 of 1

Participant ID

Comments

Form Completion Date

7  
ptid

Comments

8  
COMdt

Site Number

Participant Number

Chk

dd

MMM

yy

**Instructions:** Use this form to record additional information about a specific participant or to clarify data recorded on another form. For Visit Code, enter the visit code of the form or visit which you are commenting on.

**Please print information legibly.**

Record the acronym(s) of the form(s) to which the comments apply: <sup>9</sup>COMacro or <sup>10</sup>COMacrna

(See upper right hand corner of form for acronym. For example, this form's acronym is COM-1.)

Comments:

11

COMcomm

Plate 463 MV-1: Missed Visit

Visit  
Code

6  
visit

1

HPTN 039 (093)

MV-1 (463)

Page 1 of 1

Participant ID

Missed Visit

Form Completion Date

7  
ptid

Missed Visit

8  
mvdt

Site Number

Participant Number

Chk

dd

MMM

yy

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

9  
Comments: MVcomm

Plate 465 PT-1: Participant Transfer

Visit Code 6 visit

HPTN 039 (093)

PT-1 (465)

Page 1 of 1

Participant ID

Participant Transfer

Form Completion Date

7 ptid - - Chk  
 Site Number Participant Number

Participant Transfer

8 PTdt - -  
 dd MMM yy

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

1. Name of transferring study site: 9 PTtsite 10 PTtuid Unit ID

2. Name of receiving study site: 11 PTTrsite 12 PTTruid Unit ID

3. Visit Code of last completed contact with participant: 13 PTvisit

4. Date participant records were sent to receiving study site: 14 PTsentdt  
 dd MMM yy

Comments: 15 PTcomm

16 17 18 19  
 bit465\_465\_465\_465 18-AUG-03

20 21  
 formlang sfdt\_465  
 Language Staff Initials / Date

Plate 466 PRC-1: Participant Receipt

Visit  
Code 6 visit

HPTN 039 (093)

PRC-1 (466)

Page 1 of 1

## Participant ID

Participant Receipt

## Form Completion Date

7  
ptid - - - - -  
Site Number Participant Number Chk

## Participant Receipt

8  
PRCdt - - - - -  
dd MMM yy

**Instructions:** The **receiving** study site completes this form when a participant transfers from another study site. Record the Participant ID assigned by the transferring study site (i.e., keep original Participant ID). **Do not** assign a new Participant ID.

1. Name of receiving study site: 9  
PRCrsite 10  
PRCruid Unit ID
2. Name of transferring study site: 11  
PRCTsite 12  
PRCTuid Unit ID
3. Date informed consent signed at receiving study site: 13  
PRCrcdt - - - - -  
dd MMM yy
4. Did participant provide informed consent for specimen storage at receiving study site? yes no  
14  
PRCconsn
- 4a. Date informed consent for specimen storage signed: 15  
PRCcondt - - - - -  
dd MMM yy

16  
Comments: PRCcomm17 18 19 20  
bit466\_466\_466\_466 18-AUG-0321  
formlang 22  
sfdt\_466  
Language Staff Initials / Date

Plate 487 PIL-1: Participant Incident Log

Page 6  
visit

HPTN 039 (093)

PIL-1 (487)

Participant Incident Log

Participant ID

7									
ptid									
Site Number									Chk

Participant Incident Log –  
For Internal Use Only

Form Completion Date: 

8							
PILfcdt							

SC Staff Name: 

9							
PILstaff							

Source of Information: 

10							
PILsourc							

If applicable:

Plate #: 

11							
PILplate							

Visit: 

12							
PILvisit							

Subject: Mark all that apply.

13							
PILforms							

14							
PILprot							

15							
PILdata							

16							
PILlab							

17							
PILenrol							

18							
PILrand							

19							
PILsubo							

Other, specify: \_\_\_\_\_

20							
PILsubox							

Event and resolution details:

21							
PILevnt							

22	23	24	25
bit487	bit487	bit487	bit487

			x
--	--	--	---

 26-APR-04

Plate 489 ESI-1: End of Study Inventory

Visit Code 6 visit

HPTN 039 (093)

ESI-1 (489)

Page 1 of 1

Participant ID

End of Study Inventory

Form Completion Date

7 ptid - - Chk  
 Site Number Participant Number

End of Study Inventory

8 ESI dt - -  
 dd MMM yy

1. What is the visit code of the participant's last visit? .....

Visit Code 9 ESI visit

2. What was the last SAE page number submitted for this participant? .....

10 ESI saepg Page # OR 11 ESI nosae No SAEs

3. How many interim visits were conducted for this participant during the study? .....

12 ESI intvs # of Interim Visits

Item 4 for female participants only. Male participants, end of form.

4. Was the participant pregnant at any time while enrolled in the study?.....

yes no  
 13 ESI preg

14 15 16 17  
 bit 4b 163b 162b 489 18 AUG-03

18 form lang 19 sfdt 489  
 Language Staff Initials / Date

Plate 490 TM-1: Termination

Visit Code 6 visit

HPTN 039 (093)

TM-1 (490)

Page 1 of 1

## Participant ID

7 ptid - - - - -  
Site Number Participant Number Chk

Termination

Termination

dd MMM yy

1. Termination Date: 8 TMtmdt - - - - -

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

2. Reason for termination. Mark only one.

9 2a. Scheduled exit visit/end of study. —► End of form.  
TMreas

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

dd MMM yy  
2b1. Date of death 10 TMdthdt - - - - - OR 11 TMdthunk - - - - -  
Date unknown2b2. Cause of death 12 TMdcaus - - - - - OR 13 TMdcunk - - - - -  
Cause unknownComplete  
or update  
Serious Adverse  
Experience Log.

2c. Participant refused further participation, specify: 14 TMrefrx - - - - -

2d. Participant unable to adhere to visit schedule.

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

2f. Investigator decision, specify: 15 TMinvdx - - - - -

2g. Unable to contact participant.

2h. HIV infection.

2i. Inappropriate enrollment.

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

2k. Other, specify: 16 TMtrmox - - - - -

3. Was termination associated with...

yes no don't know  
3a. Serious Adverse Experience? 17 TMsae - - - - -Record  
Serious  
Adverse  
Experience  
Log page(s):page # page # page #  
18 TMsaelpg 19 TMsaelpg 20 TMsaelpg

Comments: 21 TMcomm - - - - -

22 23 24 25  
bit 4b100b102b100 18 AUG-0326 formlang  
Language27 sfdt\_490  
Staff Initials / Date