

**Proposal to the National Institute of Child  
Health and Human Development**

**Appendix 2**  
**Case Report Forms**

RFP NIH-NICHD-2000-09

*Hormonal Contraception  
and the Risk of HIV Acquisition*

July 17, 2000

*Charles Morrison, PhD*  
FAMILY HEALTH INTERNATIONAL

SAMPLE: DO NOT FAX TO DATAFAX

HIV021 HC Screening (053)

Visit Code [ ][ ]

SE (001)

Screening ID

[ ][ ][ ][ ][ ][ ]

Screening Eligibility

Visit Date

[ ][ ] [ ][ ] [ ][ ]  
dd mm yy

DEMOGRAPHICS

Make sure that the participant signed/marked the screening informed consent before beginning this form.

[ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

Clinic Record Number

The following are some basic questions regarding your background.

1. What is your age? (completed years) [ ][ ] years

If participant is younger than 18 or older than 35, she is ineligible. End of form. Fax first page (SE-1) only to HIVNET DataFax.

1a. Birthdate, if available: [ ][ ] [ ][ ] [ ][ ]  
dd mm yy

2. What is your current marital status?

- never married
married (monogamy)
married (polygyny)
separated
divorced
widowed

3. Are you currently living with your husband/partner? yes no

4. For how many years did you go to school? Please do not include kindergarten or years when you repeated a grade. [ ][ ] years

5. What is your occupation? Mark all that apply.

- none/housewife, civil service/government, factory worker, student, office/store employee, farmer/fisherwoman, teacher, other, specify, general laborer, trader/self-employed, professional

6. What is your husband's/partner's occupation? Mark all that apply.

- not applicable, general laborer, trader/self-employed, professional, none, civil service/government, factory worker, student, office/store employee, farmer/fisherman, teacher, other, specify

[ ] [ ] [ ] [X] December 1, 1999

SAMPLE—English

01 Staff ID [ ][ ]  
Language

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Visit Code

HIV021 HC Screening (053)

SE (002)

Screening ID

**Screening Eligibility**

7. What is your ethnicity or tribe? *Mark all that apply.*

**UGANDA:**

- Muganda
- Munyankole
- Mukiga
- Munyarwanda
- Munyoro
- Mutoro
- other, specify: \_\_\_\_\_

**ZIMBABWE:**

- Shona
- Ndebele
- other, specify: \_\_\_\_\_

**THAILAND:**

- Thai
- Cambodian
- Laotian
- Burmese
- Malaysian
- Hilltribe, specify: \_\_\_\_\_
- other, specify: \_\_\_\_\_

**SCREENING ELIGIBILITY**

8. Have you had a hysterectomy (the removal of your womb or uterus)? .....

yes  no

*If yes, participant is ineligible. Go to item 18.*

9. Have you been using family planning pills **regularly** for the last 3 months?

*If no, go to item 10.*

9a. Do you intend to continue using family planning pills for at least the next 12 months? .....

*If no, participant is currently ineligible. Go to item 18.*

9b. Which brands of family planning pills have you taken in the last 3 months? Use Pill Poster.

Brand Name	Code
_____	<input type="text"/>
_____	<input type="text"/>
_____	<input type="text"/>

9c. Are **all** brands taken in the last 3 months low-dose combined oral contraceptives (COC)? .....

yes  no

*If no, participant is currently ineligible. Go to item 18.*

*If yes, go to item 12.*

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FAX TO DATAFAX**

Visit Code

HIV021 HC Screening (053)

SE (007)

Screening ID

Screening Eligibility

- 10. Prior to today's visit, in the last 4 months, have you received a Depo-Provera injection, the family planning injection that is given every 3 months? .....  *yes*  *no* → *If no, go to item 11.*
- 10x. Have you been using Depo-Provera as your method of family planning for at least the last 3 months, that is, since \_\_\_\_\_ (day/month/year)? .....  *yes*  *no* → *If no, participant is currently ineligible. Go to item 18.*
- 10a. Do you intend to continue using Depo-Provera for at least the next 12 months? .....  *yes*  *no* → *If no, participant is currently ineligible. Go to item 18.*
- 11. Have you used any of the following methods of family planning? .....  *yes*  *no* → *If yes, go to item 12.*
- 11a. Depo-Provera within the last 6 months? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*
- 11b. Other family planning injections or Norplant within the last 3 months? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*
- 11c. IUD ("coil"/ "loop") within the last month? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*
- 11d. Any family planning pills in the last 3 months? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*
- 12. Have you had sex at least 3 times in the last 3 months? .....  *yes*  *no* → *If no, participant is currently ineligible. Go to item 18.*
- 13. Have you ever given birth (including stillbirth)? .....  *yes*  *no* → *If no, go to item 14.*
- 13a. Was your last birth within the last 4.5 months? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*
- 14. Do you intend to become pregnant in the next 12 months? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*
- 15. Have you had a miscarriage or induced abortion within the last month? .....  *yes*  *no* → *If yes, participant is currently ineligible. Go to item 18.*

December 1, 1999

SAMPLE—English

Language

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FAX TO DATAFAX**



Visit Code

HIV021 HC Screening (053)

SE (004)

Screening ID

**Screening Eligibility**

16. Have you injected illegal drugs within the last 3 months?.....  <sup>yes</sup>  <sup>no</sup>  
 If yes, participant is currently ineligible. Go to item 18.
17. Have you had a blood transfusion or received any blood products in the last 3 months?.....    
 If yes, participant is currently ineligible.

**SEXUAL BEHAVIOR HISTORY**

The following questions are related to your sexual behavior. I want to remind you that all the information you provide in this interview will be kept confidential.

18. At what age did you first have sex?  years

19. How many sexual partners have you had in your lifetime?  partners

20. Have you ever engaged in commercial sex? .....  <sup>yes</sup>  <sup>no</sup>  
 don't know

21. Have you ever had sex when a male or female condom was used?     
 yes no

22. Is the participant still eligible?   → If no, end of form. Fax pages SE-1 through SE-4 only to HIVNET DataFax.

23. Are you currently participating in any other HIV-prevention or family planning studies?.....  <sup>yes</sup>  <sup>no</sup> → If no, go to item 23b.

23a. Does the study that the participant is in make her ineligible for this study (check site list)? .....    
 If yes, participant is ineligible. End of form. Fax pages SE-1 through SE-4 to HIVNET Datafax.

23b. If you plan to join another study while you are in this study, will you tell us first? .....  <sup>yes</sup>  <sup>no</sup> → If no, participant is ineligible. End of form. Fax pages SE-1 through SE-4 to HIVNET Datafax.

December 1, 1999

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Language

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Visit Code

HIV021 HC Screening (053)

SE (005)

Screening ID

Screening Eligibility

**FOLLOW-UP**

24. Do you plan to live in this area for at least the next 12 months?.....  *yes*  *no* **→ If no, participant is ineligible. End of form. Fax pages SE-1 through SE-5 to HIVNET Datafax.**
25. Do you agree to all study procedures, including HIV testing every 3 months, follow-up clinic visits, and home visits if you miss an appointment? .....  *yes*  *no* **→ If no, participant is ineligible. End of form. Fax pages SE-1 through SE-5 to HIVNET Datafax.**

**PREGNANCY**

26. When was the first day of your last menstrual period?

**These items removed due to change in pregnancy testing criteria.**

*For non-hormone users: If record date was 6 weeks or more ago, conduct pregnancy test.*

*For pill users: If not taking during the 7-day hormone pill-free interval, conduct pregnancy test.*

*For Depo-Provera Users: Pregnancy test not necessary since all participants in Depo-Provera cohort must have had an injection within the last four months in order to be eligible.*

27. Pregnancy testing  *not done/not collected*  *positive*  *negative* **→ If positive, participant is ineligible. End of form. Fax pages SE-1 through SE-5 to HIVNET Datafax.**

**FAMILY PLANNING**

28. Was family planning provided at this visit?  *yes*  *no* **→ If no, go to instruction at the top of page 6.**
29. What was provided? Mark all that apply.

- Oral Contraceptives  
Specify brand/code: \_\_\_\_\_
- Depo-Provera injection
- Condoms
- Other  
Specify: \_\_\_\_\_

OC Code (use Pill Poster)

December 1, 1999

SAMPLE—English

Language

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HIV021 HC Screening (053)

SE (006)

Screening ID

Screening Eligibility

**This page to be completed when the participant returns for enrollment.**

**ENROLLMENT**

30. HIV test results

not done/  
not collected      positive      negative

                                          

**If positive, or sample not collected, participant is ineligible. End of form.**

31. Did the participant return for enrollment within 15 days of screening?...

yes      no

    

**If no, repeat screening.**

32. Did the participant sign/mark the enrollment informed consent for the study?.....

**If no, do not enroll. Go to item 33.**

33. Did the participant enroll in the study? .....

**If no, indicate reason in item 33a.**

33a. Reason participant did not enroll:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**If yes to all, record Participant ID number below. End of form.**

Participant ID

--

Site Number      Participant Number      Chk

Comments \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**SAMPLE: DO NOT  
FAX TO DATAFAX**



Visit Code

HIV021 HC Screening (053)

SLR (014 )

Screening ID

**Screening Laboratory  
Results**

Specimen Collection Date

dd mm yy

Clinic Record Number

**Not Done/  
Not Collected**

		negative	positive	indeterminate	
<input type="checkbox"/>	1. HIV EIA .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		→ <i>If negative, go to item 2x.</i>			
<input type="checkbox"/>	1a. HIV Rapid 1 .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	1b. HIV Rapid 2 .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	2. HIV PCR .....	<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	2x. Final HIV Status .....	<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	3. Syphilis RPR .....	<input type="checkbox"/>	<input type="checkbox"/>		
	<i>If RPR is positive, perform TPHA/TPPA.</i>	←			
<input type="checkbox"/>	3a. TPHA/TPPA syphilis serology .....	<input type="checkbox"/>	<input type="checkbox"/>		

January 25, 2000

SAMPLE

Staff ID



**SAMPLE: DO NOT  
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HIV021 HC (054)

BQ (021)

Enrollment Visit (0101)

Page 1 of 11

**Participant ID**

-       -

Site Number      Participant Number      Chk

**Baseline Questionnaire**

**Visit Date**

       

dd      mm      yy

**Screening ID**

Clinic Record Number

**PARTICIPATION IDENTIFICATION**

- Indicate participant's baseline cohort:
  - combined oral contraceptives
  - Depo-Provera
  - non-hormonal contraceptives/no modern contraceptives

2. Indicate participant's study site:

**UGANDA**

- Institute of Public Health (IPH) Family Planning Clinic
- Old Mulago Hospital Family Planning Clinic
- Family Planning Association of Uganda
- other, specify: \_\_\_\_\_

**THAILAND**

- Chiang Mai University
- Chiang Mai HPC 10
- Khonkaen University
- Khonkaen HPC 6
- Songkla University
- Hat Yai Hospital
- Rajavithi Hospital
- other, specify: \_\_\_\_\_

**ZIMBABWE**

- Mbuya Nehanda Family Planning Clinic
- Harare Central Hospital Family Planning Clinic
- Spilhaus Family Planning Clinic
- Chitungwiza Family Planning Clinic
- other, specify: \_\_\_\_\_

**REPRODUCTIVE HEALTH HISTORY**

Before we begin, I want to remind you that all the information you provide in this interview will be kept confidential. Some of these questions are about your health and sexual behavior and may be embarrassing to you, but your answers are very important and we would like you to give us your best answers.

3. How old were you when you started menstruating?.....   age in years

4. How many times have you been pregnant? Please include live births, stillbirths, abortions, miscarriages, and tubal pregnancies.....   # of times → If 0, go to item 6.

4a. When was your last pregnancy completed? .....   mm      yy

4b. How many live births have you had?.....   # of live births → If 0, go to item 6.

June 14, 2000

SAMPLE—English

Staff ID

Language

**SAMPLE: DO NOT  
FAX TO DATAFAX**

HIV021 HC (054)

BQ (022)

Enrollment Visit (0101)

Page 2 of 11

**Participant ID**

-      -

Site Number      Participant Number      Chk

**Baseline Questionnaire**

5. Have you ever breastfed? .....  *yes*     *no* → *If no, go to item 6.*
- 5a. In the last 12 months, did you breastfeed? .....  *yes*     *no* → *If no, go to item 6.*
- 5a1. In the last 12 months, for how many months did you breastfeed? .....   # of months
- 5b. Are you currently breastfeeding? .....  *yes*     *no* → *If yes, go to item 6.*
- 5b1. When did you stop breastfeeding? .....   *mm*      *yy*

**MEDICAL HISTORY**

6. Have you ever had any of the following?  
*Read categories.*
- |                                  | <i>yes</i>               | <i>no</i>                | <i>don't know</i>        | <i>If yes, year first diagnosed</i>         | <i>Ongoing?</i>          |
|----------------------------------|--------------------------|--------------------------|--------------------------|---|--------------------------|
|                                  |                          |                          |                          | <i>yy</i>                                   |                          |
| 6a. tuberculosis                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> | <input type="checkbox"/> |
| 6b. heart disease                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> | <input type="checkbox"/> |
| 6c. high blood pressure          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> | <input type="checkbox"/> |
| 6d. hepatitis                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> | <input type="checkbox"/> |
| 6e. diabetes                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> | <input type="checkbox"/> |
| 6f. cervical dysplasia or cancer | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> | <input type="checkbox"/> |
| 6g. blood transfusion            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | → <input type="text"/> <input type="text"/> |                          |

June 14, 2000

SAMPLE—English

Language

SAMPLE: DO NOT FAX TO DATAFAX



HIV021 HC (054)

BQ (023)

Enrollment Visit (0101)

Page 3 of 11

Participant ID

000- - - - - Chk

Baseline Questionnaire

7. In the last 3 months, have you had any of the following symptoms? Read categories.

- 7a. unexplained fever
7b. excessive night sweats
7c. loss of appetite and weight
7d. fatigue that interferes with daily activities
7e. diarrhea (3+ loose stools per day for greater than 7 days)
7f. yeast infection in your mouth or vagina (white, itchy patches or discharge)
7g. persistent swollen lymph nodes (glands)
7h. herpes zoster (including a scar from a painful, blister-like rash)
7i. any other unexplained rash
7j. severe headaches

Response grid for items 7a-7j with columns: In the last 3 months? (yes, no) and If yes, within the last 2 weeks? (yes, no)

In the last 3 months, outside of menstruation, have you had any of the following symptoms?

- 7k. nausea
7l. breast tenderness

Response grid for items 7k-7l with columns: In the last 3 months? (yes, no) and If yes, within the last 2 weeks? (yes, no)

8. Have you ever been hospitalized for anything other than childbirth?

yes no don't know

8a. What have you been hospitalized for?

If no or don't know, go to item 9.

Specify: \_\_\_\_\_

June 14, 2000

SAMPLE-English

01

Language



SAMPLE: DO NOT FAX TO DATAFAX

HIV021 HC (054)

BQ (025)

Enrollment Visit (0101)

Page 5 of 11

Participant ID

000- - - - -

Baseline Questionnaire

CONTRACEPTIVE HISTORY

Now I'm going to ask you about your use of family planning.

Hormonal Contraceptive Methods

- 11. Have you ever used family planning pills?
11a. For how many years in total have you used family planning pills?
12. Have you ever used Depo-Provera, the family planning injection that is given every 3 months?
12a. For how many years in total have you used Depo-Provera?
13. Have you ever used any type of injections for family planning other than Depo-Provera?
13a. For how many years in total have you used family planning injections other than Depo-Provera?
13b. Which family planning injections other than Depo-Provera have you used?

- 14. Have you ever used Norplant implants, the small rods that are inserted into your upper arm for family planning?
14a. For how many years in total have you used Norplant?
15. In the last 12 months, that is, since (month/year), have you used any family planning pills, injections, or implants?
15a. Which have you used in the last 12 months?

June 14, 2000

SAMPLE—English

01 Language

**SAMPLE: DO NOT  
FAX TO DATAFAX**



HIV021 HC (054)

BQ (026)

Enrollment Visit (0101)

Page 6 of 11

Participant ID

0 0 0 - [ ] [ ] [ ] [ ] - [ ]  
 Site Number                  Participant Number                  Chk

**Baseline Questionnaire**

16. Now I'd like to record the dates when you were using family planning pills, injections, or implants in the last 12 months.

Start with the current month and go back, month by month, through the same month of last year. Record the hormonal contraceptive type(s) that the participant used in each box (using abbreviations "PIL," "DEP," "NOR," etc.) and then summarize the information in items 16a through 16i. See the Hormonal Contraceptive History Instruction Card for more detailed instructions.

Year	DEC	NOV	OCT	SEP	AUG	JUL	JUN	MAY	APR	MAR	FEB	JAN
(current)												
(last)												
(year before last)												

	Contraceptive Type Code (see below)	Date Started		Date Stopped		Pill Code (use Pill Poster)	Continuing? <input type="checkbox"/>
		mm	yy	mm	yy		
16a.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
16b.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16c.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16d.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16e.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16f.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16g.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16h.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
16i.	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Contraceptive Type:	1 = Pills	3 = Norplant	5 = Cyclofem	7 = Other
	2 = Depo-Provera	4 = Net-En	6 = Mesigyna	

June 14, 2000

SAMPLE—English

0 1  
Language



SAMPLE: DO NOT FAX TO DATAFAX

HIV021 HC (054)

BQ (028)

Enrollment Visit (0101)

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Participant ID

0	0	0	-							-	
Site Number				Participant Number							Chk

Baseline Questionnaire

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.

SEXUAL BEHAVIOR—LAST 12 MONTHS

First I'm going to ask you some questions about your sexual behavior during the last 12 months, that is, the period since \_\_\_\_\_ (month/year).

27. During the last 12 months, how many sexual partners have you had? [ ][ ] # of partners

28. During the last 12 months, have you engaged in commercial sex work? ..... [ ] yes [ ] no [ ] don't know -> If no or don't know, go to item 29.

28a. During the last 3 months, have you engaged in commercial sex work? ..... [ ] [ ] [ ]

SEXUAL BEHAVIOR—LAST 3 MONTHS

Now I'd like to ask you some questions about your sexual behavior during the last 3 months, that is, the period since \_\_\_\_\_ (day/month/year).

29. During the last 3 months, how many sexual partners have you had? [ ][ ] # of partners -> If 1, go to item 31.

30. During the last 3 months, have you had sex with one man while you were still sexually involved with another man? ..... [ ] yes [ ] no [ ] don't know

31. During the last 3 months, have you ever had sex during menstruation? ..... [ ] [ ] [ ]

32. During the last 3 months, have you ever had oral sex, that is when your partner put his penis in your mouth? ..... [ ] [ ] [ ]

33. During the last 3 months, have you ever had anal sex, that is when your partner put his penis in your anus? ..... [ ] [ ] [ ]

34. During the last 3 months, did you ever have sex while under the influence of alcohol or drugs? ..... [ ] [ ] [ ]

35. During the last 3 months, have you had any new sex partners, that is, a person with whom you have not had sex with over the previous year? ..... [ ] [ ] [ ]

[ ] [ ] [x] [ ] June 14, 2000

SAMPLE—English

[0] [1] Language



SAMPLE: DO NOT FAX TO DATAFAX

HIV021 HC (054)

BQ (029)

Enrollment Visit (0101)

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Participant ID

0	0	0	-							-	
Site Number				Participant Number							Chk

Baseline Questionnaire

SEXUAL BEHAVIOR—LAST 3 MONTHS: PARTNER-SPECIFIC QUESTIONS

36. Do you have a primary partner? By primary partner I mean your husband, someone with whom you live, or your boyfriend. ....  *yes*  *no* → *If no, go to item 37.*
- 36a. What is this partner's age? .....   *years*  *don't know*
- 36b. Is this partner circumcised? .....  *yes*  *no*  *don't know*
- 36c. Has this partner had a vasectomy? .....  *yes*  *no*  *don't know*
- 36d. During the **last 30 days**, how many days in total did this partner spend overnight away from home (working, etc.)?   *days*
- 36e. During the **last 3 months**, that is, since \_\_\_\_\_ (day/month/year), has this partner had an ulcer or sore on his penis?.....  *yes*  *no*  *don't know*
- 36f. During the **last 3 months**, has this partner had any abnormal discharge from his penis?.....  *yes*  *no*  *don't know*
- 36g. During the **last 3 months**, has this partner had significant weight loss? .....  *yes*  *no*  *don't know*
- 36h. During the **last 3 months**, has this partner had chronic diarrhea (3+ loose stools per day for greater than 7 days)? .....  *yes*  *no*  *don't know*
- 36i. Has this partner ever tested positive for HIV? .....  *yes*  *no*  *don't know*
- 36j. During the last 3 months, **in a typical month**, how many times did you have sex with this partner? .....    *# of times/month*
- 36k. During the last 3 months, **in a typical month**, how many times has this partner used a male condom during sex with you? .....    *# of times/month*
- 36l. During the last 3 months, **in a typical month**, how many times have you used a female condom with this partner? .....    *# of times/month*
- 36m. During the last 3 months, **in a typical month**, how many times have you used a spermicide with this partner? .....    *# of times/month*
- 36n. During the **last 3 months**, do you think this partner has had sex with anyone besides you? .....  *yes*  *no*  *don't know* → *If no or don't know, go to item 37.*
- 36o. Do you think he had sex with a commercial sex worker in the **last 3 months**?.....  *yes*  *no*  *don't know*

June 14, 2000

SAMPLE—English

Language

SAMPLE: DO NOT FAX TO DATAFAX

HIV021 HC (054)

BQ (030)

Enrollment Visit (0101)

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Participant ID

0	0	0	-							-	
Site Number				Participant Number						Chk	

Baseline Questionnaire

37. During the last 3 months, have you had sex with any other men besides a primary partner? .....

yes      no

      → If no, go to item 38.

37a. During the last 3 months, in a typical month, how many times in total did you have sex with all other partners? .....

# of times/month

37b. During the last 3 months, in a typical month, how many times did you use a male condom with other partners? .....

# of times/month

37c. During the last 3 months, in a typical month, how many times did you use a female condom with other partners? .....

# of times/month

37d. During the last 3 months, in a typical month, how many times have you used a spermicide with other partners? .....

# of times/month

37e. Have any of these other partners ever tested positive for HIV?

yes      no      don't know

          

OTHER HEALTH PRACTICES/OTHER RISK FACTORS

Now I'm going to ask you some questions about other health practices.

38. Have you ever smoked cigarettes regularly? By regularly, I mean one or more cigarettes every day for at least a month. ....

yes      no

      → If no, go to item 39.

38a. Do you currently smoke cigarettes? .....

    

38b. How many years total have you/did you smoke(d)? .....

# of years       don't know

(If less than 6 months, code 00.)

38c. When you smoke(d), how many cigarettes do/did you smoke in a typical day? .....

# of cigarettes/day       don't know

39. During the last 30 days, how often, on average, did you drink beer, wine, or other alcohol? Read categories.

never	one day per week or less	2-6 days per week	every day
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

40. Have you ever used a needle to inject illegal drugs? .....

yes      no

      → If no, go to item 41.

40a. In the last 3 months, have you injected illegal drugs? .....

      → If no, go to item 41.

40b. In the last 3 months, have you injected illegal drugs with a needle that someone else had already used? .....

don't know

          

June 14, 2000

SAMPLE—English

Language

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HIV021 HC (054)

BQ (031)

Enrollment Visit (0101)

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Participant ID

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Baseline Questionnaire

41. In the last 3 months, did you ever use anything to dry or tighten your vagina for sex? .....

yes no [ ] [ ]

If no, go to item 42.

41a. What did you use? Mark all that apply.

- water, paper, cloth, cottonwool, herbs, other, specify, detergent

41b. During the last 3 months, in a typical month, how many times did you use anything to dry or tighten your vagina? .....

[ ][ ] # of times/month

42. In the last 3 months, did you use anything to clean the inside of your vagina, for instance, when you're bathing? .....

yes no [ ] [ ]

If no, go to item 43. (For Thailand, if no, end of form.)

42a. What did you use to clean the inside of your vagina? Read categories. Mark all that apply.

- water, commercial product, water with vinegar that you mixed yourself, other, specify, soap

42b. With what did you clean the inside of your vagina? Read categories. Mark all that apply.

- finger(s), douche bag, bulb enema, cloth, other, specify

42c. During the last 3 months, in a typical month, about how many times did you clean the inside of your vagina?

[ ][ ] # of times/month

For Uganda and Zimbabwe sites only:

43. Have you ever been intentionally scarred? .....

yes no [ ] [ ]

For Uganda, if no, go to item 44. For Zimbabwe, if no, end of form.

43a. How old were you the last time you had it done?

[ ][ ] years

For Uganda site only:

44. Have you been circumcised? .....

yes no [ ] [ ]

If no, end of form.

44a. How old were you when the circumcision was done?

[ ][ ] years

[ ] [ ] [x] [ ] June 14, 2000

SAMPLE—English

01 Language

**SAMPLE: DO NOT  
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Visit Code

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HIV021 HC (054)

FQ (061)

Participant ID

-       -

Site Number      Participant Number      Chk

Follow-up Questionnaire

Visit Date

dd      mm      yy

Clinic Record Number

Before we begin, I want to remind you that all the information you provide in this interview will be kept confidential. Some of these questions are about your health and sexual behavior and may be embarrassing to you, but your answers are very important and we would like you to give us your best answers.

1. Since your last regular visit in \_\_\_\_\_ (month/year), how many times have you been pregnant? Please include live births, stillbirths, abortions, miscarriages, and tubal pregnancies.....   # of times → **If 0, go to item 2.**
  - 1a. When was your last pregnancy completed? Again, please include live births, stillbirths, abortions, miscarriages, and tubal pregnancies. ....     mm yy
  - 1b. Since your last regular visit in \_\_\_\_\_ (month/year), did you breastfeed? .....   yes no → **If no, go to item 2.**
  - 1c. Are you currently breastfeeding? .....   yes no → **If yes, go to item 2.**
    - 1c1. When did you stop breastfeeding? .....     mm yy

**MEDICAL HISTORY**

2. Since your last regular visit in \_\_\_\_\_ (month/year), have you had any of the following? *Read categories.*

	yes	no	don't know	Ongoing?	
				yes	no

  - 2a. tuberculosis    →
  - 2b. blood transfusion
3. Since your last regular visit in \_\_\_\_\_ (month/year), have you been newly diagnosed with any of the following? *Read categories.*

	yes	no	don't know
--	-----	----	------------

  - 3a. heart disease
  - 3b. high blood pressure
  - 3c. hepatitis
  - 3d. diabetes
  - 3e. cervical dysplasia or cancer

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Language

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0 0 0 - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Follow-up Questionnaire

4. In the last 3 months, that is, since \_\_\_\_\_ (month/year), have you had any of the following symptoms? Read categories.

- 4a. unexplained fever .....
4b. excessive night sweats .....
4c. loss of appetite and weight .....
4d. fatigue that interferes with daily activities .....
4e. diarrhea (3+ loose stools per day for greater than 7 days)
4f. yeast infection in your mouth or vagina (white, itchy patches or discharge) .....
4g. persistent swollen lymph nodes (glands) .....
4h. herpes zoster (including a scar from a painful, blister-like rash) .....
4i. any other unexplained rash .....
4j. severe headaches .....

Response grid for items 4a-4j with columns: In the last 3 months? (yes, no) and If yes, within the last 2 weeks? (yes, no)

In the last 3 months, that is, since \_\_\_\_\_ (month/year), outside of menstruation, have you had any of the following symptoms?

- 4k. nausea .....
4l. breast tenderness .....

Response grid for items 4k-4l with columns: In the last 3 months? (yes, no) and If yes, within the last 2 weeks? (yes, no)

5. Since your last regular visit in \_\_\_\_\_ (month/year), have you been hospitalized for anything other than childbirth?

yes [ ] no [ ] don't know [ ]

5a. What have you been hospitalized for?

If no or don't know, go to item 6.

Specify: \_\_\_\_\_

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HIV021 HC (054)

FQ (063)

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Participant ID

-  -   
Site Number Participant Number Chk

Follow-up Questionnaire

**SEXUALLY TRANSMITTED DISEASES (STD) HISTORY**

6. Since your last regular visit in \_\_\_\_\_ (month/year), have you had any of the following symptoms? *Read categories.*

	yes	no	don't know	Date you last had this symptom		Symptom ongoing?	
				mm	yy	yes	no
6a. abnormal vaginal discharge (color, consistency, smell).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
6b. genital itching .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
6c. lower abdominal pain unrelated to menstruation.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
6d. pain during sex .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
6e. bleeding between periods .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

  

7. Since your last regular visit in \_\_\_\_\_ (month/year), have you had any of the following? *Read categories.*

	yes	no	don't know	Date you were last told that you had this condition		Condition ongoing?	
				mm	yy	yes	no
7a. genital ulcers/sores .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
7b. genital warts .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
7c. pelvic inflammatory disease (PID) (infection of tubes and uterus).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
7d. positive test for gonorrhea.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		
7e. positive blood test for syphilis.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		

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HIV021 HC (054)

FQ (064)

Participant ID

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Site Number Participant Number Chk

Follow-up Questionnaire

CONTRACEPTIVE HISTORY

Now I'm going to ask you about your use of family planning.

8. Are you continuing to use the family planning method you received or were using at your last regular visit?

yes [ ] no [ ]  
If yes, go to item 9.

8a. What is the main reason you are not continuing to use this method?

- [ ] unintended (accidental) pregnancy
- [ ] desires/desired pregnancy
- [ ] bleeding problems (amenorrhea, irregular bleeding, etc.)
- [ ] other side effects
- [ ] other non-medical reason

Hormonal Contraceptive Methods

9. Beginning with your last regular visit in \_\_\_\_\_ (month/year), have you used any family planning pills, injections, or implants?

yes [ ] no [ ] don't know [ ]  
If no or don't know, go to item 11.

9a. Which of these methods have you used? Mark all that apply.

- [ ] pills
  - [ ] Depo-Provera
  - [ ] other injection
  - [ ] Norplant
- Go to item 10.

9a1. How many total active pills have you missed since your last visit? Read categories.

none [ ] 1-10 [ ] 11-20 [ ] 21-28 [ ] >28 [ ]

Interviewer collect empty pill packets and review study ID card for start and stop dates. After completing interview, record number of packets returned and remaining active pills in item 38 on page 10.

[ ] [ ] [ X ] [ ] June 14, 2000

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Language





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HIV021 HC (054)

FQ (066)

Participant ID

000 - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Follow-up Questionnaire

Other Contraceptive Methods

11. Since your last regular visit in \_\_\_\_\_ (month/year), did you use an IUD ("coil"/"loop")? yes no don't know [ ] [ ] [ ] → If no or don't know, go to item 12.

11a. Most recent IUD.

Record the date of the most recent IUD insertion. Record the removal date of that IUD or mark "not removed" box if applicable.

IUD Insertion Date: [ ][ ] mm [ ][ ] yy  
IUD Removal Date: [ ][ ] mm [ ][ ] yy or: [ ] not removed

11b. IUD prior to most recent.

If the participant had another IUD since her last visit (prior to the one recorded in 11a), record the date it was inserted and removed. If she had no other IUD other than that in 11a, mark "not applicable."

not applicable [ ] or: IUD Insertion Date: [ ][ ] mm [ ][ ] yy  
IUD Removal Date: [ ][ ] mm [ ][ ] yy

12. Since your last regular visit in \_\_\_\_\_ (month/year), did you have a hysterectomy? ..... yes no don't know [ ] [ ] [ ] → Hysterectomy Date: [ ][ ] mm [ ][ ] yy

13. Since your last regular visit in \_\_\_\_\_ (month/year), did you have your tubes tied (get sterilized)? ..... yes no don't know [ ] [ ] [ ] → Sterilization Date: [ ][ ] mm [ ][ ] yy

Ask the participant about each contraceptive method below. For any method she used since her last regular visit, also ask her if it was used the last time she had sex.

Since your last regular visit in \_\_\_\_\_ (month/year), did you ...

a. The last time you had sex, did you ...

14. use emergency contraception? ..... yes no don't know [ ] [ ] [ ] → yes no don't know [ ] [ ] [ ]  
15. use the withdrawal method (when the man withdraws his penis before ejaculation)? ..... yes no don't know [ ] [ ] [ ] → yes no don't know [ ] [ ] [ ]  
16. use the rhythm method (when the couple only has sexual intercourse during the safe period)? ..... yes no don't know [ ] [ ] [ ] → yes no don't know [ ] [ ] [ ]  
17. use a diaphragm? ..... yes no don't know [ ] [ ] [ ] → yes no don't know [ ] [ ] [ ]  
18. have sex when your partner used a male condom? ..... yes no don't know [ ] [ ] [ ] → yes no don't know [ ] [ ] [ ]

[ ] [ ] [X] [ ] June 14, 2000

SAMPLE—English

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Language

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HIV021 HC (054)

FQ (067)

Participant ID

000- - Chk

Follow-up Questionnaire

Since your last regular visit in (month/year), did you ...

19. use a female condom? yes no don't know

20. use spermicide (foam, cream, jelly, film)?

a. The last time you had sex, did you ...

21. use any other forms of contraception that we have not yet discussed? Please specify: yes no don't know yes no don't know

SEXUAL BEHAVIOR

Now I'm going to ask you about your sexual practices in the last 3 months, that is, since (month/year). 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.

In the last 3 months...

22. have you engaged in commercial sex work? yes no don't know

23. how many sexual partners have you had? # of partners If 0, probe for confirmation, then go to item 32. If 1, go to item 25.

24. have you had sex with one man while you were still sexually involved with another man? yes no don't know

25. have you had sex during menstruation?

26. have you had oral sex, that is when your partner put his penis in your mouth?

27. have you had anal sex, that is when your partner put his penis in your anus?

28. did you have sex while under the influence of alcohol or drugs?

29. have you had any new sex partners, that is, someone you have not had sex with in the previous year?

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HIV021 HC (054)

FQ (068)

Participant ID

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Site Number Participant Number Chk

Follow-up Questionnaire

SEXUAL BEHAVIOR—LAST 3 MONTHS: PARTNER-SPECIFIC QUESTIONS

- 30. In the last 3 months, have you had a primary partner? By primary partner I mean your husband, someone with whom you live, or your boyfriend. ...
30a. Is this the same primary partner whom you had at your last regular visit?
30a1. What is this partner's age?
30a2. Is this partner circumcised?
30b. Has this primary partner had a vasectomy?
30c. Has this partner ever tested positive for HIV?
30d. During the last 30 days, how many days in total did this partner spend overnight away from home (working, etc.)?

- In the last 3 months...
30e. has this partner had an ulcer or sore on his penis?
30f. has this partner had any abnormal discharge from his penis?
30g. has this partner had significant weight loss?
30h. has this partner had chronic diarrhea (3+ loose stools per day for greater than 7 days)?
30i. in a typical month, how many times did you have sex with this partner?
30j. in a typical month, how many times has this partner used a male condom during sex with you?
30k. in a typical month, how many times have you used a female condom with this partner?
30l. in a typical month, how many times have you used a spermicide with this partner?
30m. do you think this partner has had sex with anyone besides you?
30m1. do you think he had sex with a commercial sex worker?

[ ] [ ] [x] [ ] June 14, 2000

SAMPLE—English

[0] [1] Language

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HIV021 HC (054)

FQ (069)

Participant ID

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Follow-up Questionnaire

31. In the last 3 months, have you had sex with any other men besides your primary partner?.....

yes no

If no, go to item 32.

In the last 3 months...

31a. in a typical month, how many times in total did you have sex with all other partners? .....

# of times/month

31b. in a typical month, how many times did you use a male condom with other partners? .....

# of times/month

31c. in a typical month, how many times did you use a female condom with other partners? .....

# of times/month

31d. in a typical month, how many times have you used a spermicide with other partners? .....

# of times/month

31e. Have any of these other partners tested positive for HIV?.....

yes no don't know

OTHER HEALTH PRACTICES/OTHER RISK FACTORS

Now I'm going to ask you some questions about other health practices.

32. Since your last regular visit in \_\_\_\_\_ (month/year), have you smoked cigarettes regularly? By regularly, I mean one or more cigarettes every day for at least a month.....

yes no

33. During the last 30 days, how often, on average, did you drink beer, wine, or other alcohol? Read categories.

never one day per week or less 2-6 days per week every day

34. Since your last regular visit in \_\_\_\_\_ (month/year), have you used a needle to inject illegal drugs?.....

yes no

If no, go to item 35.

34a. Since your last regular visit in \_\_\_\_\_ (month/year), have you injected illegal drugs with a needle that someone else had already used?.....

don't know

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01 Language

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FQ (070)

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Participant ID

Participant ID form: Site Number (000), Participant Number ( ), Chk ( )

Follow-up Questionnaire

35. Since your last regular visit in \_\_\_\_\_ (month/year), did you ever use anything to dry or tighten your vagina for sex? yes no

35a. What did you use? Mark all that apply.

- water, paper, cloth, cottonwool, herbs, other, specify: \_\_\_\_\_, detergent

35b. Since your last regular visit in \_\_\_\_\_ (month/year), in a typical month, how many times did you use anything to dry or tighten your vagina? # of times/month

36. Since your last regular visit in \_\_\_\_\_ (month/year), did you use anything to clean the inside of your vagina, for instance, when you're bathing? yes no

36a. What did you use to clean the inside of your vagina? Read categories. Mark all that apply.

- water, commercial product, specify: \_\_\_\_\_, water with vinegar that you mixed yourself, other, specify: \_\_\_\_\_, soap

36b. With what did you clean the inside of your vagina? Read categories. Mark all that apply.

- finger(s), douche bag, bulb enema, cloth, other, specify: \_\_\_\_\_

36c. Since your last regular visit in \_\_\_\_\_ (month/year), in a typical month, about how many times did you clean the inside of your vagina? # of times/month

For Uganda and Zimbabwe sites only:

37. Since your last regular visit in \_\_\_\_\_ (month/year), have you been intentionally scarred? yes no

For ALL Sites:

38. How many pill packets did the participant bring to the visit? # of pill packets not applicable, participant did not use pills

38a. How many total active pills were left in these packet(s)? Do not include pills that she still plans to take. # of pills

[ ] [ ] [X] [ ] June 14, 2000

SAMPLE—English

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HIV021 HC (054)

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**Participant ID**

Site Number	Participant Number						Chk					

**Interim Visit**

**Visit Date**

dd	mm	yy			

Clinic Record Number

1. **Date of the last regular visit**

dd      mm      yy

**If last regular visit was 10 or more weeks ago, STOP and DO NOT fax this form. Complete a full study visit with appropriate forms as required.**

2. **What is the reason for the participant's visit? Mark all that apply.**

STD symptom(s) → **Complete this form (go to item 3), and complete Physical Exam form (and Laboratory Results form, if applicable).**  
**Record any antibiotic, antifungal, hormone, or steroidal prescriptions on the Treatment form.**

Serious Adverse Experience → **Complete this form (go to item 3) and complete Serious Adverse Experience form.**  
**If exam is clinically indicated, complete Physical Exam form (and Laboratory Results form, if applicable).**  
**Record any antibiotic, antifungal, hormone, or steroidal prescriptions on the Treatment form.**

other gynecologic problem

contraceptive side effects

contraception refill

change in contraception

illness

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

} → **Complete this form (go to item 3).**  
**If exam is clinically indicated, complete Physical Exam form (and Laboratory Results form, if applicable).**  
**Record any antibiotic, antifungal, hormone, or steroidal prescriptions on the Treatment form.**

**HORMONAL CONTRACEPTIVES**

3. Since your last regular visit on \_\_\_\_\_ (day/month/year), have you used any family planning pills, injections or implants?

yes      no

      → **If no, go to item 5.**

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LanguageStaff ID

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HIV021 HC (054)

IV (052)

**Participant ID**

-      -   
 Site Number Participant Number Chk

**Interim Visit**

4. Now I'd like to record the dates when you were using family planning pills, injections, or implants since your last regular visit in \_\_\_\_\_ (month/year).

*Start with the current month and go back, month by month, through the month of her last regular visit. Record the hormonal contraceptive type(s) that the participant used in each box (using abbreviations "PIL," "DEP," "NOR," etc.) and then summarize the information in items 4a through 4e. See the Hormonal Contraceptive History Instruction Card for more detailed instructions.*

Year	DEC	NOV	OCT	SEP	AUG	JUL	JUN	MAY	APR	MAR	FEB	JAN
(current)												
(last)												

	Contraceptive Type Code (see below)	Date Started		Date Stopped		Pill Code (use Pill Poster)	Continuing?
		mm	yy	mm	yy		
4a.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
4b.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
4c.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
4d.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
4e.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Contraceptive Type:	1 = Pills	3 = Norplant	5 = Cyclofem	7 = Other
	2 = Depo-Provera	4 = Net-En	6 = Mesigyna	

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HIV021 HC (054)

**Participant ID**

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Site Number Participant Number Chk

**Interim Visit**

**INTRAUTERINE DEVICE (IUD)**

5. Since your last visit, have you used an IUD? .....   **yes no** → *If no, go to item 6.*

5a. When was the IUD inserted and removed? *Record last insertion date even if it was before last visit.*  
Insertion Date Removal Date not removed  
□□ □□ □□ □□ □□ □□ □  
dd mm yy dd mm yy

**CONTRACEPTIVE SIDE EFFECTS**

6. Are you experiencing any side effects from your current method of family planning?   **yes no** → *If no, go to item 7.*

6a. Which side effects are you experiencing? *Mark all that apply.*

- bleeding between periods
- breast tenderness
- headache
- bloating/weight gain
- nausea/vomiting
- other, specify: \_\_\_\_\_

*If Physical Exam form is being completed during this visit, end of form. Otherwise go to item 7.*

**FAMILY PLANNING**

7. Was family planning provided at this visit?   **yes no** → *If no, end of form.*

8. What was provided? *Mark all that apply.*

- Oral Contraceptives  
Specify brand/code: \_\_\_\_\_ OC Code (use Pill Poster) □□
- Depo-Provera injection
- Other injection  
Specify: \_\_\_\_\_
- Norplant
- IUD
- Other  
Specify: \_\_\_\_\_

□□□  September 10, 1999

SAMPLE—English

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Language



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Visit Code

Visit Code boxes

1

HIV021 HC (054)

PE (041)

Participant ID

Participant ID boxes: Site Number, Participant Number, Chk

Physical Exam

Visit Date

Visit Date boxes: dd, mm, yy

1. Oral temperature: [ ] [ ] . [ ] °C

Clinic Record Number boxes

2. First day of last menstrual period: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] don't know

2a. Menstrual cycle: regular [ ] irregular [ ] amenorrhea [ ]

For non-hormone user: If recorded date was 6 weeks or more ago, conduct pregnancy test.
For pill user: If no bleeding during the 7-day inactive pill/pill-free interval, conduct pregnancy test.
For Depo-Provera User: If no injection in > 4 months, conduct pregnancy test.

3. Severe reaction to medications:

At Baseline Visit, ask this version of the question:

Have you ever had a severe reaction to any medications? .....

yes no don't know

At Interim and Follow-up Visits, ask this version of the question:

Since your last regular visit, have you had a severe reaction to any medications? .....

yes checkbox

no checkbox

don't know checkbox

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

3a. What are the names of the medications?

3a. Medication names input lines

3b. What was the participant's reaction?

3b. Reaction input lines

Physical Examination

4. Palpable Inguinal Adenopathy..... none [ ] unilateral left [ ] unilateral right [ ] bilateral [ ] not assessed [ ]

If none or not assessed, go to item 5.

4a. Inguinal lymph node tenderness [ ] [ ] [ ] [ ] [ ]

4b. Number of palpable inguinal nodes..... [ ] [ ] number of nodes

4c. Size of largest inguinal node ..... [ ] [ ] cm

[ ] [ ] [ ] [x] September 10, 1999

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01 Language

Staff ID

Staff ID boxes



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Visit Code [ ][ ] [ ]

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HIV021 HC (054)

PE (043)

Participant ID

0 0 0 - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Physical Exam

7. Is vaginal discharge present? .....  present  absent  not assessed/menses **→ If absent or not assessed, go to item 8.**

7a. Color of vaginal discharge:

- clear
- white/cream-colored/grey
- yellow/green
- bloody
- mixed, specify: \_\_\_\_\_
- not assessed

7b. Quantity of vaginal discharge:

- small, doesn't flow into lower speculum blade (present only on lateral vaginal walls)
- moderate, lower speculum blade less than half full
- abundant, lower speculum blade at least half full
- not assessed

7c. Character of vaginal discharge:

- normal
- thin, flows easily
- thick, does not flow easily
- not assessed

7d. Consistency of vaginal discharge:

- non-homogeneous, normal
- non-homogeneous, curdy
- homogeneous, smooth
- homogeneous, frothy
- not assessed

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Visit Code [ ][ ] [ ]

1

HIV021 HC (054)

PE (044)

Participant ID

000- [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Physical Exam

8. Vaginal Epithelium..... [ ] normal [ ] abnormal [ ] not assessed  
If normal or not assessed, go to item 9.

8a. Degree of inflammation

- [ ] none, normal
- [ ] mild/moderate erythema, no friability or tenderness
- [ ] severe erythema, friability, or tenderness
- [ ] not assessed

8b. Ulcerations..... [ ] yes [ ] no [ ] not assessed  
If no or not assessed, go to item 8c.

- 8b1. Any ulcers purulent? ..... [ ] [ ] [ ]
- 8b2. Any ulcers friable? ..... [ ] [ ] [ ]
- 8b3. Any ulcers tender? ..... [ ] [ ] [ ]

8c. Warts ..... [ ] [ ] [ ]

9. Cervical Mucus

9a. Quantity of cervical mucus: [ ] mild-moderate, mucus visible at os  
[ ] abundant, mucus flowing from os  
[ ] not assessed/menses

9b. Color of cervical mucus:  
[ ] clear [ ] bloody  
[ ] white/cream-colored/grey [ ] mixed, specify: \_\_\_\_\_  
[ ] yellow/green [ ] not assessed/menses

10. Cervical Epithelium..... [ ] normal [ ] abnormal [ ] not assessed  
If normal, go to item 10f. If not assessed, go to item 11.

[ ] [ ] [ ] [x] September 10, 1999

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Visit Code

HIV021 HC (054)

PE (046)

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**Participant ID**

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Site Number                      Participant Number                      Chk

**Physical Exam**

**PID SIGNS**

	<i>yes</i>	<i>no</i>	<i>not assessed</i>
12. Lower abdominal tenderness .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Cervical motion tenderness .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Uterine tenderness.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Adnexal tenderness .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Adnexal mass.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**ONSITE LAB TESTS**

	<i>positive</i>	<i>negative</i>	<i>not done</i>
17. Yeast: pseudohyphae / buds (KOH prep).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Trichomonads (saline prep).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Clue cells (saline prep).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Amine (whiff) test .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Vaginal pH <input type="text"/> <input type="text"/>			<input type="checkbox"/>
22. Pregnancy Test .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**CLINICAL IMPRESSIONS**

	<i>yes</i>	<i>no</i>
23. Candidiasis.....	<input type="checkbox"/>	<input type="checkbox"/>
24. Trichomoniasis .....	<input type="checkbox"/>	<input type="checkbox"/>
25. Bacterial Vaginosis (must have 3 of 4 criteria for diagnosis)....	<input type="checkbox"/>	<input type="checkbox"/>
26. Mucopurulent Cervicitis.....	<input type="checkbox"/>	<input type="checkbox"/>
27. Pelvic Inflammatory Disease (PID) .....	<input type="checkbox"/>	<input type="checkbox"/>
28. Warts.....	<input type="checkbox"/>	<input type="checkbox"/>

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Visit Code

Visit Code input boxes

9

HIV021 HC (054)

LR (015)

Participant ID

Participant ID input boxes: Site Number, Participant Number, Chk

Laboratory Results

Specimen Collection Date

Specimen Collection Date input boxes: dd, mm, yy

Clinic Record Number input boxes

Clinic Record Number

Not Done/ Not Collected

- 1. HIV EIA ..... negative positive indeterminate
1a. HIV Rapid 1.....
1b. HIV Rapid 2.....
2. Western Blot.....
3. HIV PCR.....
3x. Final HIV Status .....
4. Gonorrhea PCR .....
5. Chlamydia PCR.....
6. Syphilis RPR .....
6a. TPHA/TPPA syphilis serology .....

- 7. Which Pap Smear scale was used? Scale 1 Scale 2 (only required at Baseline)

7a. Pap Smear result: Use only one scale.

- within normal limits inflammation ASCUS low grade squamous intraepithelial lesion high grade squamous intraepithelial lesion squamous cell carcinoma adenocarcinoma specimen unsatisfactory other, specify: normal CIN I CIN II CIN III carcinoma in situ squamous cell carcinoma adenocarcinoma specimen unsatisfactory other, specify:

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Staff ID

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Visit Code [ ][ ] [ ]

1

HIV021 HC (054)

TRT (012)

Participant ID

000 - [ ][ ][ ][ ][ ] - [ ]  
Site Number Participant Number Chk

Treatment

Visit Date

[ ][ ] [ ][ ] [ ][ ]  
dd mm yy

Were any of the following categories of medications prescribed at this visit?

[ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]  
Clinic Record Number

1. Antibiotics/Antivirals:  yes  no

Drug Name	Code	Dose/Frequency	Route/Duration	Indication
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____

2. Antifungals:  yes  no

Drug Name	Code	Dose/Frequency	Route/Duration	Indication
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____

3. Hormones (to treat bleeding or for emergency contraception):  yes  no

Drug Name	Code	Dose/Frequency	Route/Duration	Indication
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____

4. Steroids:  yes  no

Drug Name	Code	Dose/Frequency	Route/Duration	Indication
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____
_____	[ ][ ][ ]	_____	_____	_____

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Staff ID [ ][ ]



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Page

HIV021 HC (054)

SAE (415)

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

Participant ID

000- - - - -

Serious Adverse Experience

- - - - -

Instructions: Refer to definition of Serious Adverse Experience below. Fax this form to FHI and HIVNET DataFax whenever a new Serious Adverse Experience is recorded or information on this form is updated. Fax only pages with new entries or revisions.

Serious Adverse Experience

Onset Date:

Outcome Date:

Leave blank for "Continuing."

dd mm yy dd mm yy

Diagnosis or Symptom (Diagnosis is preferred)

Severity, Relationship to Contraceptive Method, Contraceptive Method Administration, Treatment, Outcome

Serious Adverse Experience Definition: Death, a life-threatening experience, new or prolonged inpatient hospitalization, persistent or significant disability/incapacity, or a congenital anomaly/birth defect. See forms instructions for complete definition.

Staff ID, This SAE reported at Visit

Comments

Signature of Study Clinician, Signature of Principal Investigator, dd mm yy

September 10, 1999, SAMPLE, Language 01

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HIV021 HC (054)

TM (490)

Participant ID

0	0	0	-							-	
Site Number				Participant Number							Chk

Termination

Clinic Record Number									

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

1. Termination Date: 

--	--

<sup>dd</sup>

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<sup>mm</sup>

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<sup>yy</sup>

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

2. Reason for termination: Mark only one.

- 2a. Scheduled exit visit.
- 2b. Death (please indicate date and cause if known).

Cause of death \_\_\_\_\_ OR  Cause unknown

Date of death 

--	--

<sup>dd</sup>

--	--

<sup>mm</sup>

--	--

<sup>yy</sup> OR  Date unknown

2c. Early termination. Please indicate primary reason below. Mark only one.

- Participant refused further participation.
- Investigator decision, please specify: \_\_\_\_\_
- HIV seroconversion.
- Inappropriate enrollment, please specify: \_\_\_\_\_
- Invalid ID due to duplicate screening/enrollment.
- Other reason, please specify: \_\_\_\_\_

2d. Participant lost to follow-up at end of study (check only if study has ended).

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

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 Staff ID 

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Visit Code

HIV021 HC (054)

COM (461)

Participant ID

-      -

Site Number Participant Number Chk

Comments

Form Completion Date

dd mm 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 on which you are commenting. Please print information legibly.

Clinic Record Number

Record the acronym(s) of the form(s) to which the comments apply:

\_\_\_\_\_ or  not applicable

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

Comments:

\_\_\_\_\_

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