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
DEMOGRAPHICS

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

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: ___ ___ ___

2. What is your current marital status?
   □ never married
   □ married (monogamy)
   □ married (polygyny)
   □ separated
   □ divorced
   □ widowed
   yes no

3. Are you currently living with your husband/partner? ................................................. □

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/fisherman □ 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: ____________

□ □ □ □ December 1, 1999

SAMPLE—English

01 Staff ID □□
7. What is your ethnicity or tribe? Mark all that apply.

UGANDA:
- [ ] Muganda
- [ ] Munyoro
- [ ] Munyankole
- [ ] Mutoro
- [ ] Mukiga
- [ ] other, specify
- [ ] Munyarwanda

ZIMBABWE:
- [ ] Shona
- [ ] Ndebele
- [ ] other, specify:

THAILAND:
- [ ] Thai
- [ ] Malaysian
- [ ] Cambodian
- [ ] Hilltribe, specify:
- [ ] Laoian
- [ ] Burmese
- [ ] other, specify:

SCREENING ELIGIBILITY

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

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

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

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

Use Pill Poster.

<table>
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<tr>
<th>Brand Name</th>
<th>Code</th>
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9c. Are all brands taken in the last 3 months low-dose combined oral contraceptives (COC)? ..............................................................................................................................................................................

<table>
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<tr>
<th>yes</th>
<th>no</th>
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</table>

If yes, participant is ineligible. Go to item 18.
If no, go to item 18.

If no, participant is currently ineligible. Go to item 18.
If yes, go to item 12.

[ ] [ ] [ ] December 1, 1999

SAMPLE—English

Language
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.

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.

10b. 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 yes, participant is currently ineligible. Go to item 18.

11. Have you used any of the following methods of family planning?

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.
Screening ID

Screening Eligibility

16. Have you injected illegal drugs within the last 3 months?

17. Have you had a blood transfusion or received any blood products in the last 3 months?

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?

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

20. Have you ever engaged in commercial sex?

21. Have you ever had sex when a male or female condom was used?

22. Is the participant still eligible?

23. Are you currently participating in any other HIV-prevention or family planning studies?

23a. Does the study that the participant is in make her ineligible for this study (check site list)?

23b. If you plan to join another study while you are in this study, will you tell us first?

If yes, participant is currently ineligible.

If yes, participant is currently ineligible.

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

If no, end of form. Fax pages SE-1 through SE-4 only to HIVNET DataFax.

If no, go to item 23b.

If yes, participant is ineligible. End of form. Fax pages SE-1 through SE-4 to HIVNET Datafax.

If no, participant is ineligible. End of form. Fax pages SE-1 through SE-4 to HIVNET Datafax.
FOLLOW-UP

24. Do you plan to live in this area for at least the next 12 months?..............
   \[\text{[ ]} \quad \text{[ ]}\] 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?..............
   \[\text{[ ]} \quad \text{[ ]}\] If no, participant is ineligible. End of form. Fax pages SE-1 through SE-5 to HIVNET Datafax.

PREGNANCY

These items removed due to change in pregnancy testing criteria.

27. Pregnancy testing
   \[\text{[ ]} \quad \text{[ ]} \quad \text{[ ]}\] 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?..............
   \[\text{[ ]} \quad \text{[ ]}\] If no, go to instruction at the top of page 6.

29. What was provided? Mark all that apply.
   \[\text{[ ]} \quad \text{[ ]} \quad \text{[ ]} \quad \text{[ ]} \quad \text{[ ]}\]
   
   \[\text{[ ]} \quad \text{[ ]}\] OC Code (use Pill Poster)

   \(\text{Specify brand/code: }\)  
   \(\text{Specify: }\)
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.

If no, indicate reason in item 33a.

33. Did the participant enroll in the study?

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

December 1, 1999

SAMPLE—English
HIVNET Statistical and Clinical Coordinating Center

Sample: Do Not Fax To DataFax
HIV021 HC Screening (053) SLR (014)

Screening ID

Screening Laboratory Results

Specimen Collection Date
dd mm yy

Visit Code

Not Done/Not Collected

☐ 1. HIV EIA ................................................................. negative positive indeterminate
   ☐ 1a. HIV Rapid 1 .................................................
   ☐ 1b. HIV Rapid 2 .................................................
   ☐ 2. HIV PCR .............................................................
   ☐ 2x. Final HIV Status .............................................
   ☐ 3. Syphilis RPR ..................................................... negative positive
       If RPR is positive, perform TPHA/TPPA.
   ☐ 3a. TPHA/TPPA syphilis serology ....................

☐ January 25, 2000

SAMPLE

01 Staff ID

Language

/hivnet/forms/HIV021_Hormone/forms/screen_laboratory_results.fm
PARTICIPATION IDENTIFICATION

1. 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
   - [THAILAND]
     - □ Chiang Mai University
     - □ Chiang Mai HPC 10
     - □ Khonkaen University
     - □ Khonkaen HPC 6
     - □ Songkla University
     - □ Hat Yai Hospital
     - □ Rajavithi Hospital
   - [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? ...................... □□ □□

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

☑ ☐ ☑ June 14, 2000 SAMPLE—English

[01] Language Staff ID □□
5. Have you ever breastfed? □ □ → If no, go to item 6.
   5a. In the last 12 months, did you breastfeed? □ □ → 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? □ □ → If yes, go to item 6.
   5b1. When did you stop breastfeeding? □ □ □

MEDICAL HISTORY
6. Have you ever had any of the following?
   Read categories.
   □ □ □ □ □ □
   yes no don’t know

6a. tuberculosis □ □ □ □
6b. heart disease □ □ □ □
6c. high blood pressure □ □ □ □
6d. hepatitis □ □ □ □
6e. diabetes □ □ □ □
6f. cervical dysplasia or cancer □ □ □ □
6g. blood transfusion □ □ □ □
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 ..............................................

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

7k. nausea ...................................................................

7l. breast tenderness ..............................................

In the last 3 months?  If yes, within the last 2 weeks?

7a. no

7b. no

7c. no

7d. no

7e. no

7f. no

7g. no

7h. no

7i. no

7j. no

In the last 3 months?  If yes, within the last 2 weeks?

7k. no

7l. no

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

8a. What have you been hospitalized for?

Specify: ........................................................................

If no or don’t know, go to item 9.
SEXUALLY TRANSMITTED DISEASES (STD) HISTORY

9. In the last 12 months, have you had any of the following symptoms? Read categories.
   Date you last had this symptom
   Symptom ongoing?
   
   9a. abnormal vaginal discharge (color, consistency, smell)..............
       yes no don't know

   9b. genital itching ........................................
       [ ] [ ] [ ]

   9c. lower abdominal pain unrelated to menstruation.........................
       [ ] [ ] [ ]

   9d. pain during sex ...........................................
       [ ] [ ] [ ]

   9e. bleeding between periods ...................................
       [ ] [ ] [ ]

10. In your lifetime, have you ever had any of the following? Read categories.
    Date you were last told that you had this condition
    Condition ongoing?
    
    10a. genital ulcers/sores ......................................
         yes no don't know

    10b. genital warts ...........................................
         [ ] [ ] [ ]

    10c. pelvic inflammatory disease (PID) (infection of tubes and uterus)........
         [ ] [ ] [ ]

    10d. positive test for gonorrhea ................................
         [ ] [ ] [ ]

    10e. positive blood test for syphilis..........................
         [ ] [ ] [ ]
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? ................................................................. yes □ no □ don't know □

11a. For how many years in total have you used family planning pills? Read categories. ...................................................... <1 year □ 1-4 years □ 5 or more years □

12. Have you ever used Depo-Provera, the family planning injection that is given every 3 months? ................................................................. yes □ no □ don't know □

12a. For how many years in total have you used Depo-Provera? Read categories. ...................................................... <1 year □ 1-4 years □ 5 or more years □

13. Have you ever used any type of injections for family planning other than Depo-Provera? This includes injections given every month or every 2 months ................................................................. yes □ no □ don't know □

13a. For how many years in total have you used family planning injections other than Depo-Provera? Read categories. ...................... <1 year □ 1-4 years □ 5 or more years □

13b. Which family planning injections other than Depo-Provera have you used? Read categories. Mark all that apply. NET-EN/Noristerat □ Cyclolem □ Mesigyna □ other, specify: □ don't know □

14. Have you ever used Norplant implants, the small rods that are inserted into your upper arm for family planning? ...................... yes □ no □ don't know □

14a. For how many years in total have you used Norplant? Read categories. ...................................................... <1 year □ 1-4 years □ 5 or more years □

15. In the last 12 months, that is, since __________ (month/year), have you used any family planning pills, injections, or implants? yes □ no □ don't know □

15a. Which have you used in the last 12 months? Mark all that apply. pills □ Depo-Provera □ other injection □ Norplant □

June 14, 2000
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.

<table>
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<th>DEC</th>
<th>NOV</th>
<th>OCT</th>
<th>SEP</th>
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<th>JUL</th>
<th>JUN</th>
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**Contraceptive Type Code (see below)**

<table>
<thead>
<tr>
<th>Contraceptive Type Code (see below)</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Pill Code (use Pill Poster)</th>
<th>Continuing?</th>
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**Contraceptive Type:**

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

Ask the participant about each contraceptive method below. For any method ever used, also ask the participant if it was used in the last 3 months. If it was used in the last 3 months, ask her if it was used the last time she had sex.

a. Did you ever...  b. In the last 3 months, did you...  c. The last time you had sex, did you...

17. use an IUD ("coil"/"loop")? .........
   yes  no  don't know

18. use emergency contraception?
   yes  no  don't know

19. use the withdrawal method (when the man withdraws his penis before ejaculation)? .........
   yes  no  don't know

20. use the rhythm method (when the couple only has sexual intercourse during the safe period)? .........
   yes  no  don't know

21. use a diaphragm? .................
   yes  no  don't know

22. have sex when your partner used a male condom? .........
   yes  no  don't know

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

24. use spermicide (foam, cream, jelly, film)? .................
   yes  no  don't know

25. have your tubes tied (get sterilized)? .................
   yes  no  don't know

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

Please specify: .................................................................

If no or don't know, go to item 18.

If no or don't know, go to item 19.

If no or don't know, go to item 20.

If no or don't know, go to item 21.

If no or don't know, go to item 22.

If no or don't know, go to item 23.
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?  

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?

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?
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 □

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 □

36g. During the last 3 months, has this partner had significant weight loss? .................................................................
   □ yes □ no □

36h. During the last 3 months, has this partner had chronic diarrhea (3+ loose stools per day for greater than 7 days)? .............
   □ yes □ no □

36i. Has this partner ever tested positive for HIV? .........................
   □ yes □ no □

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 □

□ □ □ June 14, 2000

SAMPLE—English

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

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. ................................................................. [ ] [ ] → 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 [ ] [ ] [ ] [ ]

   yes no [ ] [ ] → If no, go to item 41.

40. Have you ever used a needle to inject illegal drugs? ................................................................. [ ] [ ] → If no, go to item 41.

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

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

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

SAMPLE—English

Language 01
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
- □ cloth
- □ herbs
- □ paper
- □ cottonwool
- □ 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
- □ water with vinegar that you mixed yourself
- □ soap
- □ commercial product, specify: ____________________________
- □ other, specify: ____________________________

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.

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
Sample: Do Not FAX To DATA FAX

HIV021 HC (054)

FQ (061)

Visit Code

I 0 1

Page 1 of 10

Participant ID

0 0 0 -

Site Number

Participant Number

0

Clin.

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

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? ..............................................................

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?

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

June 14, 2000

Sample—English

0 1

Staff ID

Language
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 ....................................................................

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 ...................................................................

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

5a. What have you been hospitalized for?

Specify: _______________________________________________________

[□] [□] [x] [□] June 14, 2000  SAMPLE—English  [0] [1] Language

/nnvnet/forms/HIV021_Hormone/forms/followup_questionnaire.fm
**SEXUALLY TRANSMITTED DISEASES (STD) HISTORY**

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

- **6a. abnormal vaginal discharge** (color, consistency, smell) .................
  - yes □  no □  don't know □
  - □ □ □

- **6b. genital itching** ..................................................
  - □ □ □

- **6c. lower abdominal pain unrelated to menstruation** .........................
  - □ □ □

- **6d. pain during sex** ...................................................
  - □ □ □

- **6e. bleeding between periods** ........................................
  - □ □ □

<table>
<thead>
<tr>
<th>Date you last had this symptom</th>
<th>Symptom ongoing?</th>
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<tr>
<td>mm yy</td>
<td>yes □  no □</td>
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</table>

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

- **7a. genital ulcers/sores** ........................................
  - □ □ □

- **7b. genital warts** ................................................
  - □ □ □

- **7c. pelvic inflammatory disease (PID)** (infection of tubes and uterus) ........
  - □ □ □

- **7d. positive test for gonorrhea** ...................................
  - □ □ □

- **7e. positive blood test for syphilis** ..................................
  - □ □ □

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<thead>
<tr>
<th>Date you were last told that you had this condition</th>
<th>Condition ongoing?</th>
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<tr>
<td>mm yy</td>
<td>yes □  no □</td>
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□ □ x □ June 14, 2000

SAMPLE—English
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?

   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 SAMPLE—English 0 1 Language
10. Now I'd like to record the dates when you were using family planning pills, injections, or implants beginning with your last regular visit in ________ (month/year).

Start with the current month and go back, month by month, through the month of the participant's last regular visit. Include injections that she got at 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 10a through 10i. See the Hormonal Contraceptive History Instruction Card for more detailed instructions.

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Start with the most recent episode.

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<tr>
<th>Contraceptive Type Code (see below)</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Pill Code</th>
<th>Continuing?</th>
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<td>mm yy</td>
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<td>10i.</td>
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Contraceptive Type:  1 = Pills  3 = Norplant  5 = Cyclofen  7 = Other  2 = Depo-Provera  4 = Net-En  6 = Mesigyna
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.

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.”

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

15. use the withdrawal method (when the man withdraws his penis before ejaculation)? ..............
   - 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

17. use a diaphragm? ...........................................
   - yes
   - no
   - don't know

18. have sex when your partner used a male condom?
   - yes
   - no
   - don't know

June 14, 2000

SAMPLE—English
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)? ............
   yes  no  don’t know
   ☐  ☐  ☐
a. The last time you had sex, did you ...
   yes  no  don’t know

21. use any other forms of contraception that we have not yet discussed?
   ............................................................
   Please specify.
   ☐  ☐  ☐  ☐  ☐

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? ...........................................................
   ☐  ☐  ☐
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. ...
   yes  no  If no, go to item 31.
   □  □  □  □

30a. Is this the same primary partner whom you had at your last regular visit? .........................................................
   □  □  □  □
   If yes, go to item 30b.

30a1. What is this partner's age? ........................................
   □  □  □  □

30a2. Is this partner circumcised? ......................................
   □  □  □  □
   don't know

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? ..................
   □  □  □  □  # of times/month

30j. in a typical month, how many times has this partner used a male condom during sex with you? ................................
   □  □  □  □  # of times/month

30k. in a typical month, how many times have you used a female condom with this partner? ........................................
   □  □  □  □  # of times/month

30l. in a typical month, how many times have you used a spermicide with this partner?
   □  □  □  □  # of times/month

30m. do you think this partner has had sex with anyone besides you? ....
   □  □  □  □
   If no or don't know, go to item 31.

30m1. do you think he had sex with a commercial sex worker? ....
   □  □  □  □
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?  

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

[ ] [ ] [ ] June 14, 2000

SAMPLE—English

[ ] [ ] [ ] Language
35. Since your last regular visit in _______ (month/year), did you ever use anything to dry or tighten your vagina for sex? .................................................. □ yes □ no □ → If no, go to item 36.

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

□ water
□ cloth
□ herbs
□ detergent
□ paper
□ cotton wool
□ other, specify: __________________________

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 □ → If no, go to item 37. (For Thailand, if no, go to item 38.)

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

□ water
□ water with vinegar
□ soap
□ commercial product, specify: __________________________
□ other, specify: __________________________

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 use anything to 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 □ → If 0 or not applicable, end of form.

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

3. **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.*

   [ ] Yes  

   [ ] No

   SAMPLE—English  

   Language: Language

   Staff ID:
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.

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Contraceptive Type:

1 = Pills  
2 = Depo-Provera  
3 = Norplant  
4 = Net-En  
5 = Cyclofen  
6 = Mesigyna  
7 = Other
Sample: Do Not Fax To DataFax

Participant ID

Interim Visit

HIV021 HC (054)  IV (053)  Visit Code 1

Intrauterine Device (IUD)

5. Since your last visit, have you used an IUD? .........................
   □ 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
   dd mm yy

   Removal Date
   dd mm yy

   not removed

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? □ 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: ____________________________

□ □ □ X September 10, 1999  SAMPLE—English

/hiwnevforms/HIV021_Hormones/forms/interim_visit.fm

Language 01
Physical Exam (PE-1)

Participant ID

000

Physical Exam

1. Oral temperature: [ ] [ ] °C

2. First day of last menstrual period: [ ] [ ] [ ] [ ] don't know
   - regular
   - irregular
   - amenorrhea

2a. Menstrual cycle: [ ] [ ] [ ]

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? ...........
   - 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? ...........................................................

3a. What are the names of the medications?

3b. What was the participant's reaction?

Physical Examination

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

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

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

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

[ ] [ ] [ ] September 10, 1999

SAMPLE 01 Staff ID
5. Perineum and Perianal Area
   - normal [☐]
   - abnormal [☐]
   - not assessed [☐]
   - If normal or not assessed, go to item 6.

5a. Inflammation [☐] [☐] [☐]
5b. Ulcerations [☐] [☐] [☐]
   - Any ulcers purulent? [☐] [☐] [☐]
   - Any ulcers friable? [☐] [☐] [☐]
   - Any ulcers tender? [☐] [☐] [☐]
5c. Warts [☐] [☐] [☐]

5b. Ulcerations [☐] [☐] [☐]
   - If no or not assessed, go to item 5c.

6. Vulva [☐] [☐] [☐]
   - If normal or not assessed, go to item 7.

6a. Inflammation [☐] [☐] [☐]
6b. Ulcerations [☐] [☐] [☐]
   - Any ulcers purulent? [☐] [☐] [☐]
   - Any ulcers friable? [☐] [☐] [☐]
   - Any ulcers tender? [☐] [☐] [☐]
6c. Warts [☐] [☐] [☐]

If no or not assessed, go to item 6c.
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
8. Vaginal Epithelium

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

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
   - white/cream-colored/grey
   - yellow/green
   - bloody
   - mixed, specify: ________________________
   - not assessed/menses

10. Cervical Epithelium

   - If normal, go to item 10f.
   - If not assessed, go to item 11.
10. Cervical Epithelium, continued

10a. Erythema .......................................................... □ □ □

10b. Cervical edema .................................................. □ □ □

10c. Ulcersations of the cervix ..................................... □ □ □  

10c1. Any ulcerations friable? ....................................... □ □ □

10d. Warts on the cervix .............................................. □ □ □

10e. "Strawberry" cervix ............................................. □ □ □

10f. Friability with CT/GC PCR swab:

□ none/no bleeding
□ mild, discrete spots of blood on swab
□ moderate, swab soaked, no blood flowing
□ severe, bleeding without swabbing or easily induced and flowing
□ not assessed

11. Acetic Acid Exam

11a. After acetic acid is applied, is area of ectopy visible?

□ Yes, area of ectopy visible. ——— Draw and label area of ectopy.
□ No, area of ectopy not visible. ——— Go to item 11c.
□ not assessed. ——— Go to item 11c.

11b. Ectopy (% of ectocervix with ectopy):

□ < 25%  □ ≥ 25% but < 50%  □ ≥ 50% but < 75%  □ ≥ 75%

11c. Visual inspection of the cervix with acetic acid:

□ normal, no lesions noted
□ inflammation
□ abnormal, acetowhite lesions noted (draw and label lesions on diagram above)
□ abnormal, suspicious for cancer
□ not assessed

□   □   □   □ September 10, 1999

hivnet/forms/HIV021_Hormone/forms/physical_exam.fm
Physical Exam

PID SIGNS

12. Lower abdominal tenderness

13. Cervical motion tenderness

14. Uterine tenderness

15. Adnexal tenderness

16. Adnexal mass

ONSITE LAB TESTS

17. Yeast: pseudohyphae / buds (KOH prep)

18. Trichomonads (saline prep)

19. Clue cells (saline prep)

20. Amine (whiff) test

21. Vaginal pH

22. Pregnancy Test

CLINICAL IMPRESSIONS

23. Candidiasis

24. Trichomoniasis

25. Bacterial Vaginosis (must have 3 of 4 criteria for diagnosis)

26. Mucopurulent Cervicitis

27. Pelvic Inflammatory Disease (PID)

28. Warts

Visit Code

Participant ID

Site Number Participant Number Chk

Physical Exam

yes no not assessed

positive negative not done

September 10, 1999

SAMPLE

Language
Not Done/Not Collected

1. HIV EIA .................................................. 
   negative ☐ positive ☐ indeterminate ☐

2a. HIV Rapid 1 .............................................

2b. HIV Rapid 2 .............................................

3. Western Blot ..............................................

4. HIV PCR ...................................................

5. Final HIV Status ...........................................

6. Gonorrhea PCR .......................................... 

7. Chlamydia PCR ...........................................

8. Syphilis RPR ............................................... 
   If RPR is positive, perform TPHA/TPPA.

9. TPHA/TPPA syphilis serology .........................

7. Which Pap Smear scale was used? ☐ Scale 1 
   (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: __________________________

☐ Scale 2

☐ normal ☐ CIN I ☐ CIN II ☐ CIN III
☐ carcinoma in situ ☐ squamous cell carcinoma
☐ adenocarcinoma ☐ specimen unsatisfactory
☐ other, specify: __________________________

☐ ☐ ☐ ☐ January 25, 2000

SAMPLE /hivnet/forms/HIV021_Hormone/forms/laboratory_results.fm

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

1. Antibiotics/Antivirals:
   - Drug Name
   - Code
   - Dose/Frequency
   - Route/Duration
   - Indication
   - yes  no

2. Antifungals:
   - Drug Name
   - Code
   - Dose/Frequency
   - Route/Duration
   - Indication
   - yes  no

3. Hormones (to treat bleeding or for emergency contraception):
   - Drug Name
   - Code
   - Dose/Frequency
   - Route/Duration
   - Indication
   - yes  no

4. Steroids:
   - Drug Name
   - Code
   - Dose/Frequency
   - Route/Duration
   - Indication
   - yes  no
### Serious Adverse Experience

**Participant ID**
- Site Number
- Participant Number
- Chk

**Serious Adverse Experience**

**Onset Date:**
- dd
- mm
- yy

**Outcome Date:**
- dd
- mm
- yy

**Diagnosis or Symptom (Diagnosis is preferred)**

**Severity**
- Grade 3 - Severe
- Grade 4 - Life-threatening
- Grade 5 - Death

**Relationship to Contraceptive Method**
- Definitely related
- Probably related
- Possibly related
- Not related

**Contraceptive Method Administration**
- No change
- Reduced
- Held
- Discontinued
- Not Applicable

**Treatment**
- Mark all that apply.

**Outcome**
- Continuing
- Resolved *
- Death *
- Severity Increased *
- Other

---

**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.

**Comments**

---

**Signature of Study Clinician**

**Signature of Principal Investigator**
- dd
- mm
- yy

---

**Language**

---

**Sample**

- HIV021 HC (054)
- SAE (415)

---

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

---

**Instructions:** Refer to definition of Serious Adverse Experience below. Fax this form to FHl 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.

---

**Staff ID:**

**This SAE reported at Visit:**

---

**Date:** September 10, 1999
Instructions: Complete this form whenever a participant terminates from the study.

1. Termination Date: __________ __________ __________

   (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 __________ __________ __________ 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: ________________________________________________________________

__________________________________________________________________________

□ □ □ □ September 10, 1999

SAMPLE

01 Staff ID
**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.

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:

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________