

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

DM-1 (001)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and Chk

Demographics

Visit Date

Visit Date form with boxes for dd, MMM, and yy

I will start by asking you some general questions about yourself.

Question 1: What is your date of birth? Form with boxes for dd, MMM, yy and a field for age in years.

Question 2: What is your gender? Form with checkboxes for male and female.

Question 3: Are you currently married? Form with checkboxes for yes, no, and don't know. Includes instruction: 'If no, go to item 4 on page 2.'

Question 3a: How old is your husband? Form with boxes for years and a checkbox for don't know.

Question 3b: Are you currently living with your husband? Form with checkboxes for yes and no.

Question 3c: Does your husband have more than one wife or sexual partner? Form with checkboxes for yes, no, and don't know.

Question 3d: Does your husband provide you with financial and/or material support? Form with checkboxes for yes and no.

Question 3d1: What is your husband's average monthly income? Record in local currency. Form with a long box for currency and checkboxes for don't know and no income.

Question 3e: What is your husband's highest level of education?

U.S. Education levels list: no schooling, primary school (not complete, complete), secondary (not complete, complete), attended college or university, don't know. Includes instruction: 'Go to item 5 on page 2.'

INDIA Education levels list: no schooling, 1-3, 4, complete, 5-9, 10, complete, > 10, don't know. Includes instruction: 'Go to item 5 on page 2.'

Demographics (DM-1)

This interviewer-administered form is used to collect participants' demographic and socioeconomic information.

This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: *If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

Note: *There is no visit code field on this form since this form is only administered during screening.*

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. **NOTE:** *participant must be between the ages of 18 and 50 years at the time of enrollment to be eligible for study participation.*
- **Item 3:** Record whether or not the participant is **currently** married.
- **Item 3a:** If the participant does not know her husband's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 3d:** Record whether or not the participant's husband provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 3d1:** Record the husband's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

If the husband's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 3e:** Record the husband's highest level of education in the box corresponding to the participant's site country (U.S. or India). If the participant does not know her husband's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box that corresponds to the appropriate site country.

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HPTN 059 Ph II Microbe (113)

DM-2 (002)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and Chk

Demographics

- 4. Do you currently have a male sexual partner?
4a. How old is your partner?
4b. Are you currently living with your partner?
4c. Does your partner have any other sexual partners?
4d. Does your partner provide you with financial and/or material support?
4d1. What is your partner's average monthly income?
4e. What is your partner's highest level of education?
U.S. and INDIA education levels

- 5. Do you earn an income of your own?
5a. What is your average monthly income?
5b. How do you earn your income?

Demographics (DM-2)

Item-specific Instructions:

- **Item 4:** Record whether or not the participant **currently** has a male sexual partner. If the participant reports that she currently has more than one male sexual partner, inform her that the next set of questions (items 4a through 4e) refer to the male partner she considers to be her primary sexual partner.
- **Item 4a:** If the participant does not know her sexual partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 4d:** Record whether or not the participant's sexual partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 4d1:** Record the sexual partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

If the sexual partner's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 4e:** Record the male sexual partner's highest level of education in the box corresponding to the participant's site country (U.S. or India). If she does not know her sexual partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box that corresponds to the appropriate site country.
- **Item 5a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros. If the participant's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.
- **Item 5b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment.

If the participant refuses to give a response to any item(s), draw a line through the response boxes, write "refused," and initial and date the note in the white space next to the item.

If the participant is unable to give a response to any item(s), mark the "don't know" box (if provided). Otherwise, draw a line through the response boxes, write "don't know," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

DMU-1 (018)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and Chk

Demographics—United States

Visit Date

Visit Date form with boxes for dd, MMM, and yy

1. What is your highest level of education?

- Education level options: no schooling, primary school (not/complete), secondary (not/complete), attended college or university

2. How many people live in your household? [] []

2a. How many are children? [] []

3. What is your household's average monthly income? This includes income from all sources, even income from people who may not live in the household..... [] [] [] [] [] [] [] [] don't know [] no income []

4. Have you ever had an unplanned pregnancy? yes [] no [] -> If no, go to item 5.

4a. How many unplanned pregnancies have you had? 1 [] more than 1 []

5. Do you consider yourself to be Latina or of Hispanic origin? yes [] no []

6. What is your race? Read categories aloud. Mark all that apply.

- Race categories: American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, other, specify: (Note: Latino is not a race.)

7. Interviewer: Where was the participant referred/recruited from? [] [] code

[] [] [] [x] 28-JUN-06

[0] [1] Language

Staff Initials / Date

Demographics—United States (DMU-1)

This is an interviewer-administered form (with the exception of item 7) that is used to collect additional demographic and socioeconomic information from U.S. participants.

This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: *If a participant is being re-screened, a new Demographics-United States form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

Note: *There is no visit code field on this form since this form is only administered during screening.*

- **Item 2:** Record the total number of people, including children, living in the participant's household.
- **Item 2a:** Record only the number of children living in the participant's household.
- **Item 3:** Record the **average** monthly income for the household (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

If the household's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 4:** Record whether or not the participant has ever had a known unplanned pregnancy.
- **Item 5:** *Note: Latina is not a race.*
- **Item 6:** This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "Other, specify" box and record her response on the line provided.
- **Item 7:** This is not an interviewer-administered item. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

If the participant refuses to give a response to any item(s), draw a line through the response boxes, write "refused," and initial and date the note in the white space next to the item.

If the participant is unable to give a response to any item(s), mark the "don't know" box (if provided). Otherwise, draw a line through the response boxes, write "don't know," and initial and date the note in the white space next to the item.

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HPTN 059 Ph II Microbe (113)

DMI-1 (020)

Participant ID

Site Number			Participant Number				Chk		

Demographics—India

Visit Date

dd		MMM		yy	

1. What is your highest level of education?

- no schooling
- 1–3
- 4, complete
- 5–9
- 10, complete
- > 10

2. How many children have you given birth to who were alive at birth?

--	--

 # of children

yes no

3. Do you own your home?.....

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

4. How many rooms are in your household?.....

--	--

5. What is your ethnic group or tribe? **Read categories aloud. Mark all that apply.**

- Asian
- other, specify:

Marathi: _____

English: _____

6. What is your religion?

- Hindu
- Muslim
- Christian
- Buddhist
- other, specify: Marathi: _____

English: _____

7. **Interviewer:** Where was the participant referred/recruited from?.....

--	--

 code

Demographics—India (DMI-1)

This is an interviewer-administered form (with the exception of item 7) that is used to collect additional demographic and socioeconomic information from participants in India.

This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: *If a participant is being re-screened, a new Demographics-India form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

Note: *There is no visit code field on this form since this form is only administered during screening.*

- **Item 5:** This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "other, specify" box and record her response on the line provided.
- **Item 6:** If the participant answers a religion other than the four religions listed, mark the "other, specify" box, record the participant's answer in Marathi on the line provided, and go to item 7. Once the interview is completed, go back and record the English translation of the participant's Marathi response on the English line provided.
- **Item 7:** This is not an interviewer-administered item. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-1 (072)

Participant ID

Site Number - Participant Number - Chk

Enrollment Behavior Assessment

Visit Date

dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. There are no right or wrong answers to these questions. We will ask you these same types of questions during your follow-up visits. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions I am going to ask you are about vaginal sex, and some are about anal sex. By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

Shall we continue?

1. In the past month, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex.....

of partners. If 0, go to item 3.

I am now going to ask you some questions about vaginal sex only.

2. In the past week, how many times did you have vaginal sex?

of times. If 0, go to item 3.

I know that you are counseled to use condoms for each act of vaginal sex, but I also know that this is not always possible.

2a. In the past week, how many times did you use a male or female condom during vaginal sex?

of times

3. When was the last time you had vaginal sex?

dd MMM yy

NOTE: Date of last penile-vaginal intercourse must be no earlier than 30 days prior to screening for the participant to be eligible to enroll.

Enrollment Behavior Assessment (EBA-1)

This form is used to collect baseline information about the participant's sexual behaviors, vaginal hygiene, and family planning practices. This is an interviewer-administered form, and it is administered only once to each enrolled participant as part of her Enrollment visit.

Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

***Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made during the Enrollment Visit interview only, unless requested otherwise by SCHARP. Once the participant has completed the Enrollment Visit interview in which this form is administered, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

***Note:** There is no visit code field on this form since this form is only administered at the Enrollment visit.*

- **Items 1, 2, and 2a:** Use leading zeros when needed so that all the boxes are filled.
- **Item 3:** Note that the date, as reported by the participant, should be no earlier than 30 days prior to the initial screening date (that is, the date that informed consent for screening was obtained for the current screening attempt) in order for the participant to be eligible for the study. If the participant is unable to recall the exact date, obtain her best estimate. At minimum, the month is required.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
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HPTN 059 Ph II Microbe (113)

EBA-2 (073)

Participant ID

Site Number			Participant Number						Chk	

Enrollment Behavior Assessment

4. The **last time** you had vaginal sex:

- | | | |
|--|--------------------------|--------------------------|
| | yes | no |
| 4a. did you or your partner use a male condom? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4b. did you use a female condom? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4c. did you wash inside or douche inside your vagina within 2 hours before having vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4d. did you wash inside or douche inside your vagina within 2 hours after having vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4e. did you insert paper, cloth, cotton, or cotton wool within 2 hours before having vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4f. did you insert paper, cloth, cotton, or cotton wool within 2 hours after having vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4g. did you insert any other object or substance into your vagina within 2 hours before or during vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |

If yes, specify:

Local Language: _____

English: _____

- | | | |
|--|--------------------------|--------------------------|
| | yes | no |
| 4h. did you insert any other object or substance into your vagina within 2 hours after vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |

If yes, specify:

Local Language: _____

English: _____

I am now going to ask you some questions about a different way that people have sex. This way is anal sex. These questions may not apply to you, but we ask all participants these same questions. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

- | | | |
|--------------------------------------|--------------------------|--------------------------|
| | yes | no |
| 5. Have you ever had anal sex? | <input type="checkbox"/> | <input type="checkbox"/> |

If no, go to statement before item 9 on page 3.

Enrollment Behavior Assessment (EBA-2)

Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant’s answer. If ‘yes’ is marked for items 4g or 4h, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-3 (074)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and Chk

Enrollment Behavior Assessment

6. In the past week, did you have anal sex? yes no If no, go to item 7.

I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.

6a. In the past week, did you ever, even once, have anal sex without a condom? yes no

7. When was the last time you had anal sex? dd MMM yy

8. The last time you had anal sex: yes no

8a. did you or your partner use a male condom? yes no

8b. did you use a lubricant (such as lube, K.Y.)? yes no

Now I am going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

9. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the past month. It is possible to answer "yes" more than once. If yes: How many times in the past week did you insert this item?

Questions 9a-9g with response options for yes/no and a grid for the number of times in the past week.

Local Language: _____

English: _____

Enrollment Behavior Assessment (EBA-3)

Item-specific Instructions:

- **Item 7:** If, after verbal probing, the participant is unable to provide the day she last had anal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 8:** Read each item 8a–8b aloud and mark the participant’s response.
- **Item 9:** Read each item 9a–9g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the past **week** she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 9g, record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-4 (075)

Participant ID

Site Number			Participant Number						Chk		

Enrollment Behavior Assessment

10. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **DO NOT read response categories aloud. Mark "none" or all that apply.**

none
 vaginal ring
 spermicide
 diaphragm
 sponge

➔ **Participant is ineligible.**

 intrauterine device (IUD)

➔ **If inserted less than 30 days prior to Enrollment, participant is ineligible.**

natural methods such as the withdrawal or rhythm method
 male condoms
 female condoms

➔ **Must be combined with another effective method of contraception, as defined in the protocol, for participant to be eligible.**

- family planning pills or birth control pills
- injectable contraceptives (such as Depo-Provera)
- Norplant inserts
- Ortho Evra/The Patch
- surgical sterilization (tubal ligation)
- sex with partner who had a vasectomy
- other, specify:

Local Language: _____

English: _____

Enrollment Behavior Assessment (EBA-4)

Item-specific Instructions:

- **Item 10: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each family planning method the participant reports using. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line. **During the visit**, while the participant is still at the site, compare the item 10 response(s) to the family planning method(s) documented on the non-DataFax Baseline Medical History form and/or other local baseline medical history form(s) for this participant. If inconsistencies are noted, attempt to resolve these by asking the participant for clarification. Update the appropriate form(s), as necessary, based on the participant’s response.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX

■ ■ ■ ■ ■ ■ ■ ■ ■ ■ Visit Code

□ □ . □

□ 1 □

HPTN 059 Ph II Microbe (113)

AA-1 (371)

Participant ID

□ □ □ - □ □ □ □ □ □ - □
Site Number Participant Number Chk

Acceptability Assessment

Visit Date

□ □ □ □ □ □ □ □ □ □
dd MMM yy

One goal of this research is to understand how acceptable study gel use is to women and their partners. I am now going to ask you some questions about your experiences using the study gel and how study gel use has affected your relationship(s) with sexual partners. Your honest answers will be very helpful to us.

Shall we continue?

1. What do you like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 2 on page 2.

- | | |
|--|--|
| <input type="checkbox"/> no response | <input type="checkbox"/> easy to use |
| <input type="checkbox"/> nothing | <input type="checkbox"/> method is under her control |
| <input type="checkbox"/> may protect against HIV | <input type="checkbox"/> made sex more pleasurable |
| <input type="checkbox"/> may protect against STIs | <input type="checkbox"/> did not interrupt sex |
| <input type="checkbox"/> can use without partner's knowledge | <input type="checkbox"/> appearance/smell |
| <input type="checkbox"/> other, specify: | |

Local Language: _____

English: _____

1a. Which of these do you like most? **DO NOT read response categories aloud.**

- | | |
|--|--|
| <input type="checkbox"/> no response | <input type="checkbox"/> easy to use |
| <input type="checkbox"/> nothing | <input type="checkbox"/> method is under her control |
| <input type="checkbox"/> may protect against HIV | <input type="checkbox"/> made sex more pleasurable |
| <input type="checkbox"/> may protect against STIs | <input type="checkbox"/> did not interrupt sex |
| <input type="checkbox"/> can use without partner's knowledge | <input type="checkbox"/> appearance/smell |
| <input type="checkbox"/> other, specify: | |

Local Language: _____

English: _____

Acceptability Assessment (AA-1)

This form is used to collect gel acceptability information from study participants. This is an interviewer-administered form, and it is administered at the Week 4 and 12 visits.

Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

***Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made only during the visit in which this form is completed, unless requested otherwise by SCHARP. Once the participant has completed the visit, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Item 1:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reported characteristic the participant likes about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response. If "no response" or "nothing" is marked, no other response box should be marked. If only one response box is marked, leave item 1a blank and go to item 2.
- **Item 1a:** **Do not** read any of the response categories aloud. Instead, read the question, and based on the participant's responses to item 1, record the one characteristic the participant likes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she likes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

AA-2 (372)

Participant ID

- -

Site Number

Participant Number

Chk

Acceptability Assessment

2. What do you not like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 3 on page 3.

no response

nothing

messy

interrupted sex

made sex less pleasurable

difficult to use, specify:
Local Language: _____
English: _____

remembering to use it

difficult to store and/or discard

appearance/smell

other, specify:
Local Language: _____
English: _____

2a. Which of these do you dislike most? **DO NOT read response categories aloud.**

no response

nothing

messy

interrupted sex

made sex less pleasurable

difficult to use

remembering to use it

difficult to store and/or discard

appearance/smell

other, specify:
Local Language: _____
English: _____

Acceptability Assessment (AA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 2:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each characteristic the participant does not like about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the “other, specify” box and record the verbatim (word-for-word) response. If the participant’s response is “difficult to use,” probe for more specific information as to why the study gel is difficult to use and record the participant’s verbatim (word-for-word) response. If “no response” or “nothing” is marked, no other response box should be marked. If only one response box is marked, leave item 2a blank and go to item 3.
- **Item 2a:** **Do not** read any of the response categories aloud. Instead, read the question and, based on the participant’s responses to item 2, mark the box that corresponds to the one characteristic the participant dislikes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she dislikes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response .

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code [][] . []

[1]

HPTN 059 Ph II Microbe (113)

AA-3 (373)

Participant ID

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

Acceptability Assessment

3. Is the study gel easy to apply? yes no don't know
4. In general, does the study gel have any effect on sexual intercourse? yes no don't know
→ If no, go to item 5.
- 4a. Does it improve sex for you?
- 4b. Does it improve sex for your male partner?
- 4c. Does it worsen sex for you?
- 4d. Does it worsen sex for your male partner?
5. In the past month, did you have sex with a regular male partner? yes no → If no, go to item 6 on page 4.

If this is the first time this questionnaire is being administered for this participant, skip item 5a and go to item 5b.

- 5a. Is this the same partner you had the last time you answered these questions? yes no don't know not applicable
- 5b. In the **past month**, did you have sex with this regular partner while you were using the study gel? yes no → If no, go to item 6 on page 4.
- 5c. Did he know you were using the study gel? yes no don't know
→ If no or don't know, go to item 6 on page 4.
- 5d. What was his reaction to the study gel? **DO NOT read response categories aloud.**
- he liked it
 - he did not like it
 - he had no reaction
 - don't know
 - other, specify:

Local Language: _____

English: _____

Acceptability Assessment (AA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 4:** Read each item 4a–4d aloud and mark the participant’s response.
- **Item 5:** “Regular male partner” is defined as the individual the participant considers to be her principal or primary male sex partner. If the participant’s response is “no,” leave items 5a–5d blank.
- **Item 5a:** If this is the first time this form is being administered to this participant, leave item 5a blank and go to item 5b. If the participant states she did not have a regular partner the last time she answered these questions, mark “not applicable.”
- **Item 5d:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box that corresponds to the participant’s response. If the participant gives a response that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

AA-4 (374)

Participant ID

- -
Site Number Participant Number Chk

Acceptability Assessment

6. In the **past month**, did you have sex with any other male partners while you were using the study gel? yes no **If no, go to item 7 on page 5.**

6a. In the **past month**, did you have sex with more than one other male partner (besides a regular partner) while you were using the study gel? yes no **If yes, go to item 6a2.**

6a1. Did your other partner know you were using the study gel? yes no don't know **If yes, go to item 6a3.** **If no or don't know, go to item 7 on page 5.**

6a2. The **last time** you used the study gel with one of these other partners, did he know you were using the study gel? yes no don't know **If no or don't know, go to item 7 on page 5.**

6a3. What was his reaction to the study gel? **DO NOT read response categories aloud.**

- he liked it
- he did not like it
- he had no reaction
- don't know
- other, specify:

Local Language: _____

English: _____

Acceptability Assessment (AA-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 6:** Items 6–6a3 refer to those male sex partner(s) who are **not** considered by the participant to be her regular sex partner (the partner referenced in item 5 on page 3).
- **Item 6a:** This item applies only to those participants who, in item 6, reported “yes” to having had sex with a non-regular male partner while using the study gel in the past month. The intent of this item is to identify whether or not, in the past month, the participant used the study gel with *multiple* non-regular male sex partners in the past month.
 - **For participants who reported having sex with a regular male partner in the past month (item 5 on page 3 is marked “yes”):** If the participant reports that she had sex with her regular male partner and only one other male partner in the past month, then the answer should be marked “no.” If the participant reports that she had sex with her regular male partner and two or more other (non-regular) male partners in the past month - but she did not use the study gel with at least two of these non-regular partners in the past month - then the answer should be marked “no.” If the participant reports that she had sex with her regular male partner and two or more other (non-regular) male partners in the past month – and she reports having used the study gel with at least two of these other (non-regular) male partners in the past month – then the answer should be marked “yes.”
 - **For participants who reported that they did *not* have sex with a regular male partner in the past month (item 5 on page 3 is marked “no”):** If the participant states that she had either no male sex partners or only one (non-regular) male sex partner in the past month, then the answer should be marked “no.” If the participant had two or more (non-regular) male sex partners in the past month - but she did not use the study gel with at least two of these non-regular partners in the past month - then the answer should be marked “no.” If the participant had two or more (non-regular) male sex partners in the past month - and she reports having used the study gel with at least two of these (non-regular) male partners in the past month - then the answer should be marked “yes.”
- **Items 6a3: Do not** read any of the response categories aloud. Instead, read the question and mark the box that corresponds to the participant’s response. If the participant gives a response that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response on the “Local Language” line. If the participant responds in a language other than English, provide the English translation of the response on the “English” line.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. *DO NOT FAX*
TO DATAFAX

AA-5 (375) Visit Code

□□.□

□
1

HPTN 059 Ph II Microbe (113)

AA-5 (375)

Participant ID

□□□-□□□□□-□
Site Number Participant Number Chk

Acceptability Assessment

7. In general, how important is it that a male sex partner **not** notice that you are using the study gel?
READ response categories aloud.

- very important
- somewhat important
- neutral
- not very important
- not at all important

8. Overall, do you like the study gel? **READ response categories aloud.**

- strongly like
- like
- neutral
- dislike
- strongly dislike

Acceptability Assessment (AA-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Items 7–8:** Read each of the response categories aloud, and mark the appropriate response.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE, DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FSB-1 (161)

Participant ID

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

Female Study Burden Assessment

Visit Date

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

Now I would like to ask a couple of questions about your experiences as a study participant.

- 1. Was the amount of time that you had to wait for your study visits ever a problem? yes no
- 2. Did you feel that the amount of money you were paid to participate was adequate? yes no
- 3. Did you ever have a problem understanding the instructions on how to use the gel? yes no
- 4. Have you had any other problems or concerns as a result of being in the study? yes no
 ➔ If no, go to item 5.

4a. If yes, specify:

Local Language: _____

English: _____

- 5. Is there anything else about participating in this study that you would like us to know? yes no
 ➔ If no, end of form.

5a. If yes, specify:

Local Language: _____

English: _____

Thank you for your time. We very much appreciate you sharing your thoughts with us.

Female Study Burden Assessment (FSB-1)

The Female Study Burden Assessment form records the participant's assessment of study procedures and requirements. It is an interviewer-administered form that is administered once the participant has completed her participation in the study. To improve participants' ability to speak freely, the questions on this form should be asked by a staff member who has not had previous contact with the participant (if possible). For non-CHBV participants, it should be completed at the Week 24/Early Termination Visit. For CHBV participants, it should be completed at the Week 36/Early Termination Visit.

Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- It is important for you to review the form for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

Note: There is no visit code field on this form since this form is only administered at study exit.

- **Item 4:** If “no” is marked, leave item 4a blank and go to item 5. If “yes” is marked, record the participant's verbatim (word-for-word) response in item 4a. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 5:** If “no” is marked, leave item 5a blank. If “yes” is marked, record the participant's verbatim (word-for-word) response in item 5a. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX



Visit Code

HPTN 059 Ph II Microbe (113)

FBD-1 (171)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment—
Daily Use Arm

Visit Date

dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. There are no right or wrong answers to these questions. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions I am going to ask you are about vaginal sex, and some are about anal sex. By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

Shall we continue?

1. In the **past month**, how many sex partners have you had?
By sex partner, I mean someone with whom you have had vaginal or anal sex.....

of partners
If 0, go to statement before item 9 on page 3.

I am now going to ask you some questions about vaginal sex only.

2. In the **past week**, how many times did you have vaginal sex?

of times
If 0, go to item 3.

I know that you are counseled to use condoms for each act of vaginal sex, but I also know that this is not always possible.

2a. In the **past week**, how many times did you use a male or female condom during vaginal sex?

of times

2b. In the **past week**, how many times did you insert the study gel within 2 hours **before** having vaginal sex?

of times
If 0, go to item 3.

2b1. How many of these times did you use a male or female condom?

of times

3. When was the **last time** you had vaginal sex?

dd MMM yy

Follow-up Behavior Assessment—Daily Use Arm (FBD-1)

This form is used to collect information about the participant's sexual behaviors, vaginal hygiene, and family planning practices while she is taking part in the study. This is an interviewer-administered form (with the exception of items 17-17a), and is administered at the Week 4, Week 12, and Week 24/Early Termination Visits.

Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Note: *Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made only during the interview in which this form is completed, unless requested otherwise by SCHARP. Once the interview is finished, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Items 1:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has had no sexual partners in the past month, record "00" for this item and continue the interview by reading the statement before item 9 on page 3. In this case, do record the Visit Code and PTID on page 2 of this form, and leave all other items on page 2 blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 2–2b1:** Use leading zeros when needed so that all the boxes are filled.
- **Item 3:** If, after verbal probing, the participant is unable to provide the day she last had vaginal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write "don't know" in the white space next to the item, and initial and date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBD-2 (172)

Participant ID

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

Follow-up Behavior Assessment—Daily Use Arm

4. The last time you had vaginal sex:

- 4a. did you or your partner use a male condom?
4b. did you use a female condom?
4c. did you insert the study gel before having vaginal sex?
4c1. did you insert the study gel within 2 hours before having vaginal sex?
4d. did you wash inside or douche inside your vagina within 2 hours before inserting the study gel?
4e. did you wash inside or douche inside your vagina within 2 hours after inserting the study gel?
4f. did you insert paper, cloth, cotton, or cotton wool within 2 hours before inserting the study gel?
4g. did you insert paper, cloth, cotton, or cotton wool within 2 hours after inserting the study gel?
4h. did you insert any other object or substance into your vagina within 2 hours before inserting the study gel?

yes no

If no, go to statement before item 5.

If yes, specify:

Local Language: _____

English: _____

4i. did you insert any other object or substance into your vagina within 2 hours after inserting the study gel?

yes no

If yes, specify:

Local Language: _____

English: _____

I am now going to ask you some questions about a different way that people have sex. This way is anal sex. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

5. In the past month, did you have anal sex?

yes no

If no, go to statement before item 9 on page 3.

6. In the past week, did you have anal sex?

yes no

If no, go to item 7 on page 3.

[][] [x] 28-JUN-06

01

Language

Staff Initials / Date

Follow-up Behavior Assessment—Daily Use Arm (FBD-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 4:** Read each item 4a–4i aloud and mark the participant’s response. If “yes” is marked for items 4h or 4i, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 4c:** If item 4c is marked “no,” leave items 4c1–4i blank and go to the statement above item 5.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX

Visit Code

□□□

1

HPTN 059 Ph II Microbe (113)

FBD-3 (173)

Participant ID

□□□ - □□□□□ - □
Site Number Participant Number Chk

Follow-up Behavior Assessment—
Daily Use Arm

6a. In the **past week**, did you ever insert the study gel anally during anal sex? yes no

yes no
□ □

If no, go to statement before item 6b.

6a1. In the **past week**, how many times did you insert the study gel anally during anal sex?

□□ # of times

I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.

6b. In the **past week**, did you ever, even once, have anal sex without a condom?.....

yes no
□ □

7. When was the **last time** you had anal sex?

□□ dd □□□ MMM □□ yy

8. The **last time** you had anal sex:

8a. did you or your partner use a male condom?

yes no
□ □

8b. did you use a lubricant (such as lube, K.Y.)?

□ □

8c. did you insert the study gel anally?.....

□ □

I know that you are counseled to insert the study gel at the same time each day, but I also know that this is not always possible.

9. In the **past week**, have you been able to insert the study gel at the same time each day?

yes no
□ □

If yes, go to item 10.

9a. If no, specify reason:

Local Language: _____

English: _____

10. In the **past week**, how many days did you **not** insert the study gel?

□ # of days

If 0, go to statement before item 12 on page 4.

Follow-up Behavior Assessment—Daily Use Arm (FBD-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 7:** If, after verbal probing, the participant is unable to provide the day she last had anal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 8:** Read each item 8a–8c aloud and mark the participant’s response.
- **Items 9–9a:** If “no” is marked for item 9, be sure to record the participant’s verbatim (word-for-word) response in item 9a. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 10:** Record the total number of days in the past week (the last 7 days) that the participant reports not using the study gel. The maximum number of days reported should be 7.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

FBD-4 (174)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment—
Daily Use Arm

11. For the days you did not insert the study gel, what were the reasons? **DO NOT read response categories aloud.**
Mark all that apply.

If only one response box is marked, go to statement before item 12.

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: _____

English: _____

11a. What was the main reason? **DO NOT read response categories aloud.**

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: _____

English: _____

I am now going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

12. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.

If yes: How many times in the **past week** did you insert this item?

	yes	no	# of times in past week
12a. water?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
12b. water with vinegar? Note for U.S. sites: This includes all commercial douching products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
12c. water with soap?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
12d. paper, cloth, cotton, or cotton wool?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
12e. tampons?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
12f. fingers without anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
12g. anything else? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>

Local Language: _____

English: _____

Follow-up Behavior Assessment—Daily Use Arm (FBD-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 11:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reason reported by the participant. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant gives only one reason and only one box is marked, leave item 11a blank and go to the statement above item 12.
- **Item 11a:** **Do not** read any of the response categories aloud. Instead, read the question and, based on the response to item 11, mark the one box that corresponds to the main reason why the participant did not use the study gel. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 12:** Read each item 12a–12g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the **past week** (the last 7 days) she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 12g, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX



Visit Code .

HPTN 059 Ph II Microbe (113)

FBD-5 (175)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment—
Daily Use Arm

13. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **DO NOT read response categories aloud. Mark "none" or all that apply.**

none

vaginal ring

spermicide

diaphragm

sponge

➔ Reinforce use of protocol-specified methods of effective contraception.

intrauterine device (IUD)

natural methods such as the withdrawal or rhythm method

male condoms

female condoms

➔ If not used in combination with another protocol-specified method of effective contraception, provide appropriate counseling.

family planning pills or birth control pills

injectable contraceptives (such as Depo-Provera)

Norplant inserts

Ortho Evra/The Patch

surgical sterilization (tubal ligation)

sex with partner who had a vasectomy

other, specify:

Local Language: _____

English: _____

Follow-up Behavior Assessment—Daily Use Arm (FBD-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 13: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each family planning method the participant reports using. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBD-6 (176)

Participant ID

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

Follow-up Behavior Assessment—Daily Use Arm

For the last set of questions, I am going to ask you about problems you may have had or are having while in this study. By problems, I mean any emotional, physical, financial, social, or other difficulties.

14. In the **past month**, have you had any problems with the following people as a result of being in this study:

	yes	no	not applicable
14a. your spouse or partner?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14b. people at home/family?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14c. your friends/personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14d. people at work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14e. people at school?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14f. your doctor, nurse, midwife, or other health care provider?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14g. your landlord or property owner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14h. other people? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Local Language: _____

English: _____

➔ If no to all, end of form.

15. Please describe the problem: **Do NOT record the participant's verbatim response.**

Local Language: _____

English: _____

Follow-up Behavior Assessment—Daily Use Arm (FBD-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 14:** Read each item 14a–14h aloud and mark the participant’s response. If “yes” is marked for item 14h, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant responds “no” to each item 14a–14h, end the form; record the Visit Code and PTID on pages 7 and 8 of this form, and leave the remaining form items (15-17a) blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 14f:** This item **does not** include members of the site staff.
- **Item 15:** Describe the problem. **Do not** record the participant’s verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX TO DATAFAX

Visit Code

□□□.

1

HPTN 059 Ph II Microbe (113)

FBD-7 (177)

Participant ID

□□□-□□□□□-□
Site Number Participant Number Chk

Follow-up Behavior Assessment—Daily Use Arm

16. Has this problem/have any of these problems resulted in:

16a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem? yes no → If no, go to item 16b.

16a1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: _____

English: _____

16b. physical harm to you? For example, has anyone physically hurt you as a result of this problem? yes no → If no, go to item 16c.

16b1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: _____

English: _____

Follow-up Behavior Assessment—Daily Use Arm (FBD-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 16a1 and 16b1:** Describe the problem. **Do not** record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-worker, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBD-8 (178)

Participant ID

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

Follow-up Behavior Assessment—Daily Use Arm

16c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn income? yes [] no [] If no, go to item 16d.

16c1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: _____

English: _____

16d. physical or other harm to your children?..... yes [] no [] If no, go to item 17.

16d1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: _____

English: _____

Complete items 17-17a after the interview.

17. Did any of the problem(s) require reporting as an Adverse Event (AE)?.... yes [] no [] If no, end of form.

17a. Record AE Log page number(s): AE Log Page # [][][] AE Log Page # [][][] AE Log Page # [][][]

Follow-up Behavior Assessment—Daily Use Arm (FBD-8)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 16c1 and 16d1:** Describe the problem. Do not record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-worker, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 17:** This is not an interviewer-administered item.
- **Item 17a:** This is not an interviewer-administered item. Record the AE Log page number(s) that correspond to any AEs reported in item 16. Leave any remaining AE Log page number boxes blank.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX

Visit Code

□□.□

1

HPTN 059 Ph II Microbe (113)

FBC-1 (181)

Participant ID

□□□-□□□□□-□
Site Number Participant Number Chk

Follow-up Behavior Assessment—
Coitally Dependent Arm

Visit Date

□□ □□□ □□
dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. There are no right or wrong answers to these questions. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions I am going to ask you are about vaginal sex, and some are about anal sex. By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

Shall we continue?

1. In the **past month**, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex....

□□

of partners

If 0, go to statement before item 10 on page 4.

I am now going to ask you some questions about vaginal sex only.

2. In the **past week**, how many times did you have vaginal sex?

□□

of times

If 0, go to item 4 on page 2.

I know that you are counseled to insert the study gel within 2 hours before having vaginal sex, but I also know that this is not always possible.

2a. In the **past week**, how many times did you have vaginal sex more than 2 hours **after** inserting the study gel?

□□

of times

I know that you are counseled to use condoms for each act of vaginal sex, but I also know that this is not always possible.

2b. In the **past week**, how many times did you use a male or female condom and not the study gel during vaginal sex?

□□

of times

2c. In the **past week**, how many times did you insert the study gel and not use a male or female condom during vaginal sex?

□□

of times

2d. In the **past week**, how many times did you insert the study gel and use a male or female condom during vaginal sex?

□□

of times

2e. In the **past week**, how many times did you use neither the study gel nor a male or female condom during vaginal sex?

□□

of times

If 2b AND 2e are 0, go to item 4 on page 2.

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-1)

This form is used to collect information about the participant's sexual behaviors, vaginal hygiene, and family planning practices while she is taking part in the study. This is an interviewer-administered form (with the exception of items 16-16a), and is administered at the Week 4, Week 12, and Week 24/Early Termination Visits.

Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Note: *Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made only during the interview in which this form is completed, unless requested otherwise by SCHARP. Once the interview is finished, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Item 1:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has had no sexual partners in the past month, record "00" for this item and continue the interview by reading the statement before item 10 on page 4. In this case, do record the Visit Code and PTID on pages 2 and 3 of this form, and leave all other items on pages 2 and 3 blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Items 2–2e:** Use leading zeros when needed so that all the boxes are filled.
- **Items 2b–2e:** After recording the participant's responses, check that the sum of the responses to items 2b–2e equal the response to item 2. If any inconsistency is noted, attempt to resolve it by asking the participant for clarification. Update the responses to items 2 and/or 2b–2e as appropriate.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBC-2 (182)

Participant ID

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

Follow-up Behavior Assessment—
Coitally Dependent Arm

3. For the times you had sex without inserting the study gel, what were the reasons? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 4.

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: _____

English: _____

3a. What was the main reason? **DO NOT read response categories aloud.**

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: _____

English: _____

4. When was the **last time** you had vaginal sex?..... [][] [][][][] [][]
dd MMM yy

5. The **last time** you had vaginal sex:

	yes	no
5a. did you or your partner use a male condom?	<input type="checkbox"/>	<input type="checkbox"/>
5b. did you use a female condom?	<input type="checkbox"/>	<input type="checkbox"/>
5c. did you insert the study gel before having vaginal sex?	<input type="checkbox"/>	<input type="checkbox"/>
5c1. did you insert the study gel within 2 hours before having vaginal sex?	<input type="checkbox"/>	<input type="checkbox"/>
5d. did you wash inside or douche inside your vagina within 2 hours before inserting the study gel?	<input type="checkbox"/>	<input type="checkbox"/>
5e. did you wash inside or douche inside your vagina within 2 hours after inserting the study gel?	<input type="checkbox"/>	<input type="checkbox"/>

If no, go to statement before item 6 on page 3.

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 3:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reason reported by the participant. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant gives only one reason and only one box is marked, leave item 3a blank and go to item 4.
- **Item 3a:** **Do not** read any of the response categories aloud. Instead, read the question and, based on the responses to item 3, mark the one box that corresponds to the main reason why the participant did not use the study gel. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 4:** If, after verbal probing, the participant is unable to provide the day she last had vaginal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 5:** Read each item 5a–5e aloud and mark the participant’s response. If item 5c is marked “no,” leave items 5c1–5i blank and proceed to the statement above item 6 on page 3.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBC-3 (183)

Participant ID

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

Follow-up Behavior Assessment—
Coitally Dependent Arm

5f. did you insert paper, cloth, cotton, or cotton wool within 2 hours **before** inserting the study gel? yes no

5g. did you insert paper, cloth, cotton, or cotton wool within 2 hours **after** inserting the study gel? yes no

5h. did you insert any other object or substance into your vagina within 2 hours **before** inserting the study gel? yes no

➔ If yes, specify:

Local Language: _____

English: _____

5i. did you insert any other object or substance into your vagina within 2 hours **after** inserting the study gel? yes no

➔ If yes, specify:

Local Language: _____

English: _____

I am now going to ask you some questions about a different way that people have sex. This way is anal sex. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

6. In the **past month**, did you have anal sex? yes no ➔ If no, go to statement before item 10 on page 4.

7. In the **past week**, did you have anal sex? yes no ➔ If no, go to item 8.

7a. In the **past week**, did you ever insert the study gel anally during anal sex? yes no ➔ If no, go to statement before item 7b.

7a1. In the **past week**, how many times did you insert the study gel anally during anal sex? [][] # of times

I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.

7b. In the **past week**, did you ever, even once, have anal sex without a condom? yes no

8. When was the **last time** you had anal sex? [][] dd [][][][] MMM [][][] yy

[][][] [x] 28-JUN-06

[0][1]

Language

Staff Initials / Date

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 5f-5g:** Read each item aloud and mark the participant's response.
- **Items 5h-5i:** Read each item aloud and mark the participant's response. If "yes" is marked, be sure to record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 8:** If, after verbal probing, the participant is unable to provide the day she last had anal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write "don't know" in the white space next to the item, and initial and date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBC-4 (184)

Participant ID

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

Follow-up Behavior Assessment—Coitally Dependent Arm

9. The **last time** you had anal sex: yes no
- 9a. did you or your partner use a male condom?
- 9b. did you use a lubricant (such as lube, K.Y.)?
- 9c. did you insert the study gel anally?.....

I know that you are counseled to insert the study gel each time you have vaginal sex, up to twice a day, but I also know that this is not always possible.

10. In the **past week**, how many times did you insert the study gel? # of times
➔ If 0, go to statement before item 11.
- 10a. In the **past week**, how many times did you insert the study gel and **not** have vaginal sex?..... # of times

I am now going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

11. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.
- If yes:** How many times in the **past week** did you insert this item?
- | | yes | no | # of times in past week |
|--|--------------------------|--------------------------|---|
| 11a. water?..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |
| 11b. water with vinegar? <i>Note for U.S. sites: This includes all commercial douching products.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |
| 11c. water with soap? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |
| 11d. paper, cloth, cotton, or cotton wool?..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |
| 11e. tampons?..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |
| 11f. fingers without anything else? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |
| 11g. anything else? Specify:..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> <input type="text"/> |

Local Language:

English:

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 9:** Read each item 9a–9c aloud and mark the participant’s response.
- **Item 10:** Record the number of times the participant used the study gel in the last 7 days.

Note: The maximum number of times a coitally dependent participant may use the study gel, per protocol, is twice daily. If the participant reports having used the study gel > 14 times in the past week, provide adherence counseling on proper frequency of use during the counseling portion of the visit.

- **Item 10a:** The sum of the responses to items 10a, 2c, and 2d should equal the response to item 10. If a discrepancy is noted, attempt to resolve it by asking the participant for clarification. Update the responses on this form as necessary.
- **Item 11:** Read each item 11a–11g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the **past week** she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 11g, record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX



Visit Code .

1

HPTN 059 Ph II Microbe (113)

FBC-5 (185)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment—
Coitally Dependent Arm

12. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **DO NOT read response categories aloud. Mark "none" or all that apply.**

none
 vaginal ring
 spermicide
 diaphragm
 sponge

➔ Reinforce use of protocol-specified methods of effective contraception.

intrauterine device (IUD)
 natural methods such as the withdrawal or rhythm method
 male condoms
 female condoms

➔ If not used in combination with another protocol-specified method of effective contraception, provide appropriate counseling.

family planning pills or birth control pills
 injectable contraceptives (such as Depo-Provera)
 Norplant inserts
 Ortho Evra/The Patch
 surgical sterilization (tubal ligation)
 sex with partner who had a vasectomy
 other, specify:

Local Language: _____

English: _____

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 12: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each family planning method the participant reports using. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBC-6 (186)

Participant ID

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

Follow-up Behavior Assessment—Coitally Dependent Arm

For the last set of questions, I am going to ask you about problems you may have had or are having while in this study. By problems, I mean any emotional, physical, financial, social, or other difficulties.

13. In the **past month**, have you had any problems with the following people as a result of being in this study:

	yes	no	not applicable
13a. your spouse or partner?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13b. people at home/family?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13c. your friends/personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13d. people at work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13e. people at school?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13f. your doctor, nurse, midwife, or other health care provider?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13g. your landlord or property owner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13h. other people? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Local Language: _____

English: _____

If no to all, end of form.

14. Please describe the problem. **DO NOT record the participant's verbatim response.**

Local Language: _____

English: _____

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 13:** Read each item 13a–13h aloud and mark the participant’s response. If “yes” is marked for item 13h, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant responds “no” to each item 13a–13h, end the form; record the Visit Code and PTID on pages 7 and 8 of this form, and leave the remaining form items (14-16a) blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 13f:** This item **does not** include members of the site staff.
- **Item 14:** Describe the problem. **Do not** record the participant’s verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBC-7 (187)

Participant ID

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

Follow-up Behavior Assessment—
Coitally Dependent Arm

15. Has this problem/have any of these problems resulted in:

15a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem? yes no **→ If no, go to item 15b.**

15a1. Please describe the problem: **Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.**

Local Language: _____

English: _____

15b. physical harm to you? For example, has anyone physically hurt you as a result of this problem? yes no **→ If no, go to item 15c.**

15b1. Please describe the problem: **Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.**

Local Language: _____

English: _____

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 15a1 and 15b1:** Describe the problem. **Do not** record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-worker, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 059 Ph II Microbe (113)

FBC-8 (188)

Participant ID

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

Follow-up Behavior Assessment—Coitally Dependent Arm

15c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn income? yes [] no [] -> If no, go to item 15d.

15c1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: _____

English: _____

15d. physical or other harm to your children? yes [] no [] -> If no, go to item 16.

15d1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: _____

English: _____

Complete items 16-16a after the interview.

16. Did any of the problem(s) require reporting as an Adverse Event (AE)? yes [] no [] -> If no, end of form.

16a. Record AE Log page number(s): AE Log Page # [][] AE Log Page # [][] AE Log Page # [][]

Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-8)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 15c1 and 15d1:** Describe the problem. **Do not** record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-work, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 16:** This is not an interviewer-administered item.
- **Item 16a:** This is not an interviewer-administered item. Record the AE Log page number(s) that correspond to any AEs reported in item 15. Leave any remaining AE Log page number boxes blank.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code .

1

HPTN 059 Ph II Microbe (113)

SAA-1 (472)

Participant ID

- -
Site Number Participant Number Chk

Study Exit Acceptability Assessment

Visit Date

dd MMM yy

One goal of this research is to understand how acceptable study gel use is to women and their partners. I am now going to ask you some questions about your experiences using the study gel and how study gel use has affected your relationship(s) with sexual partners. Your honest answers will be very helpful to us.

Shall we continue?

- 1. If your study gel is found to help prevent people from getting HIV, would you want to use it during sex?.....
 yes no don't know
→ If yes, go to item 2.

1a. Why not?

Local Language: _____

English: _____

2. What do you like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 3 on page 2.

- no response
- nothing
- may protect against HIV
- may protect against STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- did not interrupt sex
- appearance/smell
- other, specify:

Local Language: _____

English: _____

Study Exit Acceptability Assessment (SAA-1)

This form is used to collect gel acceptability information from study participants. This is an interviewer-administered form, and it is administered at the Study Exit visit.

Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

***Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made only during the visit in which this form is completed, unless requested otherwise by SCHARP. Once the participant has completed the visit, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Items 1–1a:** If the participant responds "yes," leave item 1a blank and proceed to item 2. If the participant responds "no," continue to item 1a and record the participant's verbatim (word-for-word) response.
- **Item 2:** Do not read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reported characteristic the participant likes about the gel. If the participant gives a response that does not correspond to one of the listed categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response. If "no response" or "nothing" is marked, no other response box should be marked. If only one response box is marked, leave item 2a blank and go to item 3.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX
TO DATAFAX

■ ■ ■ | ■ ■ | | ■ Visit Code

□ □ . □

1

HPTN 059 Ph II Microbe (113)

SAA-2 (473)

Participant ID

□ □ □ - □ □ □ □ □ - □
Site Number Participant Number Chk

Study Exit Acceptability Assessment

2a. Which of these do you like most? **DO NOT read response categories aloud.**

- no response
- nothing
- may protect against HIV
- may protect against STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- did not interrupt sex
- appearance/smell
- other, specify:

Local Language: _____

English: _____

3. What do you not like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

- no response
- nothing
- messy
- interrupted sex
- made sex less pleasurable
- difficult to use, specify:
- remembering to use it
- difficult to store and/or discard
- appearance/smell
- other, specify:

If only one response box is marked, go to item 4 on page 3.

Local Language: _____

English: _____

Local Language: _____

English: _____

Study Exit Acceptability Assessment (SAA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 2a:** **Do not** read any of the response categories aloud. Instead, read the question, and based on the participant's responses to item 2, mark the box that corresponds to the one characteristic the participant likes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she likes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response.
- **Item 3:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each characteristic the participant does not like about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response on the adjacent specify line(s). If the participant's response is "difficult to use," probe for more specific information as to why the study gel is difficult to use and record the participant's verbatim (word-for-word) response on the adjacent specify line(s). If "no response" or "nothing" is marked, no other response box should be marked. If only one response box is marked, leave item 3a (on page 3) blank and go to item 4.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code [][] . []

[1]

HPTN 059 Ph II Microbe (113)

SAA-3 (474)

Participant ID

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

Study Exit Acceptability Assessment

3a. Which of these do you dislike most? **DO NOT read response categories aloud.**

- no response
- nothing
- messy
- interrupted sex
- made sex less pleasurable
- difficult to use
- remembering to use it
- difficult to store and/or discard
- appearance/smell
- other, specify:

Local Language: _____

English: _____

4. The **last time** you had sex with a male partner while using the study gel, did he know you were using the study gel? yes no don't know

→ If no or don't know, go to item 5 on page 4.

4a. What was his reaction to the study gel? **DO NOT read response categories aloud.**

- he liked it
- he did not like it
- he had no reaction
- don't know
- other, specify:

Local Language: _____

English: _____

Study Exit Acceptability Assessment (SAA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 3a:** **Do not** read any of the response categories aloud. Instead, read the question, and based on the participant's responses to item 3, mark the box that corresponds to the one characteristic the participant dislikes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she dislikes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response.
- **Item 4:** This item refers to the last time the participant used the study gel during vaginal sex.
- **Item 4a:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box that corresponds to the participant's response. If the participant gives a response that is not listed, mark the "other, specify" box and record the participant's verbatim (word-for-word) response on the "Local Language" line. If the response is given in a language other than English, provide the English translation of the response on the "English" line.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code [][] . []

[1]

HPTN 059 Ph II Microbe (113)

SAA-4 (475)

Participant ID

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

Study Exit Acceptability Assessment

5. During your participation, did you ever use anyone else's study gel? yes no **If no, go to item 6.**

5a. Approximately how many times did you use someone else's gel?

1 time 2-5 times 6-10 times > 10 times

5b. Can you tell me why you used another participant's study gel?

Local Language: _____

English: _____

6. Did anyone else, even someone who wasn't in the study, use your study gel?..... yes no don't know

Study Exit Acceptability Assessment (SAA-4)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 5b:** Record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Page 1 of 3

Participant ID

Site Number			Participant Number						Chk	

Screening Eligibility

Form Completion Date

dd		MMM		yy	

Complete items 1–3 before the interview.

1. Was the participant willing and able to provide a written informed consent for screening? yes no **→ If no, participant is ineligible. End of form.**
2. Was the participant previously enrolled in this study? yes no **→ If yes, participant is ineligible. End of form.**
3. Is documentation of a normal Pap test result in the last 90 days available? yes no **→ If no, perform Pap test as necessary.**

I am now going to ask you some more questions about yourself. Some of these questions are personal and sensitive, but remember that we do not have your name on these papers and all of your answers will be kept confidential. Are you ready to continue?

4. Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)? yes no
5. Have you ever had an adverse or bad reaction to tenofovir (Viread) or adefovir (Hepsera)? yes no
6. Are you currently taking, or do you plan to take tenofovir (Viread), adefovir (Hepsera), or any other chronic hepatitis B medication while participating in this study? yes no
7. Have you had a hysterectomy? yes no
8. Are you breastfeeding? yes no
9. Do you plan to use a diaphragm or spermicide for birth control at any time during your study participation? yes no **→ If yes to any, participant is ineligible.**
10. In the last month (30 days), have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. yes no **→ If no, participant is ineligible.**
11. In the past 2 weeks, how many times have you had vaginal sex? ... **→ If > 28, participant is ineligible.**

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0	1
Language	

Staff Initials / Date

Screening Eligibility – 1 (nonDF)

This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 4–23), while other items are not (items 1–3 and 24). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

***Note:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 23. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.*

Item-specific Instructions:

- **Items 1–3:** These items are NOT interviewer-administered and should not be read aloud to the participant.
- **Item 2:** Review the Screening and Enrollment Log to verify that the participant has not previously enrolled in the study.
- **Item 3:** Per protocol, a participant must have either a normal Pap test result at screening or documentation of a normal Pap test result in the 90 days prior to screening in order to be eligible to enroll in the study. If the participant does not provide documentation of a normal Pap test result in the 90 days prior to screening, conduct a Pap Smear test for this participant as part of the Screening Visit pelvic exam.

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Page 2 of 3

Participant ID

Site Number				Participant Number					Chk		

Screening Eligibility

12. Have you been without menstrual periods for the past 12 months? yes no **→ If no, go to item 13.**
- 12a. Is it because of the birth control you are using, such as Depo-Provera or Norplant? **→ If no, participant is ineligible.**
13. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? yes no **→ If no, go to item 14.**

13a. When did you last give birth, have a miscarriage or abortion?

dd		MMM			yy					

If date is within the last 34 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last pregnancy outcome.

14. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C); surgery of the uterus, ovaries, or fallopian tubes, and biopsy or cryotherapy (freezing) of the cervix. yes no **→ If no, go to item 15.**

14a. When did you last have gynecological surgery?

dd		MMM			yy					

If date is within the last 34 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last gynecological surgery.

15. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ... yes no **→ If no, go to item 16.**

15a. When did you last inject drugs that were not prescribed to you?

dd		MMM			yy					

If date is within the last 309 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within one year of injection drug use.

Screening Eligibility – 2 (nonDF)

This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 4–23), while other items are not (items 1–3 and 24). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *If a participant is being re-screened, a new Screening Part 2 Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

- **Item 12:** According to the protocol, women who “are menopausal or post-menopausal at enrollment (defined as the cessation of menses of 12 calendar months, unless on long-acting progestins) will be excluded from the study.”
- **Item 13:** According to the protocol, women who are “within 90 days of last pregnancy outcome at enrollment will be excluded from the study.”
- **Item 14:** According to the protocol, women who “have had a gynecological surgical procedure in the 90 days prior to enrollment will be excluded from the study.”
- **Item 15:** According to the protocol, women who “have injected non-therapeutic drugs intravenously in the 12 calendar months prior to enrollment will be excluded from the study.”

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Participant ID

Site Number			Participant Number						Chk	

Screening Eligibility

16. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug?

yes

no

If no, go to item 17.

16a. When did you last participate in one of these studies?

dd		MMM			yy		

Schedule enrollment when participant is no longer within 30 days of other study participation.

17. Do you agree to not participate in any study that uses spermicides, vaginal microbicides, or any other device or drug while participating in this study?

yes

no

18. For the duration of the study, are you willing to use one of the following types of birth control? Depo-Provera ("the shot"), hormonal contraceptives ("the pill"), Ortho-Evra ("the patch"), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy?

19. Do you agree to use study-provided condoms each time you have intercourse for the duration of the study?

20. Are you willing to use the study product, which is Tenofovir gel or placebo gel, either once a day or with each act of vaginal sex?

21. While you are using the study gel, do you agree to use only study-provided panty liners and/or menstrual pads, if necessary, to protect from product leakage?

22. Are you willing to attend all scheduled study visits?

23. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws?

If no to any, participant is ineligible.

Complete item 24 when screening urine hCG result is available.

24. Is the participant pregnant?

yes

no

If yes, participant is ineligible.

Screening Eligibility – 3 (nonDF)

This form is used to document the participant's eligibility for the study. This is a mixed form—some of the items are interviewer-administered (items 4–23), while other items are not (items 1–3 and 24). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

- **Item 16:** According to the protocol, women who “have participated in any other spermicide and/or vaginal microbicide study or any device or drug study 30 days prior to enrollment” will be excluded from the study.
- **Item 24:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening Visit urine hCG result here.

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Page 2 of 2

Participant ID

Site Number			Participant Number						Chk	

Screening Summary

- 2u. has a history of prior participation in the study
- 2v. has a Grade 3 or higher laboratory abnormality, or creatinine level > 1.25 x ULN
- 2w. had a gynecological surgical procedure within 90 days of enrollment
- 2x. is pregnant
- 2y. is within 90 days of last pregnancy outcome at enrollment
- 2z. has an abnormal pelvic exam finding that is exclusionary, per protocol
- 2aa. is diagnosed with a current STI and/or other RTI requiring treatment according to CDC guidelines
- 2ab. has a history of non-therapeutic injection drug use in the 12 months prior to enrollment
- 2ac. participated in another study that uses spermicides, vaginal microbicides, or any other device or drug in the 30 days prior to enrollment
- 2ad. has had vaginal sex more than an average of 2 times per day in the 2 weeks prior to screening
- 2ae. is breastfeeding
- 2af. exceeded the 56-day screening window
- 2ag. has any other condition that, in the opinion of the Investigator or designee, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives

Screening Summary – 2 (nonDF)

Item-specific Instructions:

- **Item 2u:** Review Screening Eligibility form, item 2; *and* Screening and Enrollment Log.
- **Item 2v:** Review Safety Laboratory Results form, items 1–4 from the Screening Visit.
- **Item 2w:** Review Screening Eligibility form, items 14 and 14a; *and* Enrollment Eligibility form, item 5.
- **Item 2x:** Review Screening Eligibility form, item 24; *and* Enrollment Eligibility form, item 11.
- **Item 2y:** Review Screening Eligibility form, items 13 and 13a; *and* Enrollment Eligibility form, item 7.
- **Item 2z:** Review Screening and Enrollment Pelvic Exam forms, items 1 and 2, from both the Screening and Enrollment Visits; **and** the Clinical Eligibility forms, item 2, from both the Screening and Enrollment Visits.
- **Item 2aa:** Review Clinical Eligibility forms, item 1, from both the Screening and Enrollment Visits.
- **Item 2ab:** Review Screening Eligibility form, items 15 and 15a; *and* Enrollment Eligibility form, item 8.
- **Item 2ac:** Review Screening Eligibility form, items 16 and 16a; *and* Enrollment Eligibility form, item 2.
- **Item 2ad:** Review Screening Eligibility form, item 11.
- **Item 2ae:** Review Screening Eligibility form, item 8; *and* Enrollment Eligibility form, item 4.
- **Item 2af:** Review Screening Consent form, item 2a; *and* date of enrollment as recorded on the Enrollment form.
- **Item 2ag:** Review Enrollment Eligibility form, item 12.

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and Chk.

Enrollment Eligibility

Form Completion Date

Form Completion Date form with boxes for dd, MMM, and yy.

Complete item 1 before the interview.

1. Was the participant willing and able to provide a written informed consent for enrollment (as assessed by a site-specific assessment of comprehension)?

To confirm your eligibility for the study, I need to ask you a few more questions.

- 2. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug?
3. In the past 30 days, have you inserted an intrauterine device (IUD)?
4. Are you breastfeeding?
5. In the past 3 months (90 days), have you had any gynecological surgery?
6. Are you currently taking, or do you plan to take tenofovir (Viread), adefovir (Hepsera), or any other chronic hepatitis B medication while participating in this study?
7. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion?
8. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional?
9. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws?
10. Have you been without menstrual periods for the past 12 months?
10a. Is it because of the birth control you are using, such as Depo-Provera or Norplant?

Complete item 11 when enrollment urine HCG result is available.

11. Is the participant pregnant?
Complete item 12 after reviewing all Screening forms.

12. Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision or informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives?

Enrollment Eligibility – 1 (nonDF)

This form is used to document the participant's eligibility for the study at enrollment. This is a mixed form—some of the items are interviewer-administered (items 2–10a), while other items are not (items 1 and 11-12). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If a participant is being re-screened, a new Screening Eligibility form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

- **Item 1:** This item is NOT interviewer-administered and should not be read aloud to the participant.
- **Items 2–10a:** These items were also asked during the Screening visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 10a. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.
- **Item 11:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Enrollment Visit urine hCG result here.
- **Item 12:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Screening Visit has been completed. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the “yes” box, record the reason in the participant's chart notes, and do not enroll the participant in the study.