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

1. What is your date of birth? .................................. 
   \( dd \) \( MMM \) \( yy \) 
   If unknown, record age: \( \underline{\text{years}} \)

2. What is the participant's gender? ........................ 
   male \( \square \) \( \square \) female
   \( \square \) \( \square \) \( \square \) 
   \( \square \) no income

3. Are you currently married? ...............................  
   \( \square \) \( \square \) \( \square \) don't know
   \( \square \) \( \square \) \( \square \) 

   3a. How old is your husband? .........................  
       \( \square \) \( \text{years} \) \( \square \) 
   \( \square \) no income

   3b. Are you currently living with your husband?  
       \( \square \) \( \square \) 
   \( \square \) 

   3c. Does your husband have more than one  
       wife or sexual partner? .........................  
       \( \square \) \( \square \) \( \square \) don't know
   \( \square \) \( \square \) 

   3d. Does your husband provide you with  
       financial and/or material support? ..........  
       \( \square \) \( \square \) \( \square \) 

   3d1. What is your husband’s average  
        monthly income? \( \text{Record in local} \)  
        currency........................................  
        \( \square \) \( \square \) \( \square \) \( \square \) don't know \( \square \) 

   3e. What is your husband’s highest level of education?

   U.S.

   \( \square \) no schooling
   \( \square \) primary school, not complete
   \( \square \) primary school, complete
   \( \square \) secondary, not complete
   \( \square \) secondary, complete
   \( \square \) attended college or university
   \( \square \) don’t know  
   \( \square \) Go to item 5 on page 2.

   INDIA

   \( \square \) no schooling
   \( \square \) 1–3
   \( \square \) 4, complete
   \( \square \) 5–9
   \( \square \) 10, complete
   \( \square \) > 10
   \( \square \) don’t know  
   \( \square \) 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: 00 02 14 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.
4. Do you currently have a male sexual partner? ..............
   □ yes  □ no  □ don’t know  
   → If no, go to item 5.

4a. How old is your partner?.................................
   □ □ □ □ □ □ □  years  □

4b. Are you currently living with your partner? ..........  □ □ □

4c. Does your partner have any other sexual partners? ..........
   □ yes  □ no  □ don’t know

4d. Does your partner provide you with financial and/or material support?..............
   □ yes  □ no  □

4d1. What is your partner’s average monthly income? Record in local currency.............
   □ □ □ □ □ □ □ □

4e. What is your partner’s highest level of education?

   U.S.
   □ no schooling
   □ primary school, not complete
   □ primary school, complete
   □ secondary, not complete
   □ secondary, complete
   □ attended college or university
   □ don’t know

   INDIA
   □ no schooling
   □ 1–3
   □ 4, complete
   □ 5–9
   □ 10, complete
   □ > 10
   □ don’t know

5. Do you earn an income of your own?.......................  □ yes  □ no  □
   → If no, end of form.

5a. What is your average monthly income? Record in local currency.............
   □ □ □ □ □ □ □ □

5b. How do you earn your income?
   Mark all that apply. ........................................
   □ formal employment  □ self-employed  □ other, specify: __________________________

□ □ □  x  28-JUN-06
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: $0002145$

  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.
1. What is your highest level of education?
   - [ ] no schooling
   - [ ] primary school, not complete
   - [ ] secondary, not complete
   - [ ] secondary, complete
   - [ ] primary school, 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.........................

4. Have you ever had an unplanned pregnancy?.................

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.
   - [ ] 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

   [ ] [ ] [ ] 28-JUN-06

   [ ] [ ] [ ] 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: 0002145

  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.
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

3. Do you own your home? 
   yes 
   no

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
   - Buddhist
   - Muslim
   - 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.*
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.
4. The last time you had vaginal sex:

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

   b. did you use a female condom? ........................................................

   c. did you wash inside or douche inside your vagina within 2 hours before having vaginal sex? ..................................................

   d. did you wash inside or douche inside your vagina within 2 hours after having vaginal sex? ......................................................

   e. did you insert paper, cloth, cotton, or cotton wool within 2 hours before having vaginal sex? ..................................................

   f. did you insert paper, cloth, cotton, or cotton wool within 2 hours after having vaginal sex? ...................................................

   g. did you insert any other object or substance into your vagina within 2 hours before or during vaginal sex? .....................

   If yes, specify:

   Local Language: 

   English: 

4h. did you insert any other object or substance into your vagina within 2 hours after vaginal sex? ..............................

   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.

5. Have you ever had anal sex? .................................................................

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

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?

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

8. The last time you had anal sex:

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

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

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?

9a. water?

9b. water with vinegar? Note for U.S. sites: This includes all commercial douching products.

9c. water with soap?

9d. paper, cloth, cotton, or cotton wool?

9e. tampons?

9f. fingers without anything else?

9g. anything else? Specify:

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.*
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
- [ ] intrauterine device (IUD)
- [ ] natural methods such as the withdrawal or rhythm method
- [ ] male condoms
- [ ] female condoms
- [ ] 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:**

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

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

  **Participant is ineligible.**
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.*
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.**

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

   **Local Language:** ____________________________
   **English:** ____________________________

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

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

   - [ ] no response
   - [ ] easy to use
   - [ ] nothing
   - [ ] method is under her control
   - [ ] may protect against HIV
   - [ ] made sex more pleasurable
   - [ ] may protect against STIs
   - [ ] did not interrupt sex
   - [ ] can use without partner’s knowledge
   - [ ] appearance/smell
   - [ ] 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.
2. 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:
  - 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.*
3. Is the study gel easy to apply? ........................................... 

4. In general, does the study gel have any effect on sexual intercourse? ......................................................... 

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

5a. Is this the same partner you had the last time you answered these questions? ............................................. 

5b. In the past month, did you have sex with this regular partner while you were using the study gel? ............ 

5c. Did he know you were using the study gel? ............... 

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:  

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

If no, go to item 6 on page 4. 

If no or don't know, go to item 6 on page 4.
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.
Acceptability Assessment (AA-4)

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 no or don’t know, go to item 6a. If yes, go to item 6a3.

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.*
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.*
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.
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.

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

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

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

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

6. In the past week, did you have anal sex? ........................................
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.*
Follow-up Behavior Assessment—Daily Use Arm (FBD-3)

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
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</table>

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

   **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? ............................................

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.)? ...................................

   - yes
   - no

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

   - yes
   - no

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 ever 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.**

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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.*
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.

- □ forgot
- □ no gel available
- □ no time to insert it
- □ worried about side effects
- □ lack of privacy
- □ menses
- □ I didn’t like it
- □ don’t use it with that partner
- □ my partner didn’t like it
- □ other, specify:

**Local Language:**

**English:**

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

- □ forgot
- □ no gel available
- □ no time to insert it
- □ worried about side effects
- □ lack of privacy
- □ menses
- □ I didn’t like it
- □ don’t use it with that partner
- □ my partner didn’t like it
- □ 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.

12a. water?

12b. water with vinegar? **Note for U.S. sites:** This includes all commercial douching products.

12c. water with soap?

12d. paper, cloth, cotton, or cotton wool?

12e. tampons?

12f. fingers without anything else?

12g. anything else? Specify:

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th># of times in past week</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
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</tbody>
</table>

**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.*
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
- [ ] intrauterine device (IUD)
- [ ] natural methods such as the withdrawal or rhythm method
- [ ] male condoms
- [ ] female condoms
- [ ] 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.*
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:

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>14a. your spouse or partner?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14b. people at home/family?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14c. your friends/personal relationships?</td>
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<tr>
<td>14d. people at work?</td>
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<tr>
<td>14e. people at school?</td>
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<td>14f. your doctor, nurse, midwife, or other health care provider?</td>
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<td>14g. your landlord or property owner?</td>
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<tr>
<td>14h. other people? Specify:</td>
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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.
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.*
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.*
Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-1)

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...

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

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 have vaginal sex more than 2 hours after inserting the study gel?

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?

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?

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

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

Version 1.0, 28-JUN-06

N:hivnet/forms/PTN_059/forms/p059_followup_behavior_assess_coitally_depend_arm.fm
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.*

- [ ] forgot
- [ ] no gel available
- [ ] no time to insert it
- [ ] worried about side effects
- [ ] lack of privacy
- [ ] menses
- [ ] I didn't like it
- [ ] don't use it with that partner
- [ ] my partner didn't like it
- [ ] other, specify:

Local Language: _____________________________

English: _____________________________

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

- [ ] forgot
- [ ] no gel available
- [ ] no time to insert it
- [ ] worried about side effects
- [ ] lack of privacy
- [ ] menses
- [ ] I didn't like it
- [ ] don't use it with that partner
- [ ] my partner didn't like it
- [ ] other, specify:

Local Language: _____________________________

English: _____________________________

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

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

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

5. The last time you had vaginal sex:

5a. did you or your partner use a male condom? .................. 

- [ ] yes
- [ ] no

5b. did you use a female condom? ................................. 

- [ ]
- [ ]

5c. did you insert the study gel before having vaginal sex? .................. 

5c1. did you insert the study gel within 2 hours before having vaginal sex? ........................................ 

- [ ]
- [ ]

5d. did you wash inside or douche inside your vagina within 2 hours before inserting the study gel? .......................... 

- [ ]
- [ ]

5e. did you wash inside or douche inside your vagina within 2 hours after inserting the study gel? .......................... 

- [ ]
- [ ]
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.*
Follow-up Behavior Assessment—Coitally Dependent Arm

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

5f. did you insert paper, cloth, cotton, or cotton wool within 2 hours **before** inserting the study gel? ............................................

5g. did you insert paper, cloth, cotton, or cotton wool within 2 hours **after** inserting the study gel? ............................................

5h. did you insert any other object or substance into your vagina within 2 hours **before** inserting the study gel? ......................

Local Language: __________________________________________

English: __________________________________________

If yes, specify: __________________________

5i. did you insert any other object or substance into your vagina within 2 hours **after** inserting the study gel? .........................

Local Language: __________________________________________

English: __________________________________________

If yes, specify: __________________________

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

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

7a. In the **past week**, did you ever insert the study gel anally during anal sex?................................................................................

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

7b. In the **past week**, did you ever, even once, have anal sex without a condom?...........................................................

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

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

8. When was the **last time** you had anal sex?................................................
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.*
Follow-up Behavior Assessment—Coitally Dependent Arm

Participant ID

<table>
<thead>
<tr>
<th>Site Number</th>
<th>Participant Number</th>
<th>Chk</th>
</tr>
</thead>
</table>

The last time you had anal sex:

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

10a. In the past week, how many times did you insert the study gel and not have vaginal sex? ................................................................

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.

11a. water? ........................................................................................................

11b. water with vinegar? Note for U.S. sites: This includes all commercial douching products. ..............................................................

11c. water with soap? ....................................................................................... 

11d. paper, cloth, cotton, or cotton wool? ....................................................... 

11e. tampons? ................................................................................................... 

11f. fingers without anything else? ................................................................. 

11g. anything else? Specify: ............................................................................

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

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.*
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
- [ ] intrauterine device (IUD)
- [ ] natural methods such as the withdrawal or rhythm method
- [ ] male condoms
- [ ] female condoms
- [ ] 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:**

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

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

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>13a. your spouse or partner?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13b. people at home/family?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13c. your friends/personal relationships?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13d. people at work?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13e. people at school?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13f. your doctor, nurse, midwife, or other health care provider?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13g. your landlord or property owner?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13h. other people? Specify:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Local Language: ________________________________

English: ________________________________

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

Local Language: ________________________________

English: ________________________________

If no to all, end of form.
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.*
Follow-up Behavior Assessment—Coitally Dependent Arm

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 15

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 15

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.
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-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 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.*
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.**

   □ 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: 

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

  **Local Language:**

  **English:**

- [ ] remembering to use it
- [ ] difficult to store and/or discard
- [ ] appearance/smell
- [ ] other, specify:

  **Local Language:**

  **English:**

If only one response box is marked, go to item 4 on page 3.
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.*
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.*
5. During your participation, did you ever use anyone else’s study gel? 

   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)

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? ... no yes
    If > 28, participant is ineligible.
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.
12. Have you been without menstrual periods for the past 12 months?.
   12a. Is it because of the birth control you are using, such as Depo-Provera or Norplant?

13. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion?
   13a. When did you last give birth, have a miscarriage or abortion?

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.
   14a. When did you last have 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?
   15a. When did you last inject drugs that were not prescribed to you?
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.”
16. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug? .................................................................

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

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

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

Complete item 24 when screening urine hCG result is available.

24. Is the participant pregnant? .............................................................

If no to any, participant is ineligible.

If no, go to item 17.
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.
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.
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)?

   yes  no

If no, participant is ineligible. End of form.

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?

   yes  no

3. In the past 30 days, have you inserted an intrauterine device (IUD)?

   yes  no

4. Are you breastfeeding?

   yes  no

5. 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

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. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion?

   yes  no

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?

   yes  no

If yes to any, participant is ineligible.

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?

   yes  no

If no, participant is ineligible.

10. Have you been without menstrual periods for the past 12 months?

    yes  no

If no, go to statement before item 11.

10a. Is it because of the birth control you are using, such as Depo-Provera or Norplant?

    yes  no

If no, participant is ineligible.

Complete item 11 when enrollment urine HCG result is available.

11. Is the participant pregnant?

    yes  no

If no, go to statement before item 11.

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?

    yes  no

If yes, participant is ineligible.

If no, participant is ineligible.
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.