

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DM-1 (001)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk	

Demographics

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1st	2nd	3rd	4th	5th	other, specify: _____

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

1. What is your date of birth?

<input type="text"/>	<input type="text"/>
dd	yy

<input type="text"/>	<input type="text"/>	<input type="text"/>
MMM		

<input type="text"/>	<input type="text"/>
yy	

 } **If complete date of birth is not available:**
How old are you in completed years?.....

<input type="text"/>	<input type="text"/>
years	

 2. Are you currently married?.....

<input type="checkbox"/>

<input type="checkbox"/>

yes **no** **don't know** **If no, go to item 3 on page 2.**
 - 2a. How old is your husband?

<input type="text"/>	<input type="text"/>
years	

<input type="checkbox"/>

yes **no** **don't know**
 - 2b. Are you currently living with your husband?

<input type="checkbox"/>

<input type="checkbox"/>

yes **no**
 - 2c. Does your husband have more than one wife or sexual partner?

<input type="checkbox"/>

<input type="checkbox"/>

<input type="checkbox"/>

yes **no** **don't know**
 - 2d. Does your husband provide you with financial and/or material support?

<input type="checkbox"/>

<input type="checkbox"/>

yes **no**
 - 2d1. What is your husband's average monthly income?.....

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

Record in local currency. **don't know**
 - 2e. What is your husband's highest level of education?
 - no schooling
 - primary school, not complete
 - primary school, complete
 - secondary, not complete
 - secondary, complete
 - attended college or university
 - don't know**Go to item 4 on page 2.**

Demographics (DM-1), Page 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 for more instructions regarding re-screening form completion, and transmission procedures.*

General Interviewer Tips:

See Section 13.5 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.*

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 1:** When possible, record the participant's complete date of birth (**day, month, and year**). If the participant does not know her complete date of birth, leave all the date boxes blank (this will not generate a QC note) and record the participant's age in completed years in the boxes provided. Use the participant's best estimate if the exact number of years is unknown. If necessary, record the interviewer's best estimate. Do not record both a full or partial date of birth and completed years—this may generate a QC note.
- **Item 2:** Record whether or not the participant is **currently** married.
- **Item 2a:** 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 2d:** 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 2d1:** Record the husband's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

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

If the husband's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item. If the husband is unemployed write "0000000" in the boxes provided.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DM-2 (002)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk	

Demographics

	<i>1st</i>	<i>2nd</i>	<i>3rd</i>	<i>4th</i>	<i>5th</i>	<i>other, specify: _____</i>
Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Do you currently have a male sexual partner? *yes* *no* → **If no, go to item 4.**
don't know
- 3a. How old is your partner? *years* *don't know*
- 3b. Are you currently living with your partner? *yes* *no*
- 3c. Does your partner have any other sexual partners? *yes* *no* *don't know*
- 3d. Does your partner provide you with financial and/or material support? *yes* *no*
- 3d1. What is your partner's average monthly income?
Record in local currency. *don't know*
- 3e. What is your partner's highest level of education?
- no schooling
 - primary school, not complete
 - primary school, complete
 - secondary, not complete
 - secondary, complete
 - attended college or university
 - don't know

4. Do you earn an income of your own? *yes* *no* → **If no, end of form.**
- 4a. What is your average monthly income?
Record in local currency.
- 4b. How do you earn your income? **Mark all that apply.** *formal employment* *self-employed* *other, specify: _____*

Demographics (DM-2) Page 2

Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Item 3:** 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 (item 3a through 3e) should be answered for the partner she considers to be her primary sexual partner.
- **Item 3a:** 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 3d:** 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 3d1:** Record the sexual partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

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

If the sexual partner's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item. If the partner is unemployed write "0000000" in the boxes provided.

- **Item 4a:** 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 4b:** 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.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DMM-1 (013)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Site Number			Participant Number				Chk	

Demographics—Malawi

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

	1st	2nd	3rd	4th	5th	other, specify: _____
Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1. What is your highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- attended college or university

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

yes no

3. Do you own your home?

4. How many rooms are in your household?

yes no

5. Do you have electricity in your home?

6. What is your ethnic group or tribe?

Read categories, mark all that apply.

- Chewa
- Lomwe
- Yao
- Tumbuka
- White
- other African tribe, specify: _____
- other, specify: _____

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

code

Demographics—Malawi (DMM-1)

Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 6:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **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 category boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DMZ-1 (014)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number			Chk

Demographics—Zimbabwe

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

	1st	2nd	3rd	4th	5th	other, specify: _____
Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1. What is your highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- attended college or university

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

yes no

3. Do you own your home?

4. How many rooms are in your household?

5. What is your ethnic group or tribe?

Read categories, mark all that apply.

- Shona
- Ndebele
- White
- other African tribe, specify: _____
- other, specify: _____

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

code

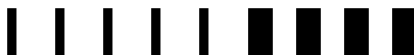
Demographics—Zimbabwe (DMZ-1)

Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 5:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **Item 6:** 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 category boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DMS-1 (015)

Participant ID

- -

Site Number Participant Number Chk

Demographics—South Africa

Visit Date

dd MMM yy

	1st	2nd	3rd	4th	5th	other, specify: _____
Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1. What is your highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- attended college or university

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

yes no

3. Do you own your home?

4. How many rooms are in your household?

5. What is your ethnic group or tribe?

Read categories, mark all that apply.

- Zulu
- Xhosa
- Indian
- Colored
- White
- other African tribe, specify: _____
- other, specify: _____

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

code

Demographics—South Africa (DMS-1)

Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 5:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **Item 6:** 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 category boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DMB-1 (016)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Site Number			Participant Number				Chk	

Demographics—Zambia

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

	1st	2nd	3rd	4th	5th	other, specify: _____
Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1. What is your highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- attended college or university

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

yes no

3. Do you own your home?

4. How many rooms are in your household?

5. What is your ethnic group or tribe?

Read categories, mark all that apply.

- Bemba
- Nyanja
- Tonga
- Lozi
- White
- other African tribe, specify: _____
- other, specify: _____

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

code

Demographics—Zambia (DMB-1)

Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 5:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **Item 6:** 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 category boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) DMU-1 (018)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk

Demographics—United States

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	1st	2nd	3rd	4th	5th	other, specify: _____

1. What is your highest level of education?

- | | |
|-------------------------------------------------------|---------------------------------------------------------|
| <input type="checkbox"/> no schooling | <input type="checkbox"/> secondary, not complete |
| <input type="checkbox"/> primary school, not complete | <input type="checkbox"/> secondary, complete |
| <input type="checkbox"/> primary school, complete | <input type="checkbox"/> 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? *yes* *no* → **If no, go to item 5.**

1 more than 1

4a. How many unplanned pregnancies have you had?

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

6. What is your race? **Read categories, 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

Demographics—United States (DMU-1)

Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of people, including children, living in the participant's household.
- **Item 2a:** Record only the number of children living in the participant's household.
- **Item 3:** Record the **average** monthly income for the household (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

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

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

- **Item 4:** Record whether or not the participant has ever had a known unplanned pregnancy.
- **Item 5: Note:** *Latina is not a race.*
- **Item 6:** This item asks about race. Read each category to the participant 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 or is unable to give a response to any item(s), draw a line through the response category boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) EBA-1 (071)

Participant ID

- -
 Site Number Participant Number Chk

Enrollment Behavior Assessment

Visit Date

dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. There are no right or wrong answers to these questions. We will ask you these same types of questions every 3 months while you are in the study. 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 3 months, how many sex partners have you had?
 By sex partner, I mean someone with whom you have had vaginal or anal sex. # of partners

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

Enrollment Behavior Assessment (EBA-1), Page 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 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.

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. Review these items for mathematical accuracy while the participant is still present. Update the responses accordingly if applicable.
- **Item 3:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had vaginal sex, draw a line through the unknown response boxes, write "don't know" in the white space next to the item, and initial and date.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) EBA-2 (072)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number							Chk

Enrollment Behavior Assessment

4. The last time you had vaginal sex:
- | | | |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------------|
| | <i>yes</i> | <i>no</i> |
| 4a. did you or your partner use a male condom? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4b. did you use a female condom? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4c. did you wash inside or douche inside your vagina within one hour before having vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4d. did you wash inside or douche inside your vagina within one hour after having vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4e. did you insert paper, cloth, cotton, or cotton wool?..... | <input type="checkbox"/> | <input type="checkbox"/> |
| 4f. did you insert any other object or substance into your vagina within one hour before or during vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| | ▶ If yes, specify: | |
| | <i>Local Language:</i> _____ | |
| | <i>English:</i> _____ | |
| 4g. did you insert any other object or substance into your vagina within one hour after vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| | ▶ If yes, specify: | |
| | <i>Local Language:</i> _____ | |
| | <i>English:</i> _____ | |
| 4h. did you receive money, gifts, material goods, drugs, or shelter for this vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |

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.

- | | | |
|--------------------------------------|----------------------------------------------------------|--------------------------|
| | <i>yes</i> | <i>no</i> |
| 5. Have you ever had anal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| | ▶ If no, go to statement before item 9 on page 3. | |

Enrollment Behavior Assessment (EBA-2), Page 2

Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant’s answer. If ‘yes’ is marked for items 4f or 4g, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) EBA-3 (073)

Participant ID

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

Enrollment Behavior Assessment

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

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

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

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

8. The last time you had anal sex: 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 receive money, gifts, material goods, drugs, or shelter for this anal sex? ... yes no

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

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

9a-9g. List of items with yes/no checkboxes and # of times boxes

Local Language: English:

Enrollment Behavior Assessment (EBA-3), Page 3

Item-specific Instructions:

- **Item 7:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had anal sex, draw a line through the unknown response boxes, and 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 answer.
- **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” boxes. If yes is marked for item 9g, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) EBA-4 (074)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Enrollment Behavior Assessment

10. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **Mark "none" or all that apply.**

- none
- family planning pills or birth control pills
- injectable contraceptives (such as Depo-Provera)
- Norplant inserts
- vaginal ring
- natural methods such as the withdrawal or rhythm method
- male condoms
- spermicide
- surgical sterilization (tubal ligation)
- other, specify:
Local Language: _____
English: _____

Enrollment Behavior Assessment (EBA-4), Page 4

Item-specific Instructions:

- **Item 10:** These response options are not read aloud to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim response. Also provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

HPTN 035 Ph II/IIb Microbe (013) FBA-1 (181)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment

Visit Date

dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. There are no right or wrong answers to these questions. We will ask you these same questions every 3 months while you are in the study. 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 3 months, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex.....

of partners

If 0, go to statement before item 9 on page 4.

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

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

of times

If 0, go to item 3 on page 2.

All Gel cohorts, go to statement before item 2b.

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

Condom-only cohort, go to item 3 on page 2.

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

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

of times

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

of times

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

of times

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

of times

Follow-up Behavior Assessment (FBA-1), Page 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, and it is administered at each Quarterly visit and at the Study Exit visit.

Interview tips:

See Section 13.5 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. This is particularly important for items 2 through 2e.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for a more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study + 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," 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 3 months, record "00" for this item and continue the interview by reading the statement before item 9 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 6 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 2:** Use leading zeros when needed so that all the boxes are filled.
- **Item 2a:** This item is completed only for participants assigned to condom-only (no gel). Use leading zeros when needed so that all the boxes are filled. Once this item has been completed for condom-only participants, check that the responses are consistent with the response to item 2, and go to item 3. For participants assigned to study gel, leave this item blank and go to the statement before item 2b.
- **Items 2b-2e:** These items are completed only for participants assigned to study gel. Use leading zeros when needed so that all the boxes are filled. After recording the participant's responses, check that the responses are consistent with the response to item 2. For participants assigned to condom-only, leave these items blank.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 035 Ph II/IIb Microbe (013) FBA-2 (182)

Participant ID

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

Follow-up Behavior Assessment

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

4. The last time you had vaginal sex: yes no

4a. did you or your partner use a male condom? [] []

4b. did you use a female condom? [] []

4c. did you use study gel? [] []

4d. did you wash inside or douche inside your vagina within one hour before having vaginal sex? [] []

4e. did you wash inside or douche inside your vagina within one hour after having vaginal sex? [] []

4f. did you insert paper, cloth, cotton, or cotton wool? [] []

4g. did you insert any other object or substance into your vagina within one hour before or during vaginal sex? [] []

→ If yes, specify:

Local Language: _____

English: _____

4h. did you insert any other object or substance into your vagina within one hour after vaginal sex? [] []

→ If yes, specify:

Local Language: _____

English: _____

4i. did you receive money, gifts, material goods, drugs, or shelter for this vaginal sex? [] []

Follow-up Behavior Assessment (FBA-2), Page 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:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had vaginal sex, 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 4:** Read each item 4a–4i aloud and mark the participant’s answer. If yes is marked for items 4g or 4h, be sure to record the participant’s verbatim response. Also 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 035 Ph II/IIb Microbe (013) FBA-3 (183)

Participant ID

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

Follow-up Behavior Assessment

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 3 months, did you have anal sex? ... [] yes [] no If no, go to statement before item 9 on page 4.
5a. In the past 3 months, did you ever use study gel anally during anal sex? ... [] yes [] no If no, go to item 6.
5b. How many times did you use study gel anally during anal sex?.... [][]
6. In the past week, did you have anal sex? ... [] yes [] no If no, go to item 7.
I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.
6a. In the past week, did you ever, even once, have anal sex without a condom?..... [] yes [] no
7. When was the last time you had anal sex? [][] dd [][][] MMM [][] yy
8. The last time you had anal sex:
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 receive money, gifts, material goods, drugs, or shelter for this anal sex?..... [] yes [] no

Follow-up Behavior Assessment (FBA-3), Page 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 5b:** Use leading zeros when needed so that all the boxes are filled.
- **Item 7:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had anal sex, draw a line through the unknown response boxes, and 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.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

1

HPTN 035 Ph II/IIb Microbe (013) FBA-4 (184)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number							Chk

Follow-up Behavior Assessment

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?

	yes	no	# of times
9a. water?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9b. water with vinegar? <i>Note for U.S. site: This includes all commercial douching products.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9c. water with soap?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9d. paper, cloth, cotton, or cotton wool?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9e. tampons?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9f. fingers without anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9g. anything else? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
<i>Local Language:</i> _____			
<i>English:</i> _____			

Follow-up Behavior Assessment (FBA-4), Page 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–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” boxes. If yes is marked for item 9g, be sure to record the participant’s verbatim response. Also 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

HPTN 035 Ph II/IIb Microbe (013) FBA-5 (185)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment

10. Which family planning method or methods are you currently using? **Mark "none" or all that apply.**

- none
- family planning pills or birth control pills
- injectable contraceptives (such as Depo-Provera)
- Norplant inserts
- vaginal ring
- diaphragm
- natural methods such as the withdrawal or rhythm method
- male condoms
- spermicide
- surgical sterilization (tubal ligation)
- other, specify:
Local Language: _____
English: _____

Follow-up Behavior Assessment (FBA-5), Page 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 10:** Family planning methods reported at previous visits should always be reviewed before asking this question. These response options are not read aloud to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim response. Also 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

HPTN 035 Ph II/IIb Microbe (013) FBA-6 (186)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number							Chk

Follow-up Behavior Assessment

For this last question, I am going to ask you about experiences you may have had or are having while in this study.

11. In the past 3 months, have you had any problems with the following people as a result of being in this study:

	<i>yes</i>	<i>no</i>
11a. your spouse or partner?.....	<input type="checkbox"/>	<input type="checkbox"/>
11b. people at home/family?.....	<input type="checkbox"/>	<input type="checkbox"/>
11c. your friends/personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>
11d. people at work?	<input type="checkbox"/>	<input type="checkbox"/>
11e. people at school?.....	<input type="checkbox"/>	<input type="checkbox"/>
11f. your doctor, nurse, midwife, or other health care provider?.....	<input type="checkbox"/>	<input type="checkbox"/>
11g. your landlord or property owner?.....	<input type="checkbox"/>	<input type="checkbox"/>
11h. other people? Specify:	<input type="checkbox"/>	<input type="checkbox"/>

Local Language: _____

English: _____

If no to all, end of form.

12. Please describe the problem:

Local Language: _____

English: _____

Follow-up Behavior Assessment (FBA-6), Page 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 11:** Read each item 11a–11h aloud and mark the participant’s response. If “yes” is marked for item 11h, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided. If the participant responds “no” to each item 11a-11h, end the form and leave item 12 blank.
- **Item 12:** Describe the problem. Do **not** record the participant’s verbatim response - describe the problem in your own words so that the nature of the problem is clear. 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

HPTN 035 Ph II/IIb Microbe (013) FBA-7 (187)

Participant ID

- -
Site Number Participant Number Chk

Follow-up Behavior Assessment

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

13a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem. *yes* *no*

no → **If no, go to item 13b.**

13a1. Please describe the problem:

Local Language: _____

English: _____

13b. physical harm to you? For example, has anyone physically hurt you as a result of this problem?..... *yes* *no*

no → **If no, go to item 13c.**

13b1. Please describe the problem:

Local Language: _____

English: _____

13c. 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*

no → **If no, go to item 13d.**

13c1. Please describe the problem:

Local Language: _____

English: _____

13d. physical or other harm to your children?..... *yes* *no*

no → **If no, go to item 14.**

13d1. Please describe the problem:

Local Language: _____

English: _____

14. Interviewer: Did any of these problem(s) require reporting as an Adverse Event (AE)?..... *yes* *no*

yes *no* → **AE Log Page #**

Follow-up Behavior Assessment (FBA-7), Page 7

Item-specific Instructions:

If no social harms were reported by the participant at this visit (that is, form items 11a through 11h are all marked “no”), do not complete this page and do not fax this form page to SCHARP DataFax. Do be sure to fax all other form pages (pages 1 through 6) to SCHARP DataFax.

- **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 13a1, 13b1, 13c1, and 13d1:** Briefly 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.
- **Item 14:** This is not an interviewer-administered item. If any of the problems described in items 13a-13d resulted in an untoward physical event to the study participant requiring reporting as an adverse event, mark the “yes” box and record the matching AE Log page number in the box provided. If the social harm resulted in more than one AE Log page, contact SCHARP for instructions on how to document additional AE Log page numbers. If no AEs resulted from the social harm, mark the “no” box and leave the “AE Log Page #” box blank.

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

SAMPLE: Do NOT FAX TO DATAFAX



Visit Code [][] . []

1

HPTN 035 Ph II/Ib Microbe (013) FPS-1 (190)

Participant ID

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

Follow-up Partner Status

Visit Date

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

BEFORE BEGINNING THE INTERVIEW

Instructions: Review the participant's Demographics (DM-1) form and indicate whether she reported being married at Screening Part 1. One of the response boxes must be completed, this item cannot be left blank.

- Married at screening (DM-1 item 2 is marked yes) -> Read introductory statement then go to item 1.
Not married at screening (DM-1 item 2 is marked no) -> Read introductory statement then go to item 5.

No data recorded on this page: This item is in the upper right corner on pages 2 and 3 only. Mark this box only if no data are recorded on that specific page based on following skip patterns.

Thinking back to your very first interview for this study, we asked you some questions about whether you were married and about your sexual partner at that time. At today's visit, we would like to ask again about your marital status and sexual partners.

- 1. At your previous interview, you reported you were married. Are you married now? yes no
2. Are you married to the same husband you told us about at your first interview? don't know
3. Have you been living with your husband since your last interview?
4. Have you told your husband you are taking part in this study? Read response categories.
5. At your previous interview, you reported you were not married. Are you married now? yes no

Follow-up Partner Status (FPS-1)

Item-specific Instructions:

- **Items 1 and 5:** Record whether or not the participant is currently married.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [][] . []

[1]

HPTN 035 Ph II/IIb Microbe (013) FPS-2 (191)

Participant ID

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

Follow-up Partner Status

No data recorded on this page

NEW HUSBANDS

- 6. How old is your husband? years OR don't know
- 7. Are you currently living with your husband? yes no
- 8. Does your husband have more than one wife or sexual partner? don't know
- 9. Does your husband provide you with financial and/or material support?
- 10. What is your husband's average monthly income? OR don't know
- 11. What is your husband's highest level of education?
 - no schooling
 - primary school, not complete
 - primary school, complete
 - secondary school, not complete
 - secondary school, complete
 - attended college or university
 - don't know
- 12. When did you start having sex with your husband? Read response categories past year more than one year ago
- 13. Have you told your husband you are taking part in this study?
 - no —> **End of form.**
 - yes, I told him on the day when I joined the study —> **End of form.**
 - yes, sometime after I joined the study —> **End of form.**

Follow-up Partner Status (FPS-2)

Item-specific Instructions:

- **Item 6:** 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 9:** 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 10:** 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: 000214 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. If the husband is unemployed write "0000000" in the boxes provided.

SAMPLE: Do NOT FAX TO DATAFAX



Visit Code [][] . []

[1]

HPTN 035 Ph II/IIb Microbe (013) FPS-3 (192)

Participant ID

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

Follow-up Partner Status

No data recorded on this page

NEW SEXUAL PARTNERS

14. Do you currently have a male sexual partner? Read response categories.

- yes, I have a partner now and he is the same partner I had when I joined the study. —> Go to item 22.
- yes, I have a partner now but he is not the same partner I had when I joined the study.
- no —> End of form.

- 15. How old is your partner? [][] years OR [] don't know
- 16. Are you currently living with your partner? [] yes [] no
- 17. Does your partner have any other sexual partners? [] [] don't know
- 18. Does your partner provide you with financial and/or material support? [] [] don't know
- 19. What is your partner's average monthly income? [][][][][][] OR []

20. What is your partner's highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary school, not complete
- secondary school, complete
- attended college or university
- don't know

21. When did you start having sex with this partner? Read response categories. [] past year [] more than one year ago

22. Have you told your partner you are taking part in this study? Read response categories.

- no
- yes, I told him on the day when I joined the study
- yes, sometime after I joined the study

Follow-up Partner Status (FPS-3)

Item-specific Instructions:

- **Item 14:** 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 15–22) should be answered for the partner she considers to be her primary sexual partner.
- **Item 15:** 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 18:** 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 19:** 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. If the partner is unemployed write "0000000" in the boxes provided.

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

HPTN 035 Ph II/IIb Microbe (013) AA-1 (371)

Participant ID

--
Site Number Participant Number Chk

Acceptability Assessment

Visit Date

dd MMM yy

Item 1 is for condom-only cohort. All Gel cohorts, go to item 2.

1. If a gel like the ones being tested in this study is found to help prevent people from getting HIV, would you want to use it during sex?

yes no

1a. Why not?

Local Language: _____

English: _____

If yes, end of form.

End of form.

2. If your study gel is found to help prevent people from getting HIV, would you want to use it during sex?

yes no

2a. Why not?

Local Language: _____

English: _____

If yes, go to item 3.

3. What do you like about your study gel? **Mark all that apply.**

- may protect against HIV
- may protect against STDs/STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- it does not interrupt sex
- other, specify: Local Language: _____

English: _____

Acceptability Assessment (AA-1), Page 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 first Quarterly visit (Month 3) visit only.

Interview tips:

See Section 13.5 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.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for a more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study + 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," etc.
- **Item 1:** This item is completed only for participants assigned to condom-only (no gel). When item 1 is completed (condom-only participants), end the form. Record the Visit Code and PTID on page 2 of this form and fax all pages of this form to SCHARP DataFax. If the participant is assigned to study gel, skip item 1 (leave it blank) and start the interview with item 2.
- **Item 3:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date. If the participant responds "nothing" to this item (meaning there is nothing she likes about the gel), mark the "other, specify" box and record "nothing" on the line provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code

HPTN 035 Ph II/IIb Microbe (013) AA-2 (372)

Participant ID

--
Site Number Participant Number Chk

Acceptability Assessment

4. What do you not like about your study gel? **Mark all that apply.**

- messy
- interrupts sex
- difficult to use, specify: *Local Language:* _____
English: _____
- remembering to use it before sex
- other, specify: *Local Language:* _____
English: _____

5. The last time you used your study gel, what were your partner's reactions to the gel? **Mark all that apply.**

- he liked it
- he did not like it
- he did not know I used the gel
- he knew I used the gel, but he had no reaction
- I don't know
- other, specify: *Local Language:* _____
English: _____

Acceptability Assessment (AA-2), Page 2

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. **For participants assigned to the condom-only arm,** record the Visit Code and PTID on this page, leave the rest of the page blank, and fax both pages of this form to SCHARP DataFax.
- **Items 4 and 5:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date. If the participant responds “nothing” to these items (meaning there is nothing she does not like about the gel), mark the “other, specify” box and record “nothing” on the line provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) SAA-1 (471)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk

Study Exit Acceptability Assessment

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

Items 1–2b are for condom-only cohort. All Gel cohorts, go to item 3.

1. If a gel like the ones being tested in this study is found to help prevent people from getting HIV, would you want to use it during sex?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If yes, go to item 2.

1a. Why not?

Local Language: _____

English: _____

2. During your participation, did you ever use anyone else's gel?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If no, end of form.

2a. Approximately how many times did you use someone else's gel?

1 time	2–5 times	6–10 times	> 10 times
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2b. Can you tell me why you used another participant's gel?

Local Language: _____

English: _____

Condom-only cohort, end of form.

3. If your study gel is found to help prevent people from getting HIV, would you want to use it during sex?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If yes, go to item 4.

3a. Why not?

Local Language: _____

English: _____

Study Exit Acceptability Assessment (SAA-1), Page 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 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.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for a more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study + 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," etc.
- **Items 1 and 2:** These items are completed only for participants assigned to condom-only (no gel). When items 1 and 2 are completed (condom-only participants), end the form. Record the Visit Code and PTID on pages 2 and 3 of this form and fax all 3 pages of this form to SCHARP DataFax. If the participant is assigned to study gel, skip these items (leave them blank) and start the interview with item 3.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) SAA-2 (472)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Study Exit Acceptability Assessment

4. What do you like about your study gel? **Mark all that apply.**

- may protect against HIV
- may protect against STDs/STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- it does not interrupt sex
- other, specify: *Local Language:* _____
English: _____

5. What do you not like about your study gel? **Mark all that apply.**

- messy
- interrupts sex
- difficult to use, specify: *Local Language:* _____
English: _____
- remembering to use it before sex
- other, specify: *Local Language:* _____
English: _____

Study Exit Acceptability Assessment (SAA-2), Page 2

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. **For participants assigned to the condom-only arm,** record the Visit Code and PTID on this page, leave the rest of the page blank, and fax all 3 pages of this form to SCHARP DataFax.
- **Items 4 and 5:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date. If the participant responds “nothing” to these items (meaning there is nothing she likes or does not like about the gel), mark the “other, specify” box and record “nothing” on the line provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) SAA-3 (473)

Participant ID

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

Study Exit Acceptability Assessment

6. The last time you used your study gel, what were your partner's reactions to the gel? Mark all that apply.

- 6. The last time you used your study gel, what were your partner's reactions to the gel? Mark all that apply.
- he liked it
- he did not like it
- he did not know I used the gel
- he knew I used the gel, but he had no reaction
- I don't know
- other, specify: Local Language: English:

7. As you know, none of the participants in this study know whether they were given BufferGel, PRO 2000 Gel, or placebo gel. Now that your participation in the study is over, we would like you to say which study gel you think you got. Of the three gels used in this study, which one do you think you have been using: BufferGel, PRO 2000 Gel, or placebo gel?

Form for question 7 with checkboxes for BufferGel, Pro 2000 Gel, and placebo

8. During your participation, did you ever use anyone else's gel?

Form for question 8 with checkboxes for yes and no, and instruction 'If no, go to item 9.'

8a. Approximately how many times did you use someone else's gel?

Form for question 8a with checkboxes for 1 time, 2-5 times, 6-10 times, and > 10 times

8b. Can you tell me why you used another participant's gel?

Form for question 8b with lines for Local Language and English responses

9. Do you know if anyone else, even someone who wasn't in the study, used your gel?

Form for question 9 with checkboxes for yes and no

Study Exit Acceptability Assessment (SAA-3), Page 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. **For participants assigned to the condom-only arm,** record the Visit Code and PTID on this page, leave the rest of the page blank, and fax all 3 pages of this form to SCHARP DataFax.
- **Item 6:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date.
- **Item 7:** This item is completed only for participants assigned to study gel. “Don’t know” is **not** an acceptable response for this item—please work with the participant to identify which study gel she thinks she has been using, and mark the corresponding response box.

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

SAMPLE: DO NOT FAX TO DATAFAX

NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

HPTN 035 Ph II/IIb Microbe (013)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Participant Number					Chk

Screening Part 1 Eligibility

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

Screening Attempt:	1st	2nd	3rd	4th	5th	other, specify: _____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?

- Are you currently participating in any other study of a vaginally-applied product?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant is ineligible.**
- Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant is ineligible.**
- In the past 6 weeks, have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant may be ineligible at this time.**
- Do you plan to become pregnant in the next 30 months (2 1/2 years)?

yes	no	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant is ineligible.**
- Do you plan to move away from this area in the next 30 months (2 1/2 years)?

yes	no	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant is ineligible.**
- Do you plan to be away from this area for more than 3 months in a row (this includes seasonal travel) in the next 30 months (2 1/2 years)?

yes	no	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant is ineligible.**
- In the past 12 months (1 year), have you used a needle to inject drugs that were not prescribed to you by a medical professional?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

→ **If yes, participant is ineligible.**

Screening Part 1 Eligibility (non-DataFax), Page 1

This interviewer-administered form is used to document the participant's eligibility for the study. If, at any point during the administration of this form, the participant is found to be ineligible, continue administering both pages of this form so that the interview is not stopped abruptly. 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 1 Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 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.*

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** This item is intended to determine if the participant has had any adverse or bad (that is, allergic or irritant) reactions to latex.
- **Item 7:** This item is intended to determine if the participant has used *non-therapeutic* injection drugs (that is, has she injected drugs that were not given to her for a medical purpose) in the 12 months prior to this visit.

SAMPLE: DO NOT FAX TO DATAFAX

NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

HPTN 035 Ph II/IIb Microbe (013)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk

Screening Part 1 Eligibility

	<i>1st</i>	<i>2nd</i>	<i>3rd</i>	<i>4th</i>	<i>5th</i>	<i>other, specify: _____</i>
Screening Attempt:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I am now going to ask you some questions about your sexual behavior. These questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

Are you ready to continue?

8. In the past 3 months, 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.**
9. In the past 2 weeks, how many times have you had vaginal sex? → **If > 28, participant is ineligible.**

Comments: _____

Screening Part 1 Eligibility (non-DataFax), Page 2

Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Item 8:** This item determines if the participant is sexually active as defined by the protocol.
- **Comments:** Record any necessary comments on the comments lines at the bottom of the form.

SAMPLE: DO NOT FAX TO DATAFAX

NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

HPTN 035 Ph II/IIb Microbe (013)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk

Screening Part 2 Eligibility

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

Screening Attempt:	1st	2nd	3rd	4th	5th	other, specify: _____
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Is this visit being conducted within 30 days of when the participant provided written informed consent for screening? ...

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- Is the participant HIV-negative based on testing performed by study staff?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- Does the participant have documented negative pregnancy tests performed by study staff at all Screening Visits, including this one?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- Phase II participants only:** Does the participant have any Grade 3 or higher laboratory abnormalities based on hematology, liver and renal function, and coagulation testing performed by study staff?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible. End of form.
- Phase IIb participants only:** Does the participant have any Grade 4 or higher laboratory abnormalities based on hematology and coagulation testing performed by study staff?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible. End of form.

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

- Are you currently participating in any other study of a vaginally-applied product?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible.
- In the past 6 weeks, have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible. End of form.

Complete item 8 after reviewing all Screening forms.

- Does the participant have any condition that, based on 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?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	

If yes, participant is ineligible. Specify reason:

Screening Part 2 Eligibility (non-DataFax)

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 6 and 7), while other items are not. 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 for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 13.5 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:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Items 1–5:** These items are NOT interviewer administered and should not be read aloud to the participant.
- **Item 4:** This item is completed only for participants screening for the Phase II portion of the study. If the participant is being screened for phase IIb, skip item 4 (leave it blank).
- **Item 5:** This item is completed only for participants screening for the Phase IIb portion of the study. If the participant is being screening for Phase II, skip item 5 (leave it blank).
- **Items 6 and 7:** These items were also asked during the Screening Part 1 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.
- **Item 8:** This is NOT an interviewer-administered item. This item should be completed by the site investigator or his/her designee once the Screening Part 2 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 qualified candidate for the study, mark the "yes" box, record the reason in the space provided, and do not enroll the participant in the study.