SAMPLE: DO NOT FAX TO DATAFAX

MTN 004 (136) DEM-1 (001)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Demographics

Form Completion Date

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

dd *MMM* *yy*

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

1. What is your date of birth?..... [ ][ ] [ ][ ][ ] [ ][ ] → If unknown, record age: [ ][ ]

dd *MMM* *yy* *years*

2. What is your gender? ..... *male* ☐ *female* ☒

NOT APPLICABLE FOR THIS PROTOCOL.

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

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

- ☐ 4a. American Indian or Alaskan Native
- ☐ 4b. Asian
- ☐ 4c. Black or African American
- ☐ 4d. Native Hawaiian or Other Pacific Islander
- ☐ 4e. White
- ☐ 4f. Mixed
- ☐ 4g. other, specify: _____

Demographics (DEM-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 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

***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.*

General Interviewer Tips:

See Section 14.5 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 24 years at the time of screening and enrollment, inclusive, and verified per site SOP, to be eligible for study participation.*
- **Item 4:** This item must be self-identified by the participant. 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.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening 1 Visit Eligibility

Form Completion Date

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

dd *MMM* *yy*

Complete items 1–3 before the interview.

		yes	no	
1.	*Was the participant willing and able to provide a written informed consent for screening?*	☐	☐ →	***If no, participant is ineligible. End of form.***
2.	*Was the participant previously enrolled in this study?*	☐ →	☐	***If yes, participant is ineligible. End of form.***
3.	*Is documentation of a normal Pap test result in the last 12 calendar months available?*	☐	☐ →	***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.

		yes	no	
4.	Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?	☐	☐	
5.	Has your male sex partner ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?	☐	☐	
6.	Have you ever had an adverse or bad reaction to any component of the study product (VivaGel and/or applicator)?	☐	☐	
7.	Are you currently using oral and/or vaginal antibiotics or antifungal medications?	☐	☐	
8.	Are you breastfeeding?	☐	☐	
9.	Do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation?	☐	☐	***If yes to any, participant is ineligible.***
10.	In the past month (30 days), how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.	[ ][ ] →		***If < 4, participant is ineligible. Go to item 12 on page 2.***

Screening 1 Visit Eligibility – Page 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 4–25), while other items are not (items 1–3 and 26–27). 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 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 14.5 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 25. 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 12 calendar months 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 12 calendar months prior to screening, conduct a Pap Smear test for this participant as part of the Screening 1 Visit pelvic exam.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐
Site Number Participant Number Chk

Screening 1 Visit Eligibility

11. Do you anticipate having vaginal sex at the same approximate frequency during your study participation? ..... yes ☐ no ☐ → ***If no, participant is ineligible.***

12. Do you have a regular menstrual cycle that is 21 days or longer? yes ☐ no ☐ → ***If yes, go to item 13.***

12a. Is it because of the birth control you are using, such as Depo-Provera or Norplant? ..... yes ☐ no ☐ → ***If no, participant is ineligible.***

13. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? ..... yes ☐ no ☐ → ***If no, go to item 14.***

13a. When did you last give birth, have a miscarriage or abortion? ☐☐ ☐☐☐ ☐☐
dd MMM yy

If date is within the last 54 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last pregnancy outcome.

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

14a. When did you last have gynecological surgery? ..... ☐☐ ☐☐☐ ☐☐
dd MMM yy

If date is within the last 54 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last gynecological surgery.

Screening 1 Visit Eligibility – Page 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 4–25), while other items are not (items 1–3 and 26–27). 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 Visit Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 14.5 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.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening 1 Visit Eligibility

15. In the past 6 months, have you been diagnosed or treated for any sexually transmitted infection, other than genital herpes (HSV) or pelvic inflammatory disease? ..... yes ☐ no ☐ → ***If no, go to item 16.***

    15a. When were you last diagnosed with or treated for a sexually transmitted infection? ..... [ ][ ] [ ][ ][ ] [ ][ ] (dd MMM yy)

If date is within 6 months of enrollment, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 6 months of STI diagnosis or treatment.

16. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ... yes ☐ no ☐ → ***If no, go to item 17.***

    16a. When did you last inject drugs that were not prescribed to you? ..... [ ][ ] [ ][ ][ ] [ ][ ] (dd MMM yy)

If date is within 12 calendar months of enrollment, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within one year of injection drug use.

17. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug (including vaccine studies)? ..... yes ☐ no ☐ → ***If no, go to item 18.***

    17a. When did you last participate in one of these studies? ..... [ ][ ] [ ][ ][ ] [ ][ ] (dd MMM yy)

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

Screening 1 Visit Eligibility – Page 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 4–25), while other items are not (items 1–3 and 26–27). 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 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 14.5 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.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening 1 Visit Eligibility

	yes	no
18. Do you agree to not participate in any study that uses spermicides, vaginal microbicides, or any other device or drug (including vaccine studies) while participating in this study?	☐	☐
19. From today, through one month after you finish using study products, do you agree 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?	☐	☐
20. Do you agree to have your partner use study-provided condoms each time you have intercourse during your study participation?	☐	☐
21. Do you agree to not receive oral or anal sex during your study participation?	☐	☐
22. From 72 hours before your enrollment through the end of your study participation, do you agree to not use any intravaginal products (other than tampons) or devices, including sex toys?	☐	☐
23. Are you willing to use the study product, which is VivaGel gel, or VivaGel placebo, or HEC gel twice a day for 14 days?	☐	☐
24. Are you willing to attend all scheduled study visits?	☐	☐
25. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws?	☐	☐

If no to any, participant is ineligible.

Complete item 26 when Screening 1 urine hCG result is available.

	yes	no
26. *Is the participant pregnant?*	☐	☐

If yes, participant is ineligible.

	yes	no
27. *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?*	☐	☐

If yes, participant is ineligible.

Screening 1 Visit Eligibility – Page 4 (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 4–25), while other items are not (items 1–3 and 26–27). 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 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 14.5 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 19:** If the participant's chose effective method of contraception is sexual activity with a vasectomized partner, site staff must obtain documentation of the vasectomy in order to enroll the participant.
- **Item 26:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening 1 Visit urine hCG result here.
- **Item 27:** 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 1 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.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN 004 (136)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening 2 Visit/ Enrollment Eligibility

Visit Date

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

dd *MMM* *yy*

12. 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.***

13. Do you have a regular menstrual cycle that is 21 days or longer? ..... *yes* ☐ *no* ☐ → ***If yes, go to statement above item 14.***

13a. 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 14 when Screening 2 urine HCG result is available.

14. *Is the participant pregnant?* ..... *yes* ☐ *no* ☐ → ***If yes, participant is ineligible.***

Complete item 15 after reviewing all Screening forms.

15. *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.***

Screening 2 Visit/Enrollment Eligibility – Page 2 (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 1–13a), while other items are not (items 1 and 14–15). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *If the Enrollment Visit does not take place on the say day as the Screening 2 Visit, all items on this form must be re-assessed on the day of enrollment (prior to enrollment) to confirm participant eligibility. A pregnancy test must be repeated on the day of enrollment (prior to enrollment) and the results should be recorded in the participant chart notes only.*

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 14.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

General Interviewer Tips:

See Section 14.5 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 14:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening 2 Visit urine hCG result here.
- **Item 15:** 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 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 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.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN 004 (136) SGA-1 (173)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Study Gel Adherence

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

I know that you are counseled to insert the study gel in the morning and in the evening each day, but I also know that this is not always possible.

1. Since your last regularly scheduled study visit, how many applicators have you used? ..... ☐☐ *# applicators*

2. Since your last regularly scheduled study visit, was there ever a day in which you used the study gel less than two times? ..... *yes* ☐ *no* ☐ → ***If no, end of form.***

2a. How many days did you use the study gel less than two times? ..... ☐☐ *# days*

Comments: _____

_____

_____

☐☐☐☒ 26-MAR-07

N:\hivnet\forms\MTN_004\forms\m004_study_gel_adherence.fm

0 1 Language

_____ Staff Initials / Date

Study Gel Adherence (SGA-1)

This form is used to collect information on study gel adherence from study participants. This is an interviewer-administered form, and it is administered at the one-week and two-week clinic visits. Note: If the participant misses her two-week clinic visit, administer this form at her three-week clinic visit.

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:** Record the total number of days since the participant's last regularly scheduled visit that she reports using the study gel less than twice a day. The number of days reported should not exceed the number of days since the participant's last regularly scheduled visit.

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

MTN 004 (136) AA-1 (272)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Acceptability Assessment

Visit Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

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

1. If your study gel is found to protect people from getting HIV, how likely would you be to use it during vaginal intercourse?

Showcard #1 *very likely* ☐ *likely* ☐ *unlikely* ☐ *very unlikely* ☐

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

- ☐ 2a. no response
- ☐ 2b. nothing
- ☐ 2c. may protect against HIV
- ☐ 2d. may protect against STIs
- ☐ 2e. can use without partner's knowledge
- ☐ 2f. easy to use
- ☐ 2g. method is under her control
- ☐ 2h. made sex more pleasurable
- ☐ 2i. did not interrupt sex
- ☐ 2j. appearance/smell
- ☐ 2k. other, specify: ..... *Local Language:* _____

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

2l. 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: _____

Acceptability Assessment (AA-1)

This form is used to collected study gel acceptability information from study participants. This is an interviewer-administered form, and it is administered only once to each enrolled participant at her Two-week Clinic Visit.

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:** If the participant refuses or is unable to give a response to any item(s), mark the "no response" box.
- **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 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 2l blank and go to item 3.
- **Item 2l:** 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.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN 004 (136) AA-2 (273)

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Acceptability Assessment

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

☐ 3a. no response
☐ 3b. nothing
☐ 3c. messy
☐ 3d. interrupted sex
☐ 3e. made sex less pleasurable
☐ 3f. difficult to use, specify:
Local Language:
_____
English:
_____
☐ 3g. remembering to use it
☐ 3h. difficult to store and/or discard
☐ 3i. appearance/smell
☐ 3j. other, specify:
Local Language:
_____
English:
_____

→ ***If only one response box is marked, end of form.***

3k. 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: _____

☐ ☐ ☐ ☒ 26-MAR-07

N:\hivnet\forms\MTN_004\forms\m004_assess_acceptability.fm

01 Language

Staff Initials / Date

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 3:** If the participant refuses or is unable to give a response to any item(s), mark the "no response" box.
- **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 3k blank.
- **Item 3k: 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.

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.*