

Page 1 of 2

dd
 MMM
 yy

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

1. What is your date of birth?.....
- dd MMM yy → If unknown, record age:
2. What is your gender?
- male female
- yes no
3. Are you currently married?
- yes no
4. Do you currently have a regular male sex partner?
- yes no
- 4a. How old is he?
- years don't know
- 4b. Are you currently living with him?
- yes no
- 4c. Does he have more than one sex partner?
- yes no don't know
- 4d. Does he provide you with financial and/or material support?
- yes no
- 4e. What is his average monthly income?
- Record in local currency. don't know no income

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 the Study-specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers.
- **Item 4:** Record whether or not the participant **currently** has a regular male sex partner.
- **Item 4a:** If the participant does not know her husband's or regular male sex partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 4d:** Record whether or not the participant's husband or regular male sex partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 4e:** Record the husband's or regular male sex 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 husband's or regular male sex 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.

SAMPLE *DO NOT FAX
TO DATAFAX*

MTN005 IVR Ring (148)

DEM-2 (002)

Page 2 of 2

Participant ID

Site Number			Participant Number				Chk		

Demographics

4f. What is his highest level of education?

U.S.

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

INDIA

- ☐ no schooling
- ☐ 1-3
- ☐ 4, complete
- ☐ 5-9
- ☐ 10, complete
- ☐ > 10
- ☐ don't know

5. Do you earn an income of your own?

yes

no

☐☐➔ **If no, end of form.**

5a. What is your average monthly income?

Record in local currency

--	--	--	--	--	--	--	--

don't know

☐

5b. How do you earn your income?

Mark all that apply.....

formal
employment☐self-
employed☐other,
specify☐

Local Language: _____

English: _____

Demographics (DEM-2)

Item-specific Instructions:

- **Item 4f:** Record the primary partner's highest level of education in the box corresponding to the participant's site country (U.S. or India). If the participant does not know her primary partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box that corresponds to the appropriate site country.
- **Item 5a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

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

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

- **Item 5b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE *DO NOT FAX
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MTN005 IVR Ring (148)



DMI-1 (020)

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Participant ID

--	--	--	--	--	--	--	--	--	--

Site Number Participant Number Chk

Demographics-India

Visit Date

--	--	--	--	--	--

dd MMM yy

1. What is your highest level of education?

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

2. Do you own your home?

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

3. How many rooms are in your household?

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

of rooms

4. Do you have a private bathroom within your household?

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

5. Do you have a private toilet within your household, use a toilet at home, a public toilet, and/or other?

yes	no	other	→ If no, go to item 6.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

5a. Is it an Indian or Western-style toilet?

Indian	Western-style
<input type="checkbox"/>	<input type="checkbox"/>

6. What is your ethnic group? *Read categories aloud. Mark all that apply.*

- ☐ Asian
- ☐ other, specify: *Local Language:* _____
- English:* _____

7. What is your religion?

- ☐ Hindu ☐ Buddhist
- ☐ Muslim ☐ other, specify: *Local Language:* _____
- ☐ Christian *English:* _____

Demographics–India (DMI-1)

This is an interviewer-administered form that is used to collect additional demographic and socioeconomic information from participants in India.

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

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

Item-specific Instructions:

- **Item 4:** A bathroom can be a space with a bath, sink, and/or toilet.
- **Item 6:** 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, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.
- **Item 7:** If the participant answers a religion other than the four religions listed, mark the "other, specify" box, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE *DO NOT FAX
TO DATAFAX*

MTN005 IVR Ring (148)

DMU-1 (018)

Page 1 of 1

Participant ID

Site Number			Participant Number				Chk

Demographics–United States**Visit Date**

dd		MMM		yy	

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, including children, live in your household?

--	--

2a. How many are children?

--	--

3. What is your household's average monthly income?
This includes income from all sources, even income from people who may not live in the household.

--	--	--	--	--	--	--

don't know *no income*
☐
☐

4. Do you consider yourself to be Latina or of Hispanic origin?

*yes**no*
☐
☐
5. What is your race? *Read categories aloud. Mark all that apply.*

- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ other, specify: _____

Demographics–United States (DMU-1)

This is an interviewer-administered form that is used to collect additional demographic and socioeconomic information from U.S. participants.

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

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

Item-specific Instructions:

- **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:** Per NIH policy, Latina or Hispanic is considered an ethnic category and not a race. It includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
- **Item 5:** This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "Other, specify" box and record her response on the line provided. If the participant states that she is "Latina", record this in item 4 only. Per NIH policy, "Latina" is an ethnic group and should not be recorded as a race category in item 5. For example, a participant originally from the Dominican Republic could have a response of "yes" to item 4, and "Black or African American" to item 5.

SAMPLE *DO NOT FAX
TO DATAFAX*

MTN005 IVR Ring (148)



RA-1 (170)

Visit Code 1

Page 1 of 1

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

Ring Adherence

Visit Date

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

1. Dates covered by this review: *First date* *Last date*
- dd MMM yy dd MMM yy

2. How many days of the diary were not completed (blank)? *# of days* **→ If 00, go to item 3.**

- 2a. What was the main reason the participant did not complete the diary every day?

Diary Code

yes no

3. Has the ring been out at any time during this review period? ☐ ☐ **→ If no, end of form.**

of times

- 3a. How many times total has the ring been out?

 → If 6 or more, add Comment after completing items 4a–4e.

4. For each instance the ring was out, complete the information below on when the ring was out, how long it was out, and why it was out.

	Date ring out			Duration ring was out			Is Duration an estimate?		Removal/Expulsion Code	If other, specify:
	dd	MMM	yy	days	hours	minutes	yes	no		
4a.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	_____
4b.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	_____
4c.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	_____
4d.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	_____
4e.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	_____

Comments: _____

☐ ☐ ☐ ☒ 15-FEB-11

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 01

Language

Staff Initials / Date

Ring Adherence (RA-1)

Purpose: To collection information on ring adherence.

General Information/Instructions: This form is completed only for participants randomized to the IVR arm. Complete this form based on discussion with the participant. As part of the discussion, the participant's diary should be reviewed and used to help identify instances where the ring has been outside of the participant's vagina. The information recorded on this form does not need to match the information on the participant's diary, especially in cases where the diary is incomplete and/or inaccurate.

Item-specific Instructions:

- **Item 1:** Record the dates of the time period being reviewed. These dates may not match the first and last dates on the diary in cases where these dates are missing from the diary. The dates should cover the time period since the last time this form was completed for the participant up through the previous day.
- **Item 2:** If the diary is not available (participant did not bring it), count each day as not completed (blank). Record "5" for item 2a.
- **Item 2a, Diary Incompletion Code:** Select from the codes below and record the code that best describes why the participant did not complete all days of her diary.

Diary Incompletion Codes

1 participant forgot	5 participant did not bring diary
2 participant felt the diary was too difficult to complete	6 participant did not have privacy to complete the diary
3 participant felt the diary took too long to complete	7 participant's partner did not want her to complete
4 participant felt she could remember without completing the diary	8 other reason not listed

- **Items 4a–4e, Removal/Expulsion Code:** Select from the codes below and record the code that best describes why the ring was taken out or came out on its own.

Removal/Expulsion Codes

Codes if the ring came out on its own
01 urinating
02 having a bowel movement
03 having sex or just finished having sex
04 physical activity or just finished physical activity
05 had or was expecting menses
06 other

Codes if the ring was taken out
10 ring caused discomfort
11 didn't feel it was correctly placed
12 had or was expecting menses
13 didn't want husband/male sex partner to know about ring
14 husband/male sex partner did not like ring and/or wanted her to remove ring
15 worried ring would be expelled during sex
16 didn't want to have vaginal sex with ring in vagina
17 site staff told her to remove ring
18 family member (other than husband/male sex partner) told her to remove ring
19 religious reasons
20 other

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

MTN005 IVR Ring (148)

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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

Enrollment Behavioral Eligibility**Form Completion Date**

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

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

1. In the past 7 days, have you inserted an intrauterine device (IUD)?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
 2. In the past 14 days, have you used, or do you plan to use a diaphragm, spermicide, contraceptive vaginal ring, vaginal antibiotic or antifungal medication, sex toys, lubricants or condoms that contain silicone, or menstrual cups while participating in this study?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 3. In the past 14 days, have you been douching or practicing another type of cleansing inside the vagina, or do you plan to during your study participation?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 4. Are you currently participating in or do you plan to participate in any study that involves any other device or drug while participating in this study?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 5. Do you plan to become pregnant while participating in this study?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
- If yes to any, participant is ineligible.**
6. Do you plan to continue using your current birth control method for the duration of your study participation?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
 7. In the last month (30 days), have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 8. Do you anticipate that you will have vaginal sex at least once a month during your study participation?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
- If no to any, participant is ineligible.**

Enrollment Behavioral Eligibility (non-DataFax)

This form is used to document the participant's behavioral eligibility for the study at enrollment. 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 Behavioral Eligibility form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

General Information/Instructions: If the participant provides a response indicating she is ineligible, continue to administer this form until all items are completed. Refrain from indicating to the participant the reason why she is ineligible.

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

MTN005 IVR Ring (148)

Page 1 of 2

Participant ID

Site Number			Participant Number				Chk		

Screening Behavioral Eligibility**Form Completion Date**

dd		MMM		yy	

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.

1. 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"/>
 2. Have you ever had an adverse or bad reaction to silicone?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 3. Have you ever had an adverse or bad reaction to titanium dioxide?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 4. Do you have a current male sex partner who has had an adverse or bad reaction to latex, silicone, or titanium dioxide?

<input type="checkbox"/>	<input type="checkbox"/>	don't know
		<input type="checkbox"/>
 5. Do you plan to become pregnant while participating in this study?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 6. Starting 14 days before your Enrollment Visit and continuing throughout your study participation, do you plan to use spermicides, diaphragms, contraceptive vaginal rings, vaginal antibiotics or antifungal medications, sex toys, lubricants or condoms that contain silicone, or menstrual cups?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
 7. Starting 14 days before your Enrollment Visit and continuing throughout your study participation, do you plan to douche or practice another type of cleansing inside the vagina?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
- If yes to any, participant is ineligible.**
8. Do you agree to not use any intravaginal product (except tampons) including douches, creams, lubricants, etc. starting 14 days before your Enrollment Visit and continuing throughout your participation in this study?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
 9. In the last month (30 days), have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.

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

→ If no to either, participant is ineligible.
 10. In the last month (30 days), how many male sexual partners have you had?

# of male sex partners	
<input type="checkbox"/>	<input type="checkbox"/>

→ If 3 or more, participant is ineligible.

Screening Behavioral Eligibility (non-DataFax) - Page 1

This form is used to document the participant's behavioral eligibility for the study at screening. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is ineligible.

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

MTN005 IVR Ring (148)

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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 Behavioral Eligibility**Form Completion Date**

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

11. Do you anticipate that you will have vaginal sex at least once a month during your study participation? ☐ *yes* ☐ *no*
12. Do you agree to not participate in any other study that involves a device or drug while participating in this study?..... ☐ ☐
13. For the duration of your study participation, are you willing to use one of the following types of birth control: hormonal contraceptives (except contraceptive vaginal rings), an intrauterine device (IUD)—inserted at least 7 days prior to enrollment, study provided male condoms, or sterilization of you or your male sex partner? ☐ ☐

→ ***If no to any, participant is ineligible.***

Screening Eligibility (non-DataFax) - Page 2

No additional instructions.