

**SAMPLE** *Do NOT FAX TO DATAFAX*



MTN-013/IPM 026 (150)

DEM-1 (001)

**Participant ID**

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

**Demographics**

**Visit Date**

<input type="text"/>					
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

**NOT APPLICABLE FOR THIS PROTOCOL.**

2. What is your gender?   
 male                  female   
                 

3. Are you currently married? .....                      
 yes                  no

**If yes, go to item 4a.**

4. Do you currently have a regular male sex partner? .....                      
 yes                  no

**If no, go to item 5 on page 2.**

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? .....                       
 don't know                  no income

4f. What is his highest level of education?   
 no schooling                   secondary, not complete   
 primary school, not complete                   secondary, complete   
 primary school, complete                   attended college or university   
 don't know

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## 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 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. 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
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- **Item 4f:** If the participant does not know her primary partner's highest level of education, record her best estimate.



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## Demographics (DEM-2)

### Item-specific Instructions:

- **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
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- **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 "Specify" line.

- **Item 9:** 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
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**SAMPLE**. Do NOT FAX  
TO DATAFAX



MTN-013/IPM 026 (150)

DEM-3 (003)

**Participant ID**

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

**Demographics**

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

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

11. 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: \_\_\_\_\_

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## Demographics (DEM-3)

### Item-specific Instructions:

- **Item 10:** 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 11:** 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.



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## Ring Adherence (RA-1)

**Purpose:** This form is used to collect participant-reported information on ring use (adherence). This includes all instances where the participant reports the ring has not been used, regardless of reason for non-use.

**General Information/Instructions:** Complete this form at the Day 7, 14, 21, and 28 visits only. This form is required at each of these visits, even if the participant has been on product hold. Do not complete this form at Interim Visits.

### Item-specific Instructions:

- **Item 1:** Record the date of enrollment and visit code "02.0" the first time this form is completed for each participant.
- **Item 2:** Per participant report, if the ring has been out (not inserted) for any amount of time since the last time the form was completed for the participant, mark "yes" and continue with the form. If the participant reports the study vaginal ring has been in continuously since the last time this form was completed, mark "no" and end the form.
- **Item 2a:** Record how many separate times the participant reports the ring has been out since the last time the form was completed.
- **Items 3a–3e:** Complete one row for each separate time the participant reports the ring has been out. For example, if the participant reported that the ring has been out for two separate times since the last time this form was completed, complete rows 3a and 3b. In this case, item 2a of the form should be "02". When possible, complete items 3a–3e in ascending order by date, with item 3a being the earliest date the ring was out and item 3e the most recent date the ring was out.
  - **Removal/Expulsion Code:** Select from the codes below and record the code that best describes why the vaginal 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

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**Participant ID**

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

**Screening Behavioral Eligibility**

**Visit Date**

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

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

- 1. Have you ever had an adverse reaction to silicone, titanium dioxide, or to any of the components of the study products? .....  *yes*  *no*
- 2. Have you used, or do you plan to use during the period of your study participation, CYP3A inducer(s) and/or inhibitor(s)? .....  *yes*  *no*
- 3. Have you used non-therapeutic injection drugs in the past 12 months? .....  *yes*  *no*
- 4. Have you used post-exposure prophylaxis for HIV exposure within the past 6 months? ....  *yes*  *no*
- 5. Are you currently breastfeeding? .....  *yes*  *no*
- 6. Do you plan to become pregnant within the next 4 months? .....  *yes*  *no*
- 7. Do you plan to move away from the area in the next 4 months? .....  *yes*  *no*
- 8. Are you currently participating in any research study involving drugs, medical devices, or vaginal products? .....  *yes*  *no*

**If any items 1–8 are marked “yes,” participant is ineligible.** ←

- 9. Are you willing to abstain from receptive sexual activity (including oral, vaginal and anal intercourse) for the 14 days prior to enrollment and continuing for the duration of your study participation? .....  *yes*  *no*
- 10. Starting before your enrollment visit and continuing through 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 28 days prior to enrollment, being a woman who identifies as a woman who has sex with women exclusively, sterilization, and/or sexually abstinent for the past 90 days? .....  *yes*  *no*
- 11. Are you willing to refrain from inserting any non-study vaginal products or objects into the vagina, including but not limited to, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, sex toys (vibrators, dildos, etc.), and tampons for the 5 days prior to enrollment throughout the duration of your study participation? .....  *yes*  *no*
- 12. Are you willing to not participate in other research studies involving drugs, medical devices, or vaginal products for the duration of your study participation? .....  *yes*  *no*

**If any items 9–12 are marked “no,” participant is ineligible.** ←

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	01-AUG-11
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0	1
Language	

Staff Initials / Date

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## Screening Behavioral Eligibility (non-DataFax)

**Purpose:** This interviewer-administered form is used to document the participant's behavioral eligibility for the study at the Screening Visit. Read all introductory statements and items aloud as they appear on the form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

**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 not eligible.

### Item-specific Instructions:

- **Items 1–4:** The interviewer should provide examples as needed in order for the participant to be able to provide an accurate response. Refer to the Study-specific Procedures Manual (SSP) for relevant examples.

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**Participant ID**

Site Number			Participant Number						Chk	

**Enrollment Behavioral Eligibility**

**Visit Date**

dd		MMM		yy	

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

- |   |   |   |
|---|---|---|
| <p>1. In the past 60 days, have you participated in any research study involving drugs, medical devices, or vaginal products? .....</p> <p>2. In the past 5 days, have you inserted, or do you plan to insert, any non-study vaginal products or objects into the vagina, including but not limited to spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, sex toys (vibrators, dildos, etc.), or tampons while participating in this study? .....</p> | <p>yes</p> <p><input type="checkbox"/></p> <p>yes</p> <p><input type="checkbox"/></p> | <p>no</p> <p><input type="checkbox"/></p> <p>no</p> <p><input type="checkbox"/></p> |
|---|---|---|

***If any items 1–2 are marked “yes,” participant is ineligible.*** ←

- |   |   |   |
|---|---|---|
| <p>3. In the past 14 days, have you abstained from receptive sexual activity (including oral, vaginal and anal intercourse), and do you plan to abstain from these activities for the duration of your study participation? .....</p> <p>4. Are you willing to abstain from receptive sexual activity (including oral, vaginal and anal intercourse) for the duration of your study participation? .....</p> <p>5. Do you plan to continue using your current birth control method for the duration of your study participation? .....</p> <p>6. Are you willing to not participate in other research studies involving drugs, medical devices, or vaginal products for the duration of your study participation? .....</p> | <p>yes</p> <p><input type="checkbox"/></p> <p>yes</p> <p><input type="checkbox"/></p> <p>yes</p> <p><input type="checkbox"/></p> <p>yes</p> <p><input type="checkbox"/></p> | <p>no</p> <p><input type="checkbox"/></p> <p>no</p> <p><input type="checkbox"/></p> <p>no</p> <p><input type="checkbox"/></p> <p>no</p> <p><input type="checkbox"/></p> |
|---|---|---|

***If any items 3–6 are marked “no,” participant is ineligible.*** ←

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## **Enrollment Behavioral Eligibility (Non-DataFax)**

**Purpose:** This interviewer-administered form is used to document/confirm the participant's behavioral eligibility for the study at the Enrollment Visit, prior to enrollment/randomization. Read all introductory statements and items aloud as they appear on the form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

**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 not eligible.