Baseline Questionnaire

**Practice Questions**

Note: while in the actual questionnaires participants are allowed to refuse to answer and skip a question, this option is NOT allowed during the practice questions. All participants will be required to give an answer to each of the practice questions. However these data will not be kept or analyzed, in case the participant has concerns. Also, as we want to keep the “refuse to answer” at a minimum, staff will explain this option to participants, but they will not be practicing it.

Q1. This question teaches participants how to answer a question where only one answer is allowed. It also shows the participant how to change an answer once it is selected.

Q2. This question gives an example of choosing answers on a scale. Every scale in the survey is ordered from negative to positive answers.

Q3. This question teaches participants how to answer a question where more than one answers is allowed. It also shows the participant how to change an answer once it is selected. This question also introduces the answer category of ‘Other.’ If a participant selects ‘Other,’ she should be instructed to fill in the box beside the response with a specific description of what ‘Other’ means. If the participant selects the last **bolded** option in a list, all other responses that have been selected will be removed because this option is incompatible with the other options. Instruct the participant to make sure to only select the last bolded option when all of the other choices do not apply.

Q4. This question shows participants how to answer a question that uses a calendar format. The calendars in the surveys show the last 8 days including today. The calendar begins with the date and day of the week 8 days ago and ends with “Today.” This calendar question asks the participant for a count of how many times she did something. If a participant asks about estimating a count, she should round up to the highest number.

**Behavioral Questions**

**Pregnancy History**

Q1. This question refers to the total number of biological pregnancies in the participant’s life. This figure should include all types of pregnancies she experienced, whether they resulted in live births, still births, terminations/abortions, miscarriages or tubal pregnancies.

Q1A. This sub-question is meant to categorize the pregnancy outcomes per Question 1. Therefore, the categorization of pregnancy outcomes must match the total in Question 1.
Menstruation History
Q2. This question asks the participant whether she has had her menses, or any menstrual bleeding or spotting in the last three months. For any question like this one that provides a time frame, if the participant has trouble figuring out the time period for the question, you can clarify. For example, if today is mid-July, clarify that three months ago would be mid-April. If she has not had menstrual bleeding or spotting, she will be skipped out of the next two questions.

Q2A. This sub-question asks about whether the participant has used tampons to manage her menstruation in the last three months per Question 2. By using tampons, we mean inserting any commercially available, (whether with or with applicators, etc...) inside her vagina.

Q2B. This sub-question asks about whether the participant has used sanitary pads or panty liners to manage her menstruation in the last three months per Question 2. By this we mean any commercially available or absorbing products that are lining the panty, and used externally.

Q2C. This sub-question asks about whether the participant has used any other products to manage her menstruation in the last three months per Question 2. If she has, she should click “yes” and describe the product(s) in the space provided. These could be menstrual cups, diaphragms, or anything else she may have used.

Use of Alcohol and Drugs and Other Behaviors
Q3. This question asks the participant to indicate how many days she drank in the past month. By past month, we mean the past 30 days. Monthly alcohol consumption is measured in days where any amount of alcohol was consumed. The participant should be instructed to count the number of days in a month she drank alcohol, no matter how many drinks were consumed on a given day. The number of days indicated should not be greater than 30.

Q3a. This sub-question refers to the participant’s typical alcohol consumption on the days she drank, to quantify the amount of drinking. This is measured in number of drinks where a drink is a glass of beer or wine, a shot of liquor or a single cocktail.

Q4. This question refers to whether a participant has smoked, swallowed or snorted a recreational drug in the past three months. By recreational drug, we are referring to a drug procured and taken on one’s own and without clinical prescription. This does NOT include legal stimulants or drugs like alcohol, tobacco, coffee or tea.

Q5. This question refers to whether the participant has ever, over the course of her lifetime, injected (with a needle) a recreational drug. Similar to Question 4, a recreational drug refers to a drug procured and taken on one’s own and without clinical prescription.

Q5a. This sub-question refers to whether the participant has injected (with a needle) a recreational drug in the past 3 months.

Q6. This question refers to whether the participant has ever over the course of her lifetime exchanged sex for food, drugs, shelter or money. This question is intended to assess if the participant has ever received a transaction [in the form of food, drugs, shelter or money] in exchange for sex. Sex can be any kind of sex: vaginal, anal, oral, finger, etc.

Q6a. This sub-question refers to whether the participant has exchanged sex for food, drugs, shelter or money in the past 3 months.
Q7. This question refers to whether the participant has ever in her life been diagnosed with or treated for a sexually transmitted infection (STI) as far as she knows. This includes bacterial STIs (like GC, or CT) as well as viral STIs (like HSV2 or HPV).

**Ring Concerns**

Q8. This question refers to any concerns or worries the participant may have about the ring right now. She should select all answers that apply. If there are additional concerns that are not listed, she should choose “other” and describe them in the space provided. If she has no concerns/worries, she should choose the last option “I am not worried about any of these things.”

**Protocol Adherence Questions**

**Sexual Behavior**

In these questions we ask about sex with both male and female partners. The section begins with a list of sexual terms and definitions of sexual behavior. If at any time a participant has questions about a specific term, refer her to the list of sexual terms and help her to understand the meaning of what is being asked.

Note: Finger sex refers to masturbation with finger insertion, as well as a partner inserting finger(s) in the participant’s vagina.

Q9. This question refers to the participant’s current sexual orientation. Even if the participant identifies with more than one response, she should select the response that best or most describes the current situation. If a participant does not identify with any of the categories listed, she should select ‘Other’ and specify her response.

Q10. This question asks whether the participant currently has a primary sex partner. “Primary sex partner” refers to a person you have sex with on a regular basis or who you consider to be your main partner. This individual may be a lover, spouse, a boyfriend or a girlfriend.

Q10a. This sub-question asks the participant to identify the gender of her primary sex partner. If the primary sex partner doesn’t identify either as a man or a woman (e.g. a transgender person) the participant can select “other” and specify her response.

Q10b. This sub-question refers to how long ago the participant started having sex with her primary partner. The participant should make her best estimate of this time frame.

Q11. This question refers to the total number of different sexual partners the participant has had penetrative vaginal or anal sex with, in her entire life.

**Recent Sexual Activity**

Q12. This question asks about the different kinds of sexual activity the participant has engaged in the past three months. If the participant has questions about the sexual terms used, please refer her back to the list of terms and definitions and clarify the meaning of the question. Clarify to the participant that this question asks about sexual activity both with and without a condom. Be sure to tell the participant that none of her answers will affect her participation in the study.

Q13. This sub-question refers to the participant’s sexual activity in the past 8 days, including today (total of 9 days). One calendar will be completed for each sexual activity selected in Question 12. The participant should indicate whether she engaged in each specific sexual activity for each calendar...
day by selecting “yes” or “no” from the drop-down choices provided. Once she has completed a calendar by answering “yes” or “no” for each day for one specific sexual activity, the next sexual activity selected in Question 12 will appear as a calendar until all calendars for all sexual activities selected in Question 12 have been completed.

Q14. This sub-question refers to sexual activity that has occurred longer than 8 days ago. It will be asked of a participant if she a) selects a sexual activity from the list in Question 12 (sexual activity in the past three months); or b) answers “no” for every day for that specific sexual activity on the calendar in Question 13. The participant should indicate how long ago she engaged in each sexual activity she has selected in Question 12 (measured in days). If she doesn’t remember exactly, remind her that she should make her best estimate for these answers. If she engaged in the sexual activity more than 30 days ago, she will not be permitted to enter a number greater than 30 in the “days ago” field, rather she will have to check the box indicating “more than 1 month ago.” If she has never engaged in that activity, which could happen if she made a mistake on Question 12, she can answer “Never.”

Intravaginal Practices

The next questions ask about items that women sometimes insert in their vaginas for a variety of reasons (contraception, personal hygiene, menstrual control or other reasons. Please note that these questions are about putting items inside the vagina and not about using them outside the vagina, on the external genitalia. Be sure to tell the participant that none of her answers will affect her participation in the study.

Q15. This question asks about all the items that a participant has inserted into her vagina ever in her lifetime. If there is an item she has used that is not listed, the participant should choose “other” and describe that item in the space provided.

Q16. This sub-question refers to how long ago the participant last used each of the items she selected in Question 15.

Q17. The sub-question refers to the items the participant has used either today or 1-8 days ago as indicated in Question 16. The participant should indicate the duration each relevant item was in her vagina (measured in number of hours from 0 to 24) for each day on the provided calendar. If it was in all day she should answer “24”(hours). If it was in her vagina, briefly, even for just a minute, she should indicate “1” (hour). Similar to Question 13 (sexual activities calendar), the participant will be presented with a calendar question for each vaginal product she selected in Question 15 that she indicated was used today or 1-8 days ago.

Q18. If the participant reported in Question 17 that she inserted any item in her vagina yesterday or today, she will then further be asked to indicate a specific time when the item was inserted and when it was removed from a drop-down menu. The participant can estimate and should round UP to the nearest hour. For example, if the participant inserted the item at 12:15am, she should choose 1am from the answer list. If she inserted the item at 1:45pm, she should choose 2pm from the answer list. If the participant had the item inserted (i.e. a tampon) since the previous day, she can select the answer “Product was in when I woke up.” For removal time, if participant did not remove the item that day, or if she inserted an item that cannot be removed (i.e. vinegar and water), she should check “Product was in when I went to sleep/I did not remove the product.” This sub-question will be asked of every relevant vaginal product that she indicated was in for 1-23 hours on that day.
Q19. This sub-question is asked of a participant if she has answered “0” on every day of the calendar in Question 17 for a specific item or if she has answered either ‘9 -14 days ago’ or ‘15-30 days ago’ for any item in Question 16. It requires the participant to indicate, for that item when she last used that item. If she last used the item today, she should enter “0” in the space provided. If she last used the item more than a month ago or never, the participant should select the correct respective response. This question is meant to capture any mistakes made in Question 17.
Ring Adherence Questionnaire

Q1. This question asks the participant whether she has worn the ring for any amount of time since her last computer interview, including today. The date of that last CASI interview should appear on screen based on the information entered by the stuffy staff person prior to the beginning of the interview. The participant should not count times when she tried the ring at the clinic.

Q1a. This sub-question refers to any reason why a participant has not worn the ring since her last computer interview. She should choose all reasons that apply. If there is a reason she has that is not listed, the participant should choose “other” and describe the reason. If she did not experience any problems, she should check the last answer on the list.

Q2. This question refers to whether a participant has inserted the ring herself since her last computer interview. She should include times that she inserted it herself at the clinic.

Q3. This question asks about whether the ring has ever come out partially or completely since her last computer interview, even if it was only (partially) out very briefly, just for a minute. The participant should include times that the ring came out on its own or was voluntarily removed. She should not include times that the ring was removed at the clinic. If the participant answers “no” to this question, she will be taken to the end of this survey.

Q3A. This sub-question refers to the number of days that the ring was out for any amount of time since the participant’s last computer interview, even if it was only out for a minute. If the ring was out several times on one day, the participant should only report 1 day.

Q4. This question asks the participant about involuntary expulsion, that is whether the ring ever came out on its own, either partially or completely, since her last computer interview.

Q4A. This sub-question refers to whether the ring came out on its own partially or completely the last time it came out on its own. Explain to the participant that this question is asking about the last time it came out on its own. If the answers “partially” or “completely” do not adequately describe the experience, the participant should choose “other” and describe what happened.

Q4b. This sub-question refers to what the participant was doing when the ring came out on its own the last time. She can choose more than one answer. Again, if the answers on the list do not adequately describe the experience, the participant should choose “other” and describe what happened. It is acceptable if the participant cannot remember, and she can indicate so.

Q4c. This sub-question refers to the position the participant was in when the ring came out on its own the last time. Here she should choose only one answer. If the answers options do not adequately describe the experience, the participant should choose “other” and describe her position. It is acceptable if the participant cannot remember, and she can indicate so.

Q5. This question asks the participant about voluntary removal of the ring since her last computer interview. This includes voluntary removals at home or at the clinic. She should include times when the ring was taken out after coming out partially on its own as well as times when the ring was entirely taken out. This also includes time when she removed it or if it was someone else, including study staff.

Q5A. This sub-question asks who removed the ring the last time it was removed.
Q5b. This sub-question refers to what position the participant was in when the ring was removed the last time it was removed. If the answer options do not adequately describe the experience, the participant should choose “other” and describe her position. It is acceptable if the participant cannot remember.

The next series of sub-questions ask about the reasons why the ring was voluntarily removed the last time it was removed. As for the above questions, the participant should focus on the last time this happened.

Q5c. This sub-question asks whether the ring was removed because it was uncomfortable. By uncomfortable it means physically uncomfortable.

Q5d. This sub-question asks whether the ring was removed because it moved or came out partially on its own.

Q5e. This sub-question asks whether the ring was removed because it was causing pain. This refers to physical pain

Q5f. This sub-question asks whether the ring was removed because it did not feel like it was correctly in place. The participant should include times when the ring got out of place when she was checking on it.

Q5g. This sub-question asks whether the ring was removed because the participant did not want to wear it during her menstrual period. This includes when she had her menses or when she was spotting.

Q5h. This sub-question asks whether the ring was removed because the participant wanted to clean it. This includes removal while taking a shower or a bath, washing or rinsing, or wiping the ring.

Q5i. This sub-question asks whether the ring was removed because the participant wanted to show it to someone.

Q5j. This sub-question asks whether the ring was removed because the participant was worried about its safety or that it may harm her.

Q5k. This sub-question asks whether the ring was removed because the participant felt or was constipated.

Q5l. This sub-question asks whether the ring was removed before or during sex. This involves any type of sexual activity.

Q5m. This sub-question asks whether the ring was removed for some other reason not already asked. If yes, the participant should explain this reason in the space provided.

Q6. This question asks what action(s) the participant took after the ring was removed the last time. If the ring was not reinserted, the participant should indicate that. If the answer options do not adequately describe her actions, the participant should choose “other” and describe what she did. If
the ring was reinserted, the participant will be asked Question 7. If it was not reinserted, she will be asked Question 8.

Q7. This sub-question asks whether the participant rinsed or washed the ring before she reinserted it the last time it was removed.

Q8. This sub-question refers to the reason that the participant did not reinsert the ring herself after the last time it was removed. She should choose all reasons that apply. If the answers on the list do not adequately describe her reason(s), the participant should choose “other” and describe the reason. If she had no concerns or worries about reinsertion, she should check the last answer on the list. If she did not experience any problems reinserting the ring, she should check the last answer on the list.
Protocol Adherence Questionnaire

This survey begins with a list of sexual terms and definitions of sexual behavior. If at any time a participant has questions about a specific term, refer her to the list of sexual terms and help her to understand the meaning of what is being asked.

Recent Sexual Activity
Q1. This question refers to the participant’s sexual activities since her last computer interview. The date of the last interview should appear on screen. The participant should select all relevant sexual activities. If she has questions about the specific sexual terms, refer her to the list of terms and definitions provided at the beginning of the survey. Be sure to let the participant know that her answers will not affect her participation in the study. Clarify to the participant that this question asks about sexual activity both with and without a condom. Be sure to tell the participant that none of her answers will affect her participation in the study.

Q1A. This sub-question asks the participant to indicate on the calendar provided when she last engaged in each sexual activity listed in Question 1. The calendar shows the last 8 days, including today. If the last computer interview is less than 8 days ago, the calendar should show the date of the last interview up through today. The participant will be asked to indicate whether or not she engaged in each selected sexual activity by answering “yes” or “no” for each one on each given calendar day. Once she has answered “yes” or “no” for one sexual activity, the next sexual activity selected in Question 1 will appear as a calendar until all sexual activities selected in Question 1 have appeared as calendars. If the participant chooses “no” for every sexual activity on every day, she will be asked Question 1B.

Q1B. This sub-question aims to determine how many days ago the participant last engaged in the sexual activities she selected in Question 1 when asked about activity since her last computer interview. This question will be asked of a participant if she a) selects a sexual activity from the list in Question 1 (recent sexual activity); and b) then answers “no” for every day for that specific sexual activity on the calendar in Question 1A. The participant should indicate how long ago she engaged in that sexual activity she has selected in Question 1 (measured in days).

If she last engaged in a given activity today, she should enter “0” in the space provided for number of days. If she doesn’t remember exactly, remind her that she should make her best estimate for these answers. If she engaged in the sexual activity prior to the date of the last CASI, she will not be permitted to enter a number greater than that number of days in the “days ago” answer, rather she will have to check the box indicating “Never since last computer interview [Date].”

Recent Intravaginal Practices
The next questions ask about items that women sometimes insert in their vaginas. This may be for contraception, personal hygiene, menstrual control or other reasons, and some women may not insert any of these items. Please note that these questions are about putting items inside the vagina and not about using them outside the vagina. Be sure to tell the participant that none of her answers will affect her participation in the study.

Q2. This question asks about all the items that a participant has inserted into her vagina since her last computer interview. If there is an item she has used that is not listed, the participant should choose “other” and describe that item in the space provided.
Q2A. The sub-question refers to the items the participant has used either since her last computer interview as indicated in Question 2. The calendar shows the last 8 days, including today. If the last computer interview is less than 8 days ago, the calendar should show the date of the last interview up through today. The participant should indicate the duration each relevant item was in her vagina (measured in number of hours from 0 to 24) for each day on the provided calendar. If the items was in all day she should answer "24" (hours). If it was in her vagina, briefly, even for just a minute, she should indicate “1” (hour). Similar to Question 1A (sexual activities calendar), the participant will be presented with a calendar question for each vaginal product she selected in Question 2 that she indicated was used since her last computer interview.

Q2B. If the participant reported in Question 2A that she had any vaginal product in for 1-23 hours, yesterday or today, she will be asked this sub-question. This question will ask the participant to indicate the approximate time that a specific item was inserted and when it was removed. If the participant is not sure of the exact time, she should round to the nearest hour. For example, if the participant inserted the item at 1:15am, she should choose 1am from the answer list. If she inserted the item at 1:45am, she should choose 2am from the answer list.

If the participant had the item inserted (i.e. a tampon) since the previous day, she can select the answer “Product was in when I woke up.” For removal time, if participant did not remove the item that day, or if she inserted an item that cannot be removed (i.e. vinegar and water), she should check “Product was in when I went to sleep/I did not remove the product.” This sub-question will be asked of every relevant vaginal product that she indicated was in for 1-23 hours, yesterday or today.

Q2C. This sub-question is asked of a participant if she has answered “0” on every day of the calendar on Question 2A for every vaginal product selected in Question 2. It requires the participant to indicate, for every item she said she had inserted since her last computer interview, when she last used that item. If she last used the item today, she should enter “0” in the space provided. If she has not used the product since last computer interview, the participant should select “never since last computer interview [Date].” This question is meant to capture any mistakes made in Question 2.
Acceptability Questionnaire

Q1. This question asks the participant whether she has worn the ring for any amount of time since she started the study, including today. The participant should not count times when she tried the ring at the clinic. If the participant answers “no” to this question, she will be skipped to Question 25 – concerns about the ring.

Q1a. This sub-question refers to any reason why a participant has not worn the ring for any amount of time since she started the study, even for a minute. She should choose all reasons that apply. If there is a reason she has that is not listed, the participant should choose “other” and describe the reason. If none of the reasons for not wearing the ring are applicable to her, she should check the last answer on the list.

Most questions in the following section are scale-based questions. The scales are ordered from most negative to most positive answers.

Q2. This question asks the participant to rate how difficult or easy it was overall to use the ring.

Q3. This question asks the participant to rate how difficult or easy it was for the participant to insert the ring the last time it was inserted. If she never inserted the ring herself, she should select “NA, did not insert the ring”.

Q4. This question asks the participant to rate how difficult or easy it was for the participant to take out the ring the last time it was removed. If she never removed the ring herself, she should select “NA, did not take out the ring myself”.

Q5. This question asks the participant to rate how comfortable she felt to have the ring in her vagina. This is about physical comfort.

Q6. This question asks the participant to indicate how often she noticed or physically felt the ring inside her since she started the study. This should refer to her normal daily activities.

Q7. This question asks the participant to indicate how often she was thinking about the ring inside her since she started the study. This is about what she was thinking, regardless of whether she felt the ring or not.

Q8. This question asks the participant to indicate whether she ever checked to see if the ring was inside her since she started the study.

Q8A. This sub-question asks the participant to rate how often she checked to see if the ring was inside her since she started the study.

Q8A. This sub-question asks the participant to indicate how she checked to see if the ring was inside her since she started the study. If she didn’t use her fingers, but used something else, she should mark “other” and specify what she used to check the ring.
Q9. This question refers to any changes in the level of moisture in the vagina that the participant has noticed from wearing the ring since she started the study.

Q9A. This question asks the participant if the changes she has noticed in her vagina from wearing the ring since she started the study have been a problem for her.

Q10. This question asks the participant to rate her ability to keep the ring inserted in her vagina over the past four weeks, as she was told or instructed by study staff. She should rate herself by selecting one of the 6-item scale.

The next set of questions asks about the level of bother and level of intensity of events, which may be experienced physically, emotionally or psychologically. By bother, we mean annoying or disturbed. By intense, we mean the degree of (i.e. the degree of discomfort).

Q11. This question asks the participant to rate how often she experienced any physical discomfort because of the ring.

Q11A. This sub-question asks the participant to rate how much the physical discomfort has bothered her.

Q12. This question asks the participant to rate how often she experienced pain because of the ring. This refers to physical pain.

Q12A. This sub-question asks the participant to rate how much the pain has bothered her.

Q13. This question asks the participant to rate how often she experienced the ring moving or not correctly in place.

Q13A. This sub-question asks the participant to rate how much that movement or displacement has bothered her.

Q14. This question asks the participant to rate how often she experienced the problems with the ring during her menstrual period.

Q14A. This sub-question asks the participant to rate how much the problems during her period have bothered her.

Q15. This question asks the participant to rate how often she experienced emotional discomfort such as worries, fears, guilt or any other unpleasant feelings with the ring.

Q15A. This sub-question asks the participant to rate how much the emotional discomfort such as worries, fears, guilt or any other unpleasant feelings with the ring has bothered her.

Q16. This question asks the participant to rate how often the ring interfered with her daily activities.

Q16A. This sub-question asks the participant to rate how much that interference has bothered her.

Q17. This question asks the participant to rate how often she experienced concerns with the ring because she wanted to clean it.
Q18. This question refers to whether the participant’s primary sex partner has any concerns or problems with the ring. The nature of the concern or problems are not specified, so they can be of any kind.

Q19. This question asks the participant to rate how often the concerns about the safety of the ring or worries that it may harm her has bothered her.

Q19A. This sub-question asks the participant to rate how much, the concerns about the safety of the ring or worries that it may harm her has bothered her.

Q20. This question asks the participant to rate how often she experienced constipation because of the ring.

Q20A. This sub-question asks the participant to rate how much the constipation has bothered her.

Q21. This question asks the participant to rate how often she experienced the ring partially coming out.

Q21A. This sub-question asks the participant to rate how much the ring partially coming out has bothered her.

Q22. This question asks the participant to rate how often she experienced the ring completely coming out.

Q22A. This sub-question asks the participant to rate how much the ring completely coming out has bothered her.

Q23. This question asks the participant whether she was ever unable to remove the ring when she tried to take it out of her vagina.

Q24. This question asks the participant to provide any additional information about other problems she has had with the ring.

Q25. This question refers to any and all concerns or worries the participant has had about the ring since she started the study, regardless of whether she actually experienced problems or not. If she did not have any of the listed concerns or worries, she should check the last answer on the list.

Q26. This question refers to whether the participant’s concerns changed over time. If the participant had no worries, she can select the last answer “NA (I had no worries)"

Q27. This question asks the participant to rate how acceptable it feels to wear the ring every day.

Q28. This question asks the participant to rate her preferences about wearing the ring every day versus episodic (not every day) use.

Q29. This question asks the participant to rate her preferences about wearing the ring during her menstrual period. If the participant didn’t have her period during the study, and can’t speak to such a preference, she can choose the last answer “NA, did not get my period during the study”

Q30. This question asks the participant to rate how much she liked the ring overall.
Q31. This question asks the participant to rate how much she likes the ring now compared with when she started the study. The participant should choose whether she likes it more, less or the same as when she started the study. If her feelings didn’t change and she doesn’t like the ring, she can choose the last answer, “Not applicable, I do not like the ring.”

Q32. This question asks the participant to rate how likely she would be to keep the ring inserted in her vagina every day if a ring was available that provided some protection against HIV, and it was similar to the one she used in this study. This is a hypothetical question about willingness to use the ring daily.