Development of Measures of Adherence (DOMA) Screener Form

Conduct Informed Consent and obtain signature before initiating survey.

As described in the consent form, the goal of this study is to develop better ways of asking people how they use products in HIV prevention research. We will also try to understand what makes it easy or difficult for people to use the products in trials. Some of our questions are about how people think about HIV prevention research and products. We will ask you those questions even if you have never participated in research. Other questions are about experiences you may have had in past research. We will only ask those questions to women who participated in past research. Past studies evaluated a vaginal ring (ASPIRE), an oral daily pill (VOICE) or a vaginal gel (VOICE and FACTS.)

How old are you?	☐☐
Have you ever participated in a clinical trial that was testing a new HIV prevention product?	0=No **SKIP to NON-Trial PPTs INFO** 1=Yes
[If yes] What type of product did you use the last time you participated in research?	1=Vaginal Ring 2=Oral Pill (PrEP) 3=Vaginal Gel 4=Other **SKIP to NON-Trial PPTs INFO**

*[**TRIAL PPTS INFO**]:*
Take a moment to think about the first time you heard about the research. Recall what you first thought about it when you heard. Think about any conversations you may have had with friends and family about the research. Then think about how you felt and what you thought as you decided to volunteer.
Now. Pretend it is the day you decided to volunteer. Try to think about what you thought about then, how you felt. How would you have answered these questions? Ready?

*[**NON-TRIAL PPTS INFO**]:*
Clinical trials are research studies that test whether a new drug or a new medical procedure works the way it is supposed to. For example, in this community several trials have been conducted to see if different products work to protect against HIV infection. Some products that have been tested include a vaginal gel, oral pills and a vaginal ring. Have you heard of any of these trials? (If yes, which trials have you heard about?)
When a woman joins this research, she may be given the product that is being tested or another product that is similar but doesn't contain the drug. The product that doesn't have the drug in it is called a placebo. A computer determines which product she receives, much like flipping a coin. All women are also counseled to use condoms.

Imagine that we were conducting new research and you were invited to participate. How much would you disagree or agree with the following statements?

ORIENT THE PARTICIPANT TO THE RESPONSE SCALE.

There are no wrong answers; I'm interested in hearing your opinion. Here's how it will work. I will read a statement out loud and then you will tell me if you agree or disagree with it - and how much you agree or disagree with it.	1=Disagree A LOT 2=Disagree Somewhat 3=Disagree A Little 4=Agree A Little 5=Agree Somewhat

		6=Agree A LOT					
	1. BELIEFS ABOUT HIV PREVENTION TRIALS						
	OK. First, we want to explore women's opinions or thoughts about HIV prevention research. If you have already participated in research, think back to your experience. What questions or concerns did you have, if any? What did you understand about the research? Consider whether you felt like you could TRULY trust the research and the staff, or whether you had conflicts with them, or with people in your community - your family or friends - about being in the research. ...						
	Perceived Ease or Difficulty of Trial Participation (3 ITEMS)						
	The first few questions are about how easy or difficult you thought it would be to do all the things [asked / required] of you during the research. We understand that participating in research can be demanding, especially if you have lots of other demands in your life. Again, please be as honest with me as you can as you respond. OK...?						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
1	The research will take a lot of my time.	1	2	3	4	5	6
2	I think the care I get as a research participant is the same as the care I get in the local clinic.	1	2	3	4	5	6
3	I do not believe that participating in research will be difficult for me.	1	2	3	4	5	6
	Sufficient Information about Trial Participation (5 ITEMS)						
	The next few items are about the information you are given when you are deciding whether or not to participate in research. Potential participants usually get information from advertisements in the community, or maybe from their friends or family members. Then, when you come to the research site, you hear about the research in detail from the staff, and are asked to sign a consent form. Do you remember this process?						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
4	The research staff told me everything I needed to know about the research.	1	2	3	4	5	6
5	I was given clear information about the research.	1	2	3	4	5	6
6	I was not given enough time to decide if I wanted to participate in the research.	1	2	3	4	5	6
7	I know that I can leave the research at any time.	1	2	3	4	5	6
8	It would be okay if I decided not to participate in the research.	1	2	3	4	5	6
	Understanding about Experimental Context (5 ITEMS)						
	The next section is about research itself. … Ready…?						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot

9	I believe that the staff will give me a product that works.	1	2	3	4	5	6
10	I do not want to take a non-active product.	1	2	3	4	5	6
11	I am worried that the product is experimental.	1	2	3	4	5	6
12	I do not want to be used for an experiment.	1	2	3	4	5	6
13	I am willing to be used for an experiment.	1	2	3	4	5	6
	Concerns about Safety or Side Effects (6 ITEMS)						
	The next items are about how you might feel about safety in the research, and about whether you were ever concerned about the product causing you distress in any way.						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
14	I don't see any danger in participating.	1	2	3	4	5	6
15	I worry that participating in research could lead to future health problems.	1	2	3	4	5	6
16	I am fairly sure that the product is safe.	1	2	3	4	5	6
17	I do not know if the research product is safe.	1	2	3	4	5	6
18	I believe that people who participate in HIV prevention research can experience unpleasant side effects.	1	2	3	4	5	6
19	I am worried that I will get HIV because I am using the research product.	1	2	3	4	5	6
	Positive/Negative Expectations about Product Use (5 ITEMS)						
	The next items are about what you might think would, both good [positive] things and not-so-good or even bad things, if you join new research.						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
20	I believe that the research product will keep me from getting HIV.	1	2	3	4	5	6
21	It's hard to believe that the research product will help me.	1	2	3	4	5	6
22	The advantages of using the research product are more than the disadvantages.	1	2	3	4	5	6
23	I think I will like using the research product more than condoms.	1	2	3	4	5	6
24	I do not trust that the research product can prevent HIV.	1	2	3	4	5	6
	SDB - Part I (8 ITEMS)						
	Now we would like you help to develop questions that would help us better know the participants who join research. These statements are not directly about the participant's understanding of the research. They are also not about their experiences in the research. Instead, they are more about the participant's general attitudes, their likes and dislikes. I will ask some questions now and some more questions later in the interview. Please listen to each statement, and tell me how much you generally disagree or agree. Then tell me whether you disagree/agree a little, somewhat or a lot.						
	ITEM	**DISAGREE**			**AGREE**		

		Lot	Some	Little	Little	Some	Lot
25	I don’t care what other people think of me.	1	2	3	4	5	6
26	I never hesitate to go out of my way to help someone in trouble.	1	2	3	4	5	6
27	I have never intensely disliked anyone.	1	2	3	4	5	6
28	I sometimes feel angry when I don't get my way.	1	2	3	4	5	6
29	I like to gossip at times. (By gossip, we mean talking behind people's backs.)	1	2	3	4	5	6
30	I do not always tell the truth.	1	2	3	4	5	6
31	No matter who I'm talking to, I'm always a good listener.	1	2	3	4	5	6
32	I can remember "playing sick" to get out of something.	1	2	3	4	5	6
	Trust or Distrust (5 ITEMS)						
	These next questions are about how much you trust - or do not trust - the research itself, or the research staff, or even the science behind the product.						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
33	I do not trust research in general.	1	2	3	4	5	6
34	I might lose more than I gain by participating in HIV prevention research.	1	2	3	4	5	6
35	I think joining the research will give me hope.	1	2	3	4	5	6
36	Researchers at the clinic are not truthful.	1	2	3	4	5	6
37	I admit I am distrustful of foreign (white) HIV prevention researchers.	1	2	3	4	5	6
	Concern about Social Stigma (2 ITEMS)						
	The next set of items are about how research participants like yourself might be treated by people in their communities and how that might impact their willingness or ability to participate in the research.						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
38	People who participate in HIV prevention research may be rejected by others.	1	2	3	4	5	6
39	I am concerned that people may harass me for participating in this research.	1	2	3	4	5	6
	2. REASONS FOR TRIAL PARTICIPATION (17 ITEMS)						
	The items we're about to review are about why women might decide to join research. What I'd like you to do is listen to each statement I will read, and without thinking too much, give me a response 1 disagree a lot-6 agree a lot. Then I'll ask you to think about the way we worded the items.						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
40	I want to contribute to scientific information.	1	2	3	4	5	6

41	I feel that I will benefit from the research, whether the product works or not.	1	2	3	4	5	6
42	Finding new HIV prevention products would be worth any inconvenience of participating.	1	2	3	4	5	6
43	I want to learn more about HIV prevention.	1	2	3	4	5	6
44	I want to take part in the fight against HIV.	1	2	3	4	5	6
45	I want to reduce my chances of getting HIV.	1	2	3	4	5	6
46	I want free health care.	1	2	3	4	5	6
47	I want to participate in HIV prevention research because research is important to improve health.	1	2	3	4	5	6
48	I want to help the researchers.	1	2	3	4	5	6
49	I feel my participation in research will help find effective HIV prevention products.	1	2	3	4	5	6
50	I want to be valuable to the community.	1	2	3	4	5	6
51	I think the research will improve my health.	1	2	3	4	5	6
52	I want to obtain the latest HIV information.	1	2	3	4	5	6
53	I am motivated by the money I get for participating in the research.	1	2	3	4	5	6
54	I am motivated by free medical check-ups.	1	2	3	4	5	6
55	I am proud to help in the fight against AIDS.	1	2	3	4	5	6
	Reasons for Trial Participation - Ranking Exercise						
	Now, I am going to read a group of statements about reasons that some women join research. Think back to when you decided to volunteer to participate in the research. From the list, choose the 3 items that were MOST TRUE for you then.						
	[Interviewer: Once the participant chooses, note all 3 of her responses by selecting them.]						

	ITEM	**1st**	**2nd**	**3rd**	**4th**	**5th**	**6th**	**7th**	**8th**
	I want to participate in HIV prevention research because research is important to improve health.	1	2	3	4	5	6	1	2
	I think the research will improve my health.	1	2	3	4	5	6	1	2
	I want to help the researchers.	1	2	3	4	5	6	1	2
	I want to obtain the latest HIV information.	1	2	3	4	5	6	1	2
	I feel my participation in research will help find effective HIV prevention products.	1	2	3	4	5	6	1	2
	I am motivated by the money I can get for volunteering for the research.	1	2	3	4	5	6	1	2
	I want to be valuable to the community.	1	2	3	4	5	6	1	2
	I am motivated by free medical check-ups.	1	2	3	4	5	6	1	2
	SDB - Part II (8 ITEMS)								

	OK. I would like to ask some more questions about participant's general attitudes, their likes and dislikes. Please tell me how much you disagree or agree with the following statements. Remember to use the number that best fits your response - from 1 (disagree a lot), 2 (disagree somewhat), 3 (disagree a little), 4 (agree a little), 5 (agree somewhat) and 6 (agree a lot.)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
56	There have been occasions when I took advantage of someone.	1	2	3	4	5	6
57	I'm always willing to admit it when I make a mistake.	1	2	3	4	5	6
58	I always try to practice what I preach.	1	2	3	4	5	6
59	I don't think it's very difficult to get along with people who talk too much and like attention.	1	2	3	4	5	6
60	I sometimes try to get even, rather than forgive and forget.	1	2	3	4	5	6
61	I do admit it if I don't know something.	1	2	3	4	5	6
62	I am always polite, even to people who are disagreeable.	1	2	3	4	5	6
63	At times I have really insisted on having things my own way.	1	2	3	4	5	6
	3. PERSONALITY TRAITS ASSOCIATED WITH COMMITMENT TO TRIAL						
	The items we're about to review are about you and how you think about your role as a research participant. There are also some other items that might seem unrelated or out of order. What I'd like you to do is listen to each statement I will read, and without thinking too much, give me a response 1 disagree a lot-6 agree a lot.						
	Commitment to Product Use (5 ITEMS)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
64	I believe that it is important to use the research product as instructed.	1	2	3	4	5	6
65	I have made a commitment to use the research product as instructed.	1	2	3	4	5	6
66	I will use the research product as instructed, even if I face some challenges.	1	2	3	4	5	6
67	I am fully confident I can use the research product even if I experience strong side effects.	1	2	3	4	5	6
68	I don't feel I can use research product every day for the next year.	1	2	3	4	5	6
	Ability to Deal with Ambiguity (7 ITEMS)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
69	There is a truth in the saying that you can't teach an old dog new tricks.	1	2	3	4	5	6
70	I am not interested in activities that will expand my experiences.	1	2	3	4	5	6
71	I like taking risks.	1	2	3	4	5	6

72	The research procedures represent a challenge I'm willing to accept.	1	2	3	4	5	6
73	I might decide to participate in research even if I had some concerns about it.	1	2	3	4	5	6
74	The idea of participating in research is appealing to me.	1	2	3	4	5	6
75	I might decide to participate in the research because I'm curious.	1	2	3	4	5	6
	Internal Locus of Control (8 ITEMS)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
76	Most things that affect my health and wellbeing happen to me by chance.	1	2	3	4	5	6
77	Luck plays a big part in determining my health.	1	2	3	4	5	6
78	God plays a big part in determining how my health is.	1	2	3	4	5	6
79	The type of help I receive from other people determines how well I do in the research.	1	2	3	4	5	6
80	I often feel overwhelmed by my responsibilities.	1	2	3	4	5	6
81	I have difficulty arranging my life in a way that is satisfying to me.	1	2	3	4	5	6
82	On a few occasions, I have given up doing something because I didn't think I could do it.	1	2	3	4	5	6
83	I often change my mind about decisions if my friends and family disagree.	1	2	3	4	5	6
	SDB - Part III (10 ITEMS)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
84	There have been occasions when I felt like hitting things.	1	2	3	4	5	6
85	I would never think of letting someone else be punished for my wrongdoings.	1	2	3	4	5	6
86	I never resent being asked to return a favor.	1	2	3	4	5	6
87	I have never been upset when people expressed ideas very different from my own.	1	2	3	4	5	6
88	There have been times when I was quite jealous of the good fortune of others.	1	2	3	4	5	6
89	I have almost never felt the urge to tell someone I think they are wrong.	1	2	3	4	5	6
90	I am sometimes irritated by people who ask favors of me.	1	2	3	4	5	6
91	I have never felt that I was punished without cause.	1	2	3	4	5	6
92	I sometimes think when people have a misfortune they only got what they deserved.	1	2	3	4	5	6
93	I have never intentionally said something that hurt someone's feelings.	1	2	3	4	5	6

	Self-Regulation (Self-Deception and/or Impression Management) (8 ITEMS)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
94	I never miss an appointment.	1	2	3	4	5	6
95	I always do what the doctor tells me.	1	2	3	4	5	6
96	It is sometimes hard for me to finish things if I am not encouraged.	1	2	3	4	5	6
97	Even if the boss wouldn't find out, I would still follow their directions exactly as I was told to.	1	2	3	4	5	6
98	I have never been late for an appointment.	1	2	3	4	5	6
99	There have been times when I refuse to listen to people in authority even though I know they are right.	1	2	3	4	5	6
100	I always know how to act in stressful situations.	1	2	3	4	5	6
101	Sometimes I wait until tomorrow to do things I have to (am supposed to) do today.	1	2	3	4	5	6
	Disclosure (New items)						
	ITEM	**DISAGREE**			**AGREE**		
		Lot	Some	Little	Little	Some	Lot
102	I will tell my partner about my involvement in the research.	1	2	3	4	5	6
103	I do not care whether my family knows about my involvement in the research.	1	2	3	4	5	6
104	It is important to tell my friends about my participation in the research.	1	2	3	4	5	6
105	It is important for my partner to know that I am participating in research.	1	2	3	4	5	6
106	I think my family should be informed about my participation in the research.	1	2	3	4	5	6
107	My partner knows that I am participating in the research.	1	2	3	4	5	6
108	I would not tell my partner that I am participating in research.	1	2	3	4	5	6
109	My friends and family know that I am participating in research.	1	2	3	4	5	6
110	It is easy to tell people in my community that I am a research participant.	1	2	3	4	5	6
111	Letting my partner know about my participation is "fear".	1	2	3	4	5	6
112	People who are around me will learn more if I tell them about my participation.	1	2	3	4	5	6
	Interviewer: Is this participant a former trial participant?	0=No 1=Yes			**SKIP TO SOCIODEM QUESTIONS** **CONTINUE TO FOLLOW-UP**		

Development of Measures of Adherence (DOMA) Follow-Up Form (Vaginal Ring)

Adherence to Research Procedures (4 items)

I want you to think about the last HIV prevention study you participated in.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
1	I was very confident that I could participate in research visits.	1	2	3	4	5	6
2	Getting to the clinic appointments was a challenge.	1	2	3	4	5	6
3	I was very confident that I could attend research visits even if the visits interfered with my daily activities.	1	2	3	4	5	6
4	I did not have any trouble remembering to attend my research visits.	1	2	3	4	5	6

General Feelings about Ring Use (17 items)

Great. Thank you. Now we'd like to understand how a participant might feel about a research product. Think back to when you were participating in the research. How much would you have disagreed or agreed with these statements about the product you were using. Again, there are no right or wrong answers. Please just let us know what you were thinking while you were in the research.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
5	I believed that the vaginal ring would reduce my chance of getting HIV	1	2	3	4	5	6
6	It was hard to believe that using the vaginal ring would help me.	1	2	3	4	5	6
7	I believed that I might get HIV if I don't use the vaginal ring as instructed.	1	2	3	4	5	6
8	I believed that my risk for HIV infection was less when I was using the vaginal ring.	1	2	3	4	5	6
9	I believed that my risk for HIV infection was the same whether I used the vaginal ring or not.	1	2	3	4	5	6
10	I had doubts about the benefits of using the vaginal ring.	1	2	3	4	5	6
11	There was a chance that the vaginal ring might cause me harm.	1	2	3	4	5	6

12	The effects of the vaginal ring lasted even if I removed it for several hours.	1	2	3	4	5	6
13	The vaginal ring worked as soon as I inserted it.	1	2	3	4	5	6
14	I was comfortable keeping the vaginal ring in continuously.	1	2	3	4	5	6
15	Wearing the vaginal ring all the time was too much of a hassle.	1	2	3	4	5	6
16	The vaginal ring helped me to feel better physically.	1	2	3	4	5	6
17	Wearing the vaginal ring gave me confidence.	1	2	3	4	5	6
18	Using the vaginal ring improved my outlook on life.	1	2	3	4	5	6
19	The benefits of wearing the vaginal ring outweighed any difficulty I might have had in using it.	1	2	3	4	5	6
20	Using the vaginal ring some of the time is better than not using it at all.	1	2	3	4	5	6
21	Using a vaginal ring to prevent HIV is better than using condoms.	1	2	3	4	5	6

Effect on Relationship or Daily Routine (9 items)

Using the research product sometimes affects a participant's relationships with her family, friends or her partner. It might also change her daily routine. Now we'd like your help with questions about relationships.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
22	It was difficult for me to explain the research to my family.	1	2	3	4	5	6
23	Vaginal ring side effects interfered with my everyday life.	1	2	3	4	5	6
24	Side effects made it difficult for me to keep using the vaginal ring.	1	2	3	4	5	6
25	Sometimes, if I felt worse when I had the vaginal ring in my body, I stopped using it.	1	2	3	4	5	6
26	The vaginal ring improved my sex life.	1	2	3	4	5	6
27	I was sometimes afraid the ring would get lost in my body.	1	2	3	4	5	6
28	I sometimes wondered if the ring was in place because I didn't even feel it.	1	2	3	4	5	6
29	Vaginal ring side effects interfered with my sex life.	1	2	3	4	5	6
30	It was difficult for me to explain the research to my friends.	1	2	3	4	5	6

Self-Efficacy (5 items)

Thank you. These next questions refer to a woman's confidence or ability to use the research product or follow the research plan. As with other sections, there are no right or wrong answers, just your opinion. Please let us know what you think.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
31	I was tempted to stop using my vaginal ring when side effects began to interfere with daily activities.	1	2	3	4	5	6
32	I was completely confident that I could continue to use the vaginal ring when I was not feeling well.	1	2	3	4	5	6
33	I was able to deal with any problems in following my research plan.	1	2	3	4	5	6
34	I needed help to follow my research plan.	1	2	3	4	5	6
35	I was not always sure that I inserted the vaginal ring correctly.	1	2	3	4	5	6

Enacted Adherence To Product (7 items)

There are many reasons that a woman may or may not be able to use her product exactly as she was instructed during the research. In previous research on vaginal rings, women have described several reasons why they removed their rings, either for short or longer periods of time. Please tell me how much you disagree or agree with the following statements, when thinking about your own use of the vaginal ring.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
36	There were times when the vaginal ring *came out by itself*.	1	2	3	4	5	6
37	I removed the vaginal ring *during my menses*.	1	2	3	4	5	6
38	I did not remove the vaginal ring at any time, except *during* a clinic visit.	1	2	3	4	5	6
39	I sometimes removed the vaginal ring *to clean it.*	1	2	3	4	5	6
40	I removed the vaginal ring *when I had sex with my partner*.	1	2	3	4	5	6
41	There were times when I removed and reinserted the vaginal ring.	1	2	3	4	5	6
42	If I took out my vaginal ring to have sex, I sometimes forgot to put it back in for several hours.	1	2	3	4	5	6

Clinic Staff Support (6 items)

In this section, we want to know more about the research staff. Many research participants have very good relationships with the staff, but some don't. And sometimes, women have good relationships with some staff, but not all the staff conducting the research. We'd like to know more about <u>your</u> experiences with research staff.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
43	The clinic staff were very friendly with me.	1	2	3	4	5	6
44	I was sure I could discuss truthfully with the clinic staff any problems related to the vaginal ring.	1	2	3	4	5	6
45	I think there were times when the research staff was disappointed in me.	1	2	3	4	5	6
46	Sometimes I felt that research staff thought I didn't understand how to use the vaginal ring.	1	2	3	4	5	6
47	I often thought the research staff didn't tell me everything they know about the research.	1	2	3	4	5	6
48	I never felt that the research staff judged me.	1	2	3	4	5	6
	Sociodemographic and Behavioral Information						
	Thank you. We're almost done! Before we end, we a few final questions about your household and your current relationships. This information will help us better understand the ways that you answered earlier questions.						
1	What type of home do you live in, is it a house, a townhouse, a flat, single room or a shack?	☐1 Free standing house ☐1 Townhouse ☐1 Flat ☐1 Single room ☐1 Shack ☐1 Other, specify:_____					
2	Who do you currently live with? *(mark all that apply)*	☐1 Parent/s (mother and/or father) ☐1 Other family (non-parent) ☐1 Primary sex partner ☐1 Own children ☐1 Other, specify:_____					
3	Do you have any children of your own?	☐0 No ☐1 Yes					
4	How many children do you have?	☐☐					
5	In total, how many people live in your household?	☐☐					

6	How would you describe your current relationship status? Would you say you are:	☐1 Married, or living as married with regular partner ☐2 Have regular partner(s), not living together ☐3 Sexually active, no regular partner(s) →Go to Q11 ☐4 Not sexually active currently→ Go to Q11
7	For how long have you had this partner? *(mark one)*	☐☐ years
8	How old is your regular (main) sex partner?	☐☐ years
9	Were you with this partner when you last participated in HIV prevention research?	☐0 No ☐1 Yes
10	Does this partner, or any other sexual partner(s) provide you with financial and/or material support?	☐0 No ☐1 Yes
11	Do any of your sexual partner(s) have sex partners other than you?	☐0 No ☐1 Yes ☐2 Don't Know
12	At your most recent sexual encounter, did you discuss condom use with your sexual partner?	☐0 No ☐1 Yes
13	The last time you had sex, how willing were you to have sex? Would you say you were:	☐1 Willing or wanted to have sex ☐2 Persuaded or coerced *(unsure, talked into sex)* ☐3 Physically forced or raped
14	The last time you had vaginal/anal sex, did you use a male or female condom?	☐0 No ☐1 Yes
15	What is your highest level of education? *(mark one)*	☐1 No schooling ☐2 Primary school, not complete ☐3 Primary school, complete ☐4 Secondary school, not complete ☐5 Secondary school, complete ☐6 Attended college or university, not complete ☐7 Attended college or university, complete
16	Do you currently earn an income of your own?	☐0 No ☐1 Yes → Go to Q17

17	How do you earn your current income? *(mark all that apply)*	☐1 Formal employment ☐2 Self-employment ☐3 Other, specify:_____
	Thank you for your time and willingness to answer our questions. As I described at the beginning of the interview, we hope that this information will help us to find better ways to support product use in future HIV prevention research. The information may also be useful for clinic providers who counsel women in use of family planning or other types of product use, where adherence is important.	

Development of Measures of Adherence (DOMA) Follow-Up Form (Vaginal Gel)

Adherence to Research Procedures (4 items)

I want you to think about the last HIV prevention study you participated in.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
1	I was very confident that I could participate in research visits.	1	2	3	4	5	6
2	Getting to the clinic appointments was a challenge.	1	2	3	4	5	6
3	I was very confident that I could attend research visits even if the visits interfered with my daily activities.	1	2	3	4	5	6
4	I did not have any trouble remembering to attend my research visits.	1	2	3	4	5	6

General Feelings about Gel Use (17 items)

Great. Thank you. Now we'd like to understand how a participant might feel about a research product. Think back to when you were participating in the research. How much would you have disagreed or agreed with these statements about the product you were using. Again, there are no right or wrong answers. Please just let us know what you were thinking while you were in the research.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
5	I believed that the vaginal gel would reduce my chance of getting HIV	1	2	3	4	5	6
6	It was hard to believe that using the vaginal gel would help me.	1	2	3	4	5	6
7	I believed that I might get HIV if I don't use the vaginal gel as instructed.	1	2	3	4	5	6

8	I believed that my risk for HIV infection was less when I was using the vaginal gel.	1	2	3	4	5	6
9	I believed that my risk for HIV infection was the same whether I used the vaginal gel or not.	1	2	3	4	5	6
10	I had doubts about the benefits of using the vaginal gel.	1	2	3	4	5	6
11	There was a chance that the vaginal gel might cause me harm.	1	2	3	4	5	6
12	The effects of the vaginal gel lasted even if some of it leaked out.	1	2	3	4	5	6
13	The vaginal gel worked as soon as I applied it.	1	2	3	4	5	6
14	I used the vaginal gel for other reasons besides HIV prevention.	1	2	3	4	5	6
15	Using the vaginal gel was too much of a hassle.	1	2	3	4	5	6
16	The vaginal gel helped me to feel better physically.	1	2	3	4	5	6
17	Using the vaginal gel gave me confidence.	1	2	3	4	5	6
18	Using the vaginal gel improved my outlook on life.	1	2	3	4	5	6
19	The benefits of using the vaginal gel outweighed any difficulty I might have had in using it.	1	2	3	4	5	6
20	Using the vaginal gel some of the time is better than not using it at all.	1	2	3	4	5	6
21	Using the vaginal gel to prevent HIV is better than using condoms.	1	2	3	4	5	6

Effect on Relationship or Daily Routine (9 items)

Using the research product sometimes affects a participant's relationships with her family, friends or her partner. It might also change her daily routine. Now we'd like your help with questions about relationships.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
22	It was difficult for me to explain the research to my family.	1	2	3	4	5	6
23	Vaginal gel side effects interfered with my everyday life.	1	2	3	4	5	6
24	Side effects made it difficult for me to keep using the vaginal gel.	1	2	3	4	5	6
25	Sometimes, if I felt worse when I used the vaginal gel, I stopped using it.	1	2	3	4	5	6
26	The vaginal gel improved my sex life.	1	2	3	4	5	6
27	Using the vaginal gel was time consuming.	1	2	3	4	5	6

28	My partner could tell when I used the vaginal gel.	1	2	3	4	5	6
29	Vaginal gel side effects interfered with my sex life.	1	2	3	4	5	6
30	It was difficult for me to explain the research to my friends.	1	2	3	4	5	6

Self-Efficacy (5 items)

Thank you. These next questions refer to a woman's confidence or ability to use the research product or follow the research plan. As with other sections, there are no right or wrong answers, just your opinion. Please let us know what you think.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
31	I was tempted to stop using my vaginal gel when side effects began to interfere with daily activities.	1	2	3	4	5	6
32	I was completely confident that I could continue to use the vaginal gel when I was not feeling well.	1	2	3	4	5	6
33	I was able to deal with any problems in following my research plan.	1	2	3	4	5	6
34	I needed help to follow my research plan.	1	2	3	4	5	6
35	I was not always sure that I applied the vaginal gel correctly.	1	2	3	4	5	6

Enacted Adherence To Product (7 items)

There are many reasons that a woman may or may not be able to use her product exactly as she was instructed during the research. In previous research on vaginal gel, women have described several reasons why they did not always use the product. Please tell me how much you disagree or agree with the following statements, when thinking about your own use of the vaginal gel.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
36	There were times when the vaginal gel *came out by itself*.	1	2	3	4	5	6
37	I did not use the vaginal gel *during my menses*.	1	2	3	4	5	6
38	I did not insert the gel all the time, except *before* a clinic visit.	1	2	3	4	5	6
39	I sometimes did not use the vaginal gel in order *to keep my vagina clean.*	1	2	3	4	5	6
40	I used the vaginal gel *when I had sex with my partner*.	1	2	3	4	5	6
41	There were times when I forgot to apply the vaginal gel before sex.	1	2	3	4	5	6

Clinic Staff Support (6 items)

In this section, we want to know more about the research staff. Many research participants have very good relationships with the staff, but some don't. And sometimes, women have good relationships with some staff, but not all the staff conducting the research. We'd like to know more about <u>your</u> experiences with research staff.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
42	The clinic staff were very friendly with me.	1	2	3	4	5	6
43	I was sure I could discuss truthfully with the clinic staff any problems related to the vaginal gel.	1	2	3	4	5	6
44	I think there were times when the research staff was disappointed in me.	1	2	3	4	5	6
45	Sometimes I felt that research staff thought I didn't understand how to use the vaginal gel.	1	2	3	4	5	6
46	I often thought the research staff didn't tell me everything they know about the research.	1	2	3	4	5	6
47	I never felt that the research staff judged me.	1	2	3	4	5	6

	Sociodemographic and Behavioral Information	
	Thank you. We're almost done! Before we end, we a few final questions about your household and your current relationships. This information will help us better understand the ways that you answered earlier questions.	
1	What type of home do you live in, is it a house, a townhouse, a flat, single room or a shack?	☐1 Free standing house ☐1 Townhouse ☐1 Flat ☐1 Single room ☐1 Shack ☐1 Other, specify:_____
2	Who do you currently live with? *(mark all that apply)*	☐1 Parent/s (mother and/or father) ☐1 Other family (non-parent) ☐1 Primary sex partner ☐1 Own children ☐1 Other, specify:_____
3	Do you have any children of your own?	☐0 No ☐1 Yes

4	How many children do you have?	☐☐
5	In total, how many people live in your household?	☐☐
6	How would you describe your current relationship status? Would you say you are:	☐1 Married, or living as married with regular partner ☐2 Have regular partner(s), not living together ☐3 Sexually active, no regular partner(s) →Go to Q11 ☐4 Not sexually active currently→ Go to Q11
7	For how long have you had this partner? *(mark one)*	☐☐ years
8	How old is your regular (main) sex partner?	☐☐ years
9	Were you with this partner when you last participated in HIV prevention research?	☐0 No ☐1 Yes
10	Does this partner, or any other sexual partner(s) provide you with financial and/or material support?	☐0 No ☐1 Yes
11	Do any of your sexual partner(s) have sex partners other than you?	☐0 No ☐1 Yes ☐2 Don't Know
12	At your most recent sexual encounter, did you discuss condom use with your sexual partner?	☐0 No ☐1 Yes
13	The last time you had sex, how willing were you to have sex? Would you say you were:	☐1 Willing or wanted to have sex ☐2 Persuaded or coerced *(unsure, talked into sex)* ☐3 Physically forced or raped
14	The last time you had vaginal/anal sex, did you use a male or female condom?	☐0 No ☐1 Yes
15	What is your highest level of education? *(mark one)*	☐1 No schooling ☐2 Primary school, not complete ☐3 Primary school, complete ☐4 Secondary school, not complete ☐5 Secondary school, complete ☐6 Attended college or university, not complete ☐7 Attended college or university, complete

16	Do you currently earn an income of your own?	☐0 No ☐1 Yes → Go to Q17
17	How do you earn your current income? *(mark all that apply)*	☐1 Formal employment ☐2 Self-employment ☐3 Other, specify:_____
	Thank you for your time and willingness to answer our questions. As I described at the beginning of the interview, we hope that this information will help us to find better ways to support product use in future HIV prevention research. The information may also be useful for clinic providers who counsel women in use of family planning or other types of product use, where adherence is important.	

Development of Measures of Adherence (DOMA) Follow-Up Form (Oral Pill)

Adherence to Research Procedures (4 items)

I want you to think about the last HIV prevention study you participated in.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
1	I was very confident that I could participate in research visits.	1	2	3	4	5	6
2	Getting to the clinic appointments was a challenge.	1	2	3	4	5	6
3	I was very confident that I could attend research visits even if the visits interfered with my daily activities.	1	2	3	4	5	6
4	I did not have any trouble remembering to attend my research visits.	1	2	3	4	5	6

General Feelings about Ring Use (17 items)

Great. Thank you. Now we'd like to understand how a participant might feel about a research product. Think back to when you were participating in the research. How much would you have disagreed or agreed with these statements about the product you were using. Again, there are no right or wrong answers. Please just let us know what you were thinking while you were in the research.

		DISAGREE			AGREE		
		Lot	Some	Little	Lot	Some	Little
5	I believed that the study pill would reduce my chance of getting HIV	1	2	3	4	5	6
6	It was hard to believe that using the study pill would help me.	1	2	3	4	5	6

7	I believed that I might get HIV if I don't use the study pill as instructed.	1	2	3	4	5	6
8	I believed that my risk for HIV infection was less when I was using the study pill.	1	2	3	4	5	6
9	I believed that my risk for HIV infection was the same whether I used the study pill or not.	1	2	3	4	5	6
10	I had doubts about the benefits of using the study pill.	1	2	3	4	5	6
11	There was a chance that the study pill might cause me harm.	1	2	3	4	5	6
12	The effects of the study pill lasted even if I did not take it for several days.	1	2	3	4	5	6
13	The study pill worked as soon as I took it.	1	2	3	4	5	6
14	I was comfortable taking the study pill daily.	1	2	3	4	5	6
15	Using the study pill every day was too much of a hassle.	1	2	3	4	5	6
16	The study pill helped me to feel better physically.	1	2	3	4	5	6
17	Using the study pill gave me confidence.	1	2	3	4	5	6
18	Using the study pill improved my outlook on life.	1	2	3	4	5	6
19	The benefits of using the study pill outweighed any difficulty I might have had in using it.	1	2	3	4	5	6
20	Using the study pill some of the time is better than not using it at all.	1	2	3	4	5	6
21	Using a study pill to prevent HIV is better than using condoms.	1	2	3	4	5	6

Effect on Relationship or Daily Routine (9 items)

Using the research product sometimes affects a participant's relationships with her family, friends or her partner. It might also change her daily routine. Now we'd like your help with questions about relationships.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
22	It was difficult for me to explain the research to my family.	1	2	3	4	5	6
23	Pill side effects interfered with my everyday life.	1	2	3	4	5	6
24	Side effects made it difficult for me to keep using the study pill.	1	2	3	4	5	6
25	It was difficult to take the study pill because it gave me nightmares.	1	2	3	4	5	6

26	Sometimes, if I felt worse when I had taken the study pill, I stopped using it.	1	2	3	4	5	6
27	The study pill improved my sex life.	1	2	3	4	5	6
28	I did not want to be seen with the study pill container.	1	2	3	4	5	6
29	I sometimes wondered if the study pill was working because I didn't even feel it.	1	2	3	4	5	6
30	The study pill side effects interfered with my sex life.	1	2	3	4	5	6
31	It was difficult for me to explain the research to my friends.	1	2	3	4	5	6

Self-Efficacy (5 items)

Thank you. These next questions refer to a woman's confidence or ability to use the research product or follow the research plan. As with other sections, there are no right or wrong answers, just your opinion. Please let us know what you think.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
32	I was tempted to stop using the study pill when side effects began to interfere with daily activities.	1	2	3	4	5	6
33	I was completely confident that I could continue to use the study pill when I was not feeling well.	1	2	3	4	5	6
34	I was able to deal with any problems in following my research plan.	1	2	3	4	5	6
35	I needed help to follow my research plan.	1	2	3	4	5	6
36	I was not always sure that I took the study pill correctly.	1	2	3	4	5	6

Enacted Adherence To Product (7 items)

There are many reasons that a woman may or may not be able to use her product exactly as she was instructed during the research. In previous research on oral pills for HIV prevention, women have described several reasons why they did not always take their pills. Please tell me how much you disagree or agree with the following statements, when thinking about your own use of the vaginal ring.

		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
37	I did not take the study pill *during my menses*.	1	2	3	4	5	6
38	I did not take the study pill at any time, except *before* a clinic visit.	1	2	3	4	5	6

39	I sometimes had trouble taking the study pill because it was too large to swallow.	1	2	3	4	5	6
40	I did not take the study pill *when my partner was with me*.	1	2	3	4	5	6
41	There were times when I took the study pill earlier or later than I normally did.	1	2	3	4	5	6
42	I sometimes forgot to take the study pill for several days at a time.	1	2	3	4	5	6
Clinic Staff Support (6 items)							
In this section, we want to know more about the research staff. Many research participants have very good relationships with the staff, but some don't. And sometimes, women have good relationships with some staff, but not all the staff conducting the research. We'd like to know more about <u>your</u> experiences with research staff.							
		DISAGREE			**AGREE**		
		Lot	Some	Little	Lot	Some	Little
43	The clinic staff were very friendly with me.	1	2	3	4	5	6
44	I was sure I could discuss truthfully with the clinic staff any problems related to the study pill.	1	2	3	4	5	6
45	I think there were times when the research staff was disappointed in me.	1	2	3	4	5	6
46	Sometimes I felt that research staff thought I didn't understand how to use the study pill.	1	2	3	4	5	6
47	I often thought the research staff didn't tell me everything they know about the research.	1	2	3	4	5	6
48	I never felt that the research staff judged me.	1	2	3	4	5	6
	Sociodemographic and Behavioral Information						
	Thank you. We're almost done! Before we end, we a few final questions about your household and your current relationships. This information will help us better understand the ways that you answered earlier questions.						
1	What type of home do you live in, is it a house, a townhouse, a flat, single room or a shack?	☐1 Free standing house ☐1 Townhouse ☐1 Flat ☐1 Single room ☐1 Shack ☐1 Other, specify:_____					

2	Who do you currently live with? *(mark all that apply)*	☐1 Parent/s (mother and/or father) ☐1 Other family (non-parent) ☐1 Primary sex partner ☐1 Own children ☐1 Other, specify:_____
3	Do you have any children of your own?	☐0 No ☐1 Yes
4	How many children do you have?	☐☐
5	In total, how many people live in your household?	☐☐
6	How would you describe your current relationship status? Would you say you are:	☐1 Married, or living as married with regular partner ☐2 Have regular partner(s), not living together ☐3 Sexually active, no regular partner(s) →Go to Q11 ☐4 Not sexually active currently→ Go to Q11
7	For how long have you had this partner? *(mark one)*	☐☐ years
8	How old is your regular (main) sex partner?	☐☐ years
9	Were you with this partner when you last participated in HIV prevention research?	☐0 No ☐1 Yes
10	Does this partner, or any other sexual partner(s) provide you with financial and/or material support?	☐0 No ☐1 Yes
11	Do any of your sexual partner(s) have sex partners other than you?	☐0 No ☐1 Yes ☐2 Don't Know
12	At your most recent sexual encounter, did you discuss condom use with your sexual partner?	☐0 No ☐1 Yes
13	The last time you had sex, how willing were you to have sex? Would you say you were:	☐1 Willing or wanted to have sex ☐2 Persuaded or coerced *(unsure, talked into sex)* ☐3 Physically forced or raped

14	The last time you had vaginal/anal sex, did you use a male or female condom?	☐ 0 No ☐ 1 Yes
15	What is your highest level of education? *(mark one)*	☐ 1 No schooling ☐ 2 Primary school, not complete ☐ 3 Primary school, complete ☐ 4 Secondary school, not complete ☐ 5 Secondary school, complete ☐ 6 Attended college or university, not complete ☐ 7 Attended college or university, complete
16	Do you currently earn an income of your own?	☐ 0 No ☐ 1 Yes → Go to Q17
17	How do you earn your current income? *(mark all that apply)*	☐ 1 Formal employment ☐ 2 Self-employment ☐ 3 Other, specify:_____
	Thank you for your time and willingness to answer our questions. As I described at the beginning of the interview, we hope that this information will help us to find better ways to support product use in future HIV prevention research. The information may also be useful for clinic providers who counsel women in use of family planning or other types of product use, where adherence is important.	