

## CHOICE IN THE HOPE STUDY

### ***What is the purpose of the HOPE study?***

The primary purpose of the HOPE study is to offer participants immediate access to a safe and effective dapivirine vaginal ring (“the ring”) as an HIV prevention option. We want to understand why participants may choose the ring as an HIV prevention method or not, and whether preferences change over time.

<b>How is HOPE different from ASPIRE?</b>	
<b>ASPIRE</b>	<b>HOPE</b>
Purpose: To determine whether the ring was effective and safe for HIV prevention.	Purpose: To understand if women will use the ring, when given the opportunity.
Tested the safety of the ring	We know the ring is very safe
Tested if the ring can prevent HIV infection	We know the ring can reduce a woman’s chance of HIV infection
Half the women received rings with study drug and half received rings without study drug	All rings contain the study drug
All participants had to agree to use the ring	Ring use is an individual choice for each participant!
...	...

### ***So you are saying women have a choice to use the ring in HOPE?***

Yes. Women can join the study whether or not they choose the ring as a prevention method. All participants receive the same benefits from study participation, regardless of ring choice. Because participants have a choice, we ask that participants only take the ring if they want to use it. Participants can also change their mind about ring use throughout the study.

### ***Since ASPIRE showed that the ring is safe and effective, why are you giving HOPE participants the choice not to use it?***

HOPE is about understanding *if and how* women will use the ring now that it is known to be safe and effective. We know that condoms are safe and effective, but still many people choose not to use them or find them difficult to use. We understand a lot about why people do or do not use condoms and we want to gather similar information about the ring. Some participants may prefer not to use the ring, but still contribute to the study by discussing what makes the ring difficult to use or undesirable to them. HIV prevention needs and preferences may also change for a participant over time. **Ultimately, we want each woman to understand her risk for HIV, all the HIV prevention options that are available to her, and choose the method(s) that fit well in her life.**

HOPE site staff and community team members can work with participants to help them determine and understand their HIV risk. We want women to feel free to choose the ring or not, and to change their minds, without judgement from staff or other participants.

### ***Do women who join HOPE but don’t choose the ring really contribute anything to the study?***

All participants who join HOPE contribute valuable information to the study, whether or not they choose the ring. Feedback from all participants will help improve our understanding of the ring and how to help women use the ring successfully in the future.

## **ADHERENCE & HIV PROTECTION IN HOPE**

### ***Why is adherence so important if I choose the ring in HOPE?***

High adherence was essential in ASPIRE to test whether the dapivirine ring could protect women from HIV. In HOPE, high adherence is important because it impacts your personal level of HIV protection.

### ***If I use the ring all the time, what level of protection will I have?***

We know that protection from HIV is highest when the ring is used all the time, and that the ring offers no protection if it is not used. It is important to know that if you wear the ring most of the time, but it is not in place when you are exposed to HIV (for example, you take it out when you have sex), you may not be protected. When researchers first announced the ASPIRE results, they had not yet looked at how adherence to the ring impacted its effectiveness. They now have had time to explore this question. New information from ASPIRE indicates that when the ring is used most of the time, protection from HIV could be 75% or higher, and when used all of the time, protection could be over 90%. Results from HOPE will help researchers understand even more clearly what level of protection the ring provides when used all of the time.

### ***Why is adherence important for the HOPE study overall?***

High adherence among women who choose the ring will allow us to understand more about the efficacy of the ring when used all the time. This information is important to know for potential future introduction of the ring in the community.

### ***What will happen if I have challenges to using the ring in HOPE?***

HOPE study staff want you to create an HIV prevention plan that fits your life. If you choose the ring but find that you have trouble using it, counsellors will help support you in overcoming any challenges. Even if you decide not to use the ring, or if you change your mind about ring use, counsellors will help support any HIV prevention plan you choose.

### ***What if my friend or family member wants to use the ring?***

For now, the ring is only available for women who are HOPE participants. It is important not to share the ring or give it away. Women who are not in the study may not get regular HIV or pregnancy testing, or regular medical care. If they use the ring and develop problems, they may not have access to the care they need. The ring can only protect you from HIV if you are using it at all times, which means not giving it to others.

### ***Will participants who had low adherence in ASPIRE be allowed to join HOPE?***

All former ASPIRE participants will be offered the opportunity to join HOPE. We are grateful to all the ASPIRE participants who helped us show that the ring was safe and helps reduce HIV risk. We recognize that some participants experienced challenges using the ring or may have even chosen not to use it. In HOPE, we feel that all former participants deserve a 'fresh start' and the opportunity to reduce their HIV risk as much as possible. Therefore, we want to provide all former participants access to the ring and other study benefits.

### ***Is the ring equally effective for women of all ages?***

In ASPIRE, women younger than 21 years old who were assigned to the dapivirine ring got HIV at the same rate as women assigned to the placebo ring. However, we know that the biggest factor limiting the dapivirine ring's effectiveness for young women in ASPIRE was inconsistent use. Researchers are doing specific studies to confirm if any other factors might impact the effectiveness of the ring in younger women. It is important to note that all women who participated in ASPIRE will be older than 21 years old by the time they join HOPE. It is up to us as study staff, participants, and the community, to engage and support young women in meaningful ways so that they can access and consistently use effective HIV prevention methods that suit their lives.

## **OPEN REPORTING & HOPE**

### ***What will happen if I choose the ring and report that I am not using it?***

There will be no negative consequences for reporting openly about ring use, even if you report that you had challenges or chose not to use the ring at all times. The HOPE team is here to help you overcome challenges to using the ring, if that is the method of HIV prevention you choose, or to support you to change prevention methods, if you think something else would work better.

### ***What tests will you be doing for adherence and what do these results mean?***

We will collect several samples to measure adherence and better understand how the ring is working, including used rings, blood, hair, and vaginal swabs. If you choose the ring, we will share with you the results that look at how much study drug (dapivirine) was released from the ring. The purpose of collecting this information is not to question what you tell us about your own ring use or punish those who are not adherent. Our purpose in sharing the results with you is to give you a general idea of the level of HIV protection you may be getting from the ring. With these results, you will be able to make more informed decisions about how best to avoid HIV infection.

### ***Why is it important for me to openly report about my ring use?***

Without open reporting of adherence, it is difficult to understand the true protection from the ring and the potential challenges of ring use. While we can test samples and get an estimate of adherence, the most valuable information we can get about ring use is from participants themselves. Your experiences with the ring will provide important information for future introduction of the ring in the community.

### ***What if I feel uncomfortable talking about my ring use with study staff?***

During ASPIRE, not all women felt comfortable telling staff when they were not able to use the ring. We hope that removing the concern of negative consequences will help you feel comfortable to openly report your HIV prevention preferences and ring use experiences to study staff. The HOPE Team is here to support your HIV prevention choices, and our counselors and nurses are receiving extra training to help you feel supported in whatever decision you make.