Study Title MATRIX-002: Trial to Assess Acceptability and Safety of Two Placebo Prototype Vaginal Films

Consent Version V1.0, 05Jul2023 **Protocol Version** V1.0 24May2023

NCT Number: NCT06046053

Document Date: 08Aug2024

MATRIX-002
Trial to Assess Acceptability and Safety of Two Placebo Prototype Vaginal Films

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SHORT TITLE: VALUE Placebo Film Study
SPONSOR: USAID
PROTOCOL: Version 1.0 24May2023
INFORMED CONSENT: Version 1.0 05Jul2023

INFORMED CONSENT
You are being invited to take part in this research study because you are an 18-45-year-old woman in good health. Approximately 100 women will take part in this study across sites in the United States (US), Kenya, South Africa, and Zimbabwe. This study is looking at two placebo vaginal films.

This study is sponsored by the US Agency for International Development (USAID) and conducted by the University of Pittsburgh/Magee-Womens Research Institute and Foundation (Pitt/MWRIF) as part of MATRIX: A USAID Project to Advance the Research and Development of Innovative HIV Prevention Products for Women. The placebo vaginal films are supplied by Pitt/MWRIF. At this site, the person in charge of this study is Katherine Bunge, MD.

KEY INFORMATION
- The study will assess the acceptability and safety of the two placebo vaginal films. The placebo films do not contain any active medication; the films do not prevent HIV.
- You would be randomly assigned to one of the two films and asked to use (self-insert) the assigned film two times (approximately one month apart). The study involves answering questions, undergoing pelvic examinations, and collecting blood and vaginal fluid samples.
- You would be in the study for approximately 9 weeks once you are enrolled.
- The study involves a total of 10 visits/contacts, including in person visits and telephone calls.
- There may be no benefit to participating.
- You cannot join this research study if you are living with HIV, pregnant, breastfeeding, or are already taking part in another research study involving drugs, medical devices, vaginal products, or vaccines.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop your participation in the study at any time.

Please take the time to read this entire form and ask questions before deciding to join the study. If you are willing to take part in the study, you will sign this form. A copy of this form will be offered to you. Signing this form does not mean you will be able to join the study. You must first complete the screening tests and exams to see if you are eligible. It is important to know that

your participation in this research study is your decision and taking part in this study is completely voluntary (see Your Rights as a Research Participant/Volunteer for more information).

WHY IS THIS RESEARCH BEING DONE?
Investigators are studying products that women can use for HIV prevention. Vaginal films are being evaluated as one potential way to deliver anti-HIV drugs into the vagina (in future studies).

This study will allow participants to use one of the placebo vaginal films twice during their participation. The study will evaluate safety and will collect information on acceptability and use.

Both vaginal films being used in this study are 2 x 2 inch placebo vaginal films (contain no medication) and are made up of the same material. They are "prototype" films for future studies and will be referred to as Film A and Film B. They differ by shape. The components of the placebo films being used in this study have been used in other products and/or have been generally regarded as safe. So that you better understand, the study team is able to show you an example of the films.

WHO WILL BE IN THIS RESEARCH STUDY?
Approximately 100 women who are 18-45 years old will be enrolled in the study across sites in the United States (US), Kenya, South Africa, and Zimbabwe.

DO I HAVE TO BE IN THIS STUDY?
Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study including any research study that is offered by your doctor. You can still get the care you need even if you do not join the study. If you join today, you can change your mind later.

WHAT WILL I BE ASKED TO DO IF I JOIN THIS RESEARCH STUDY?
You will undergo a screening visit to be sure you are eligible and interested. If you are eligible and decide to enroll in this study, you will be asked to use (self-insert) one of two placebo vaginal films, approximately one month apart. Neither you nor investigators can choose the film you will use. Both placebo films are important to the study.

You must be using an effective method of birth control for at least two weeks before screening and agree to continue to use the method throughout the duration of the study to qualify.

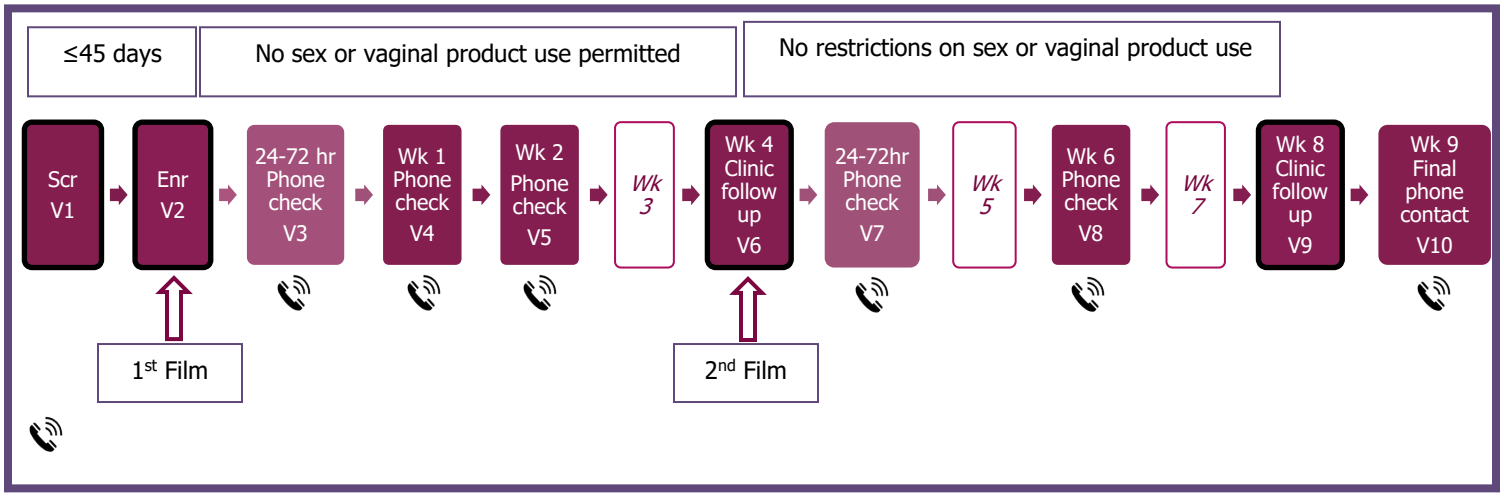
At the Enrollment Visit (V2) you will be asked to insert the first vaginal film, undergo evaluations, and provide feedback about your experience. During the first month after film insertion, you will be asked to abstain from sex and not use anything in the vagina. For example, this means no sex, fingers, tampons, menstrual cups, toys, douches, vaginal medications. If you do not think you can agree to this, you should not participate.

Approximately a month later (V6) you will be asked to insert a second film (the same assigned film), undergo evaluations, and provide feedback about your experience. During the month following this 2nd film insertion, you will be permitted to have sex and use vaginal products if you choose.

You will have scheduled follow-up clinic visits and telephone contacts as detailed below.

WHAT WILL HAPPEN DURING THE STUDY VISITS?
The study includes a total of ten (10) clinic visits or telephone contacts, including the Screening Visit today. All in-person visits will take place at this clinic. Telephone contacts may be done through a phone call. Participants who prefer to complete the telephone contacts in-person may elect to do so.

Study Visit Schedule:



Screening Visit (Visit 1) Procedures:
The procedures done at this visit will let us know if you can join this study and will take about an hour.

At the Screening Visit, you will:

- Answer questions related to
  - Demographics: date of birth, race, contact information, etc.
  - Medical and menstrual history: review of any medical problems you may have
  - Medication use: review any medication you take, including start date, dose, etc.
  - Birth control method: you must be using and agree to continue to use an acceptable, reliable method throughout the study to qualify

- Undergo counseling
  - HIV/STI (sexually transmitted infection) counseling and how to reduce your risk
  - Abstinence (no sex and no vaginal product) counseling will be reviewed. This would be for the first month, starting at the Enrollment Visit.
    - **It is important that you know if you are not currently using an acceptable method of contraception, or if you do not think you can abstain from vaginal intercourse or use of vaginal products for the first month of film use, you will not be eligible to participate in this study.**

- Have examinations
  - Physical exam
  - Pelvic exam: a speculum (device inserted into the vagina) will be used to look at the vagina and cervix
- Have baseline testing:
  - Urine pregnancy test: If you are pregnant, you will not be able to join
  - HIV test: A saliva sample will be tested for the antibody to HIV. An antibody is a substance that blood cells make to fight infection. Exposure (contact) to the HIV virus produces antibodies. Results take 20 minutes. Study staff will talk to you about the meaning of the result. Sometimes HIV test results are not clearly positive, but also not clearly negative. In that case, blood will need drawn and sent to the lab for further testing. If the test shows you have HIV, you cannot join the study.
  - Blood test: Approximately 12mL (or 2 ½ teaspoons) will be collected to look at the general health of your blood, basic kidney and liver function, and to screen for syphilis
  - STI test for gonorrhea, chlamydia and trichomonas by collecting a Q-tip like swab
  - Pap smear: If you have not had a normal result within the required period and/or the report is not available, you will have a Pap smear performed by using a soft brush to collect a sample of cells from your cervix to screen for cervical cancer
  - Additional tests may be done if you are having symptoms and as clinically indicated: urine dip stick/culture and/or microscope exam of vaginal fluid to check for infections
- Receive test results
  - Results of the tests listed above will be reviewed with you once available. Some tests results may be available while you are at today's visit (urine pregnancy test) while others may take up to a week to result (STI testing). The results of these tests will help to determine if you are eligible to participate.
  - If you are diagnosed with a urinary, vaginal (i.e., yeast or BV) or an STI (e.g., Gonorrhea, Chlamydia, trich) at Screening, you will be offered/prescribed treatment. If you are diagnosed with HIV and.or Syphilis you will be referred for treatment.
  - If there are other clinically significant findings, for example on your blood test or Pap smear, you will be referred for additional evaluations and treatment as needed
- In addition
  - Be provided reimbursement
  - May be tentatively scheduled for an Enrollment Visit within 45 days of Screening
    - Your menstrual cycle will be considered when scheduling your in-person visits because, ideally, no bleeding should occur around those visits

It may be necessary to conduct more than one clinic visit to complete all required screening procedures or if a test needs to be repeated.

If you do not join the study, blood and other samples collected at the Screening visit will not be kept or used for any tests other than those listed above.

If you are eligible and decide to enroll in the study, there are common study procedures that will happen at every in-person visit (V2, V6, V9), including:

- Review/update your contact information, including address and phone number*
- Review/update your medical and menstrual history*
- Review/update any medications you are taking/using*

- Review/update any sexual activity or intravaginal product use
- Have HIV/STI testing and counseling
    - You will be told your test results as soon as they are available. You will talk with the study staff about the meaning of your results, how you feel about them, and learn about ways to prevent HIV and other STIs. Sometimes HIV tests are not clearly positive, but also not clearly negative. In that case, we will do more tests until we are sure of your status (approximately 4 ml of blood). To participate in the study, you must receive the results of your HIV test. If the test shows you have HIV, you cannot join the study. We will refer you to available sources of medical care and other services you may need.
- Review of any new complaints or side effects once you start using the film*
- Targeted physical exam, as clinically indicated based on symptoms/complaints
- Have a urine pregnancy test
- Have pelvic exam with collection of Q-tip swabs to look at the bacteria in the vagina
- As needed tests:
    - Repeat blood tests (general health of blood, kidney and liver function)
    - Microscope exam of vaginal fluid to look for yeast or bacteria
    - Urine dip/culture
- Review of test results*
- Treatment or referral for abnormal test results as needed
- Undergo protocol counseling, including HIV/STI risk reduction and contraceptive counseling, as needed*
- Reimbursement for the study visit/contact*
- Schedule next visit/contacts*

*These procedures will also be done at the scheduled Telephone Contacts (V4, V5, V8, V10)

Enrollment Visit (Visit 2) Procedures:
Your Enrollment Visit (the visit where you enter the study) will take about an hour. You will be randomized to one of two vaginal placebo films at this visit. You will receive either placebo film A or B at this visit, to be self-inserted at the clinic.

The Enrollment Visit will take place up to 45 days after your Screening Visit.

In addition to the common study procedures listed above, at the Enrollment Visit, you will:

- Answer questions
    - About the vaginal film
    - About sexual behaviors and risk factors
    - Additional questions about the vaginal film following insertion
- Undergo counseling
    - Abstinence (refrain from sex and vaginal products) counseling
- Have examinations
    - Pelvic exam prior to inserting film
    - Visual external (outside) genital exam after insertion of film to check placement
- Take a blood sample, approximately 10mL or 2 teaspoons. This blood sample will be stored in case there is a question about your test results at a later time.
- Be randomized to use Film A or B as described above
- Review instructional materials

  - You will be provided with vaginal film instruction materials to review prior to inserting the film. Study staff will be available to answer any questions you may have.
- Self-insert the assigned vaginal film (A or B)
  - You will have two attempts to insert the vaginal film
  - If after two attempts, you are having difficulty, a clinician will insert the film using a speculum

24-72-hour Phone Check-in (Visit 3) Procedures:
This contact will take place between 24-72 hours after insertion of the first film and will take approximately 5 minutes to complete.

You will be asked if you are having any issues or concerns with the film. You will be reimbursed for this contact.

1-week and 2-week Telephone Contacts (Visits 4 and 5) Procedures:
Your 1-week and 2-week follow-up contacts will take place approximately 7 and 14 days (one and two weeks) following the Enrollment Visit. These telephone contacts will take approximately 5 minutes to complete.

In addition to the common study procedures with Telephone Contacts listed earlier, you will be asked about concerns and comfort with film use.

4-week Visit (Visit 6) Procedures:
This clinic visit will occur approximately 28 days (4 weeks) after the Enrollment Visit and will take approximately an hour to complete.

In addition to the common study procedures listed earlier, at this visit you will:
- Answer questions
  - About your experiences using the vaginal film
  - About sexual behaviors and use of vaginal products
  - Additional questions about the vaginal film following insertion
- Undergo protocol instructions/counseling
  - Reminder there are no restrictions on sex or vaginal product use
  - Explanation of (optional) sexual partner interview component
    - You will be given information to share with your partner to see if your partner would be comfortable participating in an interview
    - This is optional; if you don't feel comfortable including or asking your partner to participate, you will not be disqualified
    - Your partner would need to sign a separate consent
  - Offer male condoms
- Have examinations
  - Pelvic exam with removal of any visible film from the first insertion
  - Visual external (outside) genital exam after insertion of second film to check placement
- Review instructional materials
  - You will be provided with vaginal film instruction materials to review prior to inserting the film. Study staff will be available to answer any questions you may have.
- Self-insert second vaginal film (A or B)
  - You will be provided with your previously assigned vaginal film

- You will have two attempts to insert the vaginal film
- If after two attempts, you are having difficulty, a clinician will insert the film using a speculum

24-72-hour Phone Check-in (Visit 7) Procedures:
This contact will take place between 24-72 hours after insertion of the second film and will take approximately 5 minutes to complete.

You will be asked if you are having any issues or concerns with the film. You will be reimbursed for this contact.

6-week Telephone Contact (Visit 8) Procedures:
Your 6-week follow-up contact will take place approximately 14 days (2 weeks) after Visit 6. This telephone contact will take less than 5 minutes to complete.

In addition to the common study procedures with Telephone Contacts listed earlier, you will be asked about concerns and comfort with film use.

8-week Visit (Visit 9) Procedures:
This clinic visit will occur approximately 28 days (4 weeks) after Visit 6 and will take approximately 30 minutes to complete (not including in-depth interview, if chosen).

In addition to the common study procedures listed earlier, at this visit you will:

- Answer questions
  - About your experiences using the vaginal film
  - About sexual behaviors and use of vaginal products
  - A subset of participants (up to 35 total) will be chosen to do an in-depth interview. Participation in the interview is voluntary and is not required for you to remain in the rest of the study.
    - If asked to be interviewed and you agree, the interview will be performed remotely by a behavioral researcher. The interview will be conducted at the study office using a secure platform like Zoom to connect you with the in-depth interviewer.
    - Study staff will make every effort to ensure your privacy and confidentiality, and information you provide during the interview will not be shared with your partner
    - The interviewer may take notes, and interviews will be audio-recorded to make sure we record your words exactly how you said them
    - The interview will be focused on your experiences using the film and behaviors during the study and could take up to an hour to complete
    - The interview may occur during V9 or after up until V10
- Have examinations
  - Pelvic exam and removal of any visible film
- Blood test: Approximately 9mL or less than 2 teaspoons will be collected to look at the general health of your blood and basic kidney and liver function
- Offer male condoms
- In addition
  - Investigators will ask if you are willing to have your partner contacted/your partner contact the investigators to participate in an in-depth interview about your partner's

experience while you were in the study. This is optional and you should only agree if you (and your partner) feel comfortable.
- If you agree, you will be asked to provide our contact information to your partner so they can call us if they are interested in participating

Final Telephone Contact – Study Exit Visit (Visit 10) Procedures:
Your Final Telephone Contact will take place approximately 7 days (one week) following Visit 9. This telephone contact will take approximately 5 minutes to complete.

In addition to the common procedures with Telephone Contacts listed above, you will be asked about your wellness and any concerns. This will end your participation in the study.

Additional Visits and Procedures
In addition to the procedures listed above, it is possible that study clinicians may need to perform additional exams or tests, if necessary. For example, you may be asked to make additional clinic visits to perform these exams/tests if you report having symptoms and/or other issues, if there are abnormal test results, or due to mistakes during the collection, processing and/or shipping of your samples. These exams/tests might include the following:

- Physical and/or pelvic exam
- Test genital samples for STIs
- Test your urine for STIs or other infections
- Test your blood for STIs
- Test your blood to check the health of your blood, liver and kidneys
- Give you treatment or refer you for treatment of STIs (positive HIV/Syphilis tests will be referred for treatment) or other issues, if needed.

It is important for you to complete every study visit/contact. If you cannot make a scheduled visit/contact, please tell the study staff as soon as possible so that the visit/contact can be rescheduled.

It is important that you remember that at any time during the study, study staff can answer any questions you may have about the procedures mentioned above or any other aspect of this study.

WHAT IF I BECOME INFECTED WITH HIV?
The placebo vaginal films do not contain medications and will not prevent HIV infection. Persons living with HIV will not be included in this study. Being in this study will not cause HIV infection. However, there is always a chance that you can get HIV through sex or other activities. If you become HIV-positive, you will stop using the study product and will stop taking part in this study. The study staff will refer you for medical care and other available services. The study does not pay for this care.

Depending on local and national health requirements, the study staff may need to report certain diseases, including HIV. The reportable diseases at this site are HIV, Gonorrhea, Chlamydia, and Syphilis. We must inform the Allegheny County Health Department (ACHD) if any of these tests are positive. Outreach workers from ACHD may then contact you about informing your partner/s, since they also should be tested. If you do not want to inform your partner/s yourself, the outreach workers may contact them, according to the confidentiality guidelines of ACHD.

WHAT IF I BECOME PREGNANT?
The placebo vaginal films are not family planning methods and will not prevent pregnancy. We do not know what effect the study product(s) have on pregnancy, including any effect on the unborn babies. Because of this, pregnant women may not join this study. Also, you must use an effective family planning method (e.g., birth control pills, hormonal-based methods, intrauterine device [IUD], the patch) other than a vaginal ring for at least two weeks before screening and for the study duration.

If you become pregnant during the study, study staff will refer you to available medical care and other services. The study does not pay for this care. You will stop using the study product and will stop taking part in this study. The study staff may contact you throughout the pregnancy and once your deliver to document your pregnancy outcome (i.e. delivery date, type of delivery, etc.).

RISKS AND/OR DISCOMFORTS

Risks of Blood Draws
You may feel discomfort or pain when your blood is drawn. You may feel dizzy or faint. You may have a bruise, swelling, small clot, or infection where the needle goes into your hand or arm.

Risks of Pelvic Exams
You may feel discomfort or pressure during the pelvic exam and collection of genital samples. You may have a small amount of vaginal bleeding or spotting which should stop shortly after the exam.

Risks of Vaginal Films
You may feel discomfort, itching, irritation, and vaginal discharge during film use.

Risks of Placebo Materials
All the materials used in both films are generally regarded as safe and/or have a history of pharmaceutical use.

Risks of HIV and Sexually Transmitted Infection (STI) Testing
HIV and STI testing may make you feel anxious regardless of the test results. Finding out your HIV status may also cause problems with your family, friends, or partner.

Other Possible Risks
You may feel embarrassed and/or worried when talking about sexual activities (if you are currently sexually active), your living situation, ways to protect against HIV and STIs, and your test results. You can choose not to answer questions at any time. Trained study staff will help you with any feelings or questions you have.

We will make every effort to protect your privacy and confidentiality during the study visits. Your visits will take place in private. Reports via computer will be stored in computers that are password-protected and will not include personal information that could identify or link information to you; only your study ID number will be recorded. However, it is possible that others may learn of your participation in this study, and because of this, may treat you unfairly or discriminate against you. If you have any problems, study staff will talk with you and try to help you.

If you participate in the in-depth interviews, they will be performed in the study office via digital platform, such as Zoom. The interviews will be audio recorded and questions of a personal nature may be asked. Responding to these questions may make you uncomfortable. The audio files will be put into writing by the person conducting the interview or by another person who does not know you and does not have your personal information. You should NOT identify anyone in the interviews and any names that might be mentioned on the recording will only be noted in the transcript using a generic description. The audio files will be stored in computers that are password protected. The data that is collected during the interviews will be linked to data collected as part of the main study. This data is all labeled by study code only.

There may be a breach of confidentiality from sending/receiving text messages for appointment reminders. Text and data rates may apply based on carrier

BENEFITS

Though you may not experience any direct benefit from participation in this study, information learned from this study may help us learn ways to prevent the spread of HIV in the future. Your opinions about the film are important to scientists working to develop this new prevention option. You will receive medical exams and counseling and testing for HIV and STIs. You will also have tests to check your overall health.

This study cannot give you general medical care, but study staff will refer you to another medical provider for care, if needed. Male condoms will be available at no cost, if you need them. If you are diagnosed with an STI during the study, you will receive medicine and/or a referral, if you need it.

NEW INFORMATION

You will be told about any new information learned during this study that may affect your willingness to stay in the study. For example, we will let you know if we learn that the study product may be causing bad side-effects.

WHY YOU MAY STOP USING THE STUDY PRODUCT EARLY OR BE ASKED TO LEAVE THE STUDY

You may need to leave the study early without your permission if:

- The study is cancelled by USAID, Pitt/MWRIF, the US Office for Human Research Protections (OHRP), MATRIX, the local government or regulatory agency, or the Institutional Review Board (IRB) An IRB is a committee that watches over the safety and rights of study participants.
- You are not able to keep appointments.
- Other reasons that may prevent you from completing the study successfully.

The study doctor will ask you to stop using the study products if:

- You acquire an HIV infection (see "If You Become Infected With HIV" section).
- You become pregnant or are breastfeeding (see "If You Become Pregnant" section).
- You use drugs for HIV prevention or to prevent infection after HIV exposure.
- You use injectable drugs for reasons other than treating disease.
- You experience a serious adverse event while on study.

- You fail to follow study requirements in a manner judged by the study doctor to significantly put you at risk of an adverse reaction or otherwise affect study outcomes.
- A study clinician decides that using the study product would be harmful to you, for example, you have a bad reaction to the vaginal film(s).

If a study doctor asks you to stop using study product, we will ask you to come in for an interim visit during which some/all of the procedures scheduled to occur on Visit 9 will be completed. You will then be exited from the study, unless otherwise informed by study staff.

ALTERNATIVES TO BEING IN THE STUDY

This is a placebo study enrolling healthy, adult women. You can choose not to participate in this study without affecting your care at this or other facilities or your ability to participate in other studies.

COSTS TO YOU

There is no cost to you for study visits, study products, physical/clinical exams, laboratory tests or other procedures. We can give you treatments for STIs (other than HIV/Syphilis) at no cost while you are in the study, or we can refer you for available treatment.

REIMBURSEMENT

You will receive compensation for your time, effort, and travel to and from the clinic for each scheduled study visit.

VISIT	PAYMENT
V1 (Screening)	$40
V2 (Enrollment)	$60
V3 (24 hr call)	$20
V4 (1 week call)	$20
V5 (2 week call)	$20
V6 (2nd film)	$60
V7 (24 hr call)	$20
V8 (2 week call)	$20
V9 (last clinic visit)	$60
V10 (final call)	$20 + $60 incentive*
TOTAL	$400 (includes $60 incentive)

*paid if all visits/contacts completed within window

If you are selected for and complete the In-depth Interview you will receive $60. If you are asked to return for an interim visit, you will receive $20. All payments are processed at the completion of each study visit. On the day of your visit, you may also be offered a free parking pass for the garage at UPMC Magee-Womens Hospital (worth approximately $5).

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. Your study payments will be loaded onto a UPMC cash card at the completion of each visit. All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099-Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research study but the IRS requires that 24% of the payment

be sent by the institution to the IRS for "backup withholding", thus you would only receive 76% of the expected payment

CONFIDENTIALITY

We will make every effort to keep your information private and confidential. But we cannot guarantee it.

Study visits will take place in private. We will keep the information about your study visits in a secure place that only certain people can access for the purposes of this study. We will only enter your information into computers protected by passwords and will not include information that could identify you. Your identity on these records will be indicated by a number rather than by your name, and the information linking these numbers with your name will be kept separate from the research records. You can choose not to answer questions at any time. We will keep the audio recordings and materials from all interviews and discussions confidential and will only use study numbers or fake names. We will store the original records, including the audio recordings, for at least three years after completion of the study. These records will be stored in a secure, locked location.

Your personal information may be disclosed if required by law. For example, if we learn something that would immediately put you or others in danger, the study staff must take steps to keep you and others safe. This means that we have to share any information with the authorities (hospital, police, or social services) that tells us you may be in danger. For example, if you tell us that you plan to hurt or kill yourself, hurt or kill someone else, or if you tell us that someone is abusing or neglecting you.

This study will not use your name or identify you personally in any publication. De-identified data may be shared with other investigators and national registries in the future.

In clinical studies where study products or other medical devices are being assessed, it is important that volunteers are enrolled in only one clinical study at a time. Using more than one study product may lead to drug interactions and side effects that could potentially be harmful to your health. In addition to compromising the health of the study participant, this can affect the outcome of the study. The study staff will ask you about any other studies that you are or are planning to participate in.

Your records may be reviewed by:

- Representatives of the US Federal Government, including US OHRP, FDA, USAID and/or USAID contractors, and other US, local or international regulatory authorities
- Representatives of Pitt/MWRIF
- MATRIX representatives
- Study monitors
- University of Pittsburgh Office of Research Protections
- Authorized representatives of UPMC or affiliated health care providers to provide services and address billing and operational issues
- Study staff

Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your authorization for the use and disclosure of information protected by

the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. This includes things learned from the procedures described in this consent form. Study staff may also collect other information including your name, address, date of birth, and information from your medical records.

People outside the study team may need to see or receive your information for this study, such as those listed above. We cannot do this study without your authorization to use and give out your information to them. You do not have to give us this authorization. If you do not, then you may not join this study.

The use and disclosure of your information has no time limit. You may cancel your authorization to use and disclose your information at any time by notifying the Principal Investigator of this study in writing. If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

RESEARCH-RELATED INJURY
It is unlikely that you will be injured taking part in this placebo vaginal film study.

If you believe that participating in this study has resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any legal rights by signing this form.

CLINICALTRIALS.GOV
A description of this research study will be available on https://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

YOUR RIGHTS AS A RESEARCH PARTICIPANT/VOLUNTEER
Being in this study is completely voluntary. You may choose not to join this study or leave this study at any time. If you choose not to join or to leave the study, you can still join other studies and you can still access non-study services you would normally get at this or another clinic. Your study records may be kept for at least three years after study completion. If you want the results of the study after it is over, let the study staff members know.

PROBLEMS OR QUESTIONS
If you ever have any questions about the study, or if you have a research-related injury, you should contact the Principal Investigator, Katherine Bunge, MD at 412-641-4242.

If you have questions about your rights as a research participant, you should contact the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

CONSENT FOR LONG-TERM STORAGE AND FUTURE TESTING OF SPECIMENS and RELATED HEALTH INFORMATION

There might be a small amount of blood or genital samples left over after we have done all of the study-related testing. We would like to ask your permission to store these leftover samples and related health information for use in future studies, such as future research to fight HIV and other related diseases. This health information may include personal facts about you such as your race, ethnicity, sex, medical conditions and your age range. This health information will not include your name or any personal identifying information. The samples will be stored by your participant number only.

If you enroll in the study and agree, your samples and related health data will be stored safely and securely at facilities that are designed so that only approved researchers will have access to the samples. Some employees of the facilities will need to have access to your samples to store them and keep track of where they are, but these people will not have information that directly identifies you.

There is no time limit on how long your samples will be stored. Your samples may be shipped and/or stored outside of the country. The type of testing planned for your leftover specimens is not yet known. However, samples may be used by Pitt/MWRIF to complete additional quality assurance testing, ensuring that the tests work correctly and supply accurate data. No genetic testing on either a limited set or the full set of genes is planned for leftover samples that are stored for the purposes of future research. It is important that you know that any future testing or studies planned for these specimens must be approved by an Institutional Review Board before they can be done. You will not receive the results from any future testing of these specimens.

You can still enroll in this study if you decide not to have leftover samples stored for future studies. If you do not want the leftover samples stored, we will destroy them when all protocol-specified testing has been completed. You can withdraw your consent for the storage and future testing of specimens at any time by providing your request in writing to the person in charge of this study. However, researchers will not be able to destroy samples or information from research that is already underway.

_____
Initials and Date

I DO agree to allow my biological specimens and health data to be stored and used in future research studies. I understand my biological specimens may be shipped and stored outside of the country.

_____
Initials and Date

I DO NOT agree to allow my biological specimens and health data to be stored and used in future research studies.

CONSENT TO PARTICIPATE IN AN IN-DEPTH INTERVIEW

We would like to ask your permission to participate in a conversation-style interview (in-depth interview or IDI) at the end of the study to gather more feedback about the placebo vaginal film. If you agree and are selected to participate in the IDI, trained study staff will ask you questions about your experiences using the product, about product design, packaging and delivery, and other topics related to product use. Information you provide during the IDI will not be shared with your partner. The IDI may be conducted at the study site, over a secure digital platform, or an agreed upon location.

The IDI is anticipated to last approximately 45-60 minutes. The IDI will be conducted at the study site using a secure digital platform. Study staff will take notes and record the interview. You can choose not to answer questions at any time. We will keep the audio recordings and materials from all interviews and discussions confidential and will only use study numbers or fake names to identify them. These materials will be stored in a secure, locked location for at least three years after completion of the study.

We will reconfirm the decision you make today at later study visits should you change your mind about participating in the IDI.

You can still enroll in this study if you decide not to participate in the IDI. You can withdraw your consent to participate in the IDI at any time.

_____ I DO agree to participate in an in-depth interview. I understand the
Initials and Date interview will be recorded and notes will be taken.

_____ I DO NOT agree to participate in an in-depth interview.
Initials and Date

PERMISSION TO INCLUDE SEXUAL PARTNER

We would like to ask your permission to include your sexual partner to participate in a conversation-style interview (in-depth interview or IDI) at the end of the study to gather more feedback about the vaginal film.

If both of you agree and your partner is selected to participate in the IDI, trained study staff will ask your partner questions about their views on the vaginal film and its characteristics and about your experiences using the vaginal film. This means that your partner will be aware of your participation in this study and your use of the vaginal film but no other information will be shared with your partner. If your partner is selected, the data collected as part of your partner's IDI will be linked to the data collected as part of your participation in the main study and your IDI (if selected to participate in IDI). This data is labeled by study code only.

If you give us permission to include your sexual partner, you will be asked to provide the researchers contact information to your partner so they can call us if interested in participating.

We will reconfirm the decision you make today at later study visits should you change your mind about us including your sexual partner, if selected.

You can still enroll in this study if you decide not to give us permission to include your sexual partner. You can withdraw your permission for us to include your sexual partner at any time.

_____
Initials and Date

I DO give permission for study staff to include my sexual partner, if selected. I agree to provide my partner with the researchers contact information so my partner can call study staff for more information if interested.

_____
Initials and Date

I DO NOT give permission for study staff to talk to include my sexual partner.

SIGNATURE PAGE

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified member of the research team or by the Principal Investigator listed on the first page. I understand that I may always request that my questions, concerns or complaints be addressed by the Principal Investigator. At any time, I may also contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study for the purposes described above. A copy of this consent form will be offered to me.

_____
Participant's Name (Print)

_____ _____
Participant's Signature Date

_____
Study Staff's Name Conducting
Consent Discussion (Print)

_____ _____
Study Staff Conducting Date
Consent Discussion (Signature)