APPENDIX III: SAMPLE INFORMED CONSENT FORM (SCREENING AND ENROLLMENT)

DIVISION OF AIDS, NIAID, NIH

MTN-035

Acceptability, Tolerability, and Adherence of Three Rectal Microbicide Placebo Formulations among HIV Seronegative Cisgender Men, Transgender Men and Transgender Women Who Engage in Receptive Anal Intercourse

Version 1.0

June 15, 2018

PRINCIPAL INVESTIGATOR: ***[Site to insert]***
PHONE: ***[Site to insert]***
Short Title for the Study: Rectal Microbicide Acceptability, Tolerability, and Adherence

INFORMED CONSENT

IMPORTANT INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to take part in this research study because you are a healthy, HIV-uninfected [***SITES TO INSERT PREFERRED DESCRIPTION OF STUDY POPULATION: cisgender man, transgender man (TGM), or transgender woman (TGW) / man who has sex with men (MSM) or transgender woman (TGW)***] aged 18 to 35 years old who engages in receptive anal sex (penis into rectum). Approximately 210 people will participate in this study at multiple sites across the world. The US National Institutes of Health (NIH) sponsors this Microbicide Trials Network (MTN) study. At this site, the person in charge of this study is ***[INSERT NAME OF PRINCIPAL INVESTIGATOR]***.

Important things you should know:

- The three study products in this clinical trial are a rectal douche, a rectal suppository, and a rectal insert. All three are placebo study products.
- The purposes of the study are:
    - To find out if [***SITES TO INSERT PREFERRED DESCRIPTION OF STUDY POPULATION: cisgender men, TGM, and TGW / MSM and TGW***] would accept and tolerate three different ways to potentially deliver [***SITES TO INSERT PREFERRED DESCRIPTION: anti-HIV / antiretroviral***] drugs into the rectum when used before receptive anal sex.
    - To understand whether [***SITES TO INSERT PREFERRED DESCRIPTION OF STUDY POPULATION: cisgender men, TGM, and TGW / MSM and TGW***] would actually use these three rectal products as part of their usual practices around receptive anal sex.
    - To evaluate if each study product is safe when applied rectally and used before receptive anal sex by [***SITES TO INSERT PREFERRED DESCRIPTION OF STUDY POPULATION: cisgender men, TGM, and TGW / MSM and TGW***].

- If you qualify and choose to participate, you will be asked to use the three rectal products before receptive anal sex, each for one month (4 weeks). The order in which you will use the three products will be decided by chance ***[SITES TO INSERT PREFERRED DESCRIPTION OF 'RANDOMIZATION']***. Neither you nor the study staff can decide the order in which you use the products.
- Once enrolled, you will be asked to attend 8 clinic visits here at this study clinic, including the Screening Visit which is taking place today. You will come to the clinic every four and five weeks. The total length of your participation in the study will be approximately three and a half months.
- At some of the clinic visits, the following will occur:
    - A physical and/or rectal exam will be performed;
    - Blood will be obtained to test for HIV and/or other sexually transmitted infections (STI);
    - Urine will be collected to test for STIs and (if applicable) pregnancy;
    - Rectal, throat, and (if applicable) vaginal swabs will be collected to test for STIs;
    - You will be asked to complete a short interview. You may also be selected to complete a longer interview at the final visit.
- Some risks or discomforts from previously tested rectal products include:
    - Abdominal bloating, feeling full, or a sense of abdominal pressure and/or pain;
    - Sudden, almost uncontrollable, need to relieve the bowels;
    - Diarrhea (loose, frequent stools);
    - Passing gas from the intestinal tract;
    - Feeling a constant need to pass stools, despite an empty bowel;
    - Anal discharge.
- You may not experience any direct benefit from participation in this study, but you may learn more about HIV and other diseases and ways to protect yourself from acquiring HIV or other STIs. You will also have physical and rectal exams, receive HIV and STI counseling, and get referrals for other care if needed.
- Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. This will not affect the service you get at this clinic or clinics in surrounding areas.
- If you decide not to join this study, there are other currently available methods to prevent sexually transmitted HIV: condom use during sex and/or the use of daily oral Truvada® for pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP). Study staff can provide you with additional information about PrEP and PEP if you are interested. You may also join another study, if we have one and if you meet its requirements.

Please take time to read this entire form and ask questions before you decide if you want to join this study. Once you read and understand the study and its requirements, you can decide if you want to join. If you do decide to take part in the study, you will sign your name on this form. A copy of this document will be offered to you. Signing this consent 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 for this study these three rectal products will not contain any active drug. This means the products we will ask you to use will not protect you from acquiring HIV or any other STIs. Therefore, you should continue using HIV and STI prevention methods while in the study.

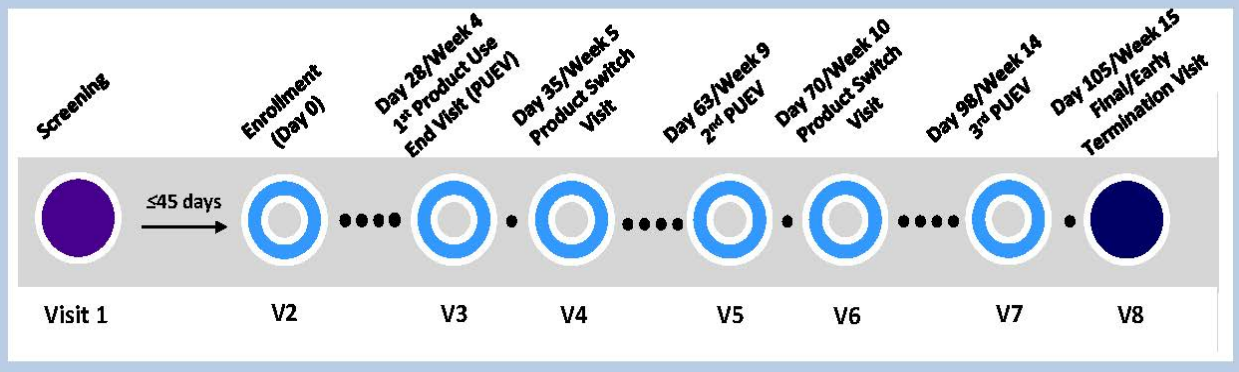
Who will be in this research study and what will I be asked to do if I join?

Approximately 210 participants will be enrolled in the MTN-035 study across 7 sites, with approximately 30 participants enrolled at each site.

If you enroll in the study, you will be asked to use the three rectal products before receptive anal sex, each for one month (4 weeks). The douche in this study will involve spraying water from the nozzle of a bottle into your rectum. The suppository is a small, cone-shaped object that you put in your rectum and dissolves quickly. An insert is a small, bullet-shaped object that you put in your rectum and dissolves quickly.

If it seems like you can join this study based on the tests done today, you will be asked to come back for an Enrollment Visit no later than 45 days from today. At your Enrollment Visit, you will begin using the first of three rectal products – douche, suppository or insert – depending on which product use sequence you have been assigned to.

Study Visit Schedule



What will happen during study visits?

Screening Visit:

The procedures done today will take about ***[SITES TO INSERT TIME]***. Multiple visits may be conducted to complete all required screening procedures.

You will:

- Answer questions to confirm you are able and willing to join the study.
- Answer questions about where you live and other questions about you, your health (including what medications you are taking), and your sexual practices.
- Provide study staff your contact information (i.e. about how we can locate you).
- Talk with study staff about STIs, HIV, HIV/STI testing, and ways to avoid HIV and other infections passed through sex, including the use of oral Truvada® for PrEP.
- Talk with study staff about the requirements of the study including, but not limited to:
    - Abstaining from using non-study rectally-administered medications or products during your participation in the study, except for personal lubricants and usual pre-RAI douches that do not contain nonoxynol-9 (N-9).
- Have a physical exam.
- Have a rectal exam. Rectal fluid will be collected using a cotton swab (like a Q-tip or earbud) to test for STIs.
    - Study staff may insert a short (10 cm or 3-4 inches) hollow tube called an anoscope inside your rectum as part of the rectal exam and rectal fluid collection. Study staff

will insert their finger(s) inside your rectum as part of the rectal exam. You may feel some discomfort or pressure in your rectum or anus from the staff person's finger(s) and/or anoscope. There is a slight risk of bleeding with the insertion of rectal swabs or sponges.

- Have your urine tested for STIs and other infections.
- [***For individuals who can get pregnant***] Have your urine tested for pregnancy.
    - If you are pregnant you cannot join this study.
    - Staff will discuss with you ways to avoid getting pregnant.
- Have a pharyngeal (throat) swab collected to test for STIs.
- ***[For individuals with a vagina or neovagina]*** Have some fluids collected from your vagina using a swab to test for STIs.
- Provide a blood sample of about 10 ml ***[SITES TO MODIFY AMOUNT IF NEEDED]***:
    - To test for STIs, including HIV and syphilis.
        - You will be told your test results as soon as they are available. You will talk with 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 can confirm your status. To participate in the study, you must receive your HIV test results. 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. The study staff will tell you about other studies you may be eligible for, if any.
- Be given treatment or a referral for treatment of STIs, if needed.
- Be informed about other services, if needed.
- Be given the results of your tests, when available. It is expected that all your results will be available by ***[SITES TO SPECIFY TIMEFRAME]***.
- Be given male condoms, if you need them.
- ***[SITES TO SPECIFY IF PARTICIPANTS MAY BE OFFERED LUBRICANT PER LOCAL STANDARD OF CARE]***
- Be reimbursed for your visit.
- Schedule your next visit to enroll in the study, if you are willing and eligible.

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

Enrollment Visit:

Your Enrollment Visit (the visit where you enter the study) will take place up to 45 days after your Screening Visit. This visit will take about ***[SITES TO INSERT TIME]***.

You will:

- Answer questions to confirm you are able and willing to join the study.
- Update study staff with your contact information (about where you live and how we can contact you).
- Be assigned the order in which you will use the three study products.
- Talk with study staff about the following:
    - The instructions and procedures of the study and how to follow the study rules, including use of non-study rectal medications or products.
    - STIs, HIV, HIV/STI testing, and ways to avoid HIV and other STIs.

- Discuss any health or medical problems you may have had in the past or since your last visit (including any medications you are taking).
- Be asked some questions about your experience and comfort using rectal products and engaging in rectal hygiene practices such as douching, among other things. These questions will be asked privately via computer.
- Be asked to respond to weekly electronic messages related to your use of the study products during each product use period.
    - You will receive instructions and training on how to receive and respond to these messages at the Enrollment Visit.
- Provide a blood sample of about 15 ml ***[SITES TO MODIFY AMOUNT IF NEEDED]***:
    - In case there's a question about your test results at a later time (about 10 ml of blood may be left unused if there is no question about your test results).
    - To test your blood for HIV.
- Have a physical exam.
- Have a rectal exam.
- [***For individuals who can get pregnant***] Have a urine test for pregnancy and discuss with study staff ways to avoid getting pregnant.
- Receive the first of three rectal products (douche, suppository, or insert) that you will use during the study, along with instructions on how to use and store your assigned product.
    - You will use your assigned study product once at the clinic under the supervision of study staff to ensure you can tolerate using the product and will be able to use it as instructed during the study.
- Be given test results, if available.
- Be given male condoms, if you need them.
- Be given lubricant to assist product insertion.
- Be reimbursed for your visit.
- Schedule your next visit, if applicable.

Product Use End Visits (PUEV) – Visits 3, 5, and 7:

Your PUEVs will take place approximately one month (4 weeks) after you begin using each of the three study products, with the first PUEV taking place approximately one month after the Enrollment Visit. These visits will take between ***[SITES TO SPECIFY TIMEFRAME]*** to complete.

You will:

- Update study staff with your contact information.
- Review the instructions and procedures of the study and how to follow the study rules, including use of non-study rectal medications or products.
- Discuss any health or medical problems you may have had since your last visit (including any medications you are taking).
- Discuss any problems that you may be experiencing as a result of using the study product, or as a result of procedures performed during the study.
- Be asked some questions about your experience using the study product. These questions will be asked privately via computer.
- Be asked to take part in a brief interview (~15 minutes) about your responses to the electronic messages during the previous month of product use. This interview will be conducted by phone or via videoconference. This interview will be audio-recorded, but your responses will be kept private and confidential.

- Have a rectal exam.
- Be given test results, if testing was done.
- Be given male condoms, if you need them.
- ***[SITES TO SPECIFY IF PARTICIPANTS MAY BE OFFERED LUBRICANT PER LOCAL STANDARD OF CARE]***
- Be reimbursed for your visit.
- Schedule your next visit or contact.

On your third PUEV (Visit 7), you will also:

- Talk with study staff about STIs, HIV, HIV/STI testing, and ways to avoid HIV and other STIs.
- Provide a blood sample of about 10 ml ***[SITES TO MODIFY AMOUNT IF NEEDED]*** to test your blood for STIs, including HIV and syphilis.
- Have your urine tested for STIs and other infections.
- Have a pharyngeal (throat) swab collected to test for STIs.
- Provide a rectal fluid sample. This will be collected using a swab to test for STIs.
- [***For individuals with vagina or neovagina***] Provide a vaginal fluid sample. This will be collected using a swab to test for STIs.

Product Switch Visits – Visits 4 and 6:

Your Product Switch Visits, Visits 4 and 6, will take place approximately one week after your first and second PUEVs, Visits 3 and 5, respectively. These visits will take between ***[SITES TO SPECIFY TIMEFRAME]*** to complete.

You will:

- Update study staff with your contact information.
- Review the instructions and procedures of the study and how to follow the study rules, including use of non-study rectal medications or products.
- Discuss any health or medical problems you may have had since your last visit (including any medications you are taking).
- Discuss any problems that you may be experiencing as a result of using the study product, or as a result of procedures performed during the study.
- Receive the rectal product assigned for your next product use period, along with instructions on how to use and store your assigned product.
    - You will use your assigned study product once at the clinic under the supervision of study staff to ensure you can tolerate using the product and will be able to use it as instructed during the study.
- Be given test results, if testing was done.
- Be given male condoms, if you need them.
- Be given lubricant to assist product insertion.
- Be reimbursed for your visit.
- Schedule your next visit or contact.

Final/Early Termination Visit – Visit 8:

Your Final/Early Termination Visit will take place approximately one week after your third PUEV, Visit 7. This visit will take approximately ***[SITES TO SPECIFY TIMEFRAME]*** to complete.

You will:

- Update study staff with your contact information.
- Discuss any health or medical problems you may have had since your last visit (including what medications you are taking).
- Discuss any problems that you may be experiencing as a result of using the study product, or as a result of procedures performed during the study.
- Be asked some questions to compare your experiences using the three study products. These questions will be asked privately via computer.
    - You may also be asked to take part in an in-depth interview (~45 minutes) about your experiences using the three study products, including questions about product design, application methods, product use influences, douching practices, and suggestions for product improvement. This interview will be conducted by phone or via videoconference. This interview will be audio-recorded, but your responses will be kept private and confidential.
- [***For individuals who can get pregnant***] Have a urine test for pregnancy and discuss with study staff ways to avoid getting pregnant.
- Be reimbursed for your visit.
- Be given test results, if available.
- Be given male condoms, if you need them.
- ***[SITES TO SPECIFY IF PARTICIPANTS MAY BE OFFERED LUBRICANT PER LOCAL STANDARD OF CARE]***

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.

Other Procedures:
In addition to the procedures listed above, it is possible that study clinicians may need to perform additional tests during any of the study visits, if necessary (e.g., if you report having symptoms of a urinary, genital, or other infection and/or other issues). These tests might include the following:

- Physical exam
- Rectal exam
- Test pharyngeal (throat), rectal and/or pelvic samples for STIs
- Test your urine for STIs or other infections
- [***For individuals who can get pregnant***] Test your urine for pregnancy
- Test your blood for HIV and/or STIs
- Give you treatment or refer you for treatment of STIs or other issues, if needed.

You may need to provide additional samples if any of the study visit procedures need to be repeated due to issues with sample processing, testing and/or shipping. Additional testing may be performed as part of quality control.

It may also be necessary for additional visits to be conducted for unforeseen events. For example, you may be asked to come to the clinic for repeat or additional testing to ensure that the study products continue to be safe for you to use. Or you may choose to come for an additional visit for any unforeseen issues, questions, or counseling.

Some of your specimens collected in this study may be shipped and stored outside your country so that study-related testing can be performed. There might be a small amount of urine, blood, or vaginal and rectal fluid left over after we have done all of the study related testing, including testing

for quality assurance and control. These leftover samples will not be stored or used for any future testing, and they will be destroyed after all testing related to this study is completed.

What are the possible risks, side effects, and discomforts of this research study?

Risks from use of rectal products
The use of any rectal product can cause some side effects. We do not yet know all the side effects of the three study products. Previously tested rectal products have been associated with:

- Abdominal bloating, feeling full, or a sense of abdominal pressure and/or pain
- A sudden, almost uncontrollable, need to relieve the bowels
- Diarrhea (loose, frequent stools)
- Passing gas from the intestinal tract
- Feeling a constant need to pass stools, despite an empty bowel
- Anal discharge
- Proctalgia (anal pain)

Risks from phlebotomy (blood tests)

- You may feel discomfort
- You may feel dizzy or faint
- You may have a bruise, swelling, small clot, or infection where the needle goes in your arm
- You may have excessive bleeding

Risks of throat swab

- A pharyngeal (throat) swab often causes a momentary gagging reflex (feeling like you want to vomit).

Risks of rectal douching

- The main risk from rectal douching is temporary discomfort. An enema bottle will be used to administer about 120-125 mL (i.e., 4 ounces or 8 tablespoons) of water into the rectum.
- You may experience some mild discomfort and a bloated or “crampy” feeling.
- If you have any hemorrhoids or other painful conditions, you might feel anal or rectal discomfort.
- Some air may be pumped into the rectum as well, causing flatulence (feeling like you need to pass gas).
- There is a remote possibility of rectal perforation.

Risks of rectal exams

- During rectal exams and collection of rectal fluid samples, insertion of the study staff’s finger(s) and/or insertion of a lubricated anoscope will likely cause mild discomfort.

Risks of rectal swab/sponge insertion

- Insertion of rectal swabs or sponges may cause mild discomfort, in addition to a slight risk of bleeding.

(*For individuals with a vagina or neovagina*) Risks of vaginal swab

- During vaginal fluid collection, you may feel discomfort or pressure in your vagina or genital area.

Other Possible Risks

- You may become embarrassed and/or worried when discussing your sexual practices, ways to protect against HIV and other infections passed through sex, and your test results.
- You may feel anxious while waiting for your test results, and after receiving them. Trained study counselors will help you deal with any feelings or questions you have.
- Finding out your HIV status could also cause problems between you and your partner(s). If you have any problems, study counselors will talk with you and/or your partner to try to help resolve them.
- Disclosure of your HIV and STI status may cause worry, sadness or depression. Disclosure of HIV-positive status has been associated with depression, suicidal ideation, and denial as well as social isolation.
- It is possible that others may learn of your participation here and, because of this, may treat you unfairly or discriminate against you. For example, you could have problems getting or keeping a job, or being accepted by your family or community.
- The interviews that take place at some of your clinic visits will be computer-administered and questions of a personal nature may be asked. Responding to these questions may make you uncomfortable. You may choose not to answer any question that makes you uncomfortable.

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 or text messages 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. You will be shown how to erase the text message sessions from your mobile phone by study staff. However, as with all text messages sent from and received on your phone, it is possible that others may see your personal messages. Precautions have been taken to ensure that questions asked via text message are vague and will not directly convey information about your participation in this research study. There is a possibility that you may exceed your cell phone plan limit and have to pay for that.

When staff talk with you about how and when you used the study products they will audio record the discussion using a digital audio recorder. These audio files will be reviewed and analyzed by another person who is outside of the research site and does not know you or have your personal information. In addition, if you agree and are selected to participate in the in-depth interviews, these will be audio recorded. The audio files will be put into writing by the person interviewing you or by another person who does not know you and does not have your personal information. Any names that might be mentioned during the interview will NOT be retained. Instead a generic description will be used in the records (i.e., if you refer to a friend's name, "FRIEND1" will be noted).

Your audio recordings and any other information that links you to the research materials will be kept in a secure location that will be accessed only by members of the MTN-035 study team for the purposes of this research. *[Sites to modify with their site-specific source documentation storage duration requirements if required by their IRBs/IECs:* The audio recordings, notes, and transcripts from these materials will be kept for at least three years after the final study report is submitted to the study sponsors.]

What are possible benefits from taking part in this study?

- There are no direct benefits for taking part in this study, but you or others may have future benefit from information learned in this study. You may also learn more about HIV and other diseases and ways to protect yourself from acquiring HIV or other STIs.
- You will have physical and rectal exams. If these exams show that you might have any health problems, you will be told about medical care and other services available to you. This will be available to you even if you do not enroll in this study. This study cannot provide you with general medical care, but study staff will refer you to other available sources of care, if needed.
- You will get counseling and testing for HIV and STIs. If you have acquired an STI other than HIV, you will be offered medicine to treat it or provided information for where you may receive treatment, and study staff will discuss options available for counseling and treatment of your partner(s). This treatment or referral for treatment is available to you even if you do not enroll in this study.
- If you acquire HIV, you will need to receive care from your own health care provider or we will provide you with a referral. This study does not provide medication for treatment of HIV/AIDS.
- You will receive free male condoms, if you need them.
- You may receive free lubricant per local standard of care.

Will the study products prevent HIV infection?

The study products used in this study are placebos and do not contain any active drugs, so they will not prevent HIV. There are other known effective ways to reduce your risk of contracting HIV: the use of condoms and/or the use of oral pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) medication. Truvada® as a PrEP is an HIV prevention method in which people who do not have HIV take an oral tablet to reduce their risk of acquiring the virus. Study staff can provide you with additional information about PrEP and PEP if you are interested in learning more. If you are interested in these alternative options you may also want to discuss them with your doctor.

What if there is new information learned during this study?

We will tell you about new information from this or other studies that may affect your willingness to stay in this study. You will also be told when study results may be available, and how to learn about them.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Is it possible that I may be taken out of the study without my consent?

A study clinician may need to remove you from the study early without your permission if:

- The study is cancelled by the US NIH, the US Office for Human Research Protections (OHRP), MTN, government or regulatory agencies, or Institutional Review Boards/Independent Ethics Committees (IRB/IEC). An IRB/IEC is a committee that watches over the safety and rights of research participants.
- The Study Monitoring Committee (SMC) recommends that the study be stopped early. A SMC reviews the progress of the study and the kinds of effects that people report while they are participating in the study.
- You acquire HIV (see “If You Acquire HIV” section below).

- (***For individuals who can get pregnant***) You become pregnant (see "If You Become Pregnant" section below).
- You report the use of non-study rectal medications or products, except personal lubricants and usual pre-RAI douches that do not contain N-9.
- A study clinician decides that using the study products would be harmful to you, for example, you have a bad reaction to the study product.
- Other reasons that may prevent you from completing the study successfully, such as you are not able or willing to reliably keep appointments or follow study rules.

In the event that you are removed from or choose to leave this study for any reason, you will be asked to complete some of the procedures described for the Final/Early Termination Visit, if you are willing to do so.

The study clinician will ask you to stop using the study products but continue to come in for follow-up visits and procedures if you have a bad reaction to the products.

If You Acquire HIV
Your participation in this study will not cause HIV infection. However, there is always a chance that through sexual activity or other activities you may acquire HIV. In the unlikely event that you acquire HIV, study staff will give you counseling and refer you to available medical care and other services you may need. The study does not pay for this care. Tests may be performed that will allow your doctor to know what HIV drugs would be best for the treatment of your type of HIV. If the HIV test shows that you have acquired HIV, you will stop using the study products. You may be referred to other research studies. Continued study participation would be of no added benefit to you, so your participation in the study will be discontinued.

(For individuals who can get pregnant) If You Become Pregnant
The study products are not birth control methods and will not prevent pregnancy. You must use an effective method of contraception for at least 30 days (inclusive) prior to Enrollment and for the duration of study participation. You must agree to use an effective method of birth control such as birth control pills or another hormonal-based method, or an intrauterine device (IUD) inserted at least 30 days prior to enrollment, or abstain from penile-vaginal intercourse for 90 days prior to enrollment and for the duration of study participation, unless you or your partner have been sterilized (i.e., no longer able to become pregnant), and/or you only have sex that cannot lead to pregnancy (no penile-vaginal intercourse).

We do not know what effect the placebo study products may have on pregnancy, including the effect on the fetuses of individuals who use the products when pregnant. Because of this, individuals who are pregnant may not join this study. Individuals who can get pregnant and who join this study will have pregnancy tests while in the study.

If you become pregnant during the study, study staff will refer you to available medical care and other services you or your baby may need. The study does not pay for this care. You will stop using the study products and you will exit the study.

Will there be any payments if I take part in this research study?
[SITES TO INSERT INFORMATION ABOUT LOCAL REIMBURSEMENT:] You will receive [***SITES TO INSERT AMOUNT*** **$xx**] for your time, effort, and travel to and from the clinic at each scheduled visit. You may receive [***SITES TO INSERT AMOUNT*** **$xx**] for any visits which occur in between your normally scheduled visits. For responding to text messages, you will receive up

to [***SITES TO INSERT AMOUNT* $xx**]. If you are selected and agree to take part in the in-depth phone interview, you will receive [***SITES TO INSERT AMOUNT* $xx**].

What are the costs?
[SITES TO COMPLETE ACCORDING TO SITE CAPACITY] There is no cost to you for study related visits, physical/rectal exams, laboratory tests or other procedures. Treatments available to you from the study site for infections passed through sex will be given to you free of charge or you will be referred for available treatment for the duration of the study.

Are there any other studies if you cannot join this one?
There may be other studies going on at this study clinic or in the community for which you may be eligible. If you wish, we will tell you about other studies that we know about. There may also be other places where you can go for HIV counseling and testing. We will tell you about those places if you wish. If you choose not to take part in this study, it will have no effect on the regular medical care that is available to you at this clinic or elsewhere.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as private as possible. All records related to your involvement in this research study will be kept in a [***SITES TO INSERT***]. 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.

Efforts will be made to keep your information confidential. However, it is not possible to guarantee confidentiality. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally. The study staff may use your personal information to verify that you are not in any other research studies. This includes studies conducted by other researchers that study staff know about.

Your records may be reviewed by:
- Study staff
- Site IRBs/IECs
- CONRAD, the organization that supplies the placebo insert
- Representatives of the US Federal Government, including OHRP, NIH and/or contractors of NIH
- Other local, US or international regulatory authorities

[Sites to include/amend the following:] [LOCAL/STATE/NATIONAL] regulations require study staff to report the names of people who test positive for HIV and other infections passed during sex to the ***[LOCAL HEALTH AUTHORITY]***. Outreach workers from the ***[LOCAL HEALTH AUTHORITY]*** may then contact you about informing your partners, since they also should be tested. If you do not want to inform your partners yourself, the outreach workers will contact them, according to the confidentiality guidelines of the ***[HEALTH AUTHORITY].***

[Sites to include/amend the following:]
The researchers will do everything they can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the US Federal Government. This Certificate protects study staff located in the US from being forced to tell people who are not connected with this study, such as the court system, about your participation or information you give for study purposes. However, if the study staff learns of possible child abuse and/or neglect or a risk of harm to you or others, they will be

required to tell the proper authorities. This Certificate does not prevent you from releasing information about yourself and your participation in the study.

What if I am injured as a result of participating in this study?
[SITES TO SPECIFY INSTITUTIONAL POLICY:] It is unlikely that you will be injured as a result of study participation. If you are injured, the ***[institution]*** will give you immediate necessary treatment for your injuries. You ***[will/will not]*** have to pay for this treatment. You will be told where you can receive additional treatment for your injuries. The U.S. National Institutes of Health (NIH) does not have a mechanism to pay money or give other forms of compensation for research related injuries. You do not give up any legal rights by signing this consent form.

May I withdraw my consent for participation in this research study?
[SITE TO SPECIFY INSTITUTIONAL POLICY:] Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. If you choose not to participate or to leave the study, you will not lose the benefit of services to which you would otherwise be entitled at this clinic, nor will the confidentiality of the care provided for you here be affected. You should feel free coming back to this facility even if you decide not to participate in this study. If you want the results of the study after the study is over, let the study staff members know.

What do I do if I have questions?
If you ever have any questions about the study, or if you have a research-related injury, you should contact ***[insert name of the investigator or other study staff]*** at ***[insert telephone number and/or physical address]***.

If you have questions about your rights as a research participant, you should contact **[insert name or title of person on the IRB or other organization appropriate for the site]** at **[insert physical address and telephone number]**.

SIGNATURES- VOLUNTARY CONSENT

[INSERT SIGNATURE BLOCKS AS REQUIRED BY THE LOCAL IRB/IEC]: If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to the study, please sign your name or make your mark below.

_____	_____	_____
Participant Name (print)	Participant Signature/Mark	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date
_____	_____	_____
Witness Name (print)	Witness Signature	Date