

# FACILITATOR'S GUIDE

THE RECTAL REVOLUTION IS HERE:

AN INTRODUCTION TO  
RECTAL MICROBICIDE CLINICAL TRIALS

**THE RECTAL REVOLUTION  
IS HERE** **NOW  
PLAYING**



# HOW TO USE THIS GUIDE

This facilitator's guide has been developed as a tool for people leading community discussions or recruitment sessions who will be showing the educational video, *The Rectal Revolution is Here: an Introduction to Rectal Microbicide Clinical Trials*. The guide has been designed for facilitators as a tool to prepare for video screenings at workshops/presentations. The information provided on rectal microbicide research and the clinical trial process is background material for the facilitator, and will be especially helpful for facilitators who are less familiar with rectal microbicide research. A set of suggested questions to ask video audiences is included in the guide. Facilitators may choose to use these questions, or come up with their own based on audience interest. If you find yourself unable to answer an audience question that comes up during a screening of the video, don't worry. No one is expected to know the answers to every potential question. Just be sure to tell the person who asked the question that you don't know, and that you will get back to him or her with an answer once you find it. Remember to get the individual's email address so you can follow up. Then send an email to [rectalmicro@gmail.com](mailto:rectalmicro@gmail.com) with the question, and someone will get back to you with the answer as soon as possible.

The guide also includes two forms that are important for obtaining feedback on the video:

**Facilitator Utilization Form:** this form is to be filled out by the facilitator, scanned, and emailed to the International Rectal Microbicide Advocates (IRMA) at [rectalmicro@gmail.com](mailto:rectalmicro@gmail.com) after each video screening.

**Participant Evaluation Form:** this form is to be printed off and distributed to each person at the workshop/presentation/recruitment session where the video is screened. Please ask the participants to complete this short form, and please scan and email them to IRMA [rectalmicro@gmail.com](mailto:rectalmicro@gmail.com).

**WE THANK YOU IN ADVANCE FOR SHARING FEEDBACK ON THE VIDEO!**

# I. INTRODUCING RECTAL MICROBICIDES AND THE VIDEO

Rectal microbicides (RMs) are products being developed to prevent HIV, and potentially other sexually transmitted infections (STIs) during receptive anal intercourse. Unprotected receptive anal intercourse is the primary driver of the HIV epidemic among gay men and other men who have sex with men (MSM). Compared to unprotected vaginal intercourse, unprotected anal sex is 10 to 20 times more likely to result in HIV infection.

As RM research expands from early Phase 1 studies to larger Phase 2 and 3 clinical trials, educational materials are needed to engage people in RM research and describe what it is like to participate in a trial. Given that the field of HIV prevention research is quite complex, it is often challenging to provide communities with accurate and understandable information about the scientific process. RM development faces additional hurdles because anal intercourse, referred to in the guide and video simply as “anal sex”, is not discussed openly due to a fair amount of stigma and discrimination, and because anal sex is illegal in many countries.

To address the need for materials about RMs, the Population Council, the International Rectal Microbicide Advocates (IRMA), and the Microbicide Trials Network (MTN) developed a video called *The Rectal Revolution is Here: an Introduction to Rectal Microbicide Clinical Trials*. The goal of *The Rectal Revolution is Here* is to encourage participation and interest in RM clinical trials, ensure consistent and accurate messages about RMs, and educate clinic staff and communities. The 14-minute video introduces important concepts that apply to all RM trials, such as voluntary participation, risks and benefits, and clinical research. Although not tied to one specific trial, the video was developed for use in MTN-017, the first Phase 2 RM clinical trial (which is testing a tenofovir-based gel).

## QUICK FACTS ABOUT “THE RECTAL REVOLUTION IS HERE” VIDEO

The video was produced by Paw Print Productions through collaboration with International Rectal Microbicide Advocates (IRMA), the Microbicide Trials Network (MTN), and the Population Council. It was filmed on location in 2012 in Bangkok, Thailand; at the Desmond Tutu HIV Foundation in Cape Town, South Africa; at Epicentro in Lima, Peru; at Magee-Womens Hospital, University of Pittsburgh Medical Center, Pittsburgh, PA, USA; and in the laboratories of the Center for Biomedical Research, Population Council, New York, NY, USA. Funding was provided by the Population



Council, with support from the Swedish Ministry of Foreign Affairs and the Swedish International Development Cooperation Agency; and an award from the MTN; and by IRMA through a grant from the MAC AIDS Fund. Additional support was provided by AIDS Foundation of Chicago where IRMA is based.

Two animated characters – Mr. Condom and his Agent – as well as scientists, advocates, community members, and a clinical trial participant explain the reasons people need new options to prevent HIV and what is being done to address this need.

The video was developed through a comprehensive process that involved a 12-member Video Advisory Committee (VAC), made-up of individuals from MTN-017 trial sites in Peru, South Africa, Thailand, and the U.S.; non-affiliated researchers; IRMA members; and community advocates. The VAC provided guidance on all aspects of the video, from script development to the final edit. The “rough cut” of the video was viewed by more than 80 participants of the Microbicides 2012 conference (Sydney, Australia) who provided feedback via a survey, and was also tested in 13 focus group discussions at five sites among more than 100 gay men, other men who have sex with men, and transgender women. The feedback from the surveys and focus groups were critical in shaping the final video.

The video is available on YouTube in 3 languages:

English – <http://tinyurl.com/RectalRevEnglish>;

Spanish – <http://tinyurl.com/RectalRevSpanish>;

Thai – <http://tinyurl.com/RectalRevThai>.

You may request a digital version of the video in English, Spanish or Thai by sending an email to IRMA at [rectalmicro@gmail.com](mailto:rectalmicro@gmail.com).



## II. RECTAL MICROBICIDE RESEARCH AND CLINICAL TRIALS: BACKGROUND AND BASICS

This section covers top-line messages and general information about rectal microbicide (RM) development and RM clinical trials.

### THE NEED FOR RECTAL MICROBICIDES

- HIV is an epidemic in many populations and places around the world, and people need options to protect themselves.
- Anal sex is commonly practiced by women and men around the world.
- Compared to unprotected vaginal sex, unprotected anal sex is 10 to 20 times more likely to result in HIV infection.
- Although condoms are an effective HIV prevention method, many people can't or simply don't want to use them every time they have sex.

### RECTAL MICROBICIDE RESEARCH AND DEVELOPMENT

Rectal microbicides (RMs) are products being developed to prevent HIV infection, and potentially other STIs, through receptive anal sex.

- Many RMs currently being tested contain some of the same medicines, called antiretrovirals (ARVs), used to treat HIV.
- Microbicide development began over 20 years ago and originally focused on products for vaginal use. The field is now also testing rectal products for use during anal sex. RMs are currently being tested in a gel form. Other formulations are being considered as well, such as, lubricants, douches, and other types of products.
- No microbicide – vaginal or rectal – has been proven effective to date; therefore, microbicides currently being tested are only available to volunteers taking part in clinical trials. No microbicide is available to the general public.



**For more background on rectal microbicide research and advocacy visit the MTN at [www.mtnstopshiv.org/node/2864](http://www.mtnstopshiv.org/node/2864) and IRMA at [www.rectalmicrobicides.org](http://www.rectalmicrobicides.org).**

## CLINICAL TRIALS OVERVIEW

- A clinical trial is a study to find out whether a product – already determined to be safe in laboratory and animal studies – is safe and effective when used by people.
- Clinical trials are conducted in a step-wise manner and under strict government and community oversight to protect study participants.
- Clinical trials for HIV prevention are carried out in phases:
  - **Phase 1** = basic safety and acceptability; conducted in a small group of people for a short period of time
  - **Phase 2** = expanded safety and acceptability; conducted in a larger group of people (perhaps several hundred) for a longer period of time; may provide very early signs that the product could be effective;
  - **Phase 3** = long-term safety and effectiveness; conducted in a group of thousands of people for a few years; to see if the product works to prevent HIV.



### For more information about clinical trials visit:

Clinical Trials Explained (ACRIA)

<http://www.acria.org/files/clinical-trials-explained.pdf>

Learn About Clinical Studies ([ClinicalTrials.gov](http://ClinicalTrials.gov))

<http://clinicaltrials.gov/ct2/info/understand>

## PARTICIPATING IN CLINICAL TRIALS FOR HIV PREVENTION TOOLS SUCH AS RMS

Joining a clinical trial is completely voluntary – it is up to each person to decide whether to join a trial or not by weighing the benefits and risks of participating.

- Through trial participation, a volunteer commits to using the study product, coming to the clinic for scheduled visits, undergoing study procedures, and openly and honestly reporting his or her experience using the product.
- Products being tested in clinical trials have not been proven to prevent HIV, so it is important for participants to continue to practice behaviors that minimize risk of exposure to HIV while participating in a study.
- All participants are counseled to use condoms with their sexual partners. Participants also receive a standard HIV prevention “package” including counseling, condoms, lubes, screening for STIs, and regular HIV testing.

## PROTECTING THE SAFETY OF STUDY PARTICIPANTS

- Each country's government where trials are conducted has laws and regulations to protect the safety and well-being of clinical trial participants.
- Ethics committees review every study to make sure the rights of study participants are protected.
- Community groups and advocacy organizations provide feedback about the study design and the plan for carrying out the study to make sure it reflects local cultural norms and practices.

**Visit these links for more information about how participants' rights are protected:**

Learn About Clinical Studies ([ClinicalTrials.gov](https://clinicaltrials.gov))

<http://clinicaltrials.gov/ct2/info/understand>

Federal Policy for the Protection of Human Subjects (U.S. Department of Health and Human Services)

<http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>

What is an IRB and its purpose? (New Hanover Regional Medical Center)

<http://www.nhrmc.org/body.cfm?id=2774>

## HOW RECTAL MICROBICIDES ARE USED

- Since they are still undergoing testing, rectal microbicides are not currently available for widespread use – they are only being used in clinical trials.
- In current trials, RMs are applied into the rectum through the use of an applicator.
- Depending on how the study is designed, RMs might be applied daily or around the time of sex.
- Future trials may use different means of applying the RM.



## DEVELOPING SAFE AND EFFECTIVE RECTAL MICROBICIDES CAN ONLY HAPPEN IF...

- People volunteer to participate in rectal microbicide clinical trials.
- Rectal microbicides are compared to other prevention products or placebos within a clinical trial. Placebos are products that look and feel exactly like the RM being tested, but don't contain the RM's active ingredient.
- Scientists, in collaboration with communities, continue to search for rectal microbicides that are safe, effective, and desirable. People must like using them if they are going to work in the "real world."

### III. FREQUENTLY ASKED QUESTIONS

Facilitators can further prepare themselves for video screenings at workshops/recruitment sessions by reading these FAQs. This section may be printed and kept handy during the discussion period following the screening.

#### WHAT ARE RECTAL MICROBICIDES?

**Q.** *What are rectal microbicides (RMs)?*

**A.** Products being developed to prevent HIV, and potentially other STIs, during receptive anal sex. RMs are currently being developed as gels, but could also be formulated in other ways, such as douches, lubricants, and other types of products.

**Q.** *How would RMs work?*

**A.** Most products currently being tested contain antiretroviral (ARV) drugs that are used to treat people living with HIV. ARVs work by keeping the amount of HIV at low or undetectable levels in the blood. Science has shown that ARVs are able to prevent HIV when taken as an oral tablet. Now scientists are testing to see if ARVs formulated as gels can work in the same way.

Most products currently being tested contain ARVs. However, scientists and advocates are interested in other types of products that either do not contain ARVs at all, or combine ARVs with other ingredients for the following reasons:

- Protection for HIV-positive individuals: HIV-positive individuals may already be taking ARVs for treatment and an ARV-based microbicide could interfere with their therapy.
- Potential resistance for HIV-positive individuals: If HIV-positive people are not on ARV treatment and they use an ARV-based microbicide that contains small amounts of only one or two drugs, the virus could become resistant and result in therapy that does not work as well.
- Lack of protection against other STIs: It is important to note that ARV-based microbicides will not be protective against all STIs.
- Lack of protection against pregnancy: ARVs do not protect against pregnancy, so products are being developed that combine ARVs with contraceptive hormones for people who wish to prevent both pregnancy and HIV infection.





**Q. Who applies the RM, the “top” or the “bottom”?**

**A.** Current RMs are being developed as gels, and would be self-applied by the receptive (bottom) partner with a specially designed applicator prior to anal sex. Or, the insertive (top) partner could use the applicator to apply the gel into the partner’s rectum. RMs currently being tested are not designed to be applied on the insertive partner’s penis, but the idea is being investigated. An ideal RM would be easy to use, like a sexual lubricant, and would fit into an individual’s current sexual behaviors. While applicators are currently being used in clinical trials, people may not like using them in the “real world.” After all, people apply lube for anal intercourse with their fingers, not applicators. As more research is conducted, scientists and advocates will be figuring out ways to apply RMs that are acceptable and desirable.

**Q. How and where are RMs applied?**

**A.** RMs are designed to be inserted in the rectum before anal sex in order to prevent HIV transmission. In the clinical trials that have occurred to date as well as those that are ongoing, the microbicide is delivered in a specific dose in a pre-filled applicator that is inserted into the receptive (“bottom”) partner’s anus prior to sex. An ideal RM would be easy to use, like a sexual lubricant, and would fit into an individual’s current sexual behaviors.

**Q. When are RMs applied?**

**A.** At the moment, different products are being tested in different ways. So, the timing of application will depend on the specific product and the specific trial. Trials are looking at daily use and are also investigating using RMs before and after sex. An ideal RM would be easy to use, like a sexual lubricant, and would fit into an individual’s current sexual behaviors. Scientists and advocates will be figuring out ways to apply RMs that are acceptable.

**Q. Where do RMs go? How does it come out?**

**A.** Each application of gel is usually only about 4 milliliters, about the amount of a teaspoon. The gel may travel throughout the rectum and is then likely to be absorbed into the rectal tissue. Very little of the gel’s active ingredient, the drug, gets into the bloodstream.

**Q. Can RMs be used by HIV-positive people to prevent transmission to HIV-negative people?**

**A.** RMs that are currently being developed contain ARVs, so they cannot be used by people who are HIV-positive. Ideally, in the future there will be microbicides that can be used by HIV-positive people to prevent transmission to HIV-negative individuals.

**Q. Could using RMs cause resistance to HIV treatment if people who are using them become HIV-positive?**

**A.** First, it is important to note that if individuals are using an ARV-based RM, they cannot become resistant to the drug when they are HIV-negative and remain HIV-negative. It is possible that being exposed to a low amount of an ARV drug in the form of a microbicide

could make an HIV-positive person's virus resistant to that drug. This may result in HIV treatment that doesn't work as well for that individual. Therefore, people using ARV-based microbicides will need to get tested for HIV regularly to ensure they remain HIV-negative.

**Q. How is potential resistance to HIV treatment handled in a clinical trial?**

**A.** To address the possibility of individuals becoming resistant to HIV treatment in a clinical trial, such as an RM study, researchers screen all potential participants for HIV infection to avoid enrolling anyone who is already HIV-positive. Participants in all studies receive regular HIV testing so if anyone becomes infected with HIV during the trial, they will immediately stop using the RM and be referred to appropriate care and treatment services. Scientists won't have all the answers about potential resistance that may occur due to use of ARV-based microbicides until these products are used widely for a long period of time.

**Q. Could the RMs being tested in trials cause side-effects and, if so, what side-effects could they cause?**

**A.** It is possible that RMs being tested in trials could cause some side effects, including anal discomfort, itching, bloating, or a "gassy" sensation. RMs being studied could also cause other problems we do not know about yet. The research and development process is designed to create products that have minimal to no side effects. If products are going to be used by people in the "real world" they will need to be desirable and have very few, if any, side effects.

**Q. Could RMs cause harm to the insertive (top) partner's penis?**

**A.** "Penile tolerance" or "penile safety" studies are carried out to ensure the product is safe and acceptable for men who are the insertive or "top" partner. These studies look to see whether potential microbicides may cause irritation to the penis or within the male urethra. This information is vital to the successful introduction of both rectal and vaginal microbicides, since a product that is irritating to the insertive partner would clearly be a non-starter.

## RECTAL MICROBICIDES AND CONDOMS...

**Q. Since people in clinical trials are encouraged to use condoms, how will they know if the RMs work?**

**A.** Despite the best of intentions, not all individuals – in a trial or in the "real world" – use condoms each and every time they have intercourse. Although people participating in clinical trials are counseled about the importance of using condoms, and are provided condoms and condom-compatible lubricant, they may not use them every time they have sex. The researchers conducting the study hope to find out whether the microbicide offers additional protection from HIV, even when people don't use condoms all the time.



**Q. Can RMs and condoms be used together?**

**A.** Absolutely. Rectal microbicides will be condom-compatible, so people will be able to use them with condoms for added protection. This could be especially beneficial if individuals have problems with condoms breaking or slipping. If RMs are found to be safe and effective, people who do not use condoms, for whatever reasons, will have an important prevention option.

## THE CLINICAL TRIAL PROCESS...

**Q. Why do people participate in clinical trials?**

**A.** People who choose to take part in trials are volunteers. They make an informed decision to join a trial to help find out if a product is safe, acceptable, and effective. Anyone interested in being in a trial goes through an informed consent process to make sure they understand everything about the trial, including the risks and benefits of participating, what they will need to do, and to ensure that any questions they have are answered.

**Q. How long will it take to find out if RMs work?**

**A.** All drugs go through a lengthy development process. Before RMs are tested in people, they go through a battery of tests in the laboratory and in animals that all drugs must go through before they can be tested in humans. Then, there are a series of different studies with humans – called “clinical trials” to see if the product is safe and effective. The whole product development process usually takes at least 10 years (until a new product is tested and available on the market).



**Q. What are the risks of being in a trial?**

**A.** Some of the procedures may cause discomfort or be burdensome. It is also possible that the product being tested could cause side-effects. Each person makes his or her own decision to enroll in a trial, and can choose to withdraw from the study at any point in time for any reason. If, at any point in time, the clinic staff feels it is not in a participant’s best interest to continue in the trial, they will let him or her know. It is also important to understand that ethics committees and other groups work to ensure that the rights of trial participants are protected and that they are kept safe through a safety oversight process that takes place throughout the entire trial.

**Q. Are participants exposed to HIV from being in the trial?**

**A.** No. The trial does not increase your chances of being exposed to HIV. In fact, to reduce the risk of HIV for people participating in trials, everyone receives frequent HIV testing and counseling on the correct and consistent use of condoms, and routine testing and access to treatment for STIs.

**Q. Are people paid to participate in trials?**

**A.** Trials compensate volunteers for the time they spend in the trial. The amount of compensation varies between trials and is usually related to how long the clinic visits are and how burdensome the clinical procedures may be.

**Q. Can women enroll in RM trials?**

**A.** At this stage, to find out if RMs work, trials are focusing on enrolling gay men, other men who have sex with men and transgender women who engage in receptive anal sex. However, many women have anal sex and have been included in early safety and acceptability studies to make sure RMs are safe and acceptable for women. It is likely that as RMs are further developed, they will continue to be tested in women as well.

**Q. How much will RMs cost?**

**A.** It is not known how much RMs will cost because they are still in the process of research and development. The goal of scientists and advocates is to create RMs that are inexpensive and easy to obtain. Creating products that people can access easily is important. It is just as important as creating products that are safe, effective, and acceptable.

## VIDEO-SPECIFIC QUESTIONS...

**Q. Why use animation about a subject that is so serious?**

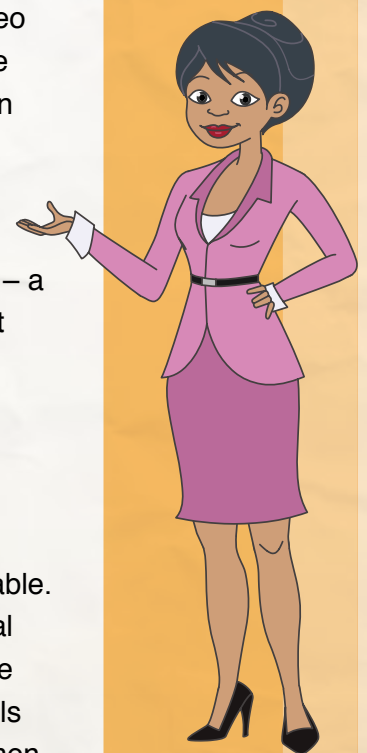
**A.** The aim of the video is to be engaging, hopeful, uplifting, and educational. The video was pre-tested in focus groups around the world and most people said they enjoyed the animation and felt it helped them better understand some of the complicated information presented.

**Q. Who is the animated woman in the video?**

**A.** She is Mr. Condom's agent, but she could be anyone the audience wants her to be – a counselor, nurse, friend, etc. The reason she is in the video is to help explain important concepts to Mr. Condom and help the audience identify with Mr. Condom.

**Q. Why was Mr. Condom the main character in a video about RMs?**

**A.** Mr. Condom played an important role in the video because condoms are currently the best-known method of preventing HIV during sex. And condoms will always be an important part of HIV prevention, even as new ways to protect ourselves become available. So, the video is making the important point that RMs will never replace condoms. Rectal microbicides, once available, will join condoms in the "prevention toolbox" and simply be another prevention option for people who have anal sex. It is conceivable that individuals will use different prevention methods at different times, in much the same way that women may choose different contraceptive methods at various points in their lives.



**Q. Why are there people in the video talking about not using condoms?**

**A.** The reality is many people don't use condoms all the time, and there are lots of reasons this happens. If human beings generally used condoms consistently and correctly each and every time they had sex, we would not have an HIV epidemic, and there would be no need for other methods of HIV prevention. Therefore, the video includes real people talking about why they may not use condoms each and every time they have sex to help explain the need for RMs.

**Q. Will everyone in RM trials have to do the same things that Rig did in the video?**

**A.** The purpose of the video was to give people an idea of what it is like to take part in an RM trial. In any trial, participants will have to use a product – but in each trial, the specific regimen (how it's used and how often) will vary. In each RM trial, participants will have an anal exam, but the frequency (weekly, monthly, etc.) will vary from one trial to another. And, in each trial, participants will have counseling, testing for HIV and other STIs, and will be asked questions about how they used the gel. But the specifics will be different. The staff at the clinic will explain the specific details to anyone thinking about enrolling in a particular trial.

**Q. Does the anal exam hurt a lot? From Rig's face, it seems like it does.**

**A.** The exam can be uncomfortable for some people, but most do not find it to be painful, especially if they are able to relax during the exam.

**Q. In the section where Brian Kanyemba is being interviewed at the Desmond Tutu HIV Foundation, he is standing in front of a poster that says, "Can a pill a day prevent HIV?" What does that refer to?**

**A.** Brian is standing in front of a poster that was designed to recruit gay men, other men who have sex with men, and transgender women into an HIV prevention trial called iPrEx. This trial investigated whether an ARV pill taken daily – in this case Truvada – would be effective in preventing HIV. The daily use of Truvada was shown to be effective in this trial, especially among participants who were most adherent. The results of the iPrEx trial were published in the New England Journal of Medicine, <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1011205>. A number of other studies have shown daily Truvada to work as HIV prevention among heterosexuals as well. In July of 2012, the U.S. Food and Drug Administration approved Truvada for use as prevention among adults at high risk for HIV infection, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm>.



## IV. SUGGESTED QUESTIONS FOR DISCUSSION

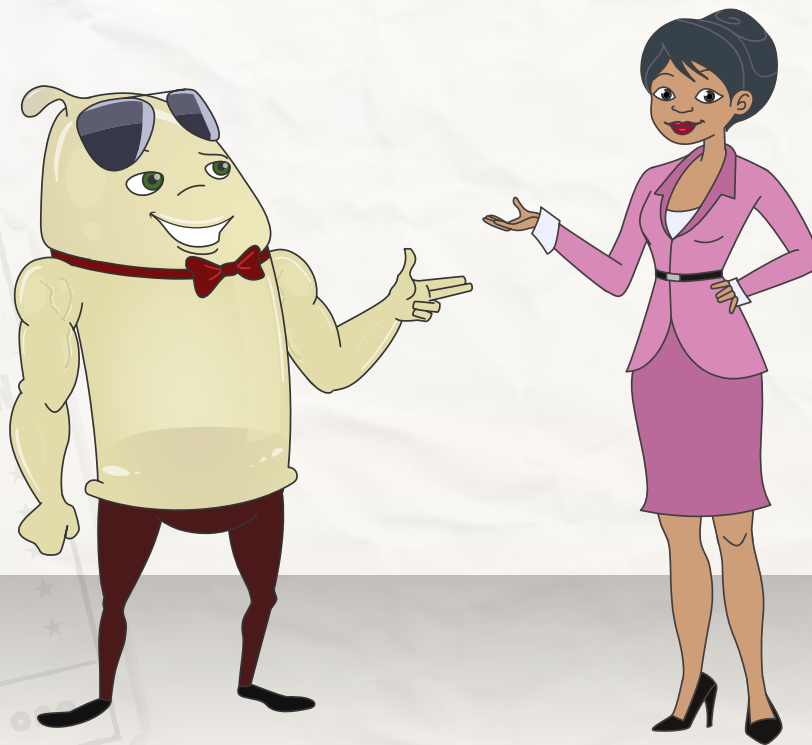
These suggested questions for discussion have no “right” or “wrong” answers. The goal is to spark discussion among viewers of the video on issues related to rectal microbicides and other HIV prevention strategies. Facilitators may choose to use these questions, or ask their own depending on the audience and where their interests lie.

1. Would you personally choose to participate in a rectal microbicide clinical trial? Why or why not?
2. Rectal microbicides are currently being developed as lubricants, but could also be delivered in a rectal douche/enema. What would you prefer and why?
3. Current rectal microbicide trials ask participants to use an applicator to apply the gel in their anus and rectum. Do you think people in the “real world” will be comfortable using applicators? Why or why not?
4. Imagine the perfect rectal microbicide. What qualities would that rectal microbicide have? How would it be formulated? How would it be applied? What else would be important to ensure that a rectal microbicide is used?
5. Even if found to be effective, it is likely that a rectal microbicide will never be as effective as using a condom. How effective would an RM need to be for you to be willing to use it?
6. If rectal microbicides become available, they will join other tools in the prevention toolbox such as male and female condoms and PrEP (pre-exposure prophylaxis). Do you think people will use rectal microbicides with condoms, or do you think they will use them on their own? Why?
7. Condoms, PrEP, and eventually rectal microbicides have different levels of effectiveness. What is the best way to communicate the differences in effectiveness of the various strategies to potential users?
8. The existence of new prevention technologies such as PrEP, and eventually rectal microbicides, causes us to re-think what the meaning of “safer sex” is. For decades the message has been “use a condom every time you have sex.” How do you think “safer sex” should be described in the future?
9. Anal sex is a common human behavior, practiced by gay and bisexual men, transgender individuals, and heterosexuals the world over. Yet many of us are uncomfortable talking about anal sex. Why is this? What are some ways we can improve this situation?
10. Anal health is an often neglected part of general healthcare. How can we improve this situation? How important is anal health in the context of rectal microbicide trials?

## V. EVALUATION FORMS

The next two pages contain two different evaluation forms. For every organized screening of the video, please fill out the Facilitator Utilization Form, and ask participants to fill out the Participant Evaluation Form. Please send the completed forms by email to IRMA at [rectalmicro@gmail.com](mailto:rectalmicro@gmail.com). This important data will help determine the impact of the video, and will aid in future efforts to develop educational videos on similar topics.

***Thank you in advance for your support!***







# PARTICIPANT EVALUATION FORM – THE RECTAL REVOLUTION IS HERE

Date of screening \_\_\_\_\_

Location of screening \_\_\_\_\_

Name of event \_\_\_\_\_

***Please circle the number that best describes your opinion and experience:***

1. The video was informative.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
2. The video was interesting.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
3. The video was the right length (not too long or too short).  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
4. The video increased my awareness of rectal microbicide clinical trials.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
5. The scientific information in the video was easy to understand.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
6. The information in the video seemed trustworthy to me.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
7. The way the video presented what it is like to be in a trial was balanced (risks and benefits, pros and cons)  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
8. I am likely to share info about rectal microbicide clinical trials with friends, colleagues.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
9. After watching the video, I am personally interested in participating in a rectal microbicide clinical trial.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)
10. I will recommend the video to friends, colleagues.  
1 (completely disagree)    2 (somewhat disagree)    3 (neutral)    4 (somewhat agree)    5 (completely agree)

***Please share other feedback/opinions regarding the video:***

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***Thank you for sharing your opinions.***

## VI. OTHER RESOURCES

For more information on rectal microbicide research and advocacy, and the broader field of new technologies for HIV prevention, visit the following links:

***International Rectal Microbicide Advocates*** – [www.rectalmicrobicides.org](http://www.rectalmicrobicides.org)

Suggested pages:

- IRMA-published materials (reports, fact sheets) – <http://www.rectalmicrobicides.org/materials.php>
- Community and scientific presentations – [www.rectalmicrobicides.org/community.php](http://www.rectalmicrobicides.org/community.php)
- Publications on rectal microbicides and anal intercourse – [www.rectalmicrobicides.org/published.php](http://www.rectalmicrobicides.org/published.php)
- IRMA YouTube page – [www.youtube.com/IRMAadvocacy](http://www.youtube.com/IRMAadvocacy)
- IRMA blog – [www.irma-rectalmicrobicides.blogspot.com](http://www.irma-rectalmicrobicides.blogspot.com)

***Microbicide Trials Network*** – [www.mtnstopshiv.org](http://www.mtnstopshiv.org)

Suggested pages:

- Background on rectal microbicides – [www.mtnstopshiv.org/node/2864](http://www.mtnstopshiv.org/node/2864)
- Information on MTN-017 – [www.mtnstopshiv.org/news/studies/mtn017](http://www.mtnstopshiv.org/news/studies/mtn017)
- Information on MTN-007 (precursor to MTN-017) – [www.mtnstopshiv.org/news/studies/mtn007](http://www.mtnstopshiv.org/news/studies/mtn007)
- Information on MTN-006 (precursor to MTN-007) – <http://www.mtnstopshiv.org/news/studies/mtn006>

***Population Council*** – [www.populationcouncil.org](http://www.populationcouncil.org)

Suggested pages:

- Overview of microbicide efforts – [www.popcouncil.org/topics/microbicides.asp](http://www.popcouncil.org/topics/microbicides.asp)

***AVAC – Global Advocacy for HIV Prevention*** – [www.avac.org](http://www.avac.org)

Suggested pages:

- Global map of HIV prevention trials – <http://data.avac.org/WorldMap.aspx>

