Instructions: To ensure all information provided by study staff about this study was clear, we would like to ask you some questions. Please choose the option that best answers each question.

Name or PTID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What is the purpose of the study?
	1. To understand the safety of the tenofovir gel and Truvada tablets in males and transgender females who have sex with men
	2. To find out how males and transgender females who have sex with men feel about tenofovir gel and Truvada tablets
	3. To understand if tenofovir gel and Truvada tables are effective in preventing HIV
	4. All the above
	5. **Answers a and b**
2. What are the possible risks in this study?
	1. Gel or tablets may cause bad effects such as headache, dizziness, upset stomach, burning, irritation, diarrhea, gas
	2. Others may treat me badly if they learn I am in the study
	3. Possibility of resistance to medicines used to treat HIV if I become HIV infected while taking study product
	4. **All of the above**
	5. None of the above
3. How will my information be protected in this study?
	1. My information will be available to everyone at the clinic
	2. My information is confidential, private, and locked away and only other participants in the study and the researchers will have access to my information
	3. My information is confidential, private, and locked away during the duration of the study. Once the study has concluded, this information will be included in publications about the study
	4. **My information is confidential, private, and locked away and only the study researchers will have access to participant information**
	5. My information will be identified only by my full name
4. What are some things I will be asked to discuss with study staff throughout my participation in the study?
	1. I will be asked about where I live and how I can be contacted
	2. I will be asked about my behavior including my sexual activities and about my health
	3. I will discuss the results of my blood tests that checks to see if product was in my body or not
	4. I will discuss how I am to take the tablets and use the gel correctly
	5. **All of the above**
5. How will you be assigned to the different groups?
	1. **Chosen by chance to each regimen. Neither I nor the staff can choose or change the order in which I use the study products**
	2. The study staff will choose the order in which I use the study products
	3. I will have the opportunity to decide which group I want to join
	4. Chosen by chance to each regimen. But if I want, I can change the order I’m taking the study product
	5. None of the above
6. What will I be asked to do while I am in this study?
	1. Come for all clinic visits until the final clinic visit ( approximately 7 months) and depending on sequence -- insert gel or take tablets as directed
	2. Have blood and urine tests, physical and rectal exams and answer personal questions during clinic visits and by phone
	3. Not share gel or tablets with anyone else and not take part in other studies
	4. **All of the above**
	5. Answers a and b
7. What will happen if you decide not to join this study?
	1. If I decide not to join, there will be no change in access to health care or participation in future studies
	2. If I decide not to join this study, I cannot join any future research study at this clinic
	3. If I decide not to join the study, the study staff will tell me about other studies that they know about and that I may be eligible for
	4. If I decide not to join this study, I cannot receive any future medical care at this clinic
	5. **Answers a and c**
8. If you join this study, how long will you be in the study?
	1. **For about 7 months (27 weeks)**
	2. For about 2 months (8 weeks)
	3. For as long as I am told by the clinic staff
	4. As long as it take to use all the study product I’m given
	5. None of the above
9. What are some of the reasons study staff will collect my blood, urine and rectal fluid during the study?
	1. To test for infections including HIV and sexually transmitted infections (STIs)
	2. To see if and how much product is in my body
	3. To see if I am healthy
	4. To see if and how my rectal fluids protect me against HIV in a laboratory
	5. **All of the above**
10. What are the possible benefits in the study?
	1. I will get paid for participating in this study. I will also receive free medical care for any condition I may have during the study
	2. **There are no direct benefits to me but I will get counseling, condoms and lubricant, medical exams, tests, clinical care, helping to find ways to prevent getting HIV and STIs during my participation in the study**
	3. If I participate in this study I will not get HIV
	4. If I participate in the study, I will not get STIs
	5. Answers c and d
11. What should you do if you have questions or concerns about your health or about what is happening in the study?
	1. Call the study clinic and ask to speak with a study staff
	2. Wait until my next visit and ask a study staff
	3. Come to the clinic and meet with study staff
	4. All my questions should be answered during the clinic visits, so I should not have any additional questions
	5. **Answers a and c**
12. What are some reasons study staff might end your participation in the study?
	1. The study staff feels it would be harmful for me to continue to stay in the study
	2. I am unable to attend study visits
	3. The study is stopped or canceled
	4. I am not able to follow study instructions
	5. **All of the above**

The following additional questions are applicable only at selected sites that will be conducting the Intensive PK/PD Sample Collection

Name or PTID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1a Why are you being asked to provide extra samples?

1. To determine if participants are actually using the study products
2. To understand how much of the study drugs gets into the rectum and how the study drugs work against HIV
3. To be stored for future research
4. **All of the above**
5. Answers a and c

2a What are you asked to do as a part of the extra samples group?

1. Have an blood test, an exam of the rectum, and an enema (a small tube used to put fluid in the rectum to clean it)
2. Have up to 20 samples (size of a grain of rice) of rectal tissue and also rectal fluid collected during each procedure
3. Agree not to put anything in the anus, including the study gel, or have receptive anal intercourse for 72 hours after the procedure
4. Agree not to take aspirin or any other medicine that can increase bleeding for 72 hours before and after the procedure
5. **All of the above**
6. None of the above

3a What are the possible risks of providing these extra samples?

1. Temporary discomfort and bloating, increase risk of getting infection, irritation, rectal bleeding, low blood pressure
2. There are no direct risks associated with providing these extra samples
3. Small chance of the procedure could cause a hole or tear in the intestine and surgery may be necessary to repair it.
4. Answers a and b
5. **Answers a and c**

4a What would happen if you decide not to provide these extra samples?

1. **It is my choice whether or not to provide rectal tissue and rectal fluid and my choice does not affect my participation in MTN-017**
2. I have to agree to the extra procedures to participate in MTN-017
3. The clinic staff will decide if I have to provide the extra samples
4. Answers a and c