

COMPETENCE TO CONSENT TO ORAL AND INJECTABLE PREP TRIALS

Fisher, C. B., Puri, L. I., Macapagal, K., Feuerstahler, L., Ahn, J. R., & Mustanski, B. (2021). Competence to consent to oral and injectable PrEP trials among adolescent males who have sex with males. *AIDS & Behavior*, 25, 1606-1618. DOI 10.1007/s10461-020-03077-9. PMID: 33247336
<http://link.springer.com/article/10.1007/s10461-020-03077-9>

Note. *This document contains the text of the online mock consent video, the survey items and coding guide. For the online survey participants first viewed the following 6-minute mock consent video about an oral and injectable PrEP comparative study. Participants then proceeded to read brief segments of the mock consent form followed by open-ended and multiple-choice questions designed to tap three MacCAT-CR standards of consent competence: Understanding, Appreciation, and Reasoning. The coding guide for the open-ended questions are provided at the end of this document. Data from the factor analysis are provided in the above article. A link to the video can be found at <https://doi.org/10.21985/N25R45>.*

BEGIN SCENE 1

Kathryn: (direct address to camera) Hi! My name's Kathryn and I'm a professor at Northwestern University in Chicago. I'm one of the folks in charge of the study you're in right now. We've asked you to be in this study because we need your help! These days, there are more and more studies being done that look at different ways to prevent HIV in LGBTQ teens.

We want to make sure that the researchers doing these studies give teens all the info they need to be able to make the best decision for themselves about whether or not to join these studies. This information is usually given on a "consent form" – the document you read before you decide to join a study! It's really important for the information on a consent form to be easy to understand so that you know what you might be getting into.

That's where you come in! For the next few minutes, you'll see a video. We'd like you to imagine that you're at a clinic, and in the video, a researcher at the clinic will tell you more about a study that they're doing with LGBTQ teens that compares two different drugs for HIV prevention. Keep in mind that the study in the video isn't real – in other words, we're not ACTUALLY asking you to join the study in the video. But, the drugs described in the video ARE real.

After the video ends, you'll read a consent form that gives you more details about the imaginary study in the video. As you read, we'll ask you questions about what you're reading. It's really important for us to know whether you understand what you're reading, so please read the form carefully, take as much time as you need, and answer the questions as best as you can.

Just to remind you – the study in the video is NOT real. Just pretend that you are being asked to participate in the study.

You being in this study can help researchers like us make HIV prevention studies better for LGBTQ teens like you in the future! So thanks for being a part of this study! Now here's the video.

END SCENE 1

-----VIDEO END-----

-----START GOANIMATE VIDEO WITH NARRATION-----

BEGIN SCENE 2

[show study coordinator/'research participant' in front of a clinic]

Study Coordinator: (direct address to camera) Welcome to Midwestern Research Clinic. Thanks for your interest in our HIV prevention study! I'm going to tell you about a medication for HIV prevention called PrEP. Then I'll give you an overview of our study, which compares how well two different forms of PrEP work in teens like you.

[Study coordinator walks into the clinic, sits down with 'researcher', and does voiceover narration]

TITLE: WHAT'S PREP?

- "Pre-exposure prophylaxis" or "PrEP" are certain types of drugs you can take to protect you from getting HIV.
- Right now PrEP drugs are available in two forms: a pill and a shot.
- The pill's called Truvada and the shot contains a drug called CAB or Cabotegravir.

[Hand writes abbreviated form of what is written above in sharpie]

- To protect against HIV the pill needs to be taken every day and the shot has to be given by a doctor every 2 months.

[Flash to a scene with a person taking a medication and the text "Pill: Truvada" below it]

[Scene in which person is given a shot by a doctor with the text "Shot: CAB" above it]

- The shot and pill are approved for HIV prevention in adults
- Neither the pill nor the shot's approved as a HIV prevention method for teens.

[A group of adults and group of teens are shown with images of a needle and pills next to them, the needle and pills by the adults have an "approved" stamp and the needle and pills for the teens show a "?" drawn over them]

- Common side effects of CAB and Truvada are headaches, diarrhea and fatigue. These side effects are mild and often go away after a month of taking the drugs.

[Slides appear with little images of a head, toilet paper and a bed with text "Side effects of Cab and Truvada" (Mild)]

- Some rare side effects of Truvada are a weakening of your bones and decrease in how your kidneys work. Doctors will monitor you closely to prevent these side effects, which go away after stopping the drug.

[Slides appear with the text on them and little images of a kidney and bone "Side effects of Truvada" (Rare)]

TITLE: WHY'S THE STUDY BEING DONE? WHAT DO WE KNOW ABOUT THE SHOT AND PILL FOR TEENS?

- This study's being done for two main reasons:
 - One, to find out how safe the shot and pill are for teens.
 - What we mean by "safe" is making sure the side effects of the drugs aren't worse than the side effects in adults. The shot and pill have been shown to be safe in studies with smaller groups of teens, but studies with bigger groups of teens are needed in order to make sure.

[A slide with a sign "safety first", pills/needle and teens are shown]

- Two, to find out how well teens can stick to taking the shot and pill.
 - The drugs only work if they're taken the way they're supposed to be taken. A few studies have shown that teens weren't always protected from getting HIV because they didn't take the drugs like they're supposed to. So, this study will look at whether teens are better at sticking to taking the shot or the pill.

[The teens are in the lower left corner and two calendar's show up. One calendar has a pill everyday and the other has gaps in daily prep usegy]

- The government needs studies like this to decide whether or not to approve these drugs for HIV prevention in teens.

[The project coordinator is shown standing next to a diagram of an arrow. Along the arrow is an image of a government building, the text "studies like this", an approved stamp and a group of teens.]

TITLE: WHAT'RE THE BENEFITS OF THIS STUDY?

- Being in this study could help protect you from HIV if you take the drugs like you're supposed to.
- It can also help researchers better understand how to prevent other teens like you from getting HIV in the future.

[Teens appear on the right hand side of the screen and an HIV comes from the left but is stopped by a shield that displays the Truvada pills on it.]

TITLE: HOW'D A STUDY COMPARING THE TRUVADA PILL AND THE CAB SHOT WORK?

- If you say yes to being in the study, you'll do the first part of the study called the "screening phase."
- For this part you'll first take an HIV test. If the test showed you had HIV, you wouldn't be able to continue in the study, but the researchers would help you find medical care.

[Slide showing each part of the screening phase, blood draw, check for HIV and be given pills if you have HIV]

- If you don't have HIV, you'll take CAB in pill form every day for 5 weeks. The reason for this is to be sure the drug's safe for you. If the researchers find that CAB isn't safe for you, you won't be able to continue in the study.

[The main character is stating the narration above. The empty magnifying glass with text “no HIV” shows that there is no HIV, followed by medication than 5 weeks is shown showing that they take the medication for 5 weeks, and a checkmark signaling that part is complete]

- If it *is* safe for you, there will be three more parts to the study, each lasting 6 months
 - You’ll get CAB in the form of a shot once every two months for 6 months.
 - You’ll take a Truvada pill once a day for another 6 months.
 - For the final 6 months of the study, you’ll choose between using the CAB shot or taking the Truvada pill.

[A diagram showing each part of the study in a tree type graph, the narration will match the mouth movements of the main character]

- You’ll be assigned to one of two groups:
 - Group A: This group gets the Truvada pills first, then the CAB shot
 - Group B: This group gets the CAB shot first, then the Truvada pills

[The group designs are shown in a table on a whiteboard that the main characters shows to audience]

- Being assigned to one of these groups is like a coin toss. Everyone has the same 50/50 chance of being in each group. You and the researchers will not be able to choose what group you are in.

[A hand is drawn with a coin in the air and the text “50/50 chance” is shown]

- You will have check-ups every few months to make sure you are healthy and don’t have HIV or a sexually transmitted infection (STI).
- During the check-ups, you will be asked questions and give samples of your blood, rectal fluids, and urine to test and make sure you are healthy.

[The researcher is seen answering questions that the participant has at the clinic office
The research participant is shown with a thought bubble reading “what kind of ‘tests?’”]

- All test results will be given to you.

[Scene with the coordinator explaining what the tests are that are being done and that the results will be given to the participants]

- To help further science we will publish papers and give presentations. We will never use your name in these papers and presentations.

[Researcher shown talking about research in front of a crowd]

TITLE: WHAT IF I DON’T WANT TO BE IN THE STUDY? OR WHAT IF I DECIDE TO STOP?

- You don’t have to be in this study. You can still get the care you need at our clinic even if you don’t join the study.

- If you join today, you can change your mind later and still get the services you'd normally get at this clinic.
- If you decide not to join this study, you can talk with your regular doctor about CAB, Truvada, and other HIV prevention tools.

[Research participant shown with thought bubbles asking what if he wants to stop or not participate anymore and arrows appear with information about things they can do if they don't want to participate anymore]

Study Coordinator: Here's the consent form, which has more info about the study. Just as a reminder, you should read the consent form carefully. Take as much time as you need! You'll be asked questions about what you just read after every couple paragraphs of information. You won't be able to look back at the information you read once you move on to the next page. You'll also get a chance to let me know what questions you have at the end.

[Coordinator shows participant a computer screen with consent form on it.]

END SCENE 3

-----END VIDEO WITH NARRATION-----

NOTE: after watching the PrEP trial video, participants will see the following instructions on the next page of the survey]

cc_instructions. The study in the video you just watched, and the consent form you'll read next, isn't real. We're not ACTUALLY asking you to join the study in the video.

You should read the consent form carefully. After each page you'll be asked 1-3 questions about what you just read. You won't be able to go back to view the information you just read. If you click the back or refresh button in your internet browser you might get locked out of the survey.

When reading though the info and answering the questions, we'd like you to pretend that you've had anal sex without condoms before, if you haven't already. This is because we'd like you to put yourself in the shoes of someone who might be asked to be in a study like the one you'll read about.

The more questions you answer correctly in this section of the survey, the higher your score will be, and the greater your chances will be for getting a bonus \$30 online Amazon gift card. So, we encourage you to try your best!

cc01_txt. Title of Research Study: A Phase 2a Crossover Trial Evaluating the Safety of and Adherence to Oral Truvada and Injectable Cabotegravir in HIV-Uninfected Cisgender Adolescent Men and Transgender Women Who Have Sex with Men

Investigator: Dr. Skylar Anderson, Midwest Research College

Introduction

This research study is funded by the National Institutes of Health (NIH), which is a part of the United States (US) government. Before you decide if you want to join this study, please read this form, which will give you information about this study.

The purpose of this study is to test two drugs that may help prevent teenagers from getting HIV. One drug is a pill called Truvada. The other drug called cabotegravir (CAB) comes in pill and injection (shot) form. The CAB shot and Truvada pill both work by stopping HIV from making copies of itself inside the body.

Why am I being asked to take part in this research study?

You are being asked to take part in this research study because you are between ages 14 and 19, a cisgender man (your birth sex and gender identity are male) or transgender woman (your birth sex is male and gender identity is female), and **have had unprotected (condomless) anal sex with male partners** which may put you at risk for HIV.

Please answer the following about the IMAGINARY study **in your own words**.

cc01.AP.WhyYou2 Name 1 personal characteristic and 1 behavior that are the reasons why you are being asked to participate in this study? (*Understanding*)

cc02_txt. What is the purpose of this study? Why is this research being done?

The Truvada pill and the CAB shot are safe and effective ways to prevent HIV in adults. In order for the drugs to be effective enough to prevent HIV, the pill has to be taken every day and people have to get a new shot every 2 months. The US Food and Drug Administration (FDA) approved both drugs for HIV prevention in adults, but not for teenagers.

This study is being done for two main reasons:

1. To find out how **safe** the shot and pill are for teenagers. What we mean by "safe" is making sure the side effects of the shot and pills are not worse than the side effects in adults.
2. To find out how well teenagers can **adhere** to taking the pill and shot. The pills and shots only work if they are taken the way they are supposed to be taken. So, what we mean by "adherence" is looking at teenagers' ability and desire to go to a doctor's office to get the shot every 2 months and/or take the pills every day in order for the drug to work well enough to prevent HIV.

So far, studies have shown the shot and pill were as safe for teenagers as adults, but the number of teenagers studied has been very small. Also, a few studies showed the drugs might not be as effective for teenagers because some did not take the pills every day or get the shot every two months, which placed them at risk for getting HIV. The FDA asked for more studies with larger groups of teenagers to learn more about the safety and effectiveness of the drugs for teenagers.

Please answer the following about the IMAGINARY study **in your own words**.

1. **cc02a.U.Often** How often do people need to get the CAB shot **AND** how often do they need to take the Truvada pill in order to protect themselves against HIV? (*Understanding*)

2. **cc02b.U.Purpose** What is the purpose of this study? That is, what two main things are scientists trying to find out by conducting this research? (*Understanding*)

cc03_txt. If you agree to be in the study, we will do two types of tests to make sure the study is safe for you.

First, you will take an **HIV test**. We will tell you your test results when they come back (up to 10 days later). You will not be able to join the study if the test shows you have HIV, because the study drugs might interfere with the drugs to treat HIV, but we will refer you to a doctor for treatment.

Second, if you don't have HIV, we will test whether the CAB medication is safe for you by asking you to **take pills containing the same drug (CAB) as the shot once a day for 5 weeks** to make sure you will not have a serious side effect to the drug in the shot. "Serious" means you have more than one abnormal test result or severe nausea, diarrhea, or vomiting that doesn't get better within a week.

Please answer the following about the IMAGINARY study in your own words.

3. **cc03.U.Tests** What are the 2 types of tests we will do to make sure the study is safe for you?
(Understanding)

cc04_txt. What happens in the next part of the study?

If you don't have HIV or a serious side effect to the CAB pill you will be asked to join the next part of the study. You will take drugs in 3 different 6 month phases.

You will be assigned to either Group A or Group B.

- Group A: If you are assigned to this group you take the Truvada pills for the first 6 months, then the CAB shot for 6 months, then during the last 6 months you decide whether to take the pill or shot.
- Group B: If you are assigned to this group you get the CAB shot for the first 6 months, then the Truvada pills for 6 months, then during the last 6 months you decide whether to take the pill or shot.

	First 6 months	Second 6 months	Third 6 months
Group A	Take <u>pills</u> every day	Get <u>shot</u> every 2 months	Your choice: shot (every 2 months) or pill (every day)
Group B	Get <u>shot</u> every 2 months	Take <u>pills</u> every day	Your choice: shot (every 2 months) or pill (every day)

Please answer the following about the IMAGINARY study in your own words.

4. **cc04a.U.Phases** You just read about 3 different phases of the study each lasting for 6 months. What are these 3 main phases? (*Understanding*)

5. **cc04b.ChoosePill** Thinking ahead, do you think you would choose the pill or the shot during the last 6 months of the study? (*Choice*)

- (1) I would definitely choose the PILL condition in the last 6 months
- (2) I would probably choose the PILL condition in the last 6 months
- (3) I would definitely choose the SHOT condition in the last 6 months
- (4) I would probably choose the SHOT condition in the last 6 months
- (-99) I do not want to answer

6. **cc04c.RN.Choice2** Please explain why you would choose the pill or shot condition in the last 6 months by comparing how the risks or benefits of the 2 different conditions would affect **you**. (*Reasoning*)

Again, put yourself in the shoes of someone who might be asked to be in this study, by imagining you've had anal sex without a condom (if you haven't already).

cc05_txt. How will I be assigned to Group A or Group B?

You will be randomly assigned into group A or B. This means that which of the two drugs you will use in the first 6 months of the study will be decided by chance. Random assignment is like a coin toss, so everyone has the same 50/50 chance of being in Group A or B. Neither you nor the study staff can decide which group you will be in. Random assignment is used so that scientists can make sure the order in which you take the drugs does not influence how well each drug works.

What are my responsibilities if I participate in the study?

As a participant you have **3 important responsibilities:**

1. **Take the study drugs the way you are supposed to.** This means that you take the pills every day and get the shot every two months. You might not be protected against HIV during the study if you don't take the pills or shot the way you are supposed to.
2. **Use a condom when you are having sex.** The Truvada pill and CAB shot work best to protect you against HIV if you use a condom during sex. It is also important to still use a condom when you are having sex because neither the CAB shot nor the pill protects you from getting other sexually transmitted infections like chlamydia, gonorrhea, or herpes.
3. **Visit the clinic for up to 13 checkups.** For each phase of the study, you will have a check-up 1 week after you start using any drug. You will then visit the clinic every 2 months when you are getting the CAB shot and visit the clinic every 3 months when you are taking the Truvada pills.

Please answer the following about the IMAGINARY study **in your own words**.

7. **cc06.AP.Responsibility** What are your 3 important responsibilities if you are in the study?

cc07_txt. Each visit will take about 2 hours to complete.

In addition to giving you the pills or shots at visits, you will fill out surveys about your sexual activity and receive free sexual health counseling, condoms, and lubricant.

Medical staff may also conduct the following medical procedures:

- Give you a physical exam to make sure you are healthy.
- Draw blood to test you for HIV, to check the levels of drug in your blood, and to make sure you are healthy. They will also give you the results of any blood tests.
- Do urine samples and rectal swabs to test for STIs.
- Treat STIs and refer you to other services, if you need them.

Please answer the following about the IMAGINARY study **in your own words**.

8. **cc07.U.Procedures** List at least three medical procedures medical staff may conduct when you visit the clinic, **not counting** the pill or shot. (*Understanding*)

cc08_txt. What makes being in this study different from regular medical care?

The Truvada pill or the CAB shot may help protect you from getting HIV, but you are not being asked to take part in this study for your own medical benefit. Being in this study is different from regular medical care that you would normally receive. In regular medical care, a doctor would give you a drug that would work best for you based on your personal characteristics and medical history. In this research study, staff will randomly assign you to Group A or Group B. You will NOT be assigned to these groups because scientists believe one group will be better for you, but because scientists are comparing the drugs to see which one will be most effective for teenagers in the future.

Please answer the following about the IMAGINARY study **in your own words**.

9. **cc08.AP.DifferentMedical** What makes being in this study different from regular medical care?
(Appreciation)

(2 of the following) I am not being asked for my own medical benefit OR will not be assigned to a group based on what is best for me OR the research is being conducted for teenagers in the future (2 pts)

Only 1 of the above (1 pt)

None of the above OR indicating they believe it is similar to medical care or that they are assigned to groups based on what is best for the m (0 pts)

cc09_txt. What if I become infected with HIV?

Being in this study will not cause HIV, but there is a chance you can get HIV through sex or other activities during the course of the study.

If you get HIV, staff will tell you to stop using the study drugs. Truvada and CAB drugs are not the usual treatment for HIV. Continuing those drugs may limit your options for HIV treatment, which is why you can't take part in this study if you have HIV and are tested for HIV at study visits.

This study can't give you general medical care, but study staff will refer you to doctors for treatment if you become infected with HIV. There are very effective treatments for HIV and most people with HIV live long and healthy lives.

Please answer the following about the IMAGINARY study **in your own words**.

10. **cc09.AP.HIVPos** Why will you be asked to stop taking the study drugs if HIV tests show that you have been infected with HIV after you are in the study? (Understanding)

cc10_txt. What are the risks of being in this study? Is there any way being in this study could be bad for me?

Risks of In-Clinic Procedures

You may feel discomfort or pain during blood draws or rectal swabs. In some cases, you may have bleeding in your rectum after a rectal swab. For both the blood draws and CAB shots, you may have a bruise, or experience swelling, a small clot, or infection where the needle goes in your arm.

Common Side Effects of Study Drugs

The most common side effects of the Truvada pill and CAB shot are nausea, diarrhea, headaches, and fatigue. These side effects are mild, don't happen in everyone, and for most people they go away after the first month of use.

Rare Side Effects of Study Drugs

There are two rare side effects of the Truvada pill. A small number (less than 1% or one in one hundred people) showed a small decrease in how their kidneys work. The other rare side effect is changes in bone mineral density (how much calcium and other minerals are in your bones which keeps them strong).

We will check your health before you join the study and during the study to reduce your chances of having any side effects. If you do have these side effects, they usually go away when you stop taking the Truvada or CAB. The doctors will monitor you and suggest extra treatment if the side effects do not disappear.

Please answer the following about the IMAGINARY study **in your own words**.

11. **cc10.AP.SideEffect** Name one common side-effect **AND** one rare side effect you might experience in this study when you take CAB or Truvada drugs. (*Understanding*)

cc11_txt. Will being in this study help me in any way?

If you take the Truvada pills daily and get the shots every 2 months, the study drugs may prevent you from getting HIV. You will get free condoms, lubricant, medical exams, sexual health counseling, and testing for HIV and STIs. If a test shows you have an STI during the study, you will get free drugs for the STI or a referral, if you need it. If a test shows you have HIV during the study, you will get a referral for treatment. This study can't give you general medical care, but study staff will refer you to another doctor for care, if needed.

Potential benefits to others

Information learned from this study may help other people as well. It may help scientists learn how to prevent teenage cisgender men and transgender women from getting HIV, the FDA decide if the drugs are safe and effective for teenagers, and teenagers get the HIV prevention drugs in the future.

Please answer the following about the IMAGINARY study **in your own words**.

1. **cc11a.U.Benefits2** Is it possible you might **not** benefit from being in this study?
 - (0) No
 - (2) Yes
 - (-99) *I do not want to answer*

12. **cc11.U.Benefits2** Name at least three potential benefits to people who participate in this study.
(understanding)

cc12_txt. What happens to the information collected for the research?

We will keep your information and your medical samples in a secure place that only certain researchers have access to. This information will only be labeled with your study ID number. Your samples will be destroyed right after the test results return. Your samples and information will not be used for profit.

There are two main times we may have to break confidentiality and share your personal information with others, as required by law:

- We have to report the names of people who test positive for HIV and other STIs, because the health department requires reporting of all cases where individuals test positive for HIV/STIs. Health department workers may contact you about telling your partners so they can be tested.
- If you tell us you are hurting or planning to hurt a child, or you're planning to hurt yourself or another person, or if you are under age 18 and someone has hurt or abused you, we are required to report it to the appropriate agencies for your safety and the safety of others.

Please answer the following about the IMAGINARY study **in your own words**.

13. **cc12.AP.Confidential** Describe the two main times in which the researchers would have to break confidentiality and share your personal information. (*Understanding*)

cc13_txt. Will I get paid? Will it cost me anything to participate in this research study?

If you agree to take part in this study, we will pay you \$55 at each visit. There is no cost to you for study visits, study drugs, physical exams, laboratory tests or other procedures or referrals.

What if I get injured during the study?

In the unlikely event that you are injured or get sick from being in this study, please tell study staff right away. We may be able to give you emergency treatment, but you or your insurance company may be charged for this treatment. This study can't offer compensation for research-related injury.

Your parents or guardians are **not** told that you are in this study. But if you are **injured** as a result of this study and you seek treatment that is paid for by their health insurance, then it is **possible** that they may find out about you being in this study.

Please answer the following about the IMAGINARY study **in your own words**.

14. **cc13.AP.Pay** Who will pay for your medical care if you are injured as a direct result of being in this study? (*Understanding*)

cc14_txt. What happens if I do not want to be in this research?

Being in this study is completely voluntary. You have the right to refuse to be in this study. You also have the right to change your mind and stop participating in the study at any time. Nothing bad will happen to you if you do not want to be in this study. Study staff will not be able to continue to give you the HIV prevention drugs, but you can still get the medical services you would normally get at this clinic

What are the alternatives to participating in this study?

If you do not want to be in this study, you may be able to join other studies here or in the community. There may be other places where you can go for HIV counseling and testing. We will tell you about those studies and those places, if you wish.

If you decide not to participate in this study, you may also wish to consult with your regular doctor about other HIV prevention tools that are available for you.

Who can I talk to?

If you have any questions or concerns about the study, or a research-related injury, contact the research team at TeenHIVStudy@midwestresearchcollege.edu or (111) 111-1111.

The Institutional Review Board (IRB) at Midwest Research College reviewed and approved this research study. You may wish to talk to an IRB member at (111) 222-2222 or irb@midwestresearchcollege.edu for the following reasons:

- Your questions or concerns are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Please answer the following about the IMAGINARY study **in your own words**.

15. **cc15.U.IRB2** Give 2 reasons why you might want to speak to an IRB member about the study:
(*Understanding*)

cc16_txt. What else do I need to know?

When the study is over, the researchers will not be able to continue to provide you with the HIV prevention medication. However, if you would like, they will refer you to a doctor who can provide you with sexual health care.

cc17_txt. Thanks! You've finished reading the consent form for our hypothetical study. Next, please imagine that you are deciding whether or not to participate in this *imaginary* study.

Again, when reading though the info and answering the questions, we'd like you to pretend that you've had anal sex without condoms, if you haven't already.

Here is a copy of the form you just read. You can refer to it when you are answering the following questions, but you don't have to: [\[pop up displays entire IC form, or IC presented side by side with questions\]](#)

(NW please score as indicated)

1. **cc17a.AP.Purpose** Do you believe the purpose of this study is primarily for research purposes or primarily to provide you with the HIV prevention treatment that is best for you? (Appreciation)
 - (0) Primarily to provide me with the HIV prevention treatment that is best for me.
 - (1) For research purposes and to provide me with the HIV prevention treatment that is best for me
 - (2) Primarily for research purposes
 - (-99) *I do not want to answer*

16. **cc17b.AP.Required** Do you have to be in this study if you do not want to participate? (Appreciation)
 - (2) No
 - (0) Yes
 - (-99) *I do not want to answer*

17. **cc17c.AP.WithdrawService** If you withdraw from this study, will you still be able to receive services you regularly receive from the clinic? (Appreciation)
 - (0) No
 - (2) Yes
 - (-99) *I do not want to answer*

18. **cc17d.AP.WithdrawMeds** If you withdraw from this study, will the research staff still be able to provide you with the HIV prevention medication? (Appreciation)
 - (2) No
 - (0) Yes
 - (-99) *I do not want to answer*

1. **cc17e.AP.Random** Please select the statement that best describes how you will be assigned to group A or group B in this study.
 - (0) The researcher will place me in the group that is best for me
 - (2) Which group I am in will be decided by chance
 - (-99) *I do not want to answer*

(Note to NW cc17c and cc17d will be added for a score of 0 – 2)

Please continue to imagine that you are deciding whether or not to participate in this *imaginary* study.

Again, when answering the questions, we'd like you to pretend that you've had anal sex without condoms, if you haven't already.

19. **cc18a.AP.AdherePrEP** How likely is it that you would take the PrEP pill everyday while you are in the study? (Appreciation)
- (1) Very unlikely
 - (2) Somewhat unlikely
 - (3) Somewhat likely
 - (4) Very likely
 - (-99) *I do not want to answer*
20. **cc18b.AP.AdhereCAB** How likely is it that you would come to the clinic every 2 months to get your CAB injection while you are in the study?
- (1) Very unlikely
 - (2) Somewhat unlikely
 - (3) Somewhat likely
 - (4) Very likely
 - (-99) *I do not want to answer*
21. **cc18c.AP.SideEffPrEP**. If you participated in the study, how much would you worry about the possible side effects of the PrEP pill?
- (1) None of the time
 - (2) Rarely
 - (3) Some of the time
 - (4) A lot of the time
 - (5) All of the time
 - (-99) *I do not want to answer*
22. **cc18d.AP.SideEffCAB**. If you participated in the study, how much would you worry about the possible side effects of the CAB shot?
- (1) None of the time
 - (2) Rarely
 - (3) Some of the time
 - (4) A lot of the time
 - (5) All of the time
 - (-99) *I do not want to answer*

Please answer the following questions **in your own words**. Again, when answering the questions, we'd like you to pretend that you've had anal sex without condoms, if you haven't already. This is because we'd like you to put yourselves in the shoes of someone who might be asked to be in a study like the one you've read about.

23. **cc19a.RN.Want**. Give a reason why you might want to be in this study based on how participating might affect your life outside the study. (Reasoning)

24. **cc19b.RN.NotWant**. Give a reason why you might **NOT** want to be in this study based on how participating might affect your life outside the study. (Reasoning)

2. **cc20a.C.FinalChoice** Based on all the information you have been given, do you think you would choose to participate or not participate in this study? (Choice)
- (1) I would definitely **NOT** choose to participate in this study
 - (2) I would probably **NOT** choose participate in this study
 - (3) I would probably choose to participate in this study
 - (4) I would definitely choose to participate in this study
 - (-99) I do not want to answer

Again, put yourself in the shoes of someone who might be asked to be in this study, by imagining you've had anal sex without a condom (if you haven't already).

3. **(If cc20a.C.FinalChoice = 3 or 4) cc20b.RN.ExplainChoiceY** In the question above you indicated "[cc20a]". Explain why you think the potential **benefits** of participating are more important than the potential **risks**. **Be sure** to specify **both** benefits and risks in your answer.

4. **(If cc20a.C.FinalChoice = 1 or 2) cc20b.RN.ExplainChoiceN** In the question above you indicated "[cc20a]". Explain why you think the potential **risks** of participating are more important than the potential **benefits**. **Be sure** to specify **both** benefits and risks in your answer.

Please rate how much you agree or disagree with each of the following statements:

Again, put yourself in the shoes of someone who might be asked to be in this study, by imagining you've had anal sex without a condom (if you haven't already).

19. **choice01** If I agreed to participate in this study, I would probably regret my decision once the study began:
- (1) Strongly disagree
 - (2) Somewhat disagree
 - (3) Neither agree/disagree
 - (4) Somewhat agree
 - (5) Strongly agree
 - (-99) I do not want to answer
20. **choice02** If I participated in this study, I would probably feel very anxious throughout the study:
- (1) Strongly disagree
 - (2) Somewhat disagree
 - (3) Neither agree/disagree
 - (4) Somewhat agree
 - (5) Strongly agree
 - (-99) I do not want to answer
21. **choice03** If I participated in this study, I would probably feel very satisfied with the experience:
- (1) Strongly disagree
 - (2) Somewhat disagree
 - (3) Neither agree/disagree
 - (4) Somewhat agree
 - (5) Strongly agree
 - (-99) I do not want to answer

