

Form Approved

OMB No. 0920-New

Expiration Date: XX/XX/XXXX

Preferences for Longer-Acting Preexposure Prophylaxis (PrEP)
Methods Among Persons in US Populations at Highest Need: A
Discrete Choice Experiment

Attachment #5

Client Screening & Consent

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Client Screening Survey & Consent

Screening Survey & Consent link:

<https://survey.rti.org/SE/1/ClientScreenerDev>

Note: text in blue indicate instructions for programming.

Specs:

- One question will be shown per screen.
- Response not required for all questions. Participants need to be able to skip questions that they prefer not to answer; if a question on screen is not answered and the participant selects to move forward in the survey, the survey will note to the participant that an item is not answered and confirm if they would like to move forward and leave the question unanswered. The survey will code this response as a refusal.

** Indicates item used to assess eligibility

U Indicates single response option only in question allowing multiple responses

The U.S. Centers for Disease Control and Prevention is conducting a survey to understand opinions on new HIV prevention options that may be available in the future. We thank you for your interest in this survey and appreciate your time.

Some survey questions are about sensitive topics, and we recommend that you complete this survey in a location where no one else can see your responses.

[Page break]

S1. How old are you? **

_____ years old [numeric entry only; REQUIRE RESPONSE]

[Page break]

S2. Which state and county or territory do you live in?

State or Territory: _____

County : _____

[include drop down of states and then counties based on state. There are 3,143 county equivalents; target based on 57 EHE jurisdictions]

[if S1. <18 years of age à END SURVEY]

[Page break]

Consent to Participate in a Research Study

Title of the research study: Choices for Prevention (C4P)

Principal Investigator: Dr. Sarah Roberts, RTI International

Study Sponsor: The Centers for Disease Control and Prevention (CDC) Division of HIV Prevention

KEY INFORMATION

- You are invited to join a research study funded by the Centers for Disease Control and Prevention (CDC) and conducted by a non-profit research organization named RTI International.
- Participation in this study is completely voluntary. You may choose not to take part in the study or leave the study at any time without any consequences.
- The purpose of this study is to understand how different features of HIV prevention services affect people's decisions to use PrEP, or pre-exposure prophylaxis, for HIV prevention. PrEP is medicine people can take to prevent getting HIV from sex or injection drug use. We especially want to understand how access to new, long-acting PrEP products will affect people's decisions.
- As part of the study, we will ask you to fill out a confidential online screening form that asks about your background (e.g., age, gender identity, race/ethnicity), your potential need for HIV prevention, and your experience with different HIV prevention methods. The screening form takes about 5 minutes to complete.
- If the screening form shows that you are eligible, you may be invited to take the online survey. In that survey, we will show you several scenarios comparing two HIV prevention services with different features and ask you which one you would choose. We will also ask you some questions about your opinion of different PrEP products and some more questions about your background and experiences with PrEP. The survey should take about 25 minutes to complete.
- All participants that complete the online survey will receive a \$20 Visa gift card. The \$20 gift card may be withheld if it is determined that you do not meet the eligibility criteria, you do not complete the survey, or there is evidence of fraud.
- You may be uncomfortable answering some questions about yourself. You can choose not to answer questions at any time.
- The study has a low level of risk. The main risk is a small chance of a loss of confidentiality. To help lower this risk, your personally identifying information (e.g., name, email address) will be kept

separate from your answers to survey questions and can only be accessed by the research staff at RTI International.

[Page break]

Introduction

You are being asked to join a research study. Before deciding if you want to take part, you need to read this Informed Consent form to understand what the study is about and what you will be asked to do. This form tells you who can be in the study and the risks and benefits of the study. This form explains how we will protect your information and who you can call if you have questions.

Purpose

The C4P Study is a research study paid for by the Centers for Disease Control and Prevention (CDC). The study is being led by researchers from CDC and from RTI International, a research organization in Research Triangle Park, North Carolina. The purpose of the study is to understand how different features of HIV prevention services affect people's decisions to use PrEP, or pre-exposure prophylaxis, for HIV prevention. PrEP is medicine people can take to prevent getting HIV from sex or injection drug use. We especially want to understand how access to new, long-acting PrEP products will affect people's decisions. We are asking you to screen for this study because you may benefit from the HIV prevention services that we want to learn about. The study will include about 1400 people.

Procedures

If you agree to participate, we will ask you to fill out a confidential online screening form. As part of this screening form, we will ask you questions about your background (e.g., age, gender identity, race/ethnicity), your potential need for HIV prevention, and your experience with different HIV prevention methods. If you are eligible for the study based on your answers, you may be chosen to take the online survey.

If you are not chosen for the online survey, you will be told in an email or SMS and thanked again for completing the screening form. If you are chosen to take the online survey, you will be invited by email or SMS. The invitation will include a link to the survey and your respondent ID. You will be asked to take the survey one time within 2 weeks after receiving the invitation. You may also have the option to complete the survey immediately after the screening form.

In the survey, we will show you several scenarios that ask you to compare two HIV prevention services that have different features and tell us which one you would choose to use. We will also ask you some direct questions about your opinion of different PrEP products and more detailed questions about your background and experiences with PrEP. There are no wrong or right answers to any of the questions that we will ask you.

All of your answers are confidential, which means your name will not be known to anyone other than the researchers.

Study Duration

The screening form should take 5 minutes to complete. If you are invited to take the online survey, we expect that you will spend about 25 minutes on the survey.

Possible Risks or Discomforts

We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet. There are no physical risks involved in this study or costs involved in participation. It is possible that some questions may make you uncomfortable. You can refuse to answer any question. There is a small chance that people outside the study could find out that you joined the study or see your answers to the survey questions. Steps to protect your information are described in the next section, but this cannot be guaranteed. You should report any problems to the researcher (contact information is below).

Confidentiality

Many precautions have been taken to protect your information. We have procedures in place to limit who can connect you/your name to your answers. We will remove your name and any other information that could directly identify you from your survey responses. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your survey responses in a secure location. Only a few research staff from RTI International who are working on this study will know your name and your code number. If findings from this study are presented at scientific meetings or published, your name will not be used.

This study has a Certificate of Confidentiality from the CDC. Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not

stop you from releasing your own information. It also does not stop you from getting copies of your own information. .

Sometimes there are opportunities for researchers to use data from previous studies or to share data with each other if they are conducting similar research. For these reasons, we may use or share your research data for future research. We will not ask for your additional informed consent for those studies. Prior to using or releasing this data for future research, we will remove any personal information that could identify you or replace it with a code to ensure that, by current scientific standards and known methods, no one should be able to identify you from the information we share. RTI International plans to destroy all of the study's records that contain the link between your identifying information and your research data before the study's end. We will do so unless legal or scientific reasons require us to keep the link beyond the study's end.

The Institutional Review Board (IRB) at RTI International has reviewed this research. An IRB is a group of people who are responsible for protecting the rights of research participants. The IRB may review study records to make sure that proper procedures were followed. A representative of the IRB may contact you about your experience with this research. This representative will be given your name, but not your confidential study data. You may refuse to answer any questions this person may ask.

Benefits

Your Benefits

There are no direct benefits to participants. You may feel satisfaction from being part of project that will help determine how best to deliver HIV prevention services to people who are vulnerable to HIV across the United States.

Benefits for Other

The results of this study could help improve delivery of HIV prevention services, which could increase use of PrEP among people who are vulnerable to HIV across the United States. Increasing PrEP use could reduce the overall number of new HIV infections and reduce racial and ethnic disparities in HIV.

Payment for Participation

There is no payment for completing the screening form. However, if you are invited to take the online survey, you will be sent a \$20 Visa gift card after completing the survey.

Your Rights

Your decision to take part in this study is completely voluntary. You can refuse any part of the study. You can stop participating at any time. You can refuse to answer any question. If you decide not to participate, or you withdraw later, you will not lose any benefits or rights you would normally have if you choose not to volunteer. No one will behave any differently toward you or be upset if you choose not to join the study. The \$20 gift card may be withheld if it is determined that you do not meet the eligibility criteria, you do not complete the survey, or there is evidence of fraud.

Your Questions

If you have any questions about the study, you may contact Dr. Sarah Roberts by calling her at (510) 665-8255 or emailing her at sroberts@rti.org. If you have any questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043.

Project Assurance of Consent

I understand what the study involves, and my questions so far have been answered. I am 18 years of age or older and I voluntarily choose to take part in this study. I understand that I may choose not to participate or to withdraw from this study at any time without consequences. I understand that I may print a copy of the informed consent for my records.

Please indicate your decision about participating in the study.

- I have decided to participate in this study. On the next page, I will provide information about how to contact me about the study and my preference related to the gift card I may earn as part of the study. I consent for this information to be used as part of this study.

- I have decided NOT to participate in this study.

[\[page break\]](#)

Your name and contact information

Your First Name: _____

Your Last Name: _____

[\[page break\]](#)

Do you prefer to receive the survey link by email or SMS? If possible, we recommend selecting "email" and completing the survey on a computer or tablet instead of a smartphone.

Email

SMS

Your [email address/mobile phone number] for sending the online survey link:

Confirm your [email address/mobile phone number] for sending the online survey link:

If you are selected to participate in the online survey, how do you prefer to receive your gift card?

eGift card emailed to my email address below

Your email address for receiving the gift card: _____

Confirm your email address for receiving the gift card: _____

Physical gift card mailed to my address below

Street Address: _____ Apartment Number: _____

City: _____ State: _____ Zip Code: _____

[page break]

Now we will move on to the screening survey questions.

S3. What sex were you assigned at birth, on your original birth certificate? **

- Male
- Female
- I don't know

[page break]

S4. Do you currently describe yourself as male, female, or transgender? **

- Male
- Female
- Transgender
- None of these

[page break]

S5. What is your ethnicity?

- Hispanic or Latino
- Not Hispanic or Latino

[page break]

S6. How would you describe your race? Please select all that apply**

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

[page break]

The next questions ask you about HIV and things you may have done to protect yourself from HIV.

S7. In the past 12 months, is getting HIV something you have...?

- Never thought about
- Rarely thought about
- Thought about some of the time
- Thought about often

[page break]

S8. Have you ever been tested for HIV?

Yes

No

[page break]

S9. What is your current HIV status? **

- Negative**
- Positive
- I don't know**

[page break]

S10. Have you ever heard of medicine to help prevent HIV infection called Pre-exposure prophylaxis or PrEP?

Yes

No

[page break]

S11. [If S10= "Yes"] Have you requested to use PrEP from a health care provider in the past 6 months? **

Yes

No

[page break]

S12. What HIV prevention products have you used in the past 6 months? Please select all that apply.

- Male condom
- Female condom
- Oral PrEP [display response option only if S10="Yes"]
- Post exposure prophylaxis (PEP)
- Other, please specify: _____ [max characters: 100]
- U** I have not used a product to prevent HIV in the past 6 months

[page break]

Next, we want to ask you a few questions about your sexual and drug use behaviors. While some of this information may feel very personal or the questions may seem embarrassing, please try to give your best answers and be as honest as possible. Remember that all of your responses are confidential and will be kept private.

S13. Have you been sexually active in the past 6 months? **

By sexually active we mean having anal or vaginal sex.

Yes**

No

[page break]

S14. [If S13 = "Yes"] Who did you have sex with in the past 6 months? Please select all that apply **

- Men
- Women
- Transgender men
- Transgender women
- Genderqueer/gender nonconforming neither exclusively male nor female
- Someone else, please specify: _____ [max characters: 100]

[page break]

S15. [If S13 = "Yes"] Some people find it difficult to use condoms when they have sex. In the past 6 months, how often was a condom used when you had anal and/or vaginal sex? **

- Never**
- Sometimes**
- Often**
- Always

[page break]

S16. [If S13 = "Yes"] Do any of your sex partners have HIV? **

- Yes, I know my sex partner has HIV
- I suspect my sex partner has HIV
- No
- I don't know**

[page break]

S17. [If S16 = "Yes, I know.." or S16="I suspect.."] Taking antiretroviral treatment (ART) reduces the amount of HIV in the body. With proper use, ART can reduce HIV to such low levels that the virus can no longer be detected in normal blood tests. When doctors say a person has detectable levels of HIV in a viral load test, it means there is a significant amount of HIV in their blood.

Do any of your sex partners have detectable viral load? **

- Yes**
- No
- I don't know**

[page break]

S18. In the past 6 months, have you been told by a doctor, nurse, or other health care provider that you have a bacterial sexually transmitted infection [(e.g., gonorrhea or syphilis)?] [If (S3="Male" and S14="Men") OR (S3="Male" and S4="Transgender", instead the text for '(e.g.' should be: (e.g., gonorrhea, syphilis or chlamydia)?] **

- Yes**
- No
- I don't know

[page break]

S19. In the past 6 months, have you injected any drugs not prescribed by a health care provider?

Yes

No

[page break]

S20. [If S19="Yes"] Are you currently enrolled in a residential treatment program or under court-ordered treatment? **

Yes

No

[page break]

S21. [If S20="No"] Have you injected using syringes/needles that you know had been used by someone else (including a close friend or partner)? **

Yes**

No

[page break]

S22. How important is it to you that new options become available for HIV prevention?

- Not at all important
- Somewhat important
- Very important

[page break]

S23. [If S12 does not="Oral PrEP"]: PrEP is short for pre-exposure prophylaxis. It is a medication in an oral pill taken daily that can prevent you from getting HIV. People who do NOT have HIV but who are at risk of getting it, can use PrEP to prevent HIV infection. When an HIV NEGATIVE person is exposed to HIV through sex or injection drug use, these medicines work to prevent the virus from reproducing or spreading throughout the body.

Currently, PrEP is available as a pill that you can get with a prescription. Anyone can use PrEP to prevent HIV infection. PrEP is very effective when it's taken as prescribed. It does not prevent other sexually transmitted infections (STIs) or pregnancy.

How interested are you in using oral PrEP? **

- Not at all interested
- Somewhat interested
- Very interested
- I intend to ask my provider for a prescription**

[page break]

Thank you for taking the time to complete this survey. We truly value the information you have provided.

We may contact you to participate in a longer survey, where we will ask about your opinion of new HIV prevention options that may be available in the future.

If you are interested in learning more about PrEP, you can visit

www.cdc.gov/hiv/basics/prep.html or <https://www.pleaseprepme.org/#>.

To find a PrEP provider or other HIV testing, prevention, and treatment services near you, visit: <https://www.greaterthan.org/find-services/>.

ELIGIBILITY:

If HIV Status (S9) != 'Positive' AND At least one of the following:

[1]. Sexually active (S13) = 'Yes' AND At least one of the following:

- HIV positive partner with unknown/undetectable viral load (S17 = 'Yes' or 'I don't know')
- Partner(s) HIV status unknown and does not always use condoms (S16 = "I don't know" AND S15 < 'Always')
- Had bacterial STI in past 6 months (S18 = 'Yes')

[2]. Sharing of injections in past 6 months (S21 = 'Yes')

[3]. Requested or used PrEP in past 6 months (S23 = 'I intend to ask my provider for prescription' OR S11 = 'Yes' OR S12 = 'Oral PrEP')

PLEASE CREATE VARIABLE ELIGIBLE 1=Yes, 0=No