

Form Approved
OMB No. 0920-New
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**mChoice: Improving PrEP Uptake and Adherence among Minority MSM through
Provider Training and Adherence Assistance in Two High Priority Settings**

**Attachment 4a
Patient Screener English**

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)

mChoice Aim 1 Patient Screener

Record ID _____

Screening Date _____

This screening form can be used by the study team members to screen volunteers over the phone. Alternatively, volunteers can be sent the screener link and complete the first part on their own. A study team member will then contact initially eligible participants to continue with the screening questions that must be completed over the phone. If the form status has a checkmark, please click the “Edit response” button at the top of the page to enter data. All questions marked with “not participant facing” are hidden from volunteers on the screening form but are visible to the study team members. *not participant facing*

Thank you for your interest in mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings (mChoice)! First, let’s give you a bit of information about the study. Then, if you are interested, you will have the opportunity to screen to see if you are eligible to participate. The ‘mChoice Study’ is an 18-month study aimed at 1) improving the overall pre-exposure prophylaxis (PrEP) experience of providers and men who have sex with men (MSM) patients by implementing evidence-based education and support tools in clinical settings; and 2) increase our understanding of provider and patient factors that influence the choice of PrEP regimen by MSM in New York City, NY and Birmingham, AL. The study plans to enroll 400 people.

The study involves a baseline assessment consisting of an online survey containing questions about demographic factors, technology use, knowledge and attitudes toward HIV, everyday discrimination, sexual and drug use behaviors, and other related factors including attitudes, beliefs, and knowledge about PrEP. At the baseline visit, you will have the opportunity to choose between three PrEP choices: oral daily, oral 2-1-1, and injectable cabotegravir (CAB-LA). You will be given a smart pill-bottle called CleverCap LITE and access to the CleverCap app to use for 12 months of the study. The 2nd visit will occur 3 months after your baseline assessment. You will return for visits every three months (i.e. at 3-, 6-, 9-, and 12-months post baseline). At each of these follow-up visits, you will discuss your PrEP regimen, complete follow-up assessments, and you may be asked to complete a urine sample. From baseline to the 12-month follow-up you will be asked to log sexual events on the CleverCap app. After the initial 12-month period, we will then ask you to come in for a follow-up assessment at 18-months. Throughout the study, we will collect data on your use of PrEP, switching of PrEP regimens, if applicable, and HIV and sexually transmitted infection (STIs) test results through Electronic Health Record (EHR) and pharmacy record data.

In terms of incentives, you will be able to receive up to \$350. You will be given \$40 at the baseline visit, \$45 at your 3-month follow-up visit, \$55 at your 6-month follow-up visit, \$60 at your 9-month follow-up visit, \$70 at your 12-month follow-up visit, and \$80 at your 18-month follow-up visit. Some participants will be asked to participate in an in-depth interview following the study period. If you are asked to participate in this interview, you will be given an additional \$35.

This study is run by the Columbia University School of Nursing and is paid for by the Centers for Disease Control & Prevention (CDC). All of the data we collect will be coded and linked to

identifiers to maintain confidentiality. The study is completely voluntary. You can decide that you don't want to participate at any time. If you have any questions about your rights as a research participant, or if you have any questions, concerns or complaints about this study, you may contact:

Human Research Protection Office,
Institutional Review Board, Columbia University Medical Center,
Address: 154 Haven Avenue, 1st Floor; New York, NY 10032,
Telephone: (212) 305-5883,
Email: irboffice@columbia.edu

If this sounds like something you'd be interested in, we can screen you to determine if you are a good fit for this study. You can complete the first part of the screening below, and, if initially eligible, a team member will contact you to complete the screening process.

Are you interested in seeing if you're eligible for this study?

(If you answer "No" you will not be asked the screening questions.)

- Yes, online right now
- No

Would you mind sharing why this project doesn't interest you?

If you change your mind, you can reach us at: NYC: 212-305-8198 or Birmingham: 205-996-7984.

Don't forget to click "Submit" below!

How did you hear about the mChoice Study?

- Printed Material – Brochure/Flyer/Palm Card
- Community Based Organization or Agency
- Hospital/Primary Care Clinic
- Online Ad
- Previous Study
- Referral from someone I know (friend/partner)
- Other

Other -- Please specify (do not use names or other identifying information):

Contact Information

Full Name:

Phone Number:

Email address:

Zipcode:

1) Are you between the ages of 18 and 39?

- Yes
- No

2) What sex were you assigned at birth, on your original birth certificate?

- Male
- Female
- Refused
- Don't know

3) Do you currently describe yourself as male, female, or transgender?

- Male
- Female
- Transgender
- None of these

3a) Just to confirm, you were assigned [response for #2] at birth and now describe yourself as [response for #3]. Is that correct?

- Yes
- No
- Refused
- Don't know

4) Which of the following best represents how you think of yourself?

- Lesbian or gay
- Straight, that is not lesbian or gay
- Bisexual
- Something else
- I don't know the answer

5) Please indicate your race or ethnic background. Are you...? Please select one.

- Hispanic or Latino
- Not Hispanic or Latino

5a) *NOT PARTICIPANT FACING*

STAFF: If person doesn't know ethnicity or refuses to pick a response option, indicate below:

- Ethnicity unknown
- Ethnicity refused

6) What race or races do you consider yourself to be? (CHOOSE ALL THAT APPLY)

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

6a) *NOT PARTICIPANT FACING*

STAFF: If person doesn't know race or refuses to pick a response option, indicate below:

- Race unknown
- Race refused

6b) *NOT PARTICIPANT FACING*

Staff: enter any relevant notes about participant's ethnicity/race: _____

7) Do you currently live in the NYC or Birmingham, AL area?

- Yes, I live in NYC
- Yes, I live in Birmingham
- No, I do not live in either the NYC or Birmingham areas

7a) Do you plan to reside in the NYC or Birmingham area for the next 12 months?

- Yes
- No
- I don't know

8) Can you speak, read, and write in English?

- Yes
- No

9) Can you speak, read, and write in Spanish?

- Yes
- No

10) Do you own a smartphone?

- Yes
- No

10a) Can you download and use apps on your smartphone without assistance?

- Yes
- No

11) Have you ever had anal sex (as a top or bottom, insertive or receptive) with a person who has a penis in the past 12 months?

- Yes
- No

12) Are you currently taking pre-exposure prophylaxis (PrEP) medication?

- Yes
- No

12a) If no, would you be willing to start taking pre-exposure prophylaxis (PrEP) medication?

- Yes
- No

13) If you are taking oral PrEP (pills), would you be willing to transfer your PrEP medications to the pill bottle that we provide for this study?

- Yes
- No
- N/A

14) Are you currently enrolled in any other PrEP-related research studies?

- Yes
- No

15) Please indicate how often you use condoms when having sex:

- Never
- Some of the time
- About half of the time
- Most of the time
- Always

16) To the best of your knowledge, have you ever had anal or vaginal sex with a HIV-positive sexual partner?

- Yes
- No

17) When were you last tested for HIV?

- I have never been tested for HIV
- Less than 6 months ago
- 6 months to 1 year ago
- Over 1 year ago
- Don't know

17a) What was your most recent test result?

- Positive
- Negative
- Unsure

18) When were you last tested for chlamydia, gonorrhea, or syphilis?

- I have never been tested for chlamydia, gonorrhea, or syphilis
- Less than 6 months ago

- 6 months to 1 year ago
- Over 1 year ago
- Don't know

19) Have you ever injected drugs?

- Yes
- No

19a) Have you ever shared drug preparation or injection equipment?

- Yes
- No

19b) To the best of your knowledge, have any of your injecting partners been HIV-positive?

- Yes
- No

20) Are you currently participating in any other PrEP-related research study?

- Yes
 - No
-

Submission

Thank you for taking the time to answer our question screening questions! A team member will reach out to you to complete the screening process with contact information you provided.

Please click the "Submit" button below.

Preliminary eligibility calculation: *NOT PARTICIPANT FACING*

NOT PARTICIPANT FACING

Participant is likely eligible for the study! Please review the screener to make sure they are eligible. If they are, try to schedule.

NOT PARTICIPANT FACING

Participant might be ineligible for the study! Please review the screener to make sure they are ineligible. If so, ask if we can keep their contact info to be contacted for future studies.

Staff determined eligibility: *NOT PARTICIPANT FACING*

- Eligible
- Ineligible
- Incomplete
- Possibly rescreen
- Not screened

Reason(s) Ineligible: *NOT PARTICIPANT FACING*

- Age
- Living with HIV
- Language
- No smartphone
- Cognitive ability
- Tech use/literacy
- Race/Ethnicity
- Sex/Gender
- Not using PrEP
- Other reason

Screener notes *NOT PARTICIPANT
 FACING* _____