mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings

OMB 0920-New

Section A: Supporting Statement

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- **Goals of the study:** The goal of this study is to implement and evaluate the effectiveness of a clinic-based intervention designed to improve PrEP adherence and persistence among young men who have sex with men (MSM).
- **Intended use:** The information collected in this study will be used to 1) describe PrEP use including factors influencing the selection and change of PrEP regimens; 2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; 3) evaluate the feasibility and acceptability of the CleverCap among MSM on PrEP; and 4) evaluate the feasibility and acceptability of the health provider training.
- **Methods to be used to collect data:** In addition to administering serial quantitative assessments to health providers and MSM participants, the study will also collect data from in-depth interviews, biological specimens, the CleverCap device and app, electronic health records, and a clinic assessment tool.
- **The subpopulation to be studied:** 400 young men who have sex with men, ages 18-39 inclusive, who are currently taking or initiating PrEP. Twenty healthcare providers will be asked to participate in a provider training. Provider participants will be any clinic staff who discusses PrEP with a patient. Four staff from participating clinics will be asked to conduct a clinic assessment.
- **How data will be analyzed:** The study will use a pre-post design to compare provider knowledge retention at pre- and post-training levels. A pre-post design will also be used to track participant PrEP adherence. Patient and provider interview data will be analyzed to describe intervention experiences and barriers and facilitators to intervention implementation. The Clinic Assessment Tool will be analyzed as an interrupted time series with historical controls.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) requests approval for 36 months of a data collection for a research study entitled "mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings" as a new information collection. This project is funded under Cooperative Agreement # U01PS005229 as part of the PrEP Choice Project.

This study will implement and evaluate the effectiveness of mChoice, a clinic-based intervention designed to improve HIV preexposure prophylaxis (PrEP) adherence and persistence among young men who have sex with men (YMSM). The intervention targets both health providers and PrEP patients by providing evidence-based training for health providers to improve clinical knowledge and enhance provider communications with patients, and CleverCap, an electronic medication monitoring device and mobile phone application that provides health information and medication and appointment reminders for patients undergoing PrEP treatment.

Men who have sex with men (MSM) represent the only subgroup of people with HIV (PWH) whose incidence has continually increased despite a stable overall number of HIV infections in the United States (US) in all other groups.[1] To illustrate, MSM comprise 2% of the US population yet represent over half of PWH and account for nearly 70% of new HIV infections annually.[2] These disparities are even more pronounced in MSM who are Black/African American (hereafter referred to as Black) and Hispanic/Latino (hereafter referred to as Latino) who have the highest rates of new HIV diagnoses in the US. CDC estimates this current rate will result in approximately one in six MSM being diagnosed with HIV in their lifetime,[3] with Black and Latino MSM having even higher expected incidence rates.[4]

Studies have shown that PrEP, when used consistently, can reduce the risk of sexual transmission of HIV by over 90%,[5] and, as a result, PrEP has been championed as one of the best tools in combatting HIV transmission[6] and is included in the Ending the HIV Epidemic: A Plan for America (EHE) initiative for prevention of new HIV infections.[7,8] At the same time, the PrEP landscape is rapidly shifting with several options available (daily, 2-1-1 regimen) and intramuscular injectable long-acting injectable cabotegravir (CAB-LA).[9,10] Educating healthcare providers about PrEP options for their patients and the likelihood of their patients engaging in switching patterns among the different PrEP regimens ensures the delivery of quality PrEP services.[11] In addition, implementation of culturally congruent strategies to facilitate identification (screening) of PrEP-eligible patients and to provide PrEP counseling can help providers ensure initiation of PrEP for their patients who need it most.[12] Thus, educating healthcare providers about evolving PrEP regimens and guidelines will ensure delivery of quality PrEP services in accordance with CDC guidelines and will increase the number of PrEP users.[11] In addition to educating healthcare providers about PrEP, culturally congruent clinical interventions to improve adherence and persistence to PrEP are needed.[13]

The purpose of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to improve PrEP adherence among YMSM. The goals of this research study are to 1) improve experience of PrEP providers and YMSM PrEP patients; and 2) increase our understanding of provider and patient factors that influence the choice of PrEP regimen by MSM in clinical settings. The intervention will deliver education and training designed to improve health providers' knowledge of PrEP options and clinical recommendations and enhance provider communications with patients. The intervention will also utilize a mobile phone-based, self-management application (CleverCap) that will enable oral PrEP users to self-monitor their medication adherence in real-time. The information collected through this study will be used to evaluate the overall effectiveness of this PrEP adherence strategy by determining if exposure to the intervention results in improvements in patient PrEP adherence and persistence.
This research will also increase our understanding of provider and patient factors that influence the choice of a PrEP regimen; adherence and persistence with various regimens; changes in regimen; CAB LA tail coverage; sexual risk behaviors while using PrEP; and the overall PrEP experience of providers and patients. Findings from this implementation study will be used to support expanded use of effective provider PrEP tools and increase understanding of PrEP use by YMSM to inform the future revisions of CDC PrEP recommendations and interventions to increase PrEP use by persons in priority populations.

This project is in alignment with the following goals and objectives of the National HIV/AIDS Strategy (2022-2025):[14]

- Goal 1: Prevent New HIV Infections
    - Objective 1.3: Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options
- Goal 3: Reduce HIV-Related Disparities and Health Inequities
    - Objective 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum

This project is also in alignment with the Prevent strategy of the U.S. Department of Health and Human Services (HHS) Ending the HIV Epidemic in the U.S. (EHE) initiative. The initiative aims to reduce new HIV infections in the U.S. by 90% by 2030 by scaling up four key HIV prevention and treatment strategies: Diagnose, Treat, Prevent and Respond Quickly[15]. Increasing the number of persons with PrEP

indications who initiate, adhere to, and persist with PrEP will help to accomplish the goals of EHE, which includes a pillar to prevent new HIV infections using HIV pre-exposure prophylaxis (PrEP).

The following section of the U.S. Federal Code is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." (**Attachment 1**)

2. Purpose and Use of the Information Collection

The purpose of the mChoice project is to rigorously evaluate the use of provider and patient education and support tools in clinical settings to increase PrEP screening, counseling, initiation, adherence, and persistence by MSM. This research project will involve interaction with human participants and intends to collect new individually identifiable data and biospecimens from the participants. This project is considered human subjects research and will be covered by the Paperwork Reduction Act.

The mChoice intervention will target healthcare providers and PrEP users. The study will provide training to healthcare providers to improve knowledge of PrEP clinical guidelines and enhance provider communications with their patients. PrEP users will receive CleverCap, an electronic medication monitoring device that is linked to the CleverCap mobile phone application that provides medication dispensing information and reminders to support medication adherence, as well as health information and appointment reminders.

The primary goal of the intervention is to increase the number of young MSM on PrEP who adhere to and persist with PrEP treatment at participating clinics. The goals of the study include:

- To test the effectiveness of a provider training to increase provider knowledge of PrEP modalities in clinical practice
- To assess the impact of the CleverCap app on PrEP adherence and persistence among young MSM using PrEP
- To assess clinic-level factors associated with the adoption and implementation of the mChoice intervention

This study will be carried out in four clinics. Columbia University Nurse Practitioner Primary Care Group, New York, NY; Callen-Lorde Community Health Center, New York, NY; the University of Alabama at Birmingham (UAB) 1917 Clinic, Birmingham, AL; and Birmingham AIDS Outreach (BAO), Birmingham, AL. All data will be collected and managed by the award recipient Columbia University and its partners. Data collection will take place over three years following OMB approval.

This study will consist of three distinct aims to implement and evaluate the mChoice intervention:

Aim 1: We will conduct a hybrid type II trial to test the effectiveness of the mChoice clinical intervention to increase PrEP adherence and persistence among a cohort of 400 young MSM using PrEP. Aim 1 participants will be young men between the ages of 18 and 39 who have sex with men; are using or initiating PrEP; and live in the New York City or Birmingham, AL area. Recruitment controls will ensure enrollment of at least 50% Black or African American or Hispanic or Latino men. We will recruit MSM patient participants in-person and using posted flyers and online advertisements (**Attachment 3a**). Online recruitment venues will include social network sites (e.g., Facebook, Instagram, Twitter) and online sexual networking apps (e.g., Grindr, Scruff). Information about the study will be posted via flyers and electronic advertisement boards in clinic waiting rooms. Study staff will attend and/or make

study presentations at selected activities and social events sponsored by community partners, e.g., community advisory boards, health fairs, and clinic/organization staff meetings. Potential participants will either complete the verbal consent for screening over the phone during recruitment calls from the study team or calls from interested participants or they will complete an online consent to screen (**Attachment 5a**). Persons who consent will be screened for eligibility once using a Research Electronic Data Capture (REDCap) screener (**Attachment 4a**). Following eligibility screening, participants will be asked to schedule an appointment at the clinic site nearest to them. Study staff on site will guide participants through the informed consent process (**Attachment 5b**). Participants will be enrolled in the study upon reviewing and signing the informed consent form. Enrolled participants will complete the Locator Form (**Attachment 4b**). The baseline survey (**Attachment 4c**) will be delivered once. Follow up surveys (**Attachment 4d**) will be administered five times during the 18-month follow up period at 3-, 6-, 9-, 12- and 18-months. The surveys will assess participant attitudes, knowledge, behavior, and experiences related to PrEP, and risk factors for HIV acquisition. All surveys will be delivered via REDCap. Participants will be given a CleverCap device to track medication dispensed from their prescription PrEP bottle. Patient participants will also be asked to download the companion CleverCap smartphone application (**Attachment 4e**). The application is designed to support PrEP adherence by providing health information, appointment reminders, medication reminders and other supportive information. Participants will be required to download the app during enrollment, but subsequent use of the app will be voluntary. Data collected from the app will include prescription adherence data from CleverCap and paradata to describe overall app use and use of app components. Data will also be collected from urine specimens to measure PrEP adherence through tenofovir levels and from electronic health records to describe the PrEP prescription regimen and any changes in PrEP regimen, evaluate PrEP adherence, and assess sexual risk through HIV and STI test results.

Aim 2: We will conduct in-depth interviews with a subset of 30 participants from Aim 1. Participants will be randomly selected and asked if they would like to take part in an interview. Prior to the interview, study staff on site will guide participants through the informed consent process (**Attachment 5c**). Qualitative data to be collected from the in-depth interview (**Attachment 4f**) will include intervention satisfaction; communications with provider(s); PrEP choice, switching, and decision making; CleverCap and app use and acceptability; and PrEP knowledge.

Aim 3: We will conduct a PrEP training for 20 healthcare providers from the four clinic sites. Providers will include but are not limited to medical doctors, nurse practitioners, physician associates, nurses, adherence counselors, pharmacists, and social workers. A provider can include any employee who discusses PrEP treatment with patients at any of the four participating clinic sites. Provider participants will be recruited via e-mail invitations and flyers posted at the clinic sites (**Attachment 3b**). Potential participants will either complete the verbal consent for screening over the phone during recruitment calls from the study team or calls from interested participants or they will complete an online consent to screen (**Attachment 5d**). Persons who consent will be screened for eligibility once using a REDCap screener (**Attachment 4g**). For eligible participants, the informed consent will be conducted in person, by project staff at the training site (**Attachment 5e**). Following informed consent, participants will be enrolled, and locator information will be collected (**Attachment 4h**). The 30-minute provider training will include education on different PrEP modalities and will be aligned with the most recent CDC PrEP guidelines. The training will also teach providers how to have conversations with Black and Latino YMSM with cultural competence to create a safe and non-judgmental environment (**Attachment 9**). Providers will complete a pre- and post- knowledge assessment as part of the training module (**Attachment 4i and 4j**). The assessment aims to identify the potential impact of the provider education training module on PrEP knowledge, attitudes, and practice. Six-months after completing the provider training and assessments, providers will be asked to complete a post-implementation interview to assess

the impact that the provider training had on the provider's work and interactions with their patients (**Attachment 4k**). Qualitative data to be collected from the provider interviews (Aim 3) will include job role; training satisfaction and opinions about the effect of the training on clinic operations, staff procedures, and client/patient responses; barriers to PrEP care; and attitudes and perceptions about PrEP. In addition to the training and provider-level assessments, every 6 months during the 36-month data collection period, a person from the clinic staff at each of the four participating clinic sites will complete the clinic assessment tool to describe PrEP services implementation at the facility level (**Attachments 4l and 4m**). Quantitative data collected from clinic assessments (Aim 3) will include information about clinic operations including hours and scheduling; patient services including pharmacy, transportation, and educational materials; PrEP services including navigation, financial assistance, client reengagement, adherence support, visit components, HIV testing services; PrEP prescribing information; and PrEP options available.

The data collected in this study will be used to: 1) test the effectiveness of a provider training to increase provider knowledge of and comfort with PrEP modalities in clinical practice; 2) assess the impact of the CleverCap app on PrEP adherence and persistence among young MSM using PrEP; 3) assess clinic-level factors associated with the successful adoption and implementation of mChoice; and 4) describe providers' attitudes and beliefs around PrEP provision for young MSM.

Study findings will be disseminated through community forums, academic and community conference presentations, and peer-reviewed publications.

3. Use of Improved Information Technology and Burden Reduction

During recruitment, interested patient and provider participants will be screened for eligibility using an online survey or over the telephone (**Attachments 4a and 4g**). This will allow participants to complete the screening form at a place and time that is most convenient to them and will enable the study team to instantaneously determine study eligibility. Patient assessments (**Attachments 4c and 4d**), provider assessments (**Attachments 4i and 4j**), and the clinic assessments (**Attachments 4l and 4m**) will be computer-assisted self-administered surveys. Using computer-assisted technology to conduct the assessments will allow us to build in computer-generated skip patterns, significantly cutting down on respondent burden. In addition, data collected through a computer application can be used to automatically generate the study database, reducing data entry burden and potential interviewer and data coding errors. Computer-assisted surveys also evoke a greater sense of privacy than surveys that involve personal interviewing, thereby encouraging participants to answer more sensitive personal questions. Patient assessments (**Attachments 4c and 4d**) will be conducted during in-person visits and study staff will be available to assist them or answer questions. The study will provide iPads for patient participants to complete the assessments. Providers will have the option to complete their assessments (**Attachments 4i and 4j**) either in-person or remotely (online). Clinic assessments (**Attachments 4l and 4m**) will be conducted remotely allowing clinic staff to complete the assessments at a time most convenient to them.

Healthcare providers will have the option to complete their interview (**Attachment 4k**) either online (via Zoom) or in-person. This will allow providers to complete the interview in a setting and time that is most convenient to their busy schedules. Both patient and provider interviews (**Attachments 4f and 4k**) will be audio-recorded. This allows researchers to capture participant responses more accurately and lets the interviewer focus on building and maintaining rapport with the respondent.

We are using Research Electronic Data Capture (REDCap), a secure, HIPAA compliant, web-based survey application hosted by the awardee (Columbia University), to support direct electronic data

capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g., for data types and range checks), audit trails, and a de-identified data export mechanism to common statistical packages. All REDCap accounts are role-based, and password protected.

4. Efforts to Identify Duplication and Use of Similar Information

Extensive literature reviews and expertise in the field among study collaborators ensures that the mChoice intervention study addresses gaps in current research and does not duplicate other studies currently in progress. Searching the published intervention research literature did not yield other studies that evaluated clinic-based PrEP interventions for both providers (to include training and practice facilitation to increase the number of providers able to prescribe PrEP) and patients (utilizing a mobile app to support PrEP uptake among YMSM) while assessing PrEP choices, use, adherence, and persistence to inform future practice. Additionally, a search of the existing literature does not reveal any studies that combine implementation science with PrEP-related interventions in order to understand implementation context as well as factors critical for PrEP adherence success. This combination approach will also maximize the likelihood that others will be able to replicate this intervention and these tools.

At present, PrEPmate is the only intervention in CDC Compendium of Evidence-based Interventions and Best Practices for HIV Prevention that demonstrates improved PrEP medication adherence and persistence and retention in PrEP Care in MSM.[16] The mChoice study will assess the use of multiple evidence-based tools in a clinical setting along with the CleverCap app to support PrEP adherence and persistence among YMSM, while also conducting an implementation study. Thus, this study is more comprehensive and will add to the evidence-based tools available to the field, but more notably supporting PrEP providers in clinical settings and patients with PrEP uptake, adherence, and persistence. We believe that no other data collection effort has been conducted or has been planned to collect similar information from this population, for this purpose. Therefore, the mChoice study requires the collection of primary data not previously collected, as proposed in this Information Collection Request.

Because the information collected here will be used to evaluate use of evidence-based provider education and patient support tools to maximize opportunities for providers and patients in a clinical setting, the Agency believes this information is not capture elsewhere. The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for this population. CDC conducted a review of similar studies prior to the issuance of the Cooperative Agreement[17] and determined that this study is collecting unique information from the populations. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

5. Impact on Small Businesses or Other Small Entities

This information collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

The study will provide the quantitative and qualitative data needed to evaluate the efficacy of the mChoice intervention to assess HIV preexposure prophylaxis (PrEP) adherence and persistence among men who have sex with men (MSM). The length of the follow up period for MSM participants is 18 months, and assessment data will be collected 5 times at 3-month intervals: baseline, 3-, 6-, 9-, and 12-months and once again at 18-months. Collecting assessment surveys less frequently than every 3 months

would limit our ability to assess PrEP adherence and persistence. The total data collection period is three years, and the clinic assessment will be collected 7 times at 6-month intervals: baseline, 6-, 12-, 18-, 24-, 30-, and 36-months. The number of participant and clinic assessments administered is the minimum required to assess any effects of the intervention and post-intervention decay.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection does not involve any special circumstances and fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-day FRN notice to solicit public comments was published on 06/13/2022, Volume 87, Number 113, Page 35781-35783 (**Attachment 2a**). CDC received three comments to the 60-Day FRN (**Attachment 2b**). The first person to comment felt too much money and time was being spent on a special interest group. The second comment recommended the inclusion of transgender persons in the study. The third comment had the following recommendations: to include participants younger than 18 years; to train participants in mobile and web security; to engage community members in the projects development to ensure cultural sensitivity; to include transgender participants; to include supportive technologies; and to consider utilizing virtual platforms for the participant interviews. No changes were made to the supporting statement or data collection instruments.

In addition, study partners the Columbia University, Tulane University, University of Alabama at Birmingham, Birmingham AIDS Outreach, and Callen-Lorde Community Health Center were consulted for the development of this study in 2021, 2022, and 2023. There were no unresolved issues associated with the consultation process.

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9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for participation are an important tool used in research and are particularly important for the population in this study. This study seeks to recruit, enroll, and follow a stigmatized population, while also asking highly sensitive questions about issues such as sexual behavior, HIV and STI status, and medication adherence. To enhance our ability to recruit 400 young men who have sex with men (YMSM) and retain at least 80% of that sample, we will provide participants with tokens of appreciation for completing baseline and quarterly study assessments. To encourage participants to remain in the study and to continue to participate in data collection activities during the 18-month follow up period, the amounts per assessment will increase with each quarterly assessment. The subset of participants (30) who are selected to complete an exit interview will also receive an additional token of appreciation for this activity. To enhance our ability to retain providers in provider training and study activities, provider participants will receive tokens of appreciation for completing study activities including assessments, training modules, and an interview. Amounts are described below.

Aim 1 Patient Trial

- $40 for the baseline assessment
- $45 for the 3-month follow up assessment
- $55 for the 6-month follow up assessment
- $60 for the 9-month follow up assessment
- $70 for the 12-month follow up assessment
- $80 for the 18-month follow up assessment

Aim 2 Patient Interview

- $35 for the in-depth interview

Aim 3 Provider Training

- $50 for the pre-training assessment, training module completion, and the post-training assessment
- $100 for the provider interview

The token of appreciation amounts proposed for this study are based on the Investigators' extensive experiences from prior similar studies involving similar study populations, such as the MyPEEPS study[18] and the mLab study[19], and were calculated to maximize continued participation throughout the 18-month follow up period. Intervention participants will be incentivized to continue participation in the study with an increasing payment amount for each additional follow-up within the intervention period.

The MyPEEPS study consisted of a randomized controlled trial of young (13-18 years old) and racially diverse same sex attracted adolescent males.[18] The purpose was to determine the efficacy of MyPEEPS Mobile, a mobile-delivered HIV prevention intervention to reduce sexual risk behaviors. Participants in the intervention arm received access to the MyPEEPS mobile application which provided educational information about HIV and STIs, minority stress, condom use, emotion regulation and communication through stories of 4 "peeps" for the first 3 months of the study whereas participants in the delayed intervention arm received access to the app at their 9-month follow-up visit. Both the intervention and delayed intervention arms completed an assessment of demographic characteristics and sexual behavior at baseline ($25 incentive), 3-month ($30 incentive), 6-month ($35 incentive) and 9-month ($40 incentive) follow-up visits. Participants in the delayed intervention arm were asked to complete an additional assessment 12 months after baseline ($45 incentive). Participants also received an additional $100 for completing all three My PEEPS mobile activities.[18]

The mLab study consisted of an RCT of young men who have sex with men (YMSM) and young transgender women (YTGW) between the ages of 18-29 years old.[19] The purpose was to test the ability of the mLab mobile phone application to improve both HIV testing rates and linkage to care among Black, Latino, and other YMSM and YTGW. Participants were randomized to one of three arms: the mLab App intervention, HIV home test kits, and standard of preventative care (Arm 1), standard of preventative care only (Arm 2), or HIV home test kits and standard of preventative care only (Arm 3). Participants in all three arms completed an assessment at their baseline ($40 incentive), 6-month ($55 incentive), and 12-month ($75 incentive) follow-up appointments.[19]

Participants in the proposed mChoice Aim 1 Patient Trial can receive up to $350 in incentives by participating in all six study assessments. Incentives for each Aim 1 study visit were determined based on a similar graduated scale to the mLab study.[19] The mChoice Aim 1 incentives are higher than the incentives used in MyPEEPS because the participants in MyPEEPS were considerably younger and not employed and the study team needed to ensure that incentives were not coercive to the young participants in any way.[18]

Healthcare provider participants in Aim 3 can receive up to $150 in incentives. Upon completing training modules and knowledge assessments as part of provider training, they will receive $50. Upon completing interviews with the study team, they will receive $100. Incentives for Aim 3 are aligned with the hourly rate of compensation for healthcare providers in the study regions (see section 12B Estimated Annualized Burden Costs).

In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions…"[20] Men who have sex with men (MSM), and especially young, minority MSM, continue to be disproportionately affected by HIV infection. Effective strategies to engage YMSM in HIV prevention and care services and related research are needed to reduce HIV disparities and promote health equity. This study seeks to recruit, enroll, and follow a stigmatized sexual minority population that includes a significant proportion of racial and ethnic minority YMSM, while also asking highly sensitive questions about issues such as sexual behavior, HIV and STI status, and substance use. Because YMSM and YMSM of color are a stigmatized and difficult to reach and retain population, we believe the proposed tokens of appreciation will increase the attractiveness of this study

to the potential participants and better engage and retain them in the data collection process that is critical to the evaluation of this important HIV prevention intervention.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHHSTP Associate Director for Science Office has reviewed this project and determined the Privacy Act applies to this information collection activity. A Privacy Impact Assessment has been conducted (**Attachment 8**).

The recipient, Columbia University, and its partners, will be responsible for collecting all data for this study. Data shared to CDC will not contain participant names, contact information, or other unique identifiers and each participant's data will be identified only by a participant identification number.

Participants will be informed that their responses will be kept private to the extent permitted by the law. Participants will be informed that the information collected from them will not be attributable directly to the respondent. The terms of the CDC Cooperative Agreement authorizing data collection require the grantee to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law. We have obtained a Certificate of Confidentiality from the CDC to further protect the confidentiality of study participants.

The terms of the CDC Cooperative Agreement authorizing data collection require the recipient to maintain the privacy of all information collected. Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d), states that the Secretary shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. This study meets those requirements. The Certificate of Confidentiality further protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information. With this Certificate, the research team cannot be forced (for example, by court subpoena) to disclose identifying information from study participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

This study will collect several types of sensitive personal information including, name, phone, email address, physical address, date of birth, and medical notes containing HIV and STI test results, PrEP use, and sex behaviors. To minimize risks to confidentiality, we will take physical and operational security measures to protect respondents personally identifying information.

All participants will be assigned a unique identification number for the study. There will be three types of files that contain participant names and contact information: consent forms, locator files and the document that links participant ID and participant name. Documents containing participant unique identification (consent and locator forms) will be stored separately from study documents identified with a participant ID (assessments, app data, electronic health record data, laboratory specimens, and interview recordings and transcripts). The linking document will be stored separately from other study documents. Only authorized study personnel have access to the code linking the participant identification number to subject identifying information. The code will be destroyed two years after publication of study findings. Access to individually identified private information about human participants will be limited to research team members who are approved by the Columbia Institutional Review Board (IRB) to collect and manage the data, site principal investigators and the principal

investigator. De-identified data will be accessible to all members of the research team involved in the data analysis. CDC will not have access to directly identifying information.

The study will utilize Research Electronic Data Capture (REDCap), a HIPAA-compliant web-based platform for data collection. Standard features include interactive data entry with real-time field validation, audit logs to record database modifications, database integrity checks, security (in logins, permissions based on need, and encryption), reporting, forms inventory, and de-identified data exports to common statistical packages for analysis. Logging tracks all data entered in REDCap so that it can be traced back to the person who entered it. No data can be changed without showing who has made the changes. This allows the study team to ensure the security and integrity of the data collected and submitted. Although users can modify data based on their permissions, they cannot delete the subject or history of that subject. Requests to delete a subject must be made to the REDCap system administrator. All REDCap accounts are password-protected, and the Principal Investigator grants access to the approved team member. REDCap is a service offered through Columbia University Irving Medical Center (CUIMC) Information Technology. All study data will be encrypted during transmission and stored on secure HIPAA-compliant servers at the CUIMC campus. CUIMC has an Information Security Office (ISO) that facilitates all aspects of information security risk management at CUIMC, with a particular focus on threat management and HIPAA compliance. The servers are in a secure campus area with all appropriate physical security measures in place. The web and database servers are monitored by CUIMC ISO staff, patched frequently, and scanned by a third-party vendor to ensure that they are protected against known vulnerabilities. The scanning application is the standard service for the entire campus. Access is by individual user ID and is restricted to the forms and/or functions that the user needs to have. The applications themselves are written using open-source tools and have also been scanned by the campus security office to ensure that the applications are also protected from known exploits. The data is backed up to electronic media on a daily basis. The electronic media is secured by CUIMC ISO and stored in a secure area separate from the servers. All study data will be kept in password-protected computers or file cabinets in locked offices.

YMSM participants will receive a CleverCap and install the CleverCap app on their mobile phones. Prior to consent, study participants will be informed as to what data the App will collect. As a starting point for ensuring privacy and security, participants will be required to password-protect their smartphones. In addition, the CleverCap app requires a password so that only study participants will be able to open the App. At the end of the 12-month follow-up, participants will have to return their CleverCap, their CleverCap app account will be disabled, and the app will be deleted from their phone. Data collected via CleverCap will be identified only by the participant ID and will be encrypted during data transfer. Encrypted data will be stored on secure HIPAA-compliant servers at the CUIMC campus.

The study will adopt a Data and Safety Monitoring Plan (DSMP) which will adhere to the protocol approved by the Columbia University Institutional Review Board (IRB) which will oversee the study activities. Routine data quality control assessments will identify and resolve data errors in both data collection (e.g., surveys) and study documentation (e.g., visit logs). Data quality resolutions will be documented for reference. Data validation tools available through the REDCap platform will be leveraged to ensure data quality assurance in study data collection and documentation such that data is checked against validation standards at the time of input. Quality assurance measures will be routinely reviewed with new measures added as necessary to address emerging data quality and safety concerns Biweekly reports for the study sites will be created by the data manager to review relevant app engagement data, barriers with recruitment/enrollment and retention, laboratory and medical records, compliance with the protocol, and accuracy and completeness of the records. Special attention will be

paid to protecting the privacy of participants and securing confidential information. The investigative team will schedule biweekly conference calls to review the reports. These regular reviews will ensure close communication between the research assistants, quickly identify potential concerns for data security, and ensure consistent management of data across the sites.

The Principal Investigator (PI) will enlist a Data Safety and Monitoring Board (DSMB) to oversee the safety and data integrity of the study. The DSMB will be comprised of individuals who are not otherwise associated with the study. The DSMB will meet every six months to review study progress and, at their discretion, adverse events, or differential outcomes. The objectives of the DSMB will be to assess the safety of the intervention and to assure the highest degree of participant safety. In the event the DSMB determines that the study or an arm of the study should be stopped for reasons of safety, this will be communicated by the DSMB to the PI and CDC; the PI will then inform the CUIMC IRB.

All proposed staff have participated in the Department of Health and Human Services required trainings for conduct of studies that involve human subjects, and any future study staff will do so upon hiring. Training for all staff includes (but is not limited to) Protection of Human Subjects, Informed Consent, Good Clinical Practice, Quality Management, Confidentiality, and Reporting of Adverse Events. Study staff will be trained to report adverse events immediately to PI. The PI will convey this information to the IRB of record (CUIMC IRB) and CDC Project Officer.

CDC requires that mechanisms for public health data sharing be included in grants, cooperative agreements, and contracts. In compliance with that requirement, public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. To ensure the protection of personal privacy of research participants and confidentiality of individually identifiable information, publicly accessible study data will be stripped of all directly identifying information such as the name, address, telephone number, or other information that is unique to an individual. Data will also be stripped of indirect identifiers including uncommon race, ethnicity, extreme age, unusual occupation, and other details; however, because the data may be released on an individual level, and because the data contains sensitive, personal information such as sexual risk behaviors, CDC will take all precautions to safeguard confidentiality of study participants. A restricted data set necessitates the use of a data sharing agreement between CDC and the requesting entity. The data sharing agreement ensures that CDC's guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity are adhered to. In order to ensure participant confidentiality, the data sharing agreement sets restrictions on the use of data; a prohibition on efforts to determine the identity of any individual, group or organization whose data appears in the dataset; a prohibition on linking the data with individual identifiable data from other datasets; a prohibition on disclosing the identity of data subjects; and order to immediately disclose to the CDC project officer if an individual identity is discovered. The Data Use Plan (**Attachment 7**) outlines the procedures for public access to study data.

To preserve and share data in a manner that enables validation of results by recipients (e.g., allowing for replication of published findings and conclusions), analytical datasets and statistical code will be retained by the Columbia University Research Team until analyses are complete and for up to three years following study closure, in line with Columbia University IRB guidelines. Study closure date will be determined by 1) final reporting to the research sponsor; 2) final financial close-out of a sponsored research award; 3) final publication of research results; or 4) cessation of an academic or research

project, regardless of whether its results are published. At that time, users must delete all data stored on their servers.

CDC will store complete de-identified data on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for 6 years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval
The study protocol and all accompanying documents have been reviewed and approved by the Columbia University Institutional Review Board (**Attachment 6a**). For purposes of this study and information collection, the study research partners/clinics will defer to the Columbia University IRB (**Attachments 6b-6d**).

Sensitive Questions
This study is designed to collect information about PrEP use and adherence, HIV and STI's, and sexual and other risk behaviors from MSM at risk of HIV infection. As such, our study entails the collection of sensitive information about personal health and behaviors. All study staff will be trained to provide respondents with referrals to sources of prevention and care, such as mental health organizations as needed. All participants will be told during the informed consent process about the nature of sensitive data that will be collected in the study (i.e., sexual activity, prevention methods, drug use, etc.). Participants will be informed that they may decline to answer any question at any time. Further, they will be told that their participation is voluntary and that they can chose to stop participating at any time, for any reason, and without consequence.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

The requested data collection period is 36 months (3 years). Total enrollment for the study is 424. For the Aim 1 patient trial, we will enroll a total of 400 YMSM; over the 3-year data collection period the estimated annual enrollment will be 134. It is expected that 50% of YMSM screened will meet study eligibility criteria and agree to join the study; therefore, we expect to screen 267 YMSM annually. The collection of initial screening information will take approximately 10 minutes to complete (**Attachment 4a**). Once enrolled, the collection of locator information will take approximately 10 minutes to complete (**Attachment 4b**). YMSM participants will complete a baseline assessment which will take approximately 45 minutes to complete (**Attachment 4c**). YMSM participants will also complete a series of follow-up assessments at 3, 6, 9, 12 and 18-month time points. The follow up assessments will take approximately 45 minutes to complete (**Attachment 4d**). Participants will receive their CleverCap and be asked to install the CleverCap app on their mobile phones (**Attachment 4e**). We estimate the CleverCap onboarding process will take approximately 10 minutes to complete. While all participants will be asked to install the app, use of the app after the initial install will be optional.

For Aim 2 of the study, a subset (30 total) of the YMSM participants will be invited to participate in an in-depth interview. The interview will take approximately 90 minutes to complete (**Attachment 4f**).

For the Aim 3 healthcare provider training, we will enroll a total of 20 healthcare providers. Over the 3-year data collection period, the estimated annual enrollment will be 7. It is expected that 50% of healthcare providers screened will meet study eligibility criteria and agree to join the study. Thus, we expect to screen 14 providers annually. The collection of initial screening information from the 14 providers will take approximately 10 minutes to complete (**Attachment 4g**). The collection of locator information from the 7 providers enrolled each year will take approximately 10 minutes to complete (**Attachment 4h**). Healthcare provider participants will be asked to complete an assessment before and after the PrEP training. The pre-training assessment and the post-training assessment are expected to take 30 minutes each to complete (**Attachments 4i and 4j**). Providers will also be asked to take part in a 60-minute interview (**Attachment 4k**).

In addition to the training and provider-level assessments, every 6 months during the 36-month data collection period, each of the four participating clinic sites will complete the clinic assessment tool to describe PrEP services implementation at the facility level. The clinic assessment will be completed by a single member of the clinic staff at each clinic (4 respondents total). Clinic-level assessments at baseline and study end are estimated to take 120 minutes to complete (**Attachment 4l**). Clinic-level assessments conducted at six-month intervals between the baseline and study end points are expected to take 90 minutes to complete (**Attachment 4m**).

There are no costs to the participant other than their time. The total number of burden hours is 2,210 across 36 months of data collection. The total estimated annualized burden hours are 549. Total burden for each activity has been rounded up to whole hours.

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hrs)	Total Burden (in hrs)*
General Public - Adults	Patient Screener (English/Spanish)	267	1	10/60	45
General Public - Adults	Patient Locator Form (English/Spanish)	134	1	10/60	23
General Public - Adults	Patient Baseline Assessment (English/Spanish)	134	1	45/60	101
General Public - Adults	Patient Quarterly Assessment (English/Spanish)	134	3	45/60	302
General Public - Adults	CleverCap App Setup (English/Spanish)	134	1	10/60	23
General Public - Adults	Patient Interview Guide (English/Spanish)	10	1	90/60	15
Health Practitioners	Provider Screener	14	1	10/90	3
Health Practitioners	Provider Locator Form	7	1	10/90	2
Health	Provider Pre-Training	7	1	30/60	4

Practitioners	Assessment				
Health Practitioners	Provider Post-Training Assessment	7	1	30/60	4
Health Practitioners	Provider Interview	7	1	60/60	7
Health Practitioners	Clinic Assessment Baseline and Final	4	1	120/60	8
Health Practitioners	Clinic Assessment Every Six Months	4	2	90/60	12
Total					549

*All activities have been rounded up to whole hours.

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May 2021 (http://www.bls.gov/oes/current/oes_nat.htm) was used to estimate the hourly wage rate for the general public and health practitioners for the purpose of this request. This cost represents the total burden hours to respondents multiplied by the average hourly wage rate for General Public Adults ($28.01) and Health Practitioners and Technical Occupations ($43.80). Annualized burden costs are $16,009.09.

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Respondent Costs
General Public - Adults	Patient Screener (English/Spanish)	45	$28.01	$1,260.45
General Public - Adults	Patient Locator Form (English/Spanish)	23	$28.01	$644.23
General Public - Adults	Patient Baseline Assessment (English/Spanish)	101	$28.01	$2829.01
General Public - Adults	Patient Quarterly Assessment (English/Spanish)	302	$28.01	$8459.02
General Public - Adults	CleverCap App Setup (English/Spanish)	23	$28.01	$644.23
General Public - Adults	Patient Interview Guide (English/Spanish)	15	$28.01	$420.15
Health Practitioners	Provider Screener	3	$43.80	$131.40
Health Practitioners	Provider Locator Form	2	$43.80	$87.60
Health Practitioners	Provider Pre-Training Assessment	4	$43.80	$175.20
Health Practitioners	Provider Post-Training Assessment	4	$43.80	$175.20
Health Practitioners	Provider Interview	7	$43.80	$306.60

Health Practitioners	Clinic Assessment Baseline and Final	8	$43.80	$350.40
Health Practitioners	Clinic Assessment every 6 months	12	$43.80	$525.60
Total				**$16,009.09**

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The annual cost to the government for the data collection is estimated to be $1,112,799 (Exhibit 14.1).

Exhibit 14.1: Annualized Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC, Project Officer (GS-13 0.30 FTE)	$ 30,436
	CDC, Project Officer (GS-13, 0.10 FTE)	$ 9,708
	CDC, Project Coordinator (GS-12, 0.40 FTE)	$ 32,655
	Subtotal, Direct Costs	**$ 72,799**
Cooperative Agreement Costs	**Annual Cooperative Agreement #PS21-003 Costs**	**$ 1,040,000**
	ANNUALIZED COST TO THE GOVERNMENT	**$ 1,112,799**

15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Our analysis will focus on questions related to the study objectives. The study will use a pre-post design to compare provider knowledge retention at pre-, baseline and post-training levels. A pre-post design will also be used to track participant PrEP adherence. Patient and Provider qualitative interview data will be analyzed to describe intervention experiences and barriers and facilitators to intervention implementation.

The project time schedule is contingent on the anticipated OMB approval date of December 2023. Following OMB approval, data collection will occur over a period of 36 months (anticipated January 2024 – December 2026); data analyses will be finalized four months after data collection is completed (anticipated April 2027); and the final data set and report will be submitted 40 months after OMB approval (anticipated April 2027). We are requesting approval for 3 years (36 months) of data collection. The project timeline is detailed in exhibit 16.1.

Exhibit 16.1: Project Time Schedule

Activity	Time Schedule
OMB Approval Date	December 2023
Develop data collection tools, sampling and data plans, study protocol	September 2021-January 2023
Recruitment	1-18 months after OMB Approval
Data Collection	1-36 months after OMB Approval
Data analysis finalized and report drafted	40 months after OMB Approval
Final de-identified data set submitted to CDC	40 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other directly identifiable information, and locations will be removed) quantitative and qualitative datasets for this study along with the corresponding data documentation, which will be made publicly available within 36 months of the end of data collection. It is anticipated that the data collected through this study will be shared as summary data tables and restricted use dataset(s). A data use plan for information collected during this study has been developed. The plan describes in detail how data access will be provided and the provisions for protection of privacy, security, intellectual property, or other rights (**Attachment 7**).

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

References

1. Centers for Disease Control and Prevention. HIV Incidence: Estimated Annual Infections in the U.S., 2010-2016. NCHHSTP Newsroom Web site. https://www.cdc.gov/nchhstp/newsroom/2019/HIV-incidence.html. Page last reviewed: February 27, 2019. Accessed December 29, 2022.
2. Centers for Disease Control and Prevention. HIV among Gay and Bisexual Men https://www.cdc.gov/hiv/group/msm/index.html. Page last reviewed: September 9, 2022. Accessed December 29, 2022.
3. Centers for Disease Control and Prevention. HIV among Gay and Bisexual Men CDC Fact Sheet Web site. https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf. Page last reviewed: June 25, 2019. Accessed December 29, 2022.
4. Lelutiu-Weinberger C, Golub SA. Enhancing PrEP Access for Black and Latino Men Who Have Sex with Men. *Journal of acquired immune deficiency syndromes* 2016;73(5):547–555.

5. Centers for Disease Control and Prevention. Daily Pill Can Prevent HIV. Vital Signs Web site. https://www.cdc.gov/vitalsigns/hivprep/index.html. Published November 24, 2015. Accessed December 29, 2022.
6. Amico KR, Bekker L. Global PrEP roll-out: recommendations for programmatic success. *The Lancet HIV.* 2019;6(2).
7. Goldenberg MM. Pharmaceutical approval update. P & T: a peer-reviewed journal for formulary management. 2012;37(10):556–558.
8. Giroir BP. The Time Is Now to End the HIV Epidemic. *American Journal of Public Health.* 2020;110(1):22-24.
9. Healthcare V. ViiV Healthcare receives FDA Breakthrough Therapy Designation for investigational, long acting cabotegravir for HIV prevention. https://viivhealthcare.com/hiv-news-and-media/news/press-releases/2020/november/viiv-healthcare-receives-fda-breakthrough-therapy-designation-fo/. Published November 17, 2020. Accessed December 29, 2022.
10. National Institutes of Health. Long-acting injectable form of HIV prevention outperforms daily pill in NIH study. News Release. https://www.nih.gov/news-events/news-releases/long-acting-injectable-form-hiv-prevention-outperforms-daily-pill-nih-study. Published July 7, 2020. Accessed December 29, 2022.
11. Hurt CB. PrEParing Providers: The Next Challenge in Implementing Human Immunodeficiency Virus Preexposure Prophylaxis. *Sexually transmitted diseases.* 2018;45(7):459–461.
12. Pinto RM, Berringer KR, Melendez R, Mmeje O. Improving PrEP Implementation Through Multilevel Interventions: A Synthesis of the Literature. *AIDS and behavior.* 2018;22(11):3681–3691.
13. Reback CJ, Clark KA, Rünger D, Fehrenbacher AE. A Promising PrEP Navigation Intervention for Transgender Women and Men Who Have Sex with Men Experiencing Multiple Syndemic Health Disparities. *Journal of community health.* 2019;44(6):1193–1203.
14. HIV.gov. National HIV/AIDS Strategy (2022-2025). Available at: http://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025. Published August 29, 2022. Accessed: December 29, 2022.
15. HIV.gov. What is 'Ending the HIV Epidemic: A Plan for America'? Available at: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview. Updated July 01, 2022. Last Accessed: December 5, 2020.
16. Centers for Disease Control and Prevention Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention. Available at: https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html. Updated February 6, 2018. Accessed March 9, 2023.
17. Grants.gov. RFA-PS-21-003 PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices. Available at: https://www.grants.gov/web/grants/view-opportunity.html?oppId=328319. Last accessed: May 5, 2022.
18. Schnall R, Kuhns LM, Pearson C, Batey DS, Bruce J, Hidalgo MA, Hirshfield S, Janulis P, Jia H, Radix A, Belkind U, Rodriguez RG, Garofalo R. Efficacy of MyPEEPS Mobile, an HIV Prevention Intervention Using Mobile Technology, on Reducing Sexual Risk Among Same-Sex Attracted Adolescent Males: A Randomized Clinical Trial. JAMA Network Open. 2022;5(9):e2231853-e. doi: 10.1001/jamanetworkopen.2022.31853.
19. Wood OR, Garofalo R, Kuhns LM, Scherr TF, Zetina APM, Rodriguez RG, Nash N, Cervantes M, Schnall R. A randomized controlled trial of an mHealth intervention for increasing access to HIV testing and care among young cisgender men and transgender women: the mLab App study protocol. BMC Public Health. 2021;21(1):1959. Epub 20211029. doi: 10.1186/s12889-021-12015-w. PubMed PMID: 34715833; PMCID: PMC8554516.

20. Office of Information and Regulatory Affairs OoMaB. Questions and Answers When Designing Surveys for Information Collections. Washinton, DCJan 2006 (Last Modified Oct 2016).