

**Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse
Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a
Transformational Era (MIC-DROP)**

OMB 0920-New

Section A: Supporting Statement

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CONTACT

Gordon Mansergh, PhD, MA, MEd
Project Officer
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
Prevention Research Branch
1600 Clifton Rd, NE, Mailstop H24-5
Atlanta, GA 30333

Telephone: 404-639-6135

Fax: 404-639-1950

E-mail: gcm2@cdc.gov

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- **Goals of the study:** To understand the strategies of men who have sex with men (MSM) to prevent HIV and sexually transmitted infections (STIs), including preexposure prophylaxis (PrEP) use and adherence, condom use, and sexual risk-taking behaviors including substance use.
- **Intended use:** Data collected through this study will be used to inform the real-time development and testing of HIV prevention messaging; to characterize the typologies of current and potential PrEP users; and to identify critical prevention gaps.
- **Methods to be used to collect data:** Participants will complete quantitative assessments at quarterly intervals during the two-year follow up period. Participants will use self-collection kits for STI and HIV testing at six-month intervals. In-depth interviews and focus groups will also be conducted with a subset of intervention participants.
- **The subpopulation to be studied:** A racially/ethnically diverse sample of 1275 HIV-negative, sexually active adult MSM living in the Atlanta, Chicago, and San Diego areas (425 from each city).
- **How data will be analyzed:** This study will retain a cohort 1275 MSM to be assessed prospectively for two years. Quantitative analysis will be conducted to identify PrEP use patterns, describe PrEP attitudes and beliefs, explain PrEP preferences, and quantify participant preferences for prevention messages. Qualitative analysis will be conducted to understand men’s experience with PrEP treatment, explore their preferences for PrEP and other HIV prevention products, and to continue to test their reactions to prevention messages developed during the study.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention’s (CDC) Division of HIV Prevention (DHP) requests approval for 36 months of data collection for a research study entitled, “Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP)” as a new information collection. This project is funded under Cooperative Agreement #U01PS005244.

The prevention of HIV in the United States is in a transformational era. In just a decade since the first finding of efficacy for daily oral preexposure prophylaxis (PrEP)¹, there is a proliferation of new PrEP agents, including long-acting injectable PrEP², and regimens, including “event-driven” (also called “on demand” or 2-1-1 dosing) PrEP.³ There has also been new knowledge about the impact of antiretrovirals (ARVs) for treatment of human immunodeficiency virus (HIV), and an emergent understanding that people living with HIV who take ARVs and maintain a suppressed viral load are incapable of transmitting HIV to their sexual partners.⁴ In this context, the idea of “protected” sex – which historically meant sex protected by condoms⁵ – has become much more complex.⁶ Men who have sex with men (MSM) and others at risk for acquiring HIV are now making decisions about how to reduce their risks of HIV infection in a world where there are many more options to reduce risks of infection, and where those options also interact with the HIV status and viral suppression status of their sex partners. Understanding men’s preferences for prevention products and strategies and what choices are

being made by men with varying risk profiles is critical to public health responses and programs to reduce new HIV infections.⁵

MSM are the most highly impacted group by HIV in the US, with transmission largely driven by high per-act risk MSM.⁷ Among MSM, Black/African American (Black) and Hispanic/Latino (Hispanic) men experience nested health inequities: in 2020, Black men comprised 13% of US men and 38% of MSM diagnosed with HIV, and Hispanic men comprised 19% of US men and 33% of MSM diagnosed with HIV.⁸ Uptake of daily oral PrEP use by Black and Hispanic MSM has been slow⁹ and the extent of PrEP use among these men has not been equitable in light of their disproportionate impact in the HIV epidemic.¹⁰ Similarly, HIV incidence is concentrated in young MSM of all races.¹¹ Thus, research to increase our understanding of men's awareness of, attitudes for and use of new prevention options must prioritize the equitable engagement of Black, Hispanic, and younger MSM.

The next 5 years will be a period of rapid changes in the rollout of new PrEP options and will likely see the introduction of new PrEP modalities (e.g., long-acting injectable PrEP, lower frequency oral dosing). Understanding the choices and patterns of PrEP use and the reasons and motivations for those choices among geographically, racially, and ethnically diverse groups of MSM will be a critical part of monitoring the public health response and in informing public health programs and messaging. Ideally, public health messaging will be driven by up-to-date information about the perceptions, preferences, and practices of those MSM at highest risk of HIV acquisition. During this era of rapid change in the available PrEP options, it is critical to have a robust system of real-time monitoring for PrEP preferences, what prevention options men are choosing, and what messages might be most impactful to support the appropriate uptake of PrEP and persistence on PrEP. Because we expect numerous changes in the availability of PrEP products and treatment guidelines, it is also critical to be able to process and interpret these data in a timely way, to best support nimble decisions in prevention messaging and programs in response to a changing landscape of prevention options.

The goal of this study is to understand the use of preexposure prophylaxis (PrEP) and other HIV and sexually transmitted infections (STI) prevention interventions over time among MSM. The study will also identify the most effective PrEP messaging and other HIV and STI prevention messaging to increase protective behaviors among MSM. This study will generate rapid reports following each wave of data collection to identify community trends and implications for prevention messaging.

This project is in alignment with the following goals and objectives of the National HIV/AIDS Strategy (2022-2025):¹¹

- 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 Quickly¹². 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 preexposure prophylaxis (PrEP).

This 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 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 information collection is to understand men’s strategies to prevent HIV/STIs, including PrEP use and adherence, condom use, sexual risk-taking behavior, and substance-using behaviors. This study will also assess men’s use and preferences for prevention modalities and their awareness, knowledge, beliefs, and perceptions of HIV/sexually transmitted disease (STD) prevention products. Additionally, this information collection will conduct structured assessments of prevention messages to develop effective messaging to close identified prevention protection gaps in behavior.

This study will be carried out in three locations: Chicago, Illinois; San Diego, California; and Atlanta, Georgia. The awardee of the cooperative agreement, Emory University, and their partners, University of Chicago, and San Diego State University, will be responsible for collecting all data for this study. Biospecimens collected during the study will be processed by Molecular Testing Labs (MTL, Vancouver, Oregon), a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory that has worked with the awardee to develop standard procedures for urethral, rectal, and pharyngeal gonorrhea/chlamydia and syphilis. Data collection will take place over three years following United States Office of Management and Budget (OMB) approval.

This study has four objectives:

1. To assess patterns in the use of available HIV prevention interventions (e.g., PrEP, condoms, prevention messaging) over time in a racially/ethnically diverse community-based sample of MSM three U.S. cities.
2. To assess HIV and STI infection and the association with type of prevention intervention among HIV-negative MSM during a transformational era with the availability of biomedical HIV prevention interventions.

3. To develop and test HIV and STI prevention messages during a transformational era with the availability of biomedical HIV prevention interventions.
4. To generate rapid reports following each wave of quantitative and qualitative assessment that include key study findings, HIV prevention trends, and recommendations for public health messaging and behavioral interventions that can be used to guide HIV prevention interventions.

To achieve the objectives of this data collection, a cohort of 1275 cisgender MSM in Atlanta, Chicago, and San Diego (425 from each city), will be recruited to the study and then assessed over 24 months (2 years). We will use recruitment controls to ensure 60% of participants will be PrEP users at baseline, and 40% will not be using PrEP. The purpose of this is to have a broader representation of MSM than only PrEP users and to better understand PrEP uptake, adherence, persistence, and gaps in prevention protection over time as new modalities of PrEP are introduced. Additionally, we will oversample Black and Hispanic MSM so that a minimum of 30% each are represented in the cohort sample.

We will recruit MSM participants in-person, using posted flyers and online advertisements (**Attachment 3**). Our primary recruitment source will be through online targeted advertisements to adult men in the three metropolitan areas, including social media channels, such as Facebook, Instagram or Snapchat, Grindr, or other dating apps. Additionally, recruitment will be done through referrals from local clinics and community-based organizations. These organizations may provide palm cards or QR codes for interested participants to reach the eligibility screening assessment.

Potential participants recruited online or through referrals will be directed to an online study page that will first ask for verbal consent to complete the eligibility screener (**Attachment 4a**). Those determined to not be eligible would be offered additional resources for HIV or STI testing or other resources upon request. After completing the screener, eligible participants will be asked to provide contact information (**Attachment 4b**), Staff will contact the participant and set up a virtual enrollment visit. The visit will take place a secure Health Insurance Portability and Accountability Act (HIPAA) compliant video conference platform (Zoom). During the enrollment visit, staff will re-screen participants for eligibility (**Attachment 4a**). Staff will then provide eligible participants with an overview of the study and study procedures and guide them to the online consent form (**Attachment 5a**). After reviewing the consent form, participants will be directed to click a box to indicate their agreement to participate in the study. The Institutional Review Board (IRB) of record has approved a waiver of participant signature on the consent form (**Attachment 6a**). Following the consent process, staff will guide participants through the completion of the first quantitative assessment (**Attachment 4c**), coordinate shipment of baseline at-home HIV and STI test kits, and assist the participant in setting up the Study Management and Retention Toolkit (SMaRT) application on their mobile phone (**Attachment 4d**). Screening, consent, contact information collection and assessments will be conducted online via Alchemer, a HIPAA-compliant online data collection platform.

Over the two-year follow up period, participants will be asked to complete assessments every three months (**Attachment 4c**). The quarterly quantitative assessments will collect information on the following topics: sociodemographic information; HIV and STI testing; condom use; PrEP

knowledge, use, preferences, sharing, perceived efficacy, and stigma; barriers to prevention services and healthcare trust; sexual partners and sexual behaviors; mental health; alcohol and substance use; and attitudes about prevention messages. For the messaging review portion of the assessment, the electronic data collection system will populate each quarterly assessment with ten pre-selected messages from the master message bank included here. Messages in the message bank were developed through previously approved research. Messages for each wave of the testing will be selected based on participant responses to previous waves of survey assessment in this study, as well as participant responses to ongoing interviews and focus groups herein. This method will allow flexibility and responsiveness to ongoing findings of respondent prevention implementation challenges and message preferences in order to provide the greatest benefit to participants.

At six-month intervals, all participants will be mailed self-collection kits to provide samples for HIV and STI testing. Specimens for STI testing include urine, rectal, and pharyngeal swabs for gonorrhea and chlamydia and dried blood spot (DBS) for syphilis testing. HIV kits will collect DBS for 4th generation HIV testing. Tests will be shipped from, returned to, and processed by a CLIA-certified laboratory. Instructions for the HIV specimen collection (**Attachment 4e**) and the STI specimen collection (**Attachment 4f**) are available English and Spanish. The instructions have been tested with MSM for acceptability¹³ and are being used through the Emory Center for AIDS Research (CFAR) for multiple National Institutes of Health (NIH)-funded studies¹⁴. For participants who prefer in-person procedures, they will have the option to meet with study staff who will provide them with the STI or HIV self-collection kit and instructions, answer questions, and provide a private room in which participants can collect their specimens. Study staff will assist with shipping specimens for those participants who opt for an in-person visit. Men who have a new HIV diagnosis during the study will be helped with accessing HIV care and treatment services and will not proceed in the study. Men with an STI diagnosis will be connected to local resources for care and treatment.

A subset of participants will be invited to participate in qualitative data collection activities. We will conduct focus group discussions (**Attachment 4g**) with 144 total participants (48 from each city). Small focus groups, averaging 8 participants, will be conducted in person or via a HIPPA-compliant teleconference platform in three waves, about six months apart. Participants will be asked to attend only one of the focus groups. Participants will undergo a second consent process (**Attachment 5b**) prior to attending the focus group discussion. We also invite an additional 45 participants (15 from each city) to join a series of three in-depth interviews (**Attachment 4h**) occurring at six-month intervals. Participants will undergo a second consent process (**Attachment 5c**) prior to the interview. Interviews will be delivered in person or via a HIPPA-compliant teleconference platform. The aims of the qualitative data collections are to understand men’s experience of PrEP, further explore their preferences for PrEP and other HIV prevention products, and to evaluate their reactions to prevention messages developed during the study.

Exhibit 2.1 Timeline of study visits, activities, and labs.

Touch points for study participants in quarterly intervals (24-months total)								
	1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th
Quantitative Assessment	X	X	X	X	X	X	X	X

HIV Testing	X		X		X		X	
STI Testing	X		X		X		X	
Qualitative Assessments		X		X		X		

The study protocol, consent forms, and all data collection instruments have been approved by the WCG Institutional Review Board (IRB) (**Attachment 6a**).

Data collected during this study will be used to better understand men’s strategies to prevent HIV/STIs, including PrEP use and adherence, condom use, sexual risk-taking behavior, and substance-using behaviors. Data collected in this study will also be used to generate rapid reports every three months to identify HIV prevention gaps and messaging opportunities and recommendations for MSM. Effective prevention messaging will be implemented in CDC messaging and community programs (e.g., mobile apps, social marketing campaigns, website information sources, other written prevention materials) to improve HIV prevention for communities of 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

Screening, consent, contact information collection, assessment completion, focus group attendance and the in-depth interview will be offered in an online format. This will allow participants to complete the study activities at a place and time that is most secure and convenient to them. Participants will also have the option to conduct data collection activities in-person. Study staff will be available to support participants during virtual and in-person data collection activities. Focus groups and in-depth interviews will be audio-recorded. This limits burden on the interviewer (the interviewer does not have to take handwritten notes), allows researchers to accurately capture participant responses, and allows the interviewer or focus group moderator to concentrate on building and maintaining rapport with the respondent.

Quantitative data collection will be conducted with Alchemer, a HIPPA-compliant web-based system previously used by the study team in collaborative research with CDC (Mobile Messaging Intervention to Present New HIV Prevention Options for Men Who have Sex with Men: Randomized Controlled Trial, OMB 0920-1209 exp. 12/31/2019) and supported by the Emory University Center for AIDS Research (CFAR). Assessments will be optimized for participants to take them through a personal computer, mobile phone, tablet, or the SMaRT study app. For participants who do not have any of these devices or prefer to not take the assessment from their personal device, each city will have research space where participants can schedule a convenient time to take the assessment on a computer or tablet that the study will provide for that purpose. The web based Alchemer system also allows us to build in computer-generated skip patterns to greatly reduce respondent burden. In addition, data collected through the web application can be used to automatically generate the study database, reducing data entry burden and potential data entry error.

The study will utilize the SMaRT (Study Management and Retention Toolkit) system, a study management platform that allows for participant management including reminder notices, scheduling, assessment administration, and communication by email and text messaging. It also includes a HIPPA-compliant companion mobile app that study participants install on their smart phones that supports several key functions of study participation including notifications of assessments available, administration of assessments, a messaging center, appointment scheduling, secure HIPPA-complaint document upload and return of laboratory results, and a HIPPA-compliant telehealth video conference platform. SMaRT develops an individualized study timeline for each participant as they are enrolled, with target dates for all study activities (assessments, testing, qualitative interviews, etc.). Participants can elect to receive messages and communicate with study staff by email, through text messages, or through the SMaRT study app. Reminders for study assessments, return of biological specimens, uploading of HIV test results and qualitative interviews will be delivered through the SMaRT system, using the method (email, SMS, app messaging) that the participant has chosen.

4. Efforts to Identify Duplication and Use of Similar Information

In 2021, CDC provided clinical guidelines¹⁵ addressing new products for PrEP for MSM, including bi-monthly injectable PrEP (Apretude, cabotegravir-long acting) and on demand oral PrEP (also known as event-driven or 2-1-1 oral dosing). Prior to 2021, behavioral research on PrEP focused solely on the daily oral modality (Truvada, Descovy) and its use and adherence among MSM in the United States.^{16,17} While some earlier studies assessed behavioral intentions related to hypothetical injectable and on demand PrEP products in this population,^{18,19} research has not yet assessed actual behavioral choices over time once products are available for MSM in the U.S. Transitioning among products is likely with emergence of new products, as well as over time for an individual, but these behaviors have not yet been assessed.²⁰ Past PrEP use and adherence studies have largely been clinic based.²¹ Other MSM cohort studies currently in development during this new era of multiple available PrEP products may focus on either current PrEP users in clinic settings (e.g., PrEPChoice) or men not using PrEP (none identified), but not on both populations of MSM when applying a standard assessment across the two groups for relevant comparisons over time. Lastly, we are not able to identify any MSM cohort studies that are focused on developing and testing prevention messages in the new era of several PrEP products, and then providing rapid reports to a federal agency about recommendations for immediate messaging by agency and funded partners.

Because the HIV prevention behavior and other information gathered in this study will focus on a large community-based, 2-year cohort of MSM that includes men who are (a) using PrEP and (b) not using PrEP at baseline, the Agency believes this study is unique in its efforts herein. Further, this study is unique in that it will develop and test prevention messages to help close identified gaps in HIV protective behavior in the cohort of MSM and provide rapid reports to the Agency following each wave of data collection. These reports will summarize key findings and give recommendations for prevention messaging by the Agency and its funded programs in this new era of multiple available PrEP products.

5. Impact on Small Businesses or Other Small Entities

This collection request does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The study will provide the quantitative and qualitative data needed to assess men’s use and preferences for prevention modalities, awareness, knowledge, beliefs and perceptions of HIV/STD prevention products, and structured assessments of prevention messages to develop effective messaging to close identified prevention protection gaps in behavior. Data will be collected over a two-year follow up period. Quantitative data will be collected at 3-month intervals and biospecimens at 6-month intervals. A series of three qualitative interviews will be conducted at 6-month intervals and qualitative focus group discussions will occur every six months. Collecting data less frequently would limit our ability to conduct real-time monitoring of PrEP use and preferences and actively assess the impact of prevention messages to rapidly inform the development and delivery of prevention messaging. The number of collections is the minimum required to ensure timely delivery of responsive and meaningful messaging.

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

There are no special circumstances. The message testing activities fully comply with the regulations and guidelines in 5 CFR 1320.5.

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

A 60-Day Federal Register Notice to solicit public comments was published on 11/16/2022, Vol. 87, No. 220, pages 68696-68698 (**Attachment 2a**). CDC received two comments during the 60-day notice period (**Attachment 2b**). The first was a letter of general support to which CDC replied thanking the respondent. The second letter had several recommendations for improving the study in the areas of study design, recruitment, participant inclusion criteria, and the provision of participant compensation to limit selection bias. CDC replied explaining the scientific rationale for the racial and ethnic makeup of the sample; the selection of two cohorts rather than three; and the inclusion criteria. CDC also reassured the respondent that the study would be utilizing the recruitment methods that they suggested, and that the study does plan to provide study participants with a token of appreciation. No changes were made to the supporting statement or data collection instruments.

In addition, Emory University, San Diego State University, and University of Chicago were involved in the development of this study in 2022 and 2023. There were no unresolved issues associated with the development process.

Patrick Sullivan, Principal Investigator Emory University 1518 Clifton Rd NE Atlanta, GA 30322 404-210-6039	Travis Sanchez, Co-Investigator Emory University 1518 Clifton Rd NE Atlanta, GA 30322 404-727-8403
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psulli@emory.edu Aaron Siegler, Investigator Emory University 1518 Clifton Rd NE Atlanta, GA 30322 404-712-9733 asiegle@emory.edu	travis.sanchez@emory.edu Keith Horvath, Investigator San Diego State University 6363 Alvarado Court, Suite 250 San Diego, CA 92120 619-594-3346 khorvath@sdsu.edu
John Schneider, Investigator University of Chicago 5841 South Maryland Ave Chicago, IL 60637 773-702-1000 Jschnei1@bsd.uchicago.edu	

9. Explanation of Any Payment or Gift to Respondents

Participants will receive a \$50 for completion of each quantitative assessment (8 total) and \$50 for each HIV/STI testing kit completed (4 total). Participants may receive a maximum token of \$600 if they complete all eight assessments and all four test kits. A subset of participants (189) will be purposively selected to participate in either a single focus group discussion (144) or a series of three in-depth interviews (45). Individuals who are selected for in-depth interviews will receive \$75 for each interview. Participants may receive a maximum token of \$225 if they complete all three interviews. Individuals who are selected to join a focus group will receive \$75 for participation in a single 90-minute focus group discussion. All payments will be provided in the form of an electronic gift card that will be emailed to participants.

MIC DROP Incentives

Data collection activity	Incentive amount	Total number of times administered	Maximum incentive
Quantitative assessment	\$50	8	\$400
825HIV/STI self-tests	\$50	4	\$200
Total for all assessments and self-tests			\$600
In-depth interview (n=45)	\$75	3	\$225
Focus group discussion (n=144)	\$75	1	\$75

The proposed incentives for the MIC-DROP study are based on the researchers' recent experiences with a similar study, Project PEACH – Parrying the Pitfalls of PrEP: Preventing Premature PrEP Discontinuation and STI's Among Young Black MSM²². Project PEACH is an intervention study with the goal of preventing new HIV infections among young, black men who have sex with men (MSM) in Atlanta, GA by increasing HIV pre-exposure prophylaxis (PrEP) use, decreasing PrEP discontinuation, and preventing sexually transmitted infections (STI) through the use of STI post-exposure prophylaxis (PEP). Participants are enrolled in the study for 2 years with frequent follow-up time points to assess PrEP and STI PEP usage and detect warning signs for PrEP discontinuation so that peer navigators and clinicians can intervene to prevent it. Like the MIC DROP study, Project PEACH study activities include downloading a

mobile phone app, engaging in ongoing web-based quantitative surveys, and serial HIV and STI self-testing. Additionally, Project PEACH participants were also asked to attend three in-person visits and complete weekly and monthly quizzes. Project PEACH launched in November 2021; however, 7 months into the study, we had only enrolled 30 people and fell significantly behind our grant milestones. Additionally, we had low engagement with our web-based surveys. To enroll this difficult to reach population and improve our retention outcomes, we had to increase our incentive amounts to \$125 for in-person surveys and testing and \$40 for web-based surveys. Seven months after making these changes to our incentives, we were able to enroll an additional 109 participants for Project PEACH. Since this time, the impact of COVID-19 and inflation have continued to make recruitment extremely challenging. We anticipate having similar challenges with enrolling participants for MIC-DROP. In order to mitigate these challenges, we propose a modest increase to the incentive amounts recommended by OMB guidelines.

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..."²³ The use of tokens of appreciation in the proposed research is appropriate according to this guidance. The primary goal of the project is to develop and assess the potential impact of practical messages about emerging HIV prevention information and approaches (e.g., PrEP, condom effectiveness, peer group HIV prevalence) for MSM, including Black and Latino MSM. This study seeks to recruit, enroll, and follow a stigmatized population, while also asking highly sensitive questions about issues such as PrEP use, HIV and STIs, and sexual behaviors. Further, offering tokens of appreciation is critical when recruiting minorities and historically underrepresented groups in research. A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among this group.²⁴

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014), the Transgender HIV Behavioral Survey (OMB 0920-0794, exp. 12/31/2010), and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), all of which included hard-to-reach populations and had a similar length of time for completing the client interview as in this proposed research. This remuneration approach and these token levels are consistent with a recent CDC study with a similar population, Mobile Messaging Intervention to Present New HIV Prevention Options for Men Who have Sex with Men (MSM): Randomized Controlled Trial (OMB 0920-1209, exp. 12/31/2019). In each of these projects, tokens of appreciation helped to increase and maintain participation rates.

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

The CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention (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 awardee, Emory University and their partners, University of Chicago, and San Diego State University, will be responsible for collecting all data for this study. Personally identifiable information will not be shared with CDC.

The terms of the CDC Cooperative Agreement authorizing data collection require the grantee 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.

To minimize risks to confidentiality, we will provide study data with all appropriate physical and operational security protections. All identifiable data collected regarding study participants will be maintained on the study server. This will be maintained separately from all other information, including baseline assessment responses, follow-up assessment responses, at-home HIV and STI test results, and qualitative assessments. A master list linking the identifiers and study data will be stored on the study server, and access to these confidential files will be managed by the Project Coordinator and Principal Investigator. All participants will be assigned a unique identification (ID) number which will be unrelated to the participants' name or other uniquely identifying information. Documents containing personally identifying information (PII) and the document linking PII and the study ID number will be maintained separately from study data in password protected files stored within a restricted folder on a secured server. The linking document and documents containing PII will be accessible only to Investigators, Project Coordinators, and other staff who will undergo training in data security procedures.

All web survey data will be collected using Alchemer, a secure, encrypted electronic platform with which the Emory site team has established a business associate agreement to ensure HIPAA-compliance. Study data stored by Alchemer are maintained on a dedicated secure server, with no co-mingling of study data with other Alchemer customer data, or between Emory projects administered by Alchemer. Data collected via Alchemer are automatically encrypted, with the coded access only available to the Project Director and the PIs. All data will be secured during transmission by using a 256-bit SSL encryption or higher, and the SSL certificate will be from a reputable provider (e.g., VeriSign).

All electronic files and records will be stored in a firewall-protected, encrypted server at Emory University. Access to printed or electronic data will be on a role-based standard; only those study staff who require access to identifying data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures and will sign a confidentiality agreement before receiving access to any participant data.

The study will rely on the HIPAA-compliant Zoom video chat service to conduct in-depth interviews and focus group discussions. Zoom provides end-to-end encryption using Advance Encryption Standard (AES) 256-bit algorithm, or similar. Session keys are generated with device unique hardware ID to avoid data being read from other devices. This ensures that the consultation cannot be eavesdropped or tampered with. These qualitative assessments will be recorded, and only the audio element will be retained on the secure study server. The recordings from the qualitative assessments will be transcribed and during the transcription process all uniquely identifying information will be removed.

The study will use a HIPAA-compliant web-based platform entitled Study Management and Retention Toolkit (SMaRT), a study management platform that supports various aspects of participant recruitment, study implementation, and retention. SMaRT includes a HIPAA-compliant companion mobile app that study participants install on their smart phones as well as an administrative portal for study staff, which allows for secure messaging, study calendar management, and longitudinal tracking of participants from screening to study completion. The ability to designate specific roles to all SMaRT users allows for greater control around permissions and accessibility to participant information.

Study staff will be trained to follow regulations for mandatory reporting of breaches in confidentiality or adverse events. All study personnel will have completed human research protections (CITI) training. All study staff will be trained to recognize, document, and report any unusual events or circumstances that occur during data collection immediately to the Principal Investigator (PI) and Emory IRB. If an adverse event appears to be research-related, it will be reported to the Office for Human Research Protections and CDC, along with summaries of discussions concerning the event. CDC will be informed of any Institutional Review Board (IRB) action taken concerning any adverse event. The Principal Investigators and Project Director will monitor staff closely. Staff deficient in any aspect of performance will be re-trained, closely monitored for proficiency, and if not adhering to established protocols and procedures, will be terminated.

Six months after study completion, participant contact information and all links between survey responses and contact information forms will be destroyed. De-linked study data will be retained for up to 25 years in accordance with Emory University Libraries and Information Technology Records Management Policy, Policy #5.21, Research Records: Clinical Trials, 21 CFR 312.62 (c); O.C.G.A. 9-3-24; (updated 10/1/2022). Regarding the public access dataset, 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).

De-identified, summary data may be used in manuscripts, presentations and reports that highlight the activities and successes of this program. Public access to the data will be provided at the completion of the study and after the dissemination of the primary findings. Any data made publicly available after the completion of the study will be de-identified and will not be linked to participant contact information. The Data Use Agreement outlines the protocols for public access

to study data (**Attachment 7**).

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

IRB Approval

The study protocol, the data collection instruments, and all accompanying documents have been reviewed and approved by WCG IRB (**Attachment 6a**). For purposes of this information collection, the study research partners, Emory University, University of Chicago, and San Diego State University, defer to the WCG IRB (**Attachments 6b, 6c, and 6d**).

Sensitive Questions

This study is designed to collect information about PrEP use and adherence, HIV and STIs, and sexual behaviors from MSM at risk of HIV infection. As such, our study entails the collection of sensitive HIV risk-related information. All study staff will be trained to provide respondents with referrals to sources of prevention and care, such as mental health organizations, as needed. Sensitive questions will be asked about PrEP use, sexual behavior, and substance use. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

The requested data collection period is 36 months. Following enrollment, the participant will be followed for 24 months. Total enrollment for the study is 1275. We anticipate that 50% of participants screened will be eligible and choose to enroll in the MIC DROP study; therefore, we expect to screen approximately 850 MSM annually. Eligibility screening is anticipated to take 5 minutes (**Attachment 4a**). Providing contact information on the Contact Information Form will (**Attachment 4b**) also take about 5 minutes. All participants will be re-screened (**Attachment 4a**) prior to consent and enrollment. Data collection will include a quantitative assessment (**Attachment 4c**) administered to each participant at enrollment and quarterly intervals throughout the two-year follow up period (8 total assessments). We estimate the quantitative assessment will take 45 minutes to complete. Participants will be asked to install the SMaRT application on their mobile phone (**Attachment 4d**). We estimate the installation process will take 10 minutes. While all participants will be asked to install the app, use of the app after the initial install will be optional. Participants will be mailed an HIV and a STI specimen collection kit at baseline and 6-month intervals during the two-year follow up period. The HIV specimen (dried blood spot) self-collection is estimated to take 20 minutes to complete (**Attachment 4e**). The STI specimen self-collection is estimated to 30 minutes to complete (**Attachment 4f**). A subset of participants (150 total) will be invited to join a focus group (**Attachment 4g**). Small group focus group discussions will convene for about 90 minutes and will be offered every six months during the follow-up period. Another subset of participants (45 total) will be invited to join a series of three in-depth interviews occurring at six-month intervals (**Attachment 4h**). The interviews will take approximately 90 minutes to complete.

There are no costs to the participant other than their time. The total number of burden hours is 12,996 across three years of data collection. The total estimated annualized burden hours are 4,332. Annualized burden was calculated by dividing the total burden hours for each data collection activity by three and working back to calculate the number of respondents and responses needed to arrive at the annualized amount equal to one-third of the total burden. Total burden for each activity has been rounded to the nearest whole hour.

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Eligibility Screener (Att. 4a)	850	2	5/60	142
General Public-Adults	Registration Contact Information Form (Att. 4b)	425	1	5/60	35
General Public-Adults	Quarterly Assessment (Att. 4c)	850	4	45/60	2550
General Public-Adults	SMaRT app install (Att. 4d)	425	1	10/60	71
General Public-Adults	HIV sample collection (Att. 4e)	850	2	20/60	567
General Public-Adults	STI sample collection (Att. 4f)	850	2	30/60	850
General Public-Adults	Focus Group Guide (Att. 4g)	48	1	90/60	72
General Public-Adults	In-Depth Interview (Att. 4h)	45	1	60/60	45
Total					4,332

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, 2022 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this request. The estimated annualized burden cost is

\$128,920.30. This cost represents the total annual burden hours of general respondents multiplied by the average hourly wage rate (\$29.76).

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Burden Hours	Hourly Wage Rate	Respondent Costs
General Public-Adults	Eligibility Screener (Att. 4a)	142	\$29.76	\$4,225.92
General Public-Adults	Registration Contact Information Form (Att. 4b)	35	\$29.76	\$1,041.60
General Public-Adults	Quarterly Assessment (Att. 4c)	2550	\$29.76	\$75,888.00
General Public-Adults	SMaRT app install (Att. 4d)	71	\$29.76	\$2,112.96
General Public-Adults	HIV sample collection (Att. 4e)	567	\$29.76	\$16,873.92
General Public-Adults	STI sample collection (Att. 4f)	850	\$29.76	\$25,296.00
General Public-Adults	Focus Group Guide (Att. 4g)	72	\$29.76	\$2,142.72
General Public-Adults	In-Depth Interview (Att. 4h)	45	\$29.76	\$1,339.20
Total				\$128,920.30

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 \$1,583,732 (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-14 0.40 FTE)	\$49,163
	CDC Scientist (GS-14, 0.20 FTE)	\$24,582
	CDC Project Coordinator (GS-12, 0.40 FTE)	\$34,987
	Subtotal, Direct Costs	\$108,732
Cooperative Agreement Costs	Annual Cooperative Agreement #PS22-004 Costs	\$1,475,000
ANNUALIZED COST TO THE GOVERNMENT		\$1,583,732

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 analytic plans for the study include descriptive analysis and rapid reporting. We will use latent class analysis to identify classes of PrEP use patterns, consistency of use and efficacy beliefs; and discrete choice experiment to quantify the strengths of preferences for PrEP modality and message content. We will also employ longitudinal analysis to model PrEP attitudes and behaviors over time. Qualitative data analysis will utilize a rapid analytic technique (RADaR) to quickly measure prevention messaging impact and promptly extract key data points for prevention message development.

Rapid reports of survey waves will be generated every three months and sent to CDC to identify HIV prevention gaps and messaging opportunities and recommendations for MSM. Analyses of survey, focus group, and interview data will be analyzed by recipients and CDC to disseminate findings in peer-reviewed journals and at conferences and meetings. Effective prevention messaging will be implemented in CDC messaging and community programs (e.g., mobile apps, social marketing campaigns, website information sources, other written prevention materials) to improve HIV prevention for communities of MSM.

Data collection will occur over a period of 36 months, beginning one month after OMB approval. If OMB approves our Information Collection Request by January 2024, analysis and report writing will be carried out from October 2026 to March 2027, and the final dataset and report will be submitted by March 2027. We are requesting approval for three (3) years of data collection. The project timeline is detailed in exhibit 16.1.

Exhibit 16.1: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	August 2022 – February 2023
OMB Submission	August 2023
Recruitment	1 month after OMB Approval
Data Collection	2-36 months after OMB Approval
Data analysis finalized and report drafted	33-39 months after OMB Approval
Final de-identified data set submitted to CDC	39 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop final, de-identified (names and other personally identifiable information will be removed) quantitative and qualitative datasets for this study along with the corresponding data documentation, which will

be made publicly available within 30 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.

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