

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

OMB 0920-1421 (Expiration Date 11/30/2026)

Section B: Supporting Statement

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1. Respondent Universe and Sampling Methods

City Selection

This study will be carried out in three metropolitan areas in the United States: Atlanta, GA; Chicago, IL; and San Diego, CA. These cities were selected not only because they have high rates of HIV, but also because significant disparities in HIV among gay, bisexual, and other men who have sex with men (collectively referred to as MSM) have been observed by race/ethnicity and age.

Atlanta is the southern study site. The South accounts for half of all new HIV diagnoses in the United States; Georgia, as a state, ranks second in the rate of HIV diagnoses among US states,¹ and as a city, Atlanta ranks second in the number of new HIV diagnoses among Black/African American (hereafter referred to as Black) MSM.² Marked racial disparities in HIV prevalence have been observed in the Atlanta metropolitan area³ and HIV incidence among young Black MSM has been estimated at nearly 11% per year.⁴

South Side Chicago has a long history of racial and ethnic segregation⁵ and challenges to access for health care and other services. In 2022, Blacks represented 75% of the population in South Chicago and the median household income was nearly 48% lower than the median household income for the greater metropolitan Chicago area.⁶ HIV continues to disproportionately impact MSM and Black communities in Chicago. HIV diagnosis is four times greater among MSM than those reporting heterosexual contact transmission.⁷ And, although Non-Hispanic Blacks represent only 17% of the population in metropolitan Chicago, greater than half (56%) of new HIV diagnoses occur in this population.⁷ In 2019, the highest rates of new HIV diagnoses in Chicago were seen in individuals residing in the South Chicago neighborhoods of Washington Park, Grand Boulevard, and Greater Grand Crossing (76.8, 68.4, and 67.4 per 100,000 respectively).⁶ The Chicago study site, Howard Brown Health clinic at 55th Street, is centrally located within three miles of these communities, making it an ideal site for HIV prevention outreach and research.

San Diego was selected as a study site because it remains an area of high HIV transmission in the United States, with significant racial and ethnic disparities. A recent study found that while Hispanics represented 31.6% of the total population of San Diego County, Hispanic/Latino MSM accounted for 44% of HIV diagnoses.^{8,9} Racial and ethnic disparities are evident with the rate of Hispanic/Latino males living with an HIV diagnosis at 1.3 times that of White males and the rate of Black males living with an HIV diagnosis at 2.3 times that of White males.¹⁰

Atlanta and Chicago have been focal points for HIV prevention research for many years. San Diego is a city less commonly represented in HIV prevention research for gay, bisexual, and other men who have sex with men; however, it is an area with high rates of HIV transmission and substantial populations of MSM. Together, the three cities of Atlanta, Chicago, and San Diego, will allow this study to recruit a sample with meaningful variance in demographic characteristics and PrEP knowledge, access, and experience.^{11,12} Additionally, all three research cities are within the 57 priority jurisdictions designated in Ending the HIV Epidemic in the United States (EHE), in support of the goals of EHE and the National Strategic Plan, and other federal prevention planning efforts.¹³

All study site locations are owned or operated by organizations with whom the study team has collaborated in the past and all locations provide HIV and sexually transmitted infections (STI) testing,

PrEP, or provide referrals to sources of these services. The locations and the organizations are listed below.

- Programs, Research, & Innovation in Sexual Minority Health (PRISM) at Emory University, Decatur, GA (Atlanta)
- Howard Brown Health 55th St., Chicago, IL, affiliated with University of Chicago
- San Diego State University, San Diego, CA

All locations listed above will have computers and private rooms available to participants for completing surveys and bathrooms for specimen self-collection, should participants opt to engage in on-site data and/or specimen collection. Private spaces will also be available for participants who opt to join in-person interviews or in-person focus groups. Data will be analyzed to describe cross-site differences in study outcomes, including differences between virtual and physical intervention sites; but the study is not sufficiently powered to compare the sites.

Target population:

This study plans to enroll 1,275 MSM living in or near the Atlanta, Chicago, and San Diego areas to develop knowledge about PrEP use and adherence, condom use, sexual risk-taking and substance using behaviors, and reactions to prevention health messaging. Men recruited in the study will be at least 18 years of age, sexually active, and HIV-negative.

Inclusion criteria:

- Male sex
- Ages 18 or older
- HIV negative (self-reported and confirmed with the initial round of HIV testing)
- ≥1 male anal sex partner in the 6 months before the baseline screener
- Live in or near Atlanta, Chicago, or San Diego
- Own a smart phone with data service and willing to download a health-related app to their phone.
- Willing to participate in a 2-year cohort study with quarterly surveys and HIV and STI self-testing.
- Able to provide ≥ 2 means of contact.

Exclusion criterion:

- Planning to move away from the Atlanta, Chicago, or San Diego area in the next 2 years.
- Adults unable or unwilling to provide informed consent.
- Individuals who are not able to clearly understand English or Spanish

As shown in Exhibit 1.1, the aim is to enroll 425 participants at each of the three study sites. We will use recruitment controls to ensure that 30% of men enrolled will be Black and 30% will be Hispanic/Latino (regardless of site). Given the racial and ethnic variance at each site, we will not set fixed, within-site proportions for race or ethnicity, but on a study-wide basis. Additional recruitment controls will be applied to ensure that, across all sites, 60% of the sample will be current PrEP users at baseline and 40% of the sample will not be using PrEP.

Exhibit 1.1: Summary of Recruitment Targets

	Atlanta, GA	Chicago, IL	San Diego, CA	
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MSM	425	425	425	1275
<ul style="list-style-type: none"> • Male • HIV negative • Ages 18 and older • Sexually active • English and Spanish speaking 				
	30% Black; 30% Hispanic/Latino			
	60% PrEP Users; 40% not using PrEP at baseline			

We will recruit men into the study through a combination of approaches, ensuring consistent modes of recruitment in each of the three cities to reduce selection bias. Our primary recruitment source will be through online targeted advertisements (**Attachment 3**) to adult men in the three metropolitan areas, including social media channels, such as Facebook, Instagram, or Snapchat, Grindr, or other dating apps. Participants will also be recruited using traditional print advertisement (flyers), in-person outreach, by word of mouth, and through referrals from local clinics and community-based organizations.

Rationale for proposed number of subjects

For the survey sample size calculation, we developed 3 scenarios -- calculating required sample sizes for each scenario -- and relied on the largest required sample size to develop our recruitment plan (see Exhibit 1.2). In scenario 1 we examined the relative risk of starting PrEP among those not on PrEP at a follow up visit between two equal subgroups (e.g., age groups) by applying the log-rank test;¹⁴ in scenario 2 we compared the rankings on a visual analogue scale of two messages between two equal subgroups in the study participants using the t-test statistic;¹⁵ and in scenario 3 we compared the proportions of Black versus White participants endorsing a specific message applying the log-rank test.¹⁴ All sample size calculations were calculated in PS: Power and Sample Size Calculation software (Vanderbilt University, v 3.1.6). Assuming at most 20% attrition (at least 80% retention) across cohort survey assessment waves, a sample size of greater than or equal to 980 (Black and Hispanic/Latino: ≥ 304 each) will be needed to achieve our study objectives. Further assuming ~31% item incompleteness (i.e., ~69% full item completion)¹⁶ of all online survey items across participants for usable data in analysis among those 80% of participants who are retained over time, an overall sample size of approximately $n=1275$ (≥ 383 each for Black and Hispanic/Latino) is needed for this cohort study.

Exhibit 1.2 Sample size calculations and assumptions for three sample outcomes.

Scenario	Group 1	Group 2	Power	Sample Size
On PrEP at f/u visit (%)	10%	RR: 2.5	0.80	200
Means of message rank/VAS (1-100)	40	50	0.80	88
Proportions of participants in two subgroups endorsing a PrEP message	20%	30%	0.80	293 in each group

We anticipate 50% of men screened will be eligible and will decide to enroll in the MIC DROP study; therefore, we expect to screen 2,550 men in order to meet our enrollment goal of 1,275.

Because the in-depth interview sample will not be randomly selected, qualitative interview findings will not be generalizable and sample size has been determined by desired variety of responses and saturation of themes (the point in data analysis where new themes no longer emerge).¹⁷ The proposed sample ($n=45$) across the three study sites ($n=15$ per site) allows us to meet our study objectives: explore

knowledge, attitudes, beliefs; explore barriers and facilitators; and identify critical support systems for PrEP use and maintenance. We have chosen 45 participants to best achieve variance in themes and assure data saturation. Because respondents will participate in a series of three interviews at six-month intervals over an 18-month period, the total interview sample size (n=45) incorporates an allowance for attrition by over-sampling up to five participants per site.

Purposive sampling will be used to identify participants for focus group discussions. Multiple focus groups will be conducted at six-month intervals with a total of 144 men (48 men per site). Focus groups are suited to obtaining perspectives and consensus from participants about the same topic. In this study, participants will be reflecting on PrEP messages. Focus groups rely on group interactions and group size is determined by ideal number of participants to conduct a guided discussion and to obtain different perspectives or consensus on the topic of discussion (the PrEP message, which is intended to be used to encourage PrEP use in the community). Ideally, focus groups will consist of eight to ten participants.¹⁸ This group size allows for discussion without overburdening any one participant and can be managed by a trained facilitator. In practice, focus groups may range from three to ten participants with the lower bound of three participants per group reflective of the challenges of enrolling participants and scheduling groups and still obtaining thematic saturation. Saturation is obtained by conducting several groups to explore perspectives on the same PrEP messages.¹⁹

2. Procedures for the Collection of Information

We will collect five types of information for this study: screening information, contact information, quantitative assessment information, test results from biological samples, and qualitative interview and focus group discussion information.

All participants recruited either online or through referrals will be directed to an online study page to complete a brief screening process for eligibility (**Attachment 4a**). Eligible participants will be asked to complete the registration form and provide contact information (**Attachment 4b**). Those determined to not be eligible would be offered additional resources for HIV or STI testing or other resources upon request. Staff will contact eligible participants and set up a virtual enrollment visit during which participants will be rescreened for eligibility (**Attachment 4a**) and staff will provide participants with an overview of the study purpose and procedures and guide them to the online consent form (**Attachment 5a**). Rescreening is necessary to ensure study eligibility, given a potential lag from the time of initial eligibility screening to the time of the baseline enrollment assessment. Following the consent process, staff will be available to assist participants with completing their first quantitative assessment (**Attachment 4c**), arrange shipping of baseline at-home HIV and STI test kits, and assist the participant with setting up the Study Management and Retention Toolkit (SMaRT) application on their mobile phone as needed (**Attachment 4d**). The SMaRT app is a HIPPA-compliant mobile app that study participants install on their smart phones that supports several key functions of study participation including notifications about assessments, administration of assessments, a messaging center, appointment scheduling, secure transmission of laboratory results, and a telehealth video conference platform. Screening, consent, contact information collection and assessments will be conducted online via Alchemer, a HIPPA-compliant online data collection platform optimized for use with computers, smart phones, tablets, or the SMaRT application. Participants will have the option to complete assessments on-site using a computer or tablet provided by the study team.

Following the completion of enrollment and baseline study activities, survey assessments will be delivered quarterly (every three months) for a total of eight waves during the two-year follow up period.

Surveys will collect information about PrEP knowledge, use, adherence, preferences, and beliefs; condom use; HIV and STI testing; sexual and risk behaviors; and feedback on prevention test messages.

At six-month intervals, 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 will be available in English and Spanish (**Attachments 4e and 4f**). Participants will have the option to self-collect their specimens on-site. Study staff will provide these participants with the STI or HIV self-collection kit and instructions and provide a room for participants to collect their specimens. Study staff will be available to answer questions and assist with shipping specimens.

A subset of the cohort will be asked to participate in qualitative data collection activities to further explore men's experience of and preferences for PrEP and other HIV prevention products, and to evaluate their reactions to prevention messages developed during the study. One hundred forty-four (144) participants (48 from each city) will be invited to participate in a focus group discussion (**Attachment 4g**) and 45 participants (15 from each city), will be invited to join a series of three in-depth interviews (**Attachment 4h**). All participants will undergo a second consent process prior attending either the focus group (**Attachment 5b**) or the interview (**Attachment 5c**). Participants will have the option to attend focus groups and interviews in-person or via a HIPPA-compliant teleconference platform accessible via computer, smart phone, tablets, or the SMaRT application.

3. Methods to Maximize Response Rates and Deal with Non-responses

We will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Participant accrual rates will be monitored by study staff to maintain consistent and accurate procedures. Race/ethnicity will be tracked across all study sites to ensure that approximately 30% of participants are Black MSM and 30% of participants are Hispanic MSM. In addition, PrEP status will be tracked across all study sites to ensure that approximately 60% of participants are currently using PrEP at enrollment, and 40% of participants are not using PrEP. We anticipate a sample size of 1,206 for analysis with targets.
- If recruitment falls short, we will work with study staff to determine the best course of action, including recruiting participants at alternative MSM venues or changing the mix of recruitment strategies in the city or cities where additional participants are needed.
- Active recruitment will be carried out at local clinics and community-based organizations the target population is familiar with.
- A \$50 token of appreciation will be provided to respondents upon completion of each quarterly assessment (\$400 total for all eight assessments), and a \$50 token of appreciation will be provided upon completion of each of the six-month HIV and STI self-tests (\$200 total for all four self-collected tests).
- For the subset of participants that are selected to take part in the series of in-depth interviews (n=45), a \$75 token of appreciation will be provided to respondents upon completion of each interview (\$225 total for all three interviews).
- For the subset of participants that are selected to take part in a 90-minute focus group discussion (n=144), a \$75 token of appreciation will be provided to respondents upon completion of the discussion (\$75 total).

- Instructions for the HIV and STI self-collected specimen kits have been tested with MSM for acceptability²⁰ and are being used through the Emory CFAR for multiple NIH-funded studies²¹.
- Screening, consent, contact information collection, survey completion, focus group attendance and the in-depth interview will be conducted virtually and specimen collection for HIV and STI collection will be completed via self-collection kits. This will allow participants to complete study activities at a time and place that is most convenient and comfortable for them. Participants will also have the option to complete surveys, specimen self-collection, focus group attendance, and in-depth interviews on-site.
- 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 survey from their personal device, each city will have research space where participants can schedule a convenient time to take the survey on a computer or tablet that the study will provide for that purpose.
- The study will utilize the SMaRT (Study Management and Retention Toolkit) system, a study management platform that develops an individualized study timeline for each participant with target dates for all data collection activities. The companion mobile app sends participants notifications about available assessments, enables secure messaging with study staff, and provides appointment scheduling.
- All recruitment materials indicate the voluntary nature of the study and high participation is due in part to interest in the study and participation from individual respondents.

4. Tests of Procedures or Methods to be Undertaken

Our research team comprises experts in HIV prevention sciences, PrEP research, measurement of HIV prevention behaviors and qualitative research. We will use this expertise to implement the proposed research aims in a way that equitably involves MSM and provides rich, novel and continuously updated data to meet these critical prevention needs. Our study team has a productive history of innovation in multiple areas relevant to the proposed study aims: mixed-methods recruitment of MSM, including Black and Hispanic MSM; unique resources to manage research participants and increase study retention; use of discrete choice experiments to evaluate complex and multicomponent prevention interventions; the innovative use of online survey software to capture complex behavioral patterns in MSM research participants; the use of mailed in specimens for STI testing and self-testing for HIV as part of research studies; and the use of prospective, longitudinal qualitative data collections in HIV prevention research. These innovative elements will facilitate the rapid recruitment and implementation of the study and will allow the expeditious collection, analysis, and study of data. The grantee study team will conduct pretesting of the screening tool and quantitative and qualitative assessments to assess question wording, skip patterns, question sensitivity, and overall flow of the data collection tools. We will have extensive training of all staff prior to initiating recruitment including review of standard operating procedures and respective roles and expectations for each study component. Interview guides will be reviewed by members of a community advisory board before data collection begins. The purpose of this review is to ensure cultural rigor within the participant population and to ensure that all concepts are being applied effectively.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the study investigators who were consulted on the aspects of research design and those who will be collecting and analyzing the data. CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. CDC staff will neither interact with nor collect data from study participants. Data will be collected by the grantee, Emory University, and their partners University of Michigan and San Diego State University. Data will be jointly analyzed by CDC and grantee study staff. Uniquely identifying information will be stripped from all data shared with or accessible by CDC staff.

Exhibit 5.1: Study Investigators and Research Consultants

Name	Title	Organization	Phone	Email
Gordon Mansergh	Project Officer	CDC	404-639-6135	gcm2@cdc.gov
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