e: 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-24-23AQ]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "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)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on November 16, 2022, to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

"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)"– New - National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting approval for three years for a data collection titled "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)." The purpose of the information collection is to understand men's strategies to prevent HIV and sexually transmitted infections (STIs), including preexposure prophylaxis (PrEP) use and adherence, condom use, sexual risk-taking behavior, and substance-using behaviors. This study will assess men's use and preferences for prevention modalities and their awareness, knowledge, beliefs, and perceptions about products that prevent the transmission of

HIV and other sexually transmitted diseases (STD). This study will also conduct structured assessments to identify HIV prevention gaps and test prevention messages for men who have sex with men (MSM).

The information collected in this study will be used to: 1) describe real-world HIV and STI prevention strategies including PrEP and condom use and adherence; 2) better understand men's use, preferences, knowledge, and perceptions about prevention modalities; 3) develop rapid reports that will allow for summary recommendations concerning gaps in prevention protection and message testing; and 4) provide timely new information to public health programs and decision makers. The study will be carried out in three cities: Atlanta, GA; Chicago, IL; and San Diego, CA. Participants will include 1,275 HIV-negative men ages 18 and older. Cohort participants will identify as cisgender male; report sex with a man in the last six months; and be fluent in written/spoken English or Spanish. We will use purposive sampling to ensure that 60% of participants will be PrEP users at baseline, and 40% will not be using PrEP at that point. We will also oversample Black/African American and Hispanic/Latino MSM to ensure that a minimum of 30% each are represented in the cohort sample. Participants will be recruited using a combination of approaches including social media, referral, and in-person outreach.

A computer-assisted quantitative assessment will collect information about participants' use of prevention modalities, as well as their awareness, knowledge, beliefs, and perceptions about HIV/STI prevention products and prevention messages. The study will utilize the SMaRT (Study Management and Retention Toolkit) system, a study management platform for participant management that includes a HIPPA-compliant companion mobile app that study participants install on their smart phones. The app supports several key functions of study participation including notifications of surveys available, administration of surveys, a messaging center, appointment scheduling, secure HIPPA-compliant document upload and return of laboratory results, and a HIPPA-compliant telehealth video conference platform. At six-month intervals starting at baseline, 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. Participants will also have the option to self-collect their specimens at a study site, where study staff will provide them with a self-collection kit and a private room in which to collect their specimens. A subset of the participant cohort will be invited to further participate in qualitative data collection activities including focus groups and in-depth interviews. The focus groups will assess the participants' awareness of PrEP messages, preferences for PrEP messages, and perceived impact/efficacy of HIV prevention and PrEP messages. The in-depth interviews will assess men's PrEP experiences, their preferences for PrEP and other HIV prevention products, and further explore their reactions to prevention messages. Participants will have the option to join virtual or in-person focus groups and interview sessions.

Total study enrollment is 1,275 over the three-year data collection period. Based on screening and enrollment numbers from similar studies, we estimate we will need to screen 2,550 individuals (850 annually) to reach total enrollment. The screening process will take approximately five minutes to complete. Participants will be rescreened at the time of the enrollment visit. Contact information will be collected from 1,275 participants (425 annually) and will take approximately five minutes to complete. The quantitative assessment will take 45 minutes to complete and will be delivered to 1,275 participants (850 annually) a total 8 times. The SMaRT app install will take 10 minutes to complete and will be completed by 1,275 participants (425 annually). The specimen kit for HIV testing will take approximately 20 minutes to complete and will be distributed to 1,275 participants (850 annually) a total of four times. The specimen kit for STI testing will take approximately 30 minutes to complete and will be distributed to 1,275 participants (850 annually) a total of four times. A subset of the cohort participants will be invited to participate in qualitative data collection activities. A total of 144

participants (48 annually) will engage in a focus group that is estimated to take 90 minutes to complete, and 45 participants will be invited to participate in a series of three in-depth interviews to be administered at six-month intervals. The interviews will take approximately 60 minutes to complete.

CDC is requesting 12,996 total burden hours across 3 years of data collection. The total estimated annualized burden hours are 4,332. Total burden for each activity has been rounded to the nearest whole hour. Participation of respondents is voluntary. There is no cost to participants other than their time.

Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hr) |
|---|---|---|---|---|
| General Public – Adults | Eligibility Screener | 850 | 2 | 5/60 |
| General Public - Adults | Locator Form | 425 | 1 | 5/60 |
| General Public - Adults | Quarterly Assessment | 850 | 4 | 45/60 |
| General Public - Adults | SMaRT App Installation | 425 | 1 | 10/60 |
| General Public - Adults | Sample Collection for HIV Test | 850 | 2 | 20/60 |
| General Public - Adults | Sample Collection for STI Test | 850 | 2 | 30/60 |
| General Public - Adults | Focus Group | 48 | 1 | 90/60 |
| General Public - Adults | In-Depth interview | 45 | 1 | 60/60 |

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