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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention

[30Day-17-17AX]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Mobile Messaging Intervention to Present New HIV Prevention Options for Men Who have Sex with Men (MSM) Study - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Public health approaches to HIV prevention and control are increasingly complex for men who have sex with men (MSM), a population with a disproportionately high burden of HIV infection. In addition to the established biomedical treatments for HIV-positive MSM, and behavioral strategies to reduce the risk of transmitting or contracting HIV, current recommendations incorporate the breakthrough biomedical risk reduction strategy of pre-exposure prophylaxis (PrEP) for HIV-negative MSM who are at high risk of contracting HIV. For maximum efficacy, health communications about HIV prevention and control should be delivered to MSM according to their HIV serostatus and risk category.

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention is requesting approval to evaluate the efficacy of a smartphone-based HIV prevention intervention for MSM, known as M<sup>3</sup>(M-Cubed) that has been designed to deliver targeted messages in six intervention domains: HIV testing, sexually transmitted infection (STI) testing, PrEP, antiretroviral (ARV) treatment, Condoms, and Engagement in Care. The smartphone and tablet application includes 36 core messages and 12 videos that were developed based on CDC-sponsored iterative formative research (OMB No. 0920-0840) and a review of HIV health communications literature. Messages will be delivered to each participant's

device. The proposed study will assess whether exposure to the message-delivery platform results in improvements in participants' self-reported sexual health and HIV prevention behaviors, beliefs and attitudes. Information will be collected at baseline and 3-month, 6-month, and 9-month follow-ups.

The study population will include 1,206 adult MSM living in Atlanta, GA, Detroit, MI and New York City, NY. These study sites were selected not only because they have high rates of HIV, but also because significant disparities in HIV among men who have sex with men (MSM) have been observed by race/ethnicity and age. Study participants will be sexually active MSM at least 18 years in age who own and use an Android and iOS smartphone. Study participants will be stratified by risk category: HIV positive (one third) and HIV negative (one third each: condomless anal sex in past three months; no condomless anal sex past three months). Across the three sites, we will ensure that at least 40% of participants are people of color (non-white or Hispanic) by quota sampling. Participants will be recruited to the study through a combination of approaches, including online advertisement, traditional print advertisement, referral, in-person outreach, and through word of mouth. Participants will be randomly assigned to an intervention group or a waitlist control group. The control group will receive the intervention after the study has been completed.

A quantitative assessment questionnaire will be administered online at four points in time. The assessment will be used to measure changes in condom use behavior, number of sex partners, HIV testing, sexually transmitted disease (STD) testing, health care engagement, pre-exposure prophylaxis uptake and adherence, and antiretroviral therapy uptake and adherence following completion of the intervention. Participants will complete the assessment in-person at baseline and 9-months, using a computer in a private location, and remotely via their personal computer or tablet device at the 3-month and 6-month follow-ups. The same information will be collected from all participants. The burden per response for each assessment is 1.5 hours.

It is expected that 50% of men screened will meet study eligibility and provide contact information, that 75 percent will schedule and show up for an in-person appointment, and that 95 percent of these men will remain eligible after reverification. We expect the initial screening to take approximately four minutes to complete, that providing contact information will take 1 minute, and the rescreening prior to study enrollment to take another four minutes.

OMB approval is requested for two years. Participation is voluntary and there are no costs to the respondents other than their time. The total estimated annual burden is 3,787 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)
Men $\geq$ 18 Years of Age Who Have Sex With Men	Participant Screening (Eligibility)	1,693	1	4/60
	Contact Information Form	847	1	1/60
	Participant Screening (Verification)	635	1	4/60
	Assessment	603	4	1.5

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 Office of Scientific Integrity  
 Office of the Associate Director for Science  
 Office of the Director  
 Centers for Disease Control and Prevention

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