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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17AX]

[Docket No. CDC-2016-0100]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed information collection project entitled "Mobile Messaging Intervention to Present New HIV Prevention Options for Men who have Sex with Men

(MSM) Study." The collect is part of a research study designed to evaluate the efficacy of smartphone-based platform for delivering sexual health and prevention messages to MSM.

DATES: Written comments will be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0100 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to

the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

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:

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention is requesting approval for two years of data collection entitled, "Mobile Messaging Intervention to Present New HIV Prevention Options for MSM." The purpose of this study is to evaluate the efficacy of a smartphone-based HIV prevention intervention, known as M^3, through a randomized controlled trial. The information collected through this study will be used to evaluate whether the M^3 mobile-messaging intervention is an effective HIV-prevention strategy, by assessing whether exposure to the message-delivery platform results in improvements in participants' self-reported sexual health and HIV prevention behaviors, beliefs and attitudes. The trial will assess whether intervention participants' behaviors significantly change from baseline to post-intervention when compared to participants in a waitlist control arm, and whether these changes are sustained at 6-month and 9-month follow-ups.

This study will be carried out in three metropolitan areas in the United States: Atlanta, Georgia, Detroit, Michigan and New York City, New York. These cities 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.

The study population will include 1,206 adult MSM living in Atlanta, Detroit, and New York City. Men recruited to the study will be at least 18 years in age, who have had anal sex with at least one man in the past 12 months, and who own and use and Android and iOS smartphone.

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.

A quantitative assessment will be used to collect information for this study, which will be delivered at the time of study enrollment and again at 3-month, 6-month and 9-month follow-ups. 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.

It is expected that 50% of men screened will meet study eligibility and provide contact information, that 75% will schedule and show up for an in-person appointment, and that 95% 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 one minute, and the rescreening prior to study enrollment to take another four minutes. The assessment will take 90 minutes (1½ hour) to complete, and will be administered to 1,206 men a total of four times. The total number of burden hours are 5,164.

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	Participant Screening (Eligibility)	1,356	1	4/60	90

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	Contact Information Form	678	1	1/60	11
General Public-Adults	Participant Screening (Verification)	508	1	4/60	34
General Public-Adults	Assessment	482	4	1.5	2,892
				Total	3,027

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Leroy A. Richardson
Chief, Information Collection Review Office
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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