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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-19BG; Docket No. CDC-2018-0102]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Web-based approaches to reach black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services."

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0102 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M.Zirger, Ph.D., 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments 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 Leroy A. Richardson, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Web-based approaches to reach black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services– 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 goal of this study is to evaluate the effectiveness of mailing out rapid HIV home-testing kits and additional testing promotion components to increase HIV testing among black/African-American or Hispanic/Latino MSM. The findings from this research will assist local and state health departments, and community based organizations in making decisions on how to improve HIV testing and linkage to HIV prevention services for black/African American and Hispanic/Latino men who have sex with men.

The research study is a randomized control trial and all survey data will be collected over the internet. There will not be any in-person surveys. We will advertise the study on internet websites frequented by black and Hispanic MSM. People will click on a banner ad and will be taken to a study website that provides a brief overview of the study. Those who are interested in participating will complete a brief survey to

determine their eligibility. Men who are eligible will complete registration information and then download a study phone app onto their smartphone. The app will allow them to complete a baseline survey. After completing the baseline survey, they will be randomized into one of three conditions.

All participants will be sent a rapid HIV test kit and they will report their results to the study. Men assigned to all study arms will use the study app to complete study activities. All participants will have access to web-based HIV counseling upon request. Participants who report a positive HIV test result will be offered web-based HIV counseling if they have not previously requested counseling. Men assigned to the control arm will only have access to the study app and web-based counseling. Men assigned to one intervention arm will also be able to access another smartphone app (HealthMindr) that will allow them to engage in additional study activities. Men assigned to the second intervention arm will have access to a web-based forum (HealthEmpowerment) covering HIV prevention and not the HealthMindr app. At four months after enrollment, all participants will complete an online survey and will be offered additional HIV testing materials to complete.

The subpopulation are individuals who: (1) identify as African-American/black or Hispanic/Latino; (2) report their HIV status as negative or report being unaware of their HIV status;

(3) are not currently using PrEP or participating in other HIV testing prevention studies; (4) have had anal intercourse with another man in the past 12 months; (5) reside in one of the study states; (6) Are 18 years or older; (7)born male; and (8) identify as male. We will evaluate the comparative effectiveness of the HIV home-testing kits and additional testing promotion components with respect to linkage of participants to appropriate services (HIV treatment, PrEP, STI testing, additional prevention and social services). These analyses will determine whether any such differences are significant within and across study arms, and by race/ethnicity.

Depending on the study arm to which participants are assigned, filling out data collection forms, engaging with testing promotion components, and completing and submitting at-home HIV testing will require between 2 hours 53 minutes and 4 hours and 13 minutes of a participant's time over the course of the entire study period.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. The total estimated annual burden hours for the proposed project are 7,011 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent per year	Average Burden Per Response (in Hrs)	Total Response Burden (in Hrs)
Potential participant	Eligibility Consent	10,000	18	10/60	1667
Potential participant	Eligibility Screener	10,000	1	3/60	500
Potential participant	Study Consent	4,000	1	10/60	667
Potential participant	Registration contact information	3,800	7	5/60	317
Enrolled participant	Baseline Survey	3,600	110	30/60	1,800
Enrolled participant	HIV Test Result Survey	3,000	10	5/60	250
Enrolled participant	Follow-up Survey	3,000	120	30/60	1,500
Enrolled participant	HIV Test Result Survey (completion)	3,000	10	5/60	250
Enrolled participant	Product ordering	1,200	2	3/60	60
Total					7,011

Jeffrey M. Zirger,

Acting Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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