DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–19BG]

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 ''Web-based approaches to reach black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services'' 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 December 6, 2018 to obtain comments from the public and affected agencies. CDC received one substantive comment 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 or send an email to *omb@cdc.gov.* 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

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 up to four rapid HIV test kits for their use and to give to their friends (hereafter referred to as ''guests'') and they will report their results to the study. Participants will use the study app to complete study activities. All participants and guests 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. Guests who receive a study HIV self-test kit will be able to report the result online.

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 and not planning to move out of the state in the next 4 months; (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 this will require between two hours 25 minutes and three hours and 45 minutes of a participant's time over the course of the entire study period. Guests who receive an HIV self-test from a study participant will take up to 37 minutes to complete the testing activities.

The total annual burden hours are 1,517. There are no other costs to respondents other than time.

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)
Potential participant	Eligibility Consent	3,333	3	2/60
Potential participant	Eligibility Screener	3,333	20	2/60
Potential participant	Study Consent	1,333	2	4/60
Potential participant	Registration contact information	1,267	7	2/60
Enrolled participant	Baseline Survey	1,200	107	20/60
Enrolled participant	Initial HIV Test Result Survey	1,000	43	5/60
Enrolled participant	Follow-up Survey	1,000	187	30/60
Enrolled participant	Final HIV Test Result Survey	1,000	18	5/60
Enrolled participant	Product ordering	400	12	3/60
Guest	Guest Consent	667	1	2/60
Guest	Guest HIV Test Result Survey	667	24	5/60

Jeffrey M. Zirger,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–1129; Docket No. CDC–2019–0058]

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 titled, Improving Fetal Alcohol Spectrum Disorders (FASD) Prevention and Practice through Practice and Implementation Centers and National Partnerships (PICs). The purpose of FASD PICs is to collect training evaluation data from healthcare practitioners and staff in health systems where FASD-related practice and systems changes are implemented, and from grantees of Practice and Implementation Centers and national partner organizations related to prevention, identification, and treatment of fetal alcohol spectrum disorders (FASDs).

DATES: CDC must receive written comments on or before September 9, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0058 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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

Improving Fetal Alcohol Spectrum Disorders (FASD) Prevention and Practice through Practice and Implementation Centers and National Partnerships'' project (OMB Control No. 0920–1129, Exp. 8/31/2019))—Revision — National Center for Birth Defects and Developmental Disability (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Prenatal exposure to alcohol is a leading preventable cause of birth defects and developmental disabilities. The term 'fetal alcohol spectrum