DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0913]

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. 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

Evaluating Locally-Developed HIV Prevention Interventions for African-American MSM in Los Angeles (OMB No. 0920-0913, expires 01/15/2015) – [Extension] — National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Data on HIV cases reported in 33 U.S. states with HIV reporting indicate the burden of HIV/AIDS is most concentrated in the African American population compared to other racial/ethnic groups. Of the 49,704 African American males

diagnosed with HIV between 2001 and 2004, 54% of these cases were among men who have sex with men (MSM). In Los Angeles County (LAC), the proportion of HIV/AIDS cases among African American males attributable to male-to-male sexual transmission is even greater (75%). In the absence of an effective vaccine, behavioral interventions represent one of the few methods for reducing high HIV incidence among African American MSM (AAMSM). Unfortunately, in the third decade of the epidemic, very few of the available HIV-prevention interventions for African American populations have been designed specifically for MSM. In fact, until very recently none of CDC's evidence-based, HIV-prevention interventions had been specifically tested for efficacy in reducing HIV transmission among MSM of color. Given the conspicuous absence of 1) evidence-based HIV interventions and 2) outcome evaluations of existing AAMSM interventions, our collaborative team intends to address a glaring research gap by implementing a best-practices model of comprehensive program evaluation.

As of November 7, 2014, 888 men were screened using the eligibility screener, 711 were eligible, and 520 men were consented, enrolled, and completed the baseline assessment. There are a total of 227 men who completed 3-month follow-up and 193 men who completed 6-month follow-up. Each enrolled participant completed a client satisfaction survey for each of

the three intervention sessions they attended. Finally, twenty-two men consented for and completed qualitative interviews. There were unanticipated delays in getting our initial OMB approval and delays in enrollment which prevented the study from reaching the desired sample size of 528 and completing data collection within the original 3-year timeframe. When the current information collection request (ICR) expires on January 31st, 2015, we will need to enroll, consent, and baseline approximately 10 more participants. To reach these additional 10 participants, we anticipate having to screen approximately more 20 men. During this extended period, an additional 185 men will complete the 3-month assessment, 225 men will complete the 6-month follow-up questionnaires, and 14 men will consent for and complete the success case study qualitative interviews. We anticipate that all data collection activities will be completed by the end of 2015.

The purpose of this project is to test in a real world setting the efficacy of an HIV transmission prevention intervention for reducing sexual risk among African American men who have sex with men in Los Angeles County. The intervention is a 3-session, group-level intervention that will provide participants with the information, motivation, and skills necessary to reduce their risk of transmitting or acquiring HIV.

The intervention is being evaluated using baseline, 3 month and 6 month follow up assessments. This project is also conducting in-depth qualitative interviews with a total of 36 men in order to assess the experiences with the intervention, elicit recommendations for improving the intervention, and to better understand the factors that put young African American MSM at risk for HIV.

CDC is requesting approval for a 1-year clearance to complete data collection. The data collection system involves screenings, limited locator information, contact information, baseline questionnaire, client satisfaction surveys, 3-month follow-up questionnaire, 6-month follow-up questionnaire, and case study interviews. An estimated 20 men will be screened for eligibility in order to enroll 10 additional men to reach the desired sample size of 528. The baseline and follow up questionnaires contain questions about participants' socio-demographic information, health and healthcare, sexual activity, substance use, and other psychosocial issues. The duration of each baseline, 3-month, and 6-month questionnaires are estimated to be 60 minutes; the Success Case Study interviews 90 minutes; Outreach Recruitment Assessment 5 minutes; limited locator information form 5 minutes; participant contact information form 10 minutes; each client satisfaction survey 5 minutes.

There is no cost to participants other than their time. The total estimated annual burden hours are 459.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses Per Respondent	Average Burden Per Respondent (in hours)
Prospective Participant	Outreach Recruitment Assessment (screener)	20	1	5/60
Prospective Participant	Limited Locator Form	20	1	5/60
Enrolled Participant	RCT Informed Consent Form	10	1	10/60
Enrolled Participant	Participant Contact Information Form	10	1	10/60
Enrolled Participant	Baseline Questionnaire	10	1	1
Enrolled Participant	Client Satisfaction Survey	30	3	5/60
Enrolled Participant	3 month follow up Questionnaire	185	1	1
Enrolled Participant	6 month follow up Questionnaire	225	1	1
Enrolled Participant	Success Case Study Informed Consent Form	14	1	10/60
Enrolled Participant	Success Case Study Interview	14	1	1.5

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