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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-12EL]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly S. Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project:

Critical Thinking and Cultural Affirmation (CTCA): Evaluation of a Locally Developed HIV Prevention Intervention - New - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

 In 2005, the Centers for Disease Control and Prevention (CDC) reported that 80,187 African Americans were diagnosed with HIV/AIDS, which represents 51% of persons diagnosed. African-American men with HIV/AIDS represented 44% of all cases among males (Centers for Disease Control and Prevention [CDC], 2005). These statistics have been consistently disproportional since the late 1990s, with African Americans bearing the greatest burden of new HIV cases in most regions of the United States. The Centers for Disease Control and Prevention estimates that at the end of 2006, Blacks were disproportionately affected by HIV. The 2006 HIV infection rate in Blacks was nearly twice the rate of Whites (92 out of every 100,000 Blacks compared to 48 per 100,000 Whites and 31 per 100,000 Hispanics). Among males, Black males accounted for the largest number of diagnosed HIV infections and have the highest HIV infection rate of any race/ ethnicity group (144 per 100,000, compared to 94 per 100,000 for White males and 50 per 100,000 for Hispanic males

While many HIV prevention and intervention studies include samples of African-American men and African-American Men who have Sex with Men (AAMSM), beyond demonstrating disparities in seroprevalence between and among racial groups, few have been specifically designed and evaluated for efficacy among African American men. Because few HIV prevention interventions targeting AAMSM have been developed and rigorously evaluated, while their HIV infection rates remain disproportionately high and continue to rise, identifying effective interventions for AAMSM is a public health imperative.

The purpose of this project is to test the efficacy of an HIV transmission prevention intervention for reducing sexual risk among African American men who have sex with men in Chicago. Illinois. The intervention is a 3-day weekend retreat, group-level CTCA intervention that combines cultural affirmation with critical thinking and empowerment, to increase reasoning skill, problem solving capacity, self-protective behavior change, and well-being which facilitates the reduction of risky sexual behaviors. A convenience sample of 438 AAMSM will be recruited to participate in the study. We anticipate recruiting potential participants for the CTCA RCT through a variety of community venues, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/handcards, internet) recruitment techniques. The intervention will be evaluated using baseline, 3-month and 6-month follow up assessments. This project will also conduct exit surveys to identify men who were more favorable—men who agreed with positive comments about the intervention and those who were less favorable—men who disagreed with positive comments about the intervention. Exit interviews will be conducted with 15 favorable and 15 less favorable men identified by the Exit Survey to help understand participants’ experiences with the CTCA intervention and their thoughts about the content of the intervention and ways in which it could be improved. Using the participant responses to the exit survey, we will categorize participants into two categories: favorable (those men reporting a favorable reaction to the intervention) and unfavorable (those men reporting an unfavorable reaction to the intervention). Once we have 50 participants in each category, we will randomly select 15 participants from each group and invite them to participate in the exit interview. We anticipate that we will need to repeat these procedures and extend an invitation to at least 65 participants in order to reach and successfully interview 15 participants in each group.

CDC is requesting approval for a 3-year clearance for data collection. Data collection will begin November 2012 and end January 2015. The data collection system involves a pre and full screening, brief locator information, record locator information, baseline assessment, 3-month follow-up assessment, 6-month follow-up assessment, participant evaluation forms, exit survey, and exit interviews. An estimated 1000 men will be pre-screened and 515 will be full-screened for eligibility in order to enroll 438 men. The baseline and follow up questionnaires will be administered electronically using audio computer assisted self-interview (ACASI). The ACASI interview includes 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 assessments are estimated to be 60 minutes; the exit survey 10 minutes; the exit interview 30 minutes; pre-screening form 5 minutes; full-screening form 10 minutes; brief locator information form 5 minutes; record locator information form 10 minutes; each participant evaluation survey 5 minutes.

There is no cost to participants other than their time.

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| Type of Respondent | Form Name | No. of Respondents | No. Responses Per Respondent | Average Burden Per Respondent (in hours) | Total Annual Burden in Hours |
| Prospective Study Participant | Pre-Screening Form  | 1000 | 1 | 5/60 | 83 |
| Prospective Study Participant | Full-Screening Form | 515 | 1 | 10/60 | 86 |
| Prospective Study Participant | Brief Locator Form | 515 | 1 | 5/60 | 43 |
| Enrolled Study Participant | Record Locator Form | 438 | 1 | 10/60 | 73 |
| Enrolled Study Participant | Baseline Assessment | 438 | 1 | 1 | 438 |
| Enrolled Study Participant | 3-month Follow-up Assessment | 395 | 1 | 1 | 395 |
| Enrolled Study Participant | 6-month Follow-up Assessment | 350 | 1 | 1 | 350 |
| Enrolled Study Participant | Participant Evaluation Forms | 438 | 6 | 5/60 | 219 |
| Enrolled Study Participant | Exit Survey | 350 | 1 | 10/60 | 58 |
| Enrolled Study Participant | Exit Interview | 30 | 1 | 30/60 | 15 |
| Total |  |  |  |  | 1760 |

DATE:

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 Kimberly S. Lane, MBA

 Acting Chief Reports Clearance Officer

 Centers for Disease Control and Prevention