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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-12AG]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to 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

HIV Prevention among Latino MSM: Evaluation of a locally developed intervention - New - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Latinos are the largest and fastest growing ethnic minority group in the U.S. and have the second highest rate of HIV/AIDS diagnoses of all racial/ethnic groups in the country. From the beginning of the epidemic through 2007, Latinos accounted for 17% of all AIDS cases reported to the CDC. Among Latino males, male-to-male sexual contact is the single most important source of HIV infection, accounting for 46% of HIV infections in U.S.-born Latino men from 2001 to 2005, and for more than one-half of HIV infections among South American, Cuban, and Mexican-born Latino men in the U.S. (CDC, 2007a; 2007b). In 2006, male-to-male sex accounted for 72% of new HIV infections among Latino males. Relative to other men who have sex with men (MSM), the rate of HIV infection among Latino MSM is twice the rate recorded among whites (43.1 vs. 19.6 per 100,000).

Despite the high levels of infection risk that affect Latino MSM, no efficacious interventions to prevent infection by HIV and other sexually transmitted diseases (STDs) are available for this vulnerable population. CDC's Prevention Research Synthesis group, whose role is to identify HIV prevention interventions that have met rigorous criteria for demonstrating evidence of efficacy, has not identified any behavioral interventions for Latino MSM that meet current efficacy

criteria, and no such interventions are listed in CDC's 2011 update of its Compendium of Evidence-Based HIV Behavioral Interventions (http://www.cdc.gov/hiv/topics/research/prs/compendium-evidence-based-interventions.htm). There is an urgent need for efficacious, culturally congruent HIV/STD prevention interventions for Latino MSM.

The purpose of this project is to test the efficacy of an HIV prevention intervention for reducing sexual risk among Latino men who have sex with men in North Carolina. The HOLA en Grupos intervention is a Spanish-language, small-group, 4-session intervention that is designed to increase consistent and correct condom use and HIV testing among Latino MSM and to affect other behavioral and psychosocial factors that can increase their vulnerability of HIV/STD infection. This study will use a randomized controlled trial design to assess the efficacy of the HOLA en Grupos intervention compared to a general health comparison intervention.

CDC is requesting approval for a 3-year clearance for data collection. The data collection system involves screening of potential study participants for eligibility, collection of participants' contact information, and measures of intervention

and comparison participants' socio-demographic characteristics, health seeking actions, HIV/STD and substance use-related risk behaviors, and psychosocial factors at baseline before intervention delivery and 6 months after intervention delivery. An estimated 350 men will be screened for eligibility in order to enroll the 300 men required for the study. The baseline and the 6-month follow-up assessments will be similar. However, the 6-month assessment will ask study participants fewer questions because there is no need to ask all questions during both assessments. Collection of eligibility information from potential participants will require about 10 minutes; collection of baseline assessment information will require about 1 hour and 45 minutes; and collection of the 6-month follow-up assessment information will require about 1 hour.

The total estimated annual burden hours are 883. There is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. Responses Per Respondent**	**Average Burden Per Respondent (in hours)**
Prospective Study Participant	Participant Screening Form	350	1	10/60
Enrolled Study Participant	Baseline Assessment	300	1	1.75

Enrolled Study Participant	6-month follow-up assessment	300	1	1

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