

Attachment B

Federal Register Notice

Background and Brief Description

CDC is planning to interview Hispanic adolescents and their parents at two high schools in Miami-Dade County to facilitate the development of targeted and culturally-appropriate HIV prevention materials for Hispanic youth in Miami-Dade County. The purpose of the proposed study is to assess the efficacy of Streamlined Familias Unidas, a 5-session version of a longer efficacious, parent-centered prevention intervention developed specifically for Hispanic families. 240 Hispanic adolescents and their primary caregivers (480 total participants) from two Miami-Dade County public high schools will be recruited and randomized into two groups: (1) The streamlined 5-session

Familias Unidas intervention group, and (2) a group that receives routine information about HIV from the high schools. Four times over 2 years, both groups will respond to computerized questionnaires that explore family function, sexual behaviors, etc. These assessment questionnaires will be computer-based (ACASI). The assessments are for the purpose of developing and improving HIV prevention materials and interventions that are culturally appropriate to the Hispanic population in Miami-Dade County. Family functioning, substance use, sexual behaviors, behavior problems, and community values will inform HIV intervention programs in this community.

This study will address some of the goals of CDC's "CDC HIV Prevention Strategic Plan: Extended Through 2010". CDC plans to meet specific goals by increasing the number of behavior prevention interventions proven effective for Hispanic adolescents, and, increasing the number of Hispanic adolescents who consistently engage in behaviors that reduce risk for acquiring HIV. Additionally, the study data will provide important information that will aid in developing and improving HIV prevention interventions for Hispanic adolescents and their families.

Questionnaires will take from approximately 45 min. (caregivers) to 60 minutes (adolescents) to complete.

There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondents and questionnaire	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Hispanic Adolescent:				
Screening	400	1	3/60	20
ACASI—Baseline	240	1	1	240
ACASI—4-month follow-up	228	1	1	228
ACASI—12 month follow-up	217	1	1	217
Primary Caregiver of Hispanic Adolescent:				
Screening	400	1	3/60	20
ACASI—Baseline	240	1	45/60	180
ACASI—4-month follow-up	228	1	45/60	171
ACASI—12 month follow-up	217	1	45/60	163
Total				1239

Dated: February 12, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-09-09AP]

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 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail 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

The National Intimate Partner and Sexual Violence Surveillance System (NISVSS), New, National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The health burden of Intimate Partner Violence (IPV), Sexual Violence (SV) and stalking are substantial. Approximately 1.5 million women and 834,700 men are raped and/or physically assaulted by an intimate partner each year. Women are more likely than men to be victimized by almost every type of IPV, including rape, physical assault, and stalking by a current or former intimate partner. The health care costs of IPV exceed \$5.8 billion each year, nearly \$3.9 billion of which is for direct medical and mental health care services.

SV also has a profound and long-term impact on the physical and mental health of the victim. Existing estimates of lifetime experiences of rape range

from 15% to 36% for females. Sexual violence against men, although less prevalent, is also a public health problem; approximately 1 in 6 women and 1 in 33 men have experienced an attempted or completed rape in their lifetime. Over 302,000 women and 92,000 men were raped in the past 12 months. Thirty percent of rape victims experience major depressions at some time in their lives; 33% of victimized women and 24.2% of victimized men are counseled by a health professional; 31% develop post traumatic stress disorder; 33% contemplate suicide; and 13% attempt suicide.

Each year, approximately 1 million women and 371,000 men in the United States are stalked. There is a strong link between stalking and other forms of violence in intimate relationships; 81% of women who were stalked by a current or former intimate partner were also physically assaulted by that partner and 31% were sexually assaulted by that partner. Furthermore, 76% of female victims of intimate partner homicides were stalked by their partners before they were killed.

Currently, the United States lacks a national data source that systematically and routinely collects valid and reliable information on the magnitude and trends in IPV, SV and stalking. Such a system is needed to (1) Help formulate

public policies and prevention strategies related to IPV, SV and stalking; (2) guide and evaluate progress in reducing the huge health and social burden associated with IPV, SV and stalking; and (3) improve the effectiveness of federal agencies responding to IPV, SV and stalking.

In order to address this important public health problem, CDC plans to develop a national surveillance system that will generate national and state level estimates of IPV, SV and stalking. A total of 20,948 eligible households will be screened; out of the households screened 10,948 are estimated to consent or agree to participate and 10,000 are estimated to complete the survey each year. The survey will be conducted among English and/or Spanish speaking male and female adults (18 years and older) living in the United States. In addition, special populations are also being targeted such as an oversample of American Indian/Alaska Native populations, female active duty military service members (first year of data collection only), and female spouses of married male active duty military service members (first year of data collection only).

Each year, NISVSS will provide precise and stable annual prevalence estimates for IPV, SV, and stalking victimization at the national level. As

data collection continues in subsequent years, sample sizes will increase and stable state-level lifetime prevalence data will also be available for both women and men in all states. All information will be collected in a 20–25 minute anonymous interview conducted over the telephone, using computer-assisted telephone interviewing (CATI) software. The use of CATI will reduce respondent burden, reduce coding errors, and increase efficiency and data quality. Questions will be asked about all forms of IPV victimization (including physical aggression, psychological aggression, and sexual violence); all forms of SV victimization by any perpetrator (including unwanted sexual situations, abusive sexual contact, and forced/nonconsensual sex [completed and attempted]); and stalking victimization by any perpetrator. NISVSS will gather information regarding experiences that occurred across the lifespan and within the 12 and 36 months preceding the survey.

Such data will help inform public policies and prevention strategies at both the national and state levels and will help guide and evaluate progress toward reducing the substantial health and social burden associated with IPV, SV, and stalking.

There are no costs to respondents other than their time.

TOTAL ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of responses	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Households	Screened	20,948	1	3/60	1,047
	Surveyed	10,000	1	25/60	4,167
Total	5,214

Dated: February 6, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 18, 2009, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4050, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn