

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****[60-Day–13–13LD]****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 Ron Otten, at 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

Formative Research, Messages and Materials Development for Birth Defects and Developmental Disabilities, Human Development and Disabilities, and Blood Disorders—NEW—Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD), requests approval for a new generic information collection package that supports formative research in birth defects and developmental disabilities; human development and disabilities, and blood disorders. Identified priority diseases, disorders, and conditions included in this information collection activity include but are not limited to

preconception health; autism spectrum disorders (ASDs) and other developmental disabilities; fetal alcohol spectrum disorders (FASDs); neural tube defects (spina bifida, anencephaly); muscular dystrophy; fragile X; deep vein thrombosis/pulmonary embolism (DVT/PE); sickle cell disease (SCD); attention-deficit/hyperactivity disorder (ADHD); and Tourette syndrome.

The Children's Health Act of 2000 required the establishment of NCBDDD. The Center is organized into three divisions, which are focused on birth defects and developmental disabilities, human development and disabilities, and blood disorders. NCBDDD promotes the health of babies, children and adults and focuses on identifying the causes of and prevention of birth defects and developmental disabilities; helping children to develop and reach their potential for full, productive living; and optimizing the health outcomes among people of all ages with disabilities. These goals are accomplished through research, partnerships, and prevention and education programs.

Birth defects affect 1 in 33 babies and are a leading cause of infant death in the United States. More than 5,500 infants die each year due to birth defects. Additionally, over 500,000 children are diagnosed with a developmental disability. With more information, the causes of these birth defects and developmental disabilities can be identified and action can be taken to protect children and to develop new ways to help women have healthy babies.

Disabilities can affect anyone of any age. About 1 in 5 Americans report having some level of disability. People with disabilities need health care and health programs to stay well, active, and a part of the community. To be healthy, people with disabilities require health care that meets their needs as a whole person, not just as a person with a disability.

Blood disorders such as sickle cell disease, anemia, and hemophilia—affect millions of people each year in the United States, cutting across the boundaries of age, race, sex, and socioeconomic status. Men, women, and children of all backgrounds live with the complications associated with these conditions, many of which are painful and potentially life-threatening. With proper preventive actions and early intervention, many of these disorders and their complications could, to a large extent, be eliminated. NCBDDD is dedicated to reducing the public health burden resulting from these conditions by contributing to a better understanding of blood disorders and

their complications; ensuring that prevention programs are developed, implemented, and evaluated; ensuring that information is accessible to consumers and health care providers; and encouraging action to improve the quality of life for people living with or affected by these conditions.

The behavioral, clinical, and surveillance projects implemented by NCBDDD are the foundation upon which recommendations and guidelines are revised and updated. Formative research is the mechanism by which evidence is obtained for priority diseases in these three (3) health condition groups and by which recommendations and guidelines are revised and updated.

NCBDDD conducts formative research for developing new messages, materials, and strategies that respond to the changing epidemiology of these priority health conditions. A generic clearance mechanism would increase productivity of CDC programs and improve the quality of public health interventions and health communication programs.

The data collection and evidence are developed using a multitude of information sources including internal and external subject matter experts, field experience, consultation with external colleagues, piloting activities, and formal evaluations. The involvement of external and internal subject matter experts produces scientifically valid instruments, interventions, and methods that enable NCBDDD to be responsive to the changing epidemiology and community needs of these priority diseases. Targeted audience members or representatives provide the information for developing clear and influential health messages, materials, and strategies that promote health and well-being. An integrated research effort is needed to fill in gaps of knowledge, awareness, screening, and prevention behaviors and could simultaneously work to reduce stigma surrounding these topics within special populations, explore cultural issues, and increase the demand for, and uptake of screening by health care providers.

Overall, these formative research activities are intended to provide information that will increase the success of the surveillance or research project through increasing response rates and decreasing response error thereby decreasing future data collection burden to the public.

This request is submitted to obtain OMB clearance for three years. The estimates of annualized burden hours are based on past experience with recruitment and the administration of

similar surveys and focus groups. It is estimated that 80,500 respondents will have to be screened annually to recruit the appropriate number of respondents

for this data collection activity. Specific information will be provided with each individual project submission. The estimated annualized burden hours for

this data collection activity is 49,667. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
General public and health care providers	Screener	80,500	1	10/60	13,417
General public and health care providers	Consent Forms	30,000	1	5/60	2,500
General public and health care providers	Moderator's Guide	30,000	1	1	30,000
General public and health care providers	Surveys	15,000	1	15/60	3,750
Total	49,667

Dated: February 28, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-12EX]

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

Formative Research for the Development of CDC's Act Against AIDS Social Marketing Campaigns Targeting Consumers—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 purpose of this study is to conduct interviews and focus groups in four rounds of data collections (exploratory research, message testing, concept testing, materials testing) with consumer groups aged 18 to 64 over a 3-year period to develop various social marketing campaigns aimed at increasing HIV testing rates, increasing HIV awareness and knowledge, challenging commonly held misperceptions about HIV, and

promoting HIV prevention and risk reduction.

The research results will be used to develop materials for six specific HIV social marketing campaigns under the umbrella of the larger *Act Against AIDS* campaign. The campaigns will target consumers aged 18–64. Some campaigns will target the general public as a whole and other campaigns will focus on specific subpopulations at greatest risk for HIV infection. The target audiences will include Latinos, men who have sex with men (MSM), HIV-positive individuals and African Americans.

The study will screen 2338 people per year for eligibility. Of the 2,338 people screened, it is expected that 500 people will participate in focus groups, 500 people will participate in in-depth interviews and 700 will participate in intercept interviews. All focus group and in-depth interview participants (total 1000) will complete a brief paper and pencil survey.

There are no costs to the respondents other than their time.

The total estimated annual burden hours are 2,311.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in Hours)
Individuals (males and females) aged 18–64.	Screening Instrument	2338	1	2/60
	In-depth interview focus group and intercept interview			
	Exploratory—HIV Testing In-depth Interview Guide	74	1	1
	Exploratory—HIV Prevention In-depth Interview Guide	74	1	1
	Exploratory—HIV Communication and Awareness In-depth Interview Guide.	74	1	1
	Exploratory—HIV Prevention with Positives In-depth Interview Guide.	74	1	1
	Consumer Message Testing In-depth Interview Guide	68	1	1
	Consumer Concept Testing In-depth Interview Guide	68	1	1
	Consumer Materials Testing In-depth Interview Guide	68	1	1
	Exploratory—HIV Testing Focus Group Interview Guide.	74	1	2
	Exploratory—HIV Prevention Focus Group Interview Guide.	74	1	2