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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention

[30Day-13-13LD]

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 (404) 639-7570 or send an email to [omb@cdc.gov](mailto: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, Messages and Materials Development for NCBDDD - 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.

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.

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.

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.

It is estimated that approximately 8 - 10 individual projects will be processed each year using this mechanism. Data collection activities from a variety of groups are anticipated. Primary respondents will be Latina Spanish-dominant women of childbearing age (ages 18-45, both childless adult women and parents of young children) and individuals who identify as a member of a specified racial/ethnic/cultural minority community and thus considered hard to reach. Members of the educational, research, and public health community may also be targeted for their subject matter expertise.

This request is submitted to obtain Office of Management and Budget (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 26,800 respondents will have to be screened annually to recruit the appropriate number of respondents for this data collection activity. Depending on the individual information collection request, information might be collected using the following modes: focus groups, in-person interviews (face-to-face or via telephone, paper-and-pencil questionnaires, or electronically. Electronic modes include handheld devices, computer-assisted self-interviews, computer-assisted personal interviews, web-based surveys, or other point-of-service collection devices.

Specific information will be provided with each individual project submission. The estimated annualized burden hours for this data collection activity are 16,550. 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
General public and health care providers	Screeners	26,800	1	10/60
General public and health care providers	Consent Forms	10,000	1	5/60
General public and health care providers	Moderator's Guide	10,000	1	1
General public and health care providers	Surveys	5,000	1	15/60

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Ron A. Otten,  
 Director  
 Office of Scientific Integrity  
 Office of the Associate Director for Science  
 Office of the Director  
 Centers for Disease Control and Prevention

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