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

[30Day-16-0010]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: 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

Birth Defects Study To Evaluate Pregnancy exposures (BD- STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB 0920-0010, Expiration 01/31/2017) - Revision - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects currently covering three counties in Metropolitan Atlanta.

Since 1997, CDC has funded case-control studies of major birth defects that utilize existing birth defect surveillance registries (including MACDP) to identify cases and study birth defects causes in participating states/municipalities across the United States.

The current study, BD-STEPS, is a case-control study that is similar to the previous CDC-funded birth defects case-control study, NBDPS, which stopped interviewing participants in 2013. As with NBDPS, BD-STEPS control infants are randomly selected from birth certificates or birth hospital records; mothers of case and control infants are interviewed using a computer-assisted telephone interview.

The results from NBDPS have improved understanding of the causes of birth defects. Over 200 articles have been written in

professional journals using the data from NBDPS, and BD-STEPS data will soon be added to NBDPS data for analysis. The current BD-STEPS revision is an addition to the study population for two BD-STEPS Centers. Specifically, in these two Centers mothers of stillbirths without major birth defects will be added to the study population for BD-STEPS and mothers of all stillbirths (with and without birth defects) and all controls in these two Centers will be asked to participate in a supplemental telephone interview.

The BD-STEPS interview takes approximately forty-five minutes to complete (burden estimate includes both the introductory telephone script/consent and questionnaire). For five Centers, a maximum of 275 interviews are planned per year per center, 200 cases and 75 controls; for the two Centers participating in additional stillbirth interviews, 495 interviews are planned per center, 200 cases with birth defects, 75 controls, and 220 stillbirths without birth defects. With seven centers planned, the maximum interview burden for all centers combined would be approximately 1,774 hours. Mothers in five of the seven BD-STEPS Centers will also be asked to provide consent for the study to access previously collected infant bloodspots. It takes approximately 15 minutes to read, sign and return the informed consent for retrieval of bloodspots. For

approximately one fifth of participants, some medical records review will be conducted. The medical records release form takes participants approximately 15 minutes to read, sign and return. In addition, it takes approximately 30 minutes for each medical record reviewer to conduct the review and send the medical record. The online questionnaire will be offered to approximately one third of participants who report certain occupations during the telephone interview; these participants will be asked to complete additional occupational questions via a website which will take approximately 20 minutes to answer. In addition, in two Centers, mothers of stillbirths with and without birth defects and controls will be asked to participate in a supplemental telephone interview that will take approximately 25 minutes to complete.

Information gathered from both the interviews and the Deoxyribonucleic acid specimens has been and will continue to be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to revise the previously estimated burden details and to request OMB clearance for three additional years. The total estimated annual burden hours are

3,034. There are no costs to the respondents other than their time.

Estimated Annualized Burden Hours

Respondents	Activity	Number of Respondents	Number of responses per respondent	Avg. burden per response (In hours)
Mothers (interview)	Telephone consent and BD-STEPS questionnaire	2,365	1	45/60
Mothers (consent for bloodspot retrieval)	Written consent for bloodspot retrieval	1,375	1	15/60
Mothers (online occupational questionnaire)	Online Occupational Questionnaire	790	1	20/60
Mothers (consent for medical records review)	Written release for medical records review	475	1	15/60
Records reviewers (medical records review)	Pulling and sending records	475	1	30/60
Mothers of all AR/MA stillbirths and controls (supplemental telephone interview)	Telephone consent and supplemental questionnaire	710	1	25/60

Jeffrey M. Zirger
Health Scientist
Acting Chief, Information Collection Review Office
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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