Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0010]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 4, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposureS (OMB Control No. 0920-0010, Exp. 02/29/2020) – Revision - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Birth defects are associated with substantial morbidity and mortality in the United States. About one in every 33 babies is born with a birth defect, which are the leading cause of infant mortality and the fifth leading cause of loss of potential years of life before age 65. One in five infant deaths is due to birth defects.

CDC's National Center on Birth Defects and Development Disabilities (NCBDDD) works to identify causes of birth defects, improve the health of those living with birth defects, and find and promote opportunities for prevention. For example, vaccination programs have reduced the incidence of congenital rubella syndrome, Rh hemolytic disease of the newborn can be prevented by appropriate medical practice, and genetic counseling can provide parents with information about the increased risk of Down syndrome associated with advanced maternal age. Perhaps most importantly, folic acid intake before and during pregnancy can prevent many cases of fatal or

permanently disabling neural tube defects, such as anencephaly and spina bifida.

For most birth defects, however, the causes are not known, making prevention efforts challenging to develop. To improve understanding of the causes of birth defects, CDC initiated active surveillance of birth defects in the wake of the thalidomide tragedy. The system has been in continuous operation since 1967 and is the longest running active surveillance system in the world. Over this period CDC adapted the system to both utilize and contribute to new findings about the epidemiology and causes of birth defects. Previous related efforts include the "Metropolitan Atlanta Congenital Defects Program" (MACDP) and the "National Birth Defects Prevention Study" (NBDPS).

In its current form, CDC conducts birth defects surveillance through the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS, OMB No. 0920-0010). BD-STEPS is a CDC-funded collaborative effort involving six CDC-funded, state-based Centers for Birth Defects Research and Prevention (CBDRP) that have legislative authority to collect population-based information on infants with major congenital malformations (Arkansas, California, Iowa, Massachusetts, New York, and North Carolina). CDC serves as an additional site on behalf of Georgia. Information collection for BD-STEPS is based on a case-control design that builds upon information obtained from state-

based vital records and birth defects tracking systems. At all CBDRP sites, mothers who have given birth to infants with birth defects are invited to participate in a computer-assisted telephone interview (CATI) to discuss their medical history, pregnancies, environmental exposures, and medications. In addition, interviews are conducted with mothers of control-infants from each CBDRP, selected randomly from live-born infants without a major birth defect. Controls are identified either from vital records (birth certificates) or from hospitals of birth, and represent the birth population from which the case infants were identified. Two CBDRP sites (Arkansas and Massachusetts) also conduct interviews with mothers of infants who are stillborn without major birth defects, and controls. In states that allow retrieval of blood spots, BD-STEPS participants are asked for permission to share a portion of the newborn blood spot for the child who is part of the study, and for mothers of multiples, the co-siblings of this child. Finally, the interviews identify mothers who work in one of eight occupational categories of interest. These respondents are asked to complete a supplemental online questionnaire designed to assess the impact of the workplace on reproductive outcomes.

During the next OMB approval period, CDC plans to implement a number of changes, many reflecting increased emphasis on birth defects with established or suspected association with maternal

infection. Five new birth defect case groups will be added. In addition, the maternal interviews will include new questions on infections, travel history, and marijuana use during pregnancy. The new case groups and questions will increase the estimated burden per interview from 45 minutes to 55 minutes. CBDRPs will also begin asking mothers for permission to access information on reportable infectious diseases from their state health departments. The estimated burden per response is 15 minutes. CDC will discontinue plans for a medical records review that was previously approved but never implemented.

Additional changes will also affect burden estimates. The estimated number of case interviews per site will increase from 200 to 270, and the number of control interviews per site will increase from 75 to 100. The number of interviews with mothers who gave birth to a stillborn infant will remain constant (220 interviews per site for the two CBDRP sites participating in this information collection activity, plus 100 control interviews per site). The number of respondents who complete the online occupational questionnaire will increase but there is no change to the estimated burden per response of 20 minutes. The number of mothers who are asked to provide permission for bloodspot retrieval will also increase, but the burden per response will not change.

CDC will use BD-STEPS data to identify modifiable maternal risk factors and to apply findings to prevention programs for birth defects and stillbirths. Data will also be used to examine hypotheses for gene-environment interactions involved in the etiology of birth defects.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden will increase from 3,034 hours to 4,433 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Response (in hours)
Mothers of birth defects cases and controls	Telephone Consent Script and BD-STEPS Computer Assisted Telephone Interview	3,030	1	55/60
Mothers of birth defects cases and controls	Consent for bloodspot retrieval	1,850	1	15/60
Mothers of birth defects cases and controls	Online Occupational Questionnaire	830	1	20/60
Mothers of birth	Infectious Disease Request	2,590	1	15/60

defects cases and controls	Form			
Mothers of stillbirths and controls	Telephone consent and supplemental interview	640	1	25/60

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[FR Doc. 2019-18207 Filed: 8/22/2019 8:45 am; Publication Date: 8/23/2019]