DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-0010; Docket No. CDC-2016-0030]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the "Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)". The purpose of BD-STEPS is to identify modifiable maternal exposures in pregnancy that may increase the risk for having a pregnancy affected by certain major, structural birth defects.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0030 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions*:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply

with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)(formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB Control No. 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 group infants are randomly selected from birth certificates or birth hospital records; mothers of

case and control group 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 (the 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.

Estimates of Annualized Burden Hours

Respondents	Activity	Number of Respondents	Number of responses per respondent	Avg. burden per response (In hours)	Total Burden Hours
Mothers (interview)	Telephone consent and BD-STEPS questionnaire	2,365	1	45/60	1,774
Mothers (consent for bloodspot retrieval)	Written consent for bloodspot retrieval	1,375	1	15/60	344
Mothers (online occupational questionnaire)	Online Occupational Questionnaire	790	1	20/60	263
Mothers (consent for medical records review)	Written release for medical records review	475	1	15/60	119
Records reviewers (medical records review)	Pulling and sending records	475	1	30/60	238
Mothers of all AR/MA stillbirths and controls (supplemental telephone interview)	Telephone consent and supplemental questionnaire	710	1	25/60	296
TOTAL					3,034

Leroy A. Richardson,
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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