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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-0010; Docket No. CDC-2019-0005]

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. This revision proposes to add stillbirths without defects to the study population for two Centers and implement a supplemental telephone interview for these two Centers' stillbirths (with and without birth defects) and their controls.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0005 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Lead, 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

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 02/29/2020) - 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 55 minutes to complete and is 10 minutes longer than the previously OMB-approved interview (the burden estimate includes both the introductory telephone script/consent and questionnaire). For the five Centers not participating in the stillbirth component of the study, a maximum of 370 interviews are planned per year per center, 270 cases and 100 controls; for the two Centers participating in additional stillbirth interviews, 590 interviews are planned per Center, 270 cases with birth defects, 100 controls, and 220 stillbirths without birth defects. With seven Centers and a maximum of 3,040 interviews, the maximum interview burden for all centers combined would be 2,787 hours per year over three years. The 55 minute burden includes the time for the telephone consent script which is reviewed with the mother at the beginning of the call to collect the information via the CATI interview.

Five of the seven BD-STEPS Centers request consent for retrieval of leftover newborn bloodspots. If a maximum of 2,600 interviews would be expected for seven Centers, a maximum of 1,850 would be expected for five Centers (excluding stillbirths, for which newborn bloodspots are not available). A maximum of 15 minutes would be expected for the participant to read the bloodspot retrieval consent request and to read and sign the consent form. The anticipated maximum burden for bloodspot consent would be 463 hours annually. With a maximum of 2,600 interviews planned annually, and approximately one third of the respondents eligible for the online questionnaire (selected based on reporting occupations queried in the questionnaire), a maximum of 830 women would receive the online questionnaire. Completion of the online questionnaire is estimated to take 20 minutes including reading introductory communication. The anticipated maximum burden for the online questionnaire is 277 hours annually.

We will request the release of reportable infectious diseases information from all women who complete the CATI. Of the 2,600 interviews planned annually, a maximum of 2,600 women would receive the infectious disease information request. Based on experience with consent forms, we expect the review, signing and mailing of the release of reportable infectious diseases information to take a maximum of 15 minutes for participants. The anticipated maximum

burden for the reportable infectious diseases information is 650 hours annually.

In the two Centers participating in the supplemental interview, mothers of infants with or without birth defects that are stillborn and controls will be asked to participate in a supplemental telephone interview. The 25 minute supplemental interview will include the time for informed consent (Attachment Z). Based on a maximum of 640 women to be interviewed with the supplemental questionnaire, the maximum burden time would be 267 hours annually.

The total estimates of annual burden hours for all activities for all individuals for all Centers is 4,443 hours. The estimates of annualized burden hours represent the total population however due to lower participation rates (no more than 60%, the actual burden will be lower as well. There are no costs to the respondents other than their time.

Estimates of Annualized Burden Hours

Respondents	Form Name	Number of Respondents *	Number of responses per respondent	Avg. burden per response (In hours)	Total Burden Hours
Mothers (interview)	Telephone Consent Script (Attachment S1/S2)/BD-STEPS Computer Assisted Telephone Interview (Attachment	3,040	1	55/60	2,787

	C1/C2)				
Mothers (consent for bloodspot retrieval)	Written consent for bloodspot retrieval (Attachment T1/T2 and U1/U2)	1,850	1	15/60	463
Mothers (online occupational questionnaire)	Online Occupational Questionnaire (Attachment M1-8)	830	1	20/60	277
Mothers (infectious disease release review)	Infectious Disease Request Form (Attachment D1/D2)	2,600	1	15/60	650
Mothers of all AR/MA stillbirths and controls (supplemental telephone interview)	Telephone consent and supplemental interview (Attachment N1/N2)	640	1	25/60	267
TOTAL					4,443

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Office of Scientific Integrity

Office of Science

Centers for Disease Control and Prevention

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