

[Pub. L. 67–13, 42 Stat. 20 (June 10, 1921).]

James R. Dalkin,

Director, Financial Management and Assurance.

[FR Doc. 2016–06051 Filed 3–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Advisory Committee on Breast Cancer in Young Women (ACBCYW)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW).

The Committee provides advice and guidance to the Secretary, Department of Human Services (HHS); the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives.

The Secretary, HHS, acting through the Director, CDC, shall appoint to the advisory committee nominees with expertise in breast cancer, disease prevention, early detection, diagnosis, public health, social marketing, genetic screening and counseling, treatment, rehabilitation, palliative care, and survivorship in young women, or in related disciplines with a specific focus on young women. Members may be invited to serve for up to four years. The next cycle of selection of candidates will begin in the Spring of 2016, for selection of potential nominees to replace members whose terms will end on November 30, 2016.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACBCYW objectives <http://www.cdc.gov/maso/FACM/facmACBCYW.htm>. The U.S. Department of Health and Human

Services will give close attention to equitable geographic distribution and to minority and female representation so long as the effectiveness of the Committee is not impaired.

Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, HIV status, disability, and cultural, religious, or socioeconomic status. Consideration is given to a broad representation of geographic areas within the U.S., with diverse representation of both genders, ethnic and racial minorities, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Candidates should submit the following items:

Current curriculum vitae or resume, including complete contact information (name, affiliation, mailing address, telephone numbers, fax number, email address); A 150 word biography for the nominee; At least one letter of recommendation from a person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by HHS.

Nominations should be submitted (postmarked or received) by April 25, 2016.

Electronic submission: You may submit nominations, including attachments, electronically to acbcyw@cdc.gov.

Regular, Express or Overnight Mail: Written nominations may be submitted to the following addressee only: Temeika L. Fairley, Ph.D., c/o ACBCYW Designated Federal Officer, CDC, 4770 Buford Highway NE., Mailstop F–76, Atlanta, Georgia 30341.

Telephone and facsimile submissions cannot be accepted. Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–06025 Filed 3–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

Correction: This notice was published in the **Federal Register** on February 25, 2016, Volume 81, Number 37, Page 9477. The meeting time and date should read as follows:

9:00 a.m.–6:00 p.m., EDT, March 31, 2016

Contact Person for More Information: Erin Stone, M.S., Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, CDC, 1600 Clifton Road NE., Mailstop A–07, Atlanta, Georgia 30333; Telephone (404) 639–4045, Email: hicpac@cdc.gov

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–06027 Filed 3–16–16; 8:45 am]

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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 May 16, 2016.

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 NE., 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 NE., 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 Web site 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	Average 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.

[FR Doc. 2016–05949 Filed 3–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–3:00 p.m., EDT, April 21, 2016.

Place: CDC, Building 19, Global Communications Center, Auditorium B3, 1600 Clifton Road NE., Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space and phone lines available. The meeting room accommodates approximately 50 people. Advance registration for in-person participation is required by April 7, 2016. The public is welcome to participate during the public comment period, which is tentatively scheduled from 2:40 p.m. to 2:45 p.m. This meeting will also be available by

teleconference. Please dial (877) 930–8819 and enter code 1579739.

Web links:

Windows Media: <http://wm.onlinevideoservice.com/CDC1>.

Flash: <http://www.onlinevideoservice.com/clients/CDC/?mount=CDC3>.

Smart Phone and Mobile Devices: <http://wowza01.sea.onlinevideoservice.com/live/CDC3/playlist.m3u8>.

If you are unable to connect using the link, copy and paste the link into your web browser. For technical support please call: (404) 639–3737.

Purpose: The Advisory Committee to the Director, CDC, shall advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The committee recommends ways to prioritize CDC’s activities, improve results, and address health disparities. It also provides guidance to help CDC work more effectively with its various private and public sector constituents to make health protection a practical reality.

Matters for Discussion: The Advisory Committee to the Director will receive updates from the State, Tribal, Local and Territorial Subcommittee; the Health Disparities Subcommittee, the Ethical Considerations for Public Private Partnerships Workgroup, the Global Workgroup, the Internal and External Laboratory Safety Workgroups, and the Public Health—Health Care

Collaboration Workgroup, as well as an update from the CDC Director.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Carmen Villar, MSW, Designated Federal Officer, ACD, CDC, 1600 Clifton Road NE., M/S D–14, Atlanta, Georgia 30329. Telephone (404) 639–7037, Email: xjj4@cdc.gov. The deadline to register for in-person attendance at this meeting is April 7, 2016. To register, please send an email to xjj4@cdc.gov.

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Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–06026 Filed 3–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.