

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-15UR]

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. Written comments and/or suggestions regarding the items contained in this notice should be directed 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

Enhanced Surveillance of Coccidioidomycosis in Low- and Non-Endemic States—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Coccidioidomycosis, also called “Valley fever,” is a nationally notifiable fungal infection caused by inhalation of soil-dwelling *Coccidioides* spp. In the United States, coccidioidomycosis is known to be endemic in the southwestern states, but new evidence suggests that the true endemic areas may be broader than previously recognized. Approximately 10,000 coccidioidomycosis cases are reported in the U.S. each year to the National Notifiable Disease Surveillance System (NNDSS), but this system captures limited clinical and epidemiological information about reported cases. Most

cases occur in Arizona or California, so the epidemiology of this disease has been well-described for these states, but little is known about the features of cases in other states.

Enhanced surveillance in low- and non-endemic states will help determine which information is most important to collect during routine surveillance and will help assess the suitability of the Council of State and Territorial Epidemiologists (CSTE) case definition for coccidioidomycosis in these areas. Primary prevention strategies for coccidioidomycosis have not yet been proven to be effective, so public health efforts may be best aimed at promoting awareness of coccidioidomycosis among healthcare providers and the general public. Improved surveillance data are essential for identifying such opportunities to promote awareness about this disease and for determining its true public health burden.

State health department personnel in participating low- and non-endemic states will conduct telephone interviews with coccidioidomycosis cases reported during one calendar year that meet the CSTE case definition and will record responses on a standardized form. State health department personnel will use the form to collect information on demographics, underlying medical conditions, travel history, symptom type and duration, healthcare-seeking behaviors, diagnosis, treatment, and outcomes.

OMB approval is requested for two years. Participation is voluntary. The total estimated annualized burden is 48 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
State Health Department Personnel	Case Report Form for Coccidioidomycosis (Valley Fever) Enhanced Surveillance.	145	1	20/60

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. 2015-13161 Filed 6-1-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

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 a meeting for the initial

review of applications in response to Funding Opportunity Announcement, RFA-EH-15-002, Development and validation of laboratory procedures using next generation sequencing technologies to assess genes causing severe combined immune deficiency (SCID) in state newborn screening laboratories.

Times and Dates: 11:00 a.m.–3:00 p.m., EDT, June 25, 2015 (CLOSED).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4)

and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Development and validation of laboratory procedures using next generation sequencing technologies to assess genes causing severe combined immune deficiency (SCID) in state newborn screening laboratories", EH15-007.

Contact Person for More Information: Jane Suen, Dr.P.H., M.S., Scientific Review Officer, CDC, 4770 Buford Highway, NE., Mailstop F63, Atlanta, Georgia 30341-3724, Telephone (770) 488-4281.

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. 2015-13314 Filed 6-1-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0010]

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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 a change in proposed data collection. Specifically, the study will not ask BD-STEPS participants to participate in saliva collection as originally planned, but we will add an opportunity for some participants to respond to an online questionnaire, and we will also ask some participants for permission to retrieve newborn bloodspots.

The BD-STEPS interview takes approximately forty-five minutes to complete. A maximum of 275 interviews are planned per year per center, 200 cases and 75 controls. With seven centers planned, the maximum interview burden for all centers combined would be approximately 1,444 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 will take participants approximately 15 minutes to read, sign and return. In addition, it will take approximately 30 minutes for each medical record reviewer to conduct the review and send the medical record. Finally, the newly planned 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.

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 2,290.

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