immediate global public health response.

WHO must rely on fast and reliable laboratory diagnostic capacity worldwide to be able to identify a re-emergence of smallpox, particularly in countries where systemic orthopoxvirus infections such as monkeypox, vaccinia virus infection or cowpox, and other non-pox viral rash illnesses, such as chicken pox, may cause clinical diagnostic confusion.

Over the past 10 years, clinical virology laboratory diagnostics has been evolving and increasingly relies on molecular techniques. This is also true with laboratory diagnoses of poxvirus infections. Precise and consistent identification of orthopoxviruses, in particular variola viruses, is now achievable using such molecular techniques as real-time Polymerase Chain Reaction (PCR), unlike earlier techniques that may have relied on direct virus isolation and identification.

WHO must be alerted when there is a potential or actual smallpox infection. Early detection and confirmation of smallpox cannot rely solely on the two WHO Collaborating Centres for smallpox and other poxvirus infections. In order to facilitate and support a prompt and effective response to mitigate the spread of the disease, these two Centres should be supported by a worldwide network of reliable laboratories able to perform PCR and real-time PCR diagnostics enabling initial detection and identification of smallpox events.

Additionally, the U.S. Government supports the development of other medical products, including vaccines and drugs, for use within the U.S. upon verification of a smallpox case. The U.S. Government, through the Office of the Assistant Secretary for Preparedness and Response (ASPR), has successfully developed vaccine products, and is actively engaged in the development of several drug candidates for smallpox therapies, which require access to the Variola virus to satisfy regulatory requirements for product approvals.

Justification: WHO is the only eligible applicant; it is the only organization that is allowed by international agreements to address the issues outlined in this proposal. WHO is the directing and coordinating authority for health within the United Nations (U.N.) system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats. States Parties to the U.N. have agreed to international standards on reporting public health incidents of concern under IHR (2005). Additionally, a majority of States Parties have also agreed to specific work-frames for pathogens such as smallpox under the Biological Weapons Convention.

Since May 1999, when the 52nd World Health Assembly (WHA) resolved to postpone the destruction of the Variola virus to allow for essential research (WHA 52.10), WHO has been charged with convening a group of experts to advise on the need for continuing such research, to review proposals for research involving viable Variola virus, to review the progress of such research, and to report to the WHA each year. The need to support the activities described in this project has not changed. In fact, WHO Member States continue to exert pressure for the WHO Secretariat to carry out this work.

The WHO Advisory Committee on Variola Virus Research (ACVVR) was established in 1999 to determine what essential research, if any, must be carried out with live Variola virus. The ACVVR monitored the research progress in order to reach global consensus on the timing for the destruction of existing Variola virus stocks. In 2007, the WHA requested the ACVVR undertake a thorough review of the approved research program with a report presented in 2010. The results were presented at the 64th WHA meeting in May of 2011. The ACVVR continues to serve a critically important function for global public health, and to oversee research requested specifically by the U.S. to complete its national strategic goals. This includes convening a group of experts, the Advisory Committee on Variola Virus Research (ACVVR), to advise on the need for continuing such research, to review proposals for research involving viable Variola virus, and to review the progress of such research.

Additional Information: The agency program contact is George Korch, who can be contacted by phone at (202) 690–5760 or via email at *George.Korch@hhs.gov.*

Dated: August 12, 2013.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–13–0010]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Leroy Richardson, at 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB 0920–0010, Expiration 04/30/2015)—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.

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, control infants will be randomly selected from birth certificates or birth hospital records; mothers of case and control infants will be interviewed using a computer-assisted telephone interview.

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. As with NBDPS, parents in BD–STEPS will be asked to collect deoxyribonucleic acid (DNA) samples from themselves and their infants. The collection of saliva cells by the mother, father and infant takes about 15 minutes per person. For the infant sample, the parent will rub long-handled sponges between the infant's cheek and gum; parents will be asked to swab a total of 5 sponges per infant. The infant's mother and father will be asked to provide their own saliva samples by spitting into a funnel connected to small collection tubes. Collection of the saliva samples takes approximately 2–5 minutes per person, but the estimate of burden is 15 minutes per person to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the saliva samples for all centers combined would be approximately 1,444 hours.

Information gathered from both the interviews and the DNA 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 obtain OMB clearance for three additional years.

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

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	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.	1,925	1	45/60	1,444
Mothers, fathers, infants (saliva samples).	Written consent for saliva collection and collection of saliva samples.	5,775	1	15/60	1,444
TOTAL					2,888

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. 2013–19839 Filed 8–14–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates to Serve on the Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for membership on the BSC, NCEH/ATSDR. The BSC, NCEH/ATSDR consists of 16 experts knowledgeable in the field of environmental public health or in related disciplines, who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agencies' mission to protect and promote people's health. The Board provides advice and guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Board's objectives. Nominees will be selected from experts having experience in preventing human diseases and disabilities caused by environmental conditions. Experts in the disciplines of toxicology, epidemiology, environmental or occupational medicine, behavioral science, risk assessment, exposure assessment, and experts in public health and other related disciplines will be considered. Members may be invited to serve up to four-year terms.

The HHS policy stipulates that committee membership be balanced in terms of points of view represented and the board's function. Consideration is given to a broad representation of geographic areas within the U.S., as well as gender, race, ethnicity, persons with disabilities, and several factors including: (1) The committee's mission; (2) the geographic, ethnic, social, economic, or scientific impact of the advisory committee's recommendations; (3) the types of specific perspectives required, for example, those of consumers, technical experts, the public at-large, academia, business, or other sectors; (4) the need to obtain divergent points of view on the issues before the advisory committee; and (5) the relevance of State, local, or tribal governments to the development of the advisory committee's recommendations. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: Name, affiliation, address, telephone number, and current curriculum vitae. Email addresses are requested if available. Nominations should be sent, in writing, and postmarked by September 30, 2013, to: Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, CDC, 4770 Buford Highway, NE., Mailstop F61, Atlanta, Georgia 30341, Email address: *sym6@CDC.GOV.* Telephone and facsimile submissions cannot be accepted.

Candidates invited to serve will be asked to submit the ''Confidential Financial Disclosure Form (OGE Form 450) for Special Government Employees