Response (ASPR), Biomedical Advanced Research and Development Authority.

ACTION: Notification of a sole source Cooperative Agreement Award to the World Health Organization for a grant titled: ''Smallpox Research Oversight Activities: WHO Advisory Committee on Variola Virus Research.''

Statutory Authority: Sections 301 and 319L of the Public Health Service Act, (42 U.S.C. 241 and 247d–7e).

Estimated Amount of Award: $290,000 USD.

Project Period: September 30, 2013 to September 29, 2014.

SUMMARY: A natural re-emergence of smallpox is not deemed possible, but if it were to occur as a result of a terrorist or deliberate event, it would be a potentially devastating threat to public health worldwide and would constitute a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR) (2005). A case of smallpox detected by a member state requires notification to World Health Organization (WHO) as soon as possible, and any confirmed smallpox case would generate an 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 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 8, 2013.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2013–19860 Filed 8–14–13; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notification of an Expansion to the Cooperative Agreement Award to the World Health Organization

AGENCY: Biomedical Advanced Research and Development Authority (BARDA), Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notification of an expansion to the Cooperative Agreement Award to the World Health Organization for a grant titled: ''Smallpox Research Oversight Activities: WHO Advisory Committee on Variola Virus Research''

Statutory Authority: Sections 301 and 319L of the Public Health Service Act, (42 U.S.C. 241 and 247d–7e)

Estimated Amount of Award: $175,000 USD.

Project Period: September 30, 2012 to September 29, 2013.

SUMMARY: A natural re-emergence of smallpox is not deemed possible, but if it were to occur as a result of a terrorist or deliberate event, it would be a potentially devastating threat to public health worldwide and would constitute a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR) (2005). A case of smallpox detected by a member state requires notification to World Health Organization (WHO) as soon as possible, and any confirmed smallpox case would generate an

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.

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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.

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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.

[FR Doc. 2013–19854 Filed 8–14–13; 8:45 am]

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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