4150-37

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Justification for a Single Source Cooperative Agreement Award for the World Health Organization

AGENCY: Department of Health and Human Services, Office of the Secretary

ACTION: Notice

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 rely 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 (unlike earlier techniques that may have relied on direct virus isolation and identification).

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.

PERIOD OF PERFORMANCE: September 30, 2014 to September 29, 2015

FOR FURTHER INFORMATION: The agency program contact is Julie Schafer, who can be contacted by phone at 202-205-1435or via email at Julie.Schafer@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Sections 42 U.S.C. 241 and 247d-7e (Sections 301 and 319L of the Public Health Service Act); ASPR's Office of Biomedical Advanced Research and Development Authority (BARDA) is the program office for this award.

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 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 the development of new antiviral agents, safer vaccines, and better diagnostics, thus strengthening our national security.

Estimated amount of award: up to $662,500 USD

HHS/ASPR/BARDA:	$225,000.
DOD	$250,000. (funds pending)
HHS/NIH/NIAID	$ 50,000.
HHS/CDC	$ 87,500.
HHS/OGA:	$ 50,000.

Procedures for Providing Public Input: All written comments must be received no later than 15 days after the posting of this announcement. Please submit comments via asprgrants@hhs.gov.

Date: August 4, 2014

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Nicole Lurie, MD, MSPH

Assistant Secretary for Preparedness and Response

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