Dated: September 26, 2006.

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Deputy Director for Operations, Office of Global Health Affairs, U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Surveillance and Response to Highly Pathogenic Avian and Pandemic Influenza in the Libyan Arab Jamahiriya

AGENCY: Office of Global Health Affairs, Office of the Secretary, DHHS.

ACTION: Notice.

Announcement Type: Single Eligibility—FY 2006 Initial Announcement.

Funding Opportunity Number: OGHA 06–025.

GSA Catalog of Federal Domestic Assistance: 93. 283.

DATES: October 2, 2006: Application Availability.

October 10, 2006: Optional Letter of Intent due by 5 p.m. ET.

October 17, 2006: Application due by 5 p.m. ET.

October 27, 2006: Award date.

SUMMARY: An influenza pandemic has greater potential than any other naturally occurring infectious disease to cause large and rapid global and domestic increases in death and serious illness. Preparedness is the key to substantially reducing the health, social, and economic impacts of an influenza pandemic and other public-health emergencies.

On November 1, 2005, President George W. Bush announced the U.S. *National Strategy for Pandemic Influenza* and the following day, Secretary Michael O. Leavitt released the HHS *Pandemic Influenza Plan.* One of the primary objectives of both documents is to leverage global partnerships to increase preparedness and response capabilities around the world with the intent of stopping, slowing, or otherwise limiting the spread of a pandemic to the United States.[1] Pillars Two and Three of the *National Strategy* set out the clear goals of ensuring the rapid reporting of outbreaks and containing outbreaks beyond the borders of the United States, by taking the following actions:

• Working through the International Partnership on Avian and Pandemic Influenza, as well as through other political and diplomatic channels, such as the United Nations and the Asia-Pacific Economic Cooperation Forum, to ensure transparency, scientific cooperation, and the rapid reporting of highly pathogenic avian and human influenza cases;

• Supporting the development of the proper scientific and epidemiological expertise in affected regions to ensure the early recognition of changes in the pattern of highly pathogenic avian or human influenza outbreaks;

• Supporting the development and maintenance of sufficient host-country laboratory capacities and diagnostic reagents in affected regions, to provide rapid confirmation of cases of influenza in animals and humans;

• Working through the International Partnership to develop a coalition of strong partners to coordinate containment efforts, that is, actions to limit the spread of an influenza with pandemic potential beyond where it is first located; and,

• Providing guidance to all levels of Government in affected nations on the range of options for risk-communication, infection-control, and containment.

We rely upon our international partnerships, with the United Nations (UN); international organizations; and private and non-profit organizations, to amplify our efforts, and will engage them on a multilateral and bilateral basis. Our international effort to contain and mitigate the effects of an outbreak of pandemic influenza is a central component of our overall strategy. In many ways, the character and quality of the U.S. response and that of our international partners could play a determining role in the severity of a pandemic.

The International Partnership on Avian and Pandemic Influenza, launched by President Bush at the UN General Assembly in September 2005, stands in support of multinational organizations and national Governments. Members of the Partnership have agreed that the following ten principles will guide their efforts:

1. International cooperation to protect the lives and health of our people;

2. Timely and sustained, high-level, global, political leadership to combat avian and pandemic influenza;

3. Transparency in reporting of influenza cases in humans and in animals caused by virus strains that have pandemic potential, to increase understanding and preparedness, and especially to ensure rapid and timely response to potential outbreaks;

4. Immediate sharing of epidemiological data and samples with the World Health Organization (WHO) and the international community to detect and characterize the nature and evolution of any outbreaks as quickly as possible, by using, where appropriate, existing networks and mechanisms;

5. Rapid reaction to address the first signs of accelerated transmission of H5N1 and other highly pathogenic influenza strains, so appropriate international and national resources can be brought to bear;

6. Prevent and contain an incipient epidemic through capacity-building and in-country collaboration with international partners;

7. Work in a manner complementary to and supportive of expanded cooperation with and appropriate support of key multilateral organizations (including WHO, Food and Agriculture Organization, and the World Organization for Animal Health);

8. Timely coordination of bilateral and multilateral resource allocations; dedication of domestic resources (human and financial); improvements in public awareness; and development of economic and trade contingency plans;

9. Increased coordination and harmonization of preparedness, prevention, response, and containment activities among nations, complementing domestic and regional preparedness initiatives and encouraging, where appropriate, the development of strategic regional initiatives; and,

10. Actions based on the best available science.

Through the Partnership and other bilateral and multilateral initiatives, we will promote these principles and support the development of an international capacity to prepare for, detect, and respond to an influenza pandemic.

Following the President's National Strategy, this announcement seeks to support selected foreign Governments through their Ministries of Health or other responsible Ministries for human-health or public-health emergency preparedness.

Proposals may only include program elements that fall within designated areas under the Three Pillars of the U.S. National Strategy assigned to the U.S. Department of Health and Human Services (HHS) as described below. This support is meant to enhance, and not to supplant, current influenza-surveillance activities. Proposals should build upon infrastructure already in place. Preference will go to countries with limited resources, where influenza surveillance is not well-established, and

[1] *National Strageggy for Pandemic Influenza,* p. 2.

which have experienced outbreaks of H5N1 influenza in animals or humans or are judged at-risk of such outbreaks by HHS and the WHO Secretariat. Only the Ministry of Health of the Great Socialist People's Libyan Arab Jamahiriya is eligible under this announcement.

The term ''containment'' as used in this announcement, warrants special consideration. ''Containment'' here refers to efforts to control the emergence of a new influenza virus with pandemic potential and high pathogenicity that is, a new influenza strain efficiently transmitted among humans and causes severe disease in a high proportion of infected persons. The goal of containment would be to identify the first outbreak with such a strain, and to apply a coordinated, integrated, intensive public-health response to interrupt transmission among humans. (Severe Acute Respiratory Syndrome, for example, was ultimately contained after it spread to a number of countries.) A principle intent of this announcement is to assist partner countries to build capacity for identification, investigation and containment of such a strain.

Pillar I. Preparedness and Communication

1. National Government Public-Health Preparedness Plans, Policy, and Coordination; and,
2. Communications:
(a) Targeting health care workers (HCW); and,
(b) National Government spokespersons and risk messages.

Pillar II. Surveillance and Detection

1. Laboratory capacity and infrastructure for virologic surveillance;
2. Epidemiology capacity and infrastructure for disease surveillance;
3. Sentinel, laboratory-based surveillance for influenza-like illness (ILI) and/or hospital-based surveillance for severe disease; development or enhancement of an in-country integrated (lab and epi) surveillance network for influenza; and
4. Comprehensive, territory-wide surveillance for cases and clusters of suspicious respiratory and febrile illness that could represent emerging new pandemics.

Note: Components 3 and 4 have distinct operational requirements, but awardees must fully integrate them into one overall, multi-disciplinary surveillance network for influenza.

Pillar III. Response and Containment

1. Local rapid-response teams; and,
2. Infection control in public health-care settings.

Pillar One

Pandemic influenza presents a massive communications challenge to all levels of a nation's Government as well as its society, economy, and critical infrastructure. The uncertainty of the course of a pandemic and unknown scientific factors, as well as unforeseen and unintended outcomes with respect to Governmental actions and statements make this a communications-management issue of formidable proportion. The economic and societal effects of such a pandemic could have a significant detrimental impact on a nation and its people.

A critical component of national preparedness for an influenza pandemic is informing the public about this potential threat and providing a solid foundation of information upon which to base future actions. To be effective, Governments should base these strategies on scientifically derived risk-communications principles that are critical before, during, and after an influenza pandemic. Effective communication guides the public, the news media, health-care providers, and other groups in responding appropriately to outbreak situations and adhering to public-health measures. These guidelines must be an integral part of a national pandemic plan as developed and coordinated by a nation's appropriate agencies, such as Ministries of Health, Agriculture, Trade, Information, and Tourism.

Public-health and health-care workers will be the first to observe and report suspicious clusters of respiratory disease, and could also be the most trusted resources of information for the populations they serve. Therefore, these audiences must be a specific target for health-communications marketing and strategy. Communication strategies should include formative evaluation, message development and testing, and summative evaluation.

In addition, these critical audiences will be integral to any national response. Yet, worksite restrictions may hamper efforts to receive and provide validated up-to-date information (lack of computers, Internet access, quarantining, *etc.*). A mechanism for the rapid dissemination of information both to national and District or Provincial health-response units and international partners is necessary.

To build trust and assure that information flows through common channels of communication, coordination of media messages, training of journalists and development of credible national Government spokespeople is also recommended.

Pillar Two

One component of pandemic preparedness involves understanding the impact annual epidemics of influenza have on a population. Data regarding impact are critical to the development of prevention and control measures, such as vaccination policies. Vaccination efforts are the cornerstone of influenza prevention, and will be the primary means of mitigating the impact of an influenza pandemic, when we have a vaccine proven safe and effective against the pandemic strain. Another critical area for preparedness is the ability to identify potential human cases of novel influenza strains, so national Governments and the international community can launch early efforts to attempt to stop outbreaks.

The systematic collection of influenza-surveillance data over time is necessary to monitor and track the activity of influenza virus and disease, and is essential to understanding the impact influenza has on a country's population. Developing influenza-surveillance networks is critical for the rapid detection of new variants, including those with pandemic potential, to contribute to the global disease-surveillance system. Global collaboration, under the coordination of the Secretariat of the World Health Organization (WHO), is a key feature of influenza surveillance.

The WHO established an international laboratory-based surveillance network for influenza in 1948, which currently consists of 113 National Influenza Center (NIC) laboratories in 84 countries, and four WHO Collaborating Centers for Reference and Research of Influenza (including one located at the HHS Centers for Disease Control and Prevention [CDC]). The primary purposes of the WHO network are to detect the emergence and spread of new antigenic variants of influenza, to use this information to update the formulation of annual human influenza vaccine, and to provide as much warning as possible about the next pandemic. This system provides the foundation of worldwide influenza prevention and control, and is a critical contribution to preserving global health security.

Monitoring of human and animal influenza viruses and providing contributions to the global disease-surveillance system, including the sharing of appropriate specimens and viral isolates, will assure the data used in the WHO Secretariat's annual vaccine recommendations are relevant to each country that participates. Increased participation in the global surveillance system for influenza viruses will enhance each country's ability to monitor severe respiratory illness, to develop vaccine policy for influenza, and to help build global and regional strategies for the prevention and control

of influenza in animals and humans. Monitoring the disease activity of influenza is important to facilitate planning for the allocation of resources, appropriate and clear communications with the public, containment and response interventions, and outbreak investigations.

Pillar Three

In the absence of available vaccine or specific antiviral treatment, infection control and related non-pharmaceutical public-health interventions are the mainstay of reducing the spread and impact of an influenza pandemic. Correct and consistent infection-control practices should be a part of routine health-care delivery, an active consideration in planning for pandemic influenza and other infectious- disease outbreaks, and an integral part of outbreak response and control. The dual goals of providing safe health-care to patients and protecting health-care personnel while they work are critical to maintaining a functional health-care system. Elements of health-care related infection-control also influence community guidance for self-protection and the prevention of infection.

The principal intent of this assistance is to support surveillance and response, to allow for the containment of a highly pathogenic virus transmissible among humans. A second intent is to support the development of epidemiologic, laboratory, and related capacity to detect, respond to, and monitor shifts in influenza viruses, as well as in severe respiratory illness syndromes. A third intent is to help strengthen the connection of national institutions, especially National Influenza Centers, to more fully participate in the WHO Influenza Program, and be more capable of sharing specimens and quality data of the circulation of influenza viruses from throughout the country.

Measurable outcomes of the program will be in alignment with the three Pillars of the HHS Pandemic Influenza Operational Plan and the Pillars of the President's *National Strategy for Pandemic Influenza,* the principles of the International Partnership on Avian and Pandemic Influenza, and the following performance goal(s) for the Office of Global Health Affairs (OGHA).

This announcement is only for non-research activities supported by HHS, including OGHA. If an applicant proposes research activities, HHS will not review the application. For the definition of ''research,'' please see the HHS/CDC Web site at the following Internet address: *http://www.cdc.gov/od/ads/opspoll1.htm.*

Recipient Activities

The proposal may include activities under all three Pillars. However, the application all of those activities should prioritize the principal intent of rapidly building epidemiologic, laboratory, and response capabilities to contain an emergent, highly pathogenic virus transmissible among humans. Applicants should allocate a minimum of 70 percent of resources to Pillar Two activities unless they present strong evidence that the key capacities represented in Pillar Two are already well-established in the country, or can be made such with less than 70 percent of the resources for which applicants have applied. Applicants can select activities other than Pillar Two based on the National Pandemic Plan. If applicants *do not propose any activities* for one or more Pillars, they must describe a brief plan for how they will address those activities, and must describe the funding sources to underwrite those activities, whether national resources or financing from an alternate partner or funding source.

Activities recipients may perform under this program are as follows:

Pillar I Preparedness and Communication

1.1 Preparedness Plans, Policy, and Coordination

- Developing a high-level, Inter-Ministerial Task Force or working group for influenza that meets regularly with representation from both the human- and animal-health sectors, Government Ministries, businesses, and non-governmental organizations (NGOs); to determine ways to improve national influenza surveillance; develop prevention and control measures such as vaccine policy; and work on national pandemic preparedness.
- Adhering to the core principles of the International Partnership on Avian and Pandemic Influenza (*http://www.state.gov/r/pa/prs/ps/2005/53865.htm*), including transparency and rapid reporting of cases.
- Establishing a national plan, based on scientifically valid information, for containing influenza in animals with human pandemic potential, and for responding to a human pandemic.
- Testing and executing those plans.
- Committing to the timely coordination of bilateral and multilateral resource allocations, the dedication of domestic resources (human and financial), and the development of contingency plans.

1.2 Communications

- Establishing a communications component as part of a National Pandemic Plan, coordinated by the Ministries of Health, Agriculture, Information, Trade, Tourism, etc., as appropriate to accomplish the following:
- Establishing a communications strategy to coordinate the development, testing and evaluation of health information among involved Ministries and bilateral/multilateral agencies that are providing assistance.
- Prepare public-health messages in local languages to ask medical and public-health workers to report unusual cases of respiratory disease to local authorities, by emphasizing that a cluster of severe pneumonia of unknown origin anywhere in the world constitutes a potential international emergency.
- Prompt reporting of cases and clusters of human infection with avian influenza A (H5N1) by doing the following:
  - Providing technical support for local-language public-health education and outreach efforts by Ministries of Health and Agriculture, the World Health Organization (WHO)/Headquarters, and the relevant WHO Regional Offices;
  - Providing local-language training for health-care providers in identifying patients with risk factors for disease caused by highly pathogenic avian influenza A (H5N1); and,
  - Supporting public-sector field staff in Districts and Provinces in detecting and reporting suspected cases of highly pathogenic avian influenza.
- Develop public-health materials in local languages for use in community-based educational campaigns that inform people about infection control and public-health containment (or ''social distancing'') measures (*e.g.,* quarantine, school closures, travel restrictions) that can control outbreaks of pandemic influenza. These materials will also provide information about the use of proper and safe antiviral drugs and vaccines.
  - Ensure these activities and messages fit together and are consistent with inter-Ministerial Governmental social- mobilization efforts and similar efforts funded by the U.S. Agency for International Development (USAID) and other donors.
- Develop local-language mass-media and community-outreach programs that promote AI awareness and behavior change, if other partners are not addressing this area consistent with the national pandemic response plan.

• Identify and train credible national Government spokespeople.

• Partner early with media editors and journalists, if other partners are not addressing this area, consistent with the national pandemic response plan, to:

○ Provide valid training on avian influenza to journalists and editors.

• Develop public-health materials in local languages that inform health-care workers about infection-control measures that can control the spread of pandemic influenza in health-care facilities and in the workplace. These materials will also provide information about antiviral use.

• Develop health-promotion and education activities in local languages to increase professional awareness of the need to detect each and every case and cluster of human respiratory infection (family, health care, or institutional) during the pandemic-alert period.

• Work with the WHO Secretariat and other multilateral organizations, existing bilateral programs, and private-sector partners to develop workplace, community- and hospital-based health prevention, promotion, and education activities.

Pillar II. Surveillance and Detection

2.1 Laboratory Capacity and Infrastructure

• Train laboratory scientists and technicians in proper laboratory techniques for influenza detection, typing, and sub-typing.

• Install and maintain laboratory equipment and infrastructure needed to carry out the functions of WHO-certified National Influenza Center, if possible, or work towards the capacity to carry out those functions.

• Maintain and assure biosafety and biosecurity of targeted laboratories according to national and international standards.

• Install and maintain information-management equipment for reporting of results from influenza laboratory work, back to the sites providing specimens, to national leaders, and to the WHO Secretariat and other international partners.

2.2 Epidemiology Capacity and Infrastructure

• Train epidemiologists at appropriate levels and sufficient scale to be able to support multiple surveillance, outbreak investigation and response, and disease-control activities involved in avian and pandemic preparedness.

• Establish needed information and data-management capacity and telecommunications capacity needed for surveillance, outbreak response, and disease control, including containment of a suspect pandemic virus.

• Establish other needed infrastructure critical to supporting outbreak detection, response, and containment efforts.

2.3 Sentinel, Laboratory-Based Surveillance for Influenza-Like Illnesses and/or Hospital-Based Surveillance for Severe Disease

• Develop a nationwide system to collect virologic and epidemiologic data for influenza, including appropriate samples and viral isolates, by establishing three or more sites with good geographic distribution throughout the country. Each site will consist of a local laboratory and one or more public or private clinics or hospitals from which to collect data. Each site should do the following:

○ Conduct virologic and epidemiologic surveillance for influenza by collecting information, including appropriate samples and specimens for virus isolation year-round;

○ Have lab capacity for performing the isolation and typing of influenza viruses; or at least molecular technology for identification;

○ Collect information on influenza-like illnesses and/or severe respiratory disease at each site by building on information already available. Possible sources of information are the following: (1) Recording visits by patients with influenza-like-illness to physicians or public or private primary-care clinics or hospitals, based on a standard case definition; (2) Monitoring hospital admissions for severe respiratory illness and pneumonia, based on a standard case definition. The sites should collect patient information, such as age, patient history and other relevant information;

○ Collect a subset of at least 10 (and preferably up to 25) specimens from the patient populations under surveillance that exhibit febrile, acute upper-respiratory illness weekly during the period of surveillance by using a standard case definition (preferably one established by the WHO Secretariat) and submit them to the local laboratory for the site;

○ During unusual outbreaks of influenza, such as outbreaks with unusual epidemiologic characteristics, or those related to infections by highly pathogenic avian or other animal influenza viruses; collect epidemiologic information to characterize the outbreak; and collect additional samples for viral isolation, including tissue samples, if appropriate; and submittal to the site laboratory. Report the outbreak to the National Influenza Center for further transmittal to one or more of the WHO-designated Collaborating Centers for Influenza;

○ Prepare and provide regular weekly reports on the epidemiologic information collected (influenza-like-illness and/or severe respiratory illness) to the local laboratory and to the National Influenza Center for further transmittal to one or more of the WHO-designated Collaborating Centers for Influenza;

○ If proper biosafety conditions exist, perform viral isolation for influenza viruses, either in tissue culture or in eggs, type positive isolates for influenza A and B, and, if possible, subtype influenza viruses;

○ Store original clinical materials at −70 degrees celsius, until the beginning of the next influenza season; and,

○ Submit viral isolates to the National Influenza Center within the country on at least a monthly basis for more complete analysis.

• Each WHO-certified National Influenza Center also will be responsible for and commit to performing the following activities:

○ Performing preliminary antigenic and, if possible, genetic characterization on the virus isolates submitted from the laboratories in the surveillance sites (including those isolates grown at the NIC);

○ Send, as quickly as possible, representative influenza virus isolates to one of the four WHO Collaborating Centers for Influenza, including any low-reacting viruses, as tested by using the WHO reagent kit, each month during the period of surveillance and more frequently, if possible;

○ If any viruses are unsubtypable as tested by using the WHO kit, alert the WHO Secretariat and send the virus isolate to one of the four WHO Collaborating Centers for Influenza immediately;

○ During the period of surveillance, provide weekly influenza-surveillance information, preferably electronically to the WHO Secretariat through FluNet;

○ Provide an annual national summary on influenza activity, virological information, and other relevant information on influenza to the WHO Secretariat and the WHO Collaborating Center for Influenza at HHS/CDC;

○ Provide technical expertise and training to support the surveillance sites and laboratories in the national network in developing the capacity to type and subtype viruses and when feasible to identify avian influenza viruses by molecular techniques; and provide reagents to national public-health laboratories as able;

○ Establish the capacity to identify avian influenza viruses in specimens collected from suspect cases using molecular diagnostic techniques;

○ Provide support for human-health diagnostic laboratories in your network by giving assistance in the development and implementation of rapid laboratory diagnostics protocols and methods, and to establish objectives for rapid screening; and,

○ Establish linkages with surveillance systems that detect influenza viruses in animal populations and with national Government authorities responsible for animal health.

• Foreign Governments that apply for funding through this announcement should play a substantial role in the development and support of the influenza-surveillance network in their countries, by committing to the following:

○ Timely and sustained high-level political leadership to combat avian and novel influenza strains;

○ Complete transparency in the reporting of influenza cases in humans and animals caused by virus strains that have pandemic potential;

○ Timely sharing of influenza-surveillance information with the WHO Global Influenza Surveillance network by facilitating the regular exchange of information and virus samples with one of the four WHO Collaborating Centers for Influenza; and,

○ Providing continued support for influenza activities within the country and developing a plan for increased participation in the global influenza surveillance network over a five-year period.

2.4 Comprehensive, National Surveillance for Clusters and Cases of Severe Respiratory and Febrile Syndromes That Might Represent Emergent Cases From a Highly Pathogenic Influenza Virus of Pandemic Potential

• Establish early-warning networks, adapt international case definitions, and implement standards for laboratory diagnostics of human and animal samples.

• Strengthen early-warning systems for reporting human cases of infection with influenza A (H5N1) by:

○ Initiating or enhancing Participation in the WHO Global Outbreak Alert and Response Network (GOARN) to report possible outbreaks of highly pathogenic avian influenza in humans and the WHO Global Influenza Surveillance Network to share specimens and viruses.

• Develop and establish village-based public-sector alert-and-response surveillance systems for human cases of influenza. By providing health education at the community level and to providers and setting up a system for reporting of suspect cases based on a standard case definition.

• Develop a system that rapidly notifies National Government authorities of suspect avian influenza cases and provides appropriate samples for testing at the national level if the capacity does not exist at a country's network site.

• Establish a system to monitor for severe cases of respiratory illness for a possible case or cluster of the H5N1 virus or other respiratory diseases that pose a global threat.

• Develop protocols and tools to investigate cases and clusters, including the widespread dissemination of specimen collection and transport materials, to allow rapid diagnosis.

Note: The WHO-certified National Influenza Center (NIC) within a country can be one of the surveillance sites, and, as such, conduct all the activities listed above under components 2.3 and 2.4. However, component 2.4 is often the responsibility of units of Ministries of Health other than the laboratory unit that serves as the National Influenza Center, and Governments might need to share resources across units and establish protocols to fulfill the requirements of components 2.3 and 2.4. If there are two or more NICs within a country, each NIC could participate as a site; however, NICs within a single country should work together and place emphasis on the addition of new surveillance sites. In addition, the NIC(s) should act as the focal point and authority within the country on influenza surveillance, and be the main point of communication with the WHO Secretariat and WHO Collaborating Centers for the rapid submittal of virus isolates and information into the global influenza surveillance system.

Pillar III. Response and Containment

3.1 Local Rapid-Response Teams (RRT)

• Develop and adopt rapid-response protocols for use in responding quickly to credible reports of human-to-human transmission that could indicate the beginnings of an influenza pandemic. Awardees may carry out this action in conjunction with HHS, USAID, the WHO Secretariat, and other donor countries.

• Develop and train in-country rapid-response teams to assess and report quickly on possible outbreaks of avian and human influenza at the village level by accomplishing the following:

○ Developing national and regional rapid-response teams deployable within 24 hours; and,

○ Working with GOARN to train members of response teams and staff from Ministries of Health and Agriculture. Training topics should include outbreak investigations, cluster investigations, case-control investigations, and case-cohort investigations.

3.2 Infection Control

• Develop local-language public-health materials, in cooperation with HHS that inform local health-care workers and hospital administrators in priority counties about infection-control measures to control the spread of pandemic influenza in health-care facilities and in workplace health facilities. The information should include guidance about the appropriate use of antiviral drugs and vaccines.

• Develop and/or field-test and evaluate culturally and economically appropriate standards for infection-control practices and infrastructure for international health-care settings.

• Develop economical and culturally acceptable standardized preventive practices for the routine delivery of health-care that will be effective in prevention of health-care-associated influenza transmission during a pandemic. (*e.g.,* routine management standards for febrile respiratory illnesses).

• Develop and/or field-test and evaluate culturally and economically feasible community-based practices for the prevention of infection in community settings.

• Develop a costed national plan for delivering basic infection-control materials to and maintaining them in District and Provincial hospitals, with guidance for distribution and use in preparation for and during the anticipated disruptions caused by a pandemic of influenza.

• Develop, in partnership with international public-health agencies, instructional material for print or broadcast to target infection-control and nursing personnel in local languages to train them in appropriate cohorting, cleaning, worker protection and the use of protective equipment (*e.g.,* gloves, gowns, masks, *etc.*).

I. Funding Opportunity Description

Authority: Sections 301(a) and 307 of the Public Health Service Act (42 U.S.C. 241(a) and 42 U.S.C. 2421).

II. Award Information

The administrative and funding instrument to be used for this program will be the cooperative agreement in which substantial OGHA/HHS scientific and/or programmatic involvement is anticipated during the performance of the project. Under the cooperative

agreement, OGHA/HHS will support and/or stimulate awardee activities by working with them in a non-directive partnership role. HHS staff is substantially involved in the program activities, above and beyond routine monitoring. Through this cooperative agreement, HHS will collaborate in an advisory capacity with the award recipient, especially during the development and implementation of a mutually agreed-upon work plan. HHS will actively participate in periodic progress reviews and a final evaluation of the program.

Approximately $1,000,000.00 in fiscal year (FY) 2006 funds is available to support the agreement under the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006 which provides funds to combat a potential influenza pandemic both domestically and internationally.

The anticipated start date is October 27, 2006. There will only be one single award made from this announcement. The project period for this agreement is for three (3) years with a budget period of 12 months.

The award recipient must comply with all HHS management requirements for meeting participation and progress and financial reporting for this cooperative agreement. (Please *see* HHS Activities and Program Evaluation sections below.)

HHS/OS/OGHA activities for this program are as follows:

Pillar One

- Organize an orientation meeting with the award recipient to brief them on applicable U.S. Government expectations, regulations, policies and key management requirements, as well as report formats and contents.
- Review and approve the process used by the grantee to select key personnel and/or post-award subcontractors and/or sub grantees to be involved in the activities performed under this agreement.
- Review and approve the grantees' annual work plan and detailed budget.
- Review and approve the grantees' monitoring and evaluation plan, including for compliance with the performance management metrics and systems developed for U.S. Government and HHS assistance related to avian and pandemic influenza.
- Meet or teleconference on a regular basis, as necessary, with the grantee to assess quarterly technical and financial progress reports and modify plans as necessary.
- Meet on an annual basis with the grantee to review annual progress report for each U.S. Government fiscal year, and to review annual work plans and budgets for subsequent year.
- Provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This could include expert technical assistance and targeted training activities in specialized areas relevant to influenza pandemic preparedness, containment, and mitigation.

Pillar Two

- Provide technical assistance on techniques and reagents for the identification of influenza viruses. Annually provide the WHO reagent kit, produced and distributed by the WHO Collaborating Center for Influenza at HHS/OGHA;
- Providing epidemiological and laboratory training;
- Providing technical consultation on the development of in-country influenza-surveillance networks;
- Providing confirmation of antigenic analysis and more detailed characterization information on the influenza virus isolates submitted to HHS/OGHA, with written reports back to the National Influenza Center; and,
- Providing technical advice on the conduct of local and regional epidemiologic outbreak investigations.

Pillar Three

- Providing technical advice and training in the development of local rapid-response teams;
- Providing technical advice for the development of policies and capabilities for rapidly mobilizing materials from stockpiles of pharmaceuticals and commodities to the site of an outbreak; and,
- Providing technical advice and training in developing plans for infection control.

III. Eligibility Information

1. Eligible Applicants

This is a single source, cooperative agreement with the Ministry of Health of the Great Socialist People's Libyan Arab Jamahiriya (Libya). On November 1, 2005, President George W. Bush announced the U.S. *National Strategy for Pandemic Influenza*, and the following day Secretary Michael O. Leavitt released the HHS *Pandemic Influenza Plan*. One of the primary objectives of both documents is to leverage global partnerships to increase preparedness and response capabilities around the world ''with the intent of stopping, slowing or otherwise limiting the spread of a pandemic to the United States.''[1] Pillars Two and Three of the *National Strategy* set out the clear goals of ensuring the rapid reporting of outbreaks and containing outbreaks beyond the borders of the United States.

We rely upon our international partnerships, with the United Nations (UN); international organizations; and private, non-profit organizations, to amplify our efforts, and will engage them on a multilateral and bilateral basis. Our international effort to contain and mitigate the effects of an outbreak of pandemic influenza is a central component of our overall strategy. In many ways, the character and quality of the U.S. response and that of our international partners could play a determining role in the severity of a pandemic.

The International Partnership on Avian and Pandemic Influenza, launched by President Bush at the UN General Assembly in September 2005, stands in support of multinational organizations and national Governments. Members of the Partnership have agreed that the following ten principles will guide their efforts:

1. International cooperation to protect the lives and health of our people;
2. Timely and sustained, high-level, global, political leadership to combat avian and pandemic influenza;
3. Transparency in reporting of influenza cases in humans and in animals caused by viruses trains that have pandemic potential, to increase understanding and preparedness, and especially to ensure rapid and timely response to potential outbreaks;
4. Immediate sharing of epidemiological data and samples with the World Health Organization (WHO) and the international community to detect and characterize the nature and evolution of any outbreaks as quickly as possible, by using, where appropriate, existing networks and mechanisms;
5. Rapid reaction to address the first signs of accelerated transmission of H5N1 and other highly pathogenic influenza strains, so appropriate international and national resources can be brought to bear;
6. Prevent and contain an incipient epidemic through capacity- building and in-country collaboration with international partners;
7. Work in a manner complementary to and supportive of expanded cooperation with and appropriate support of key multilateral organizations (including the WHO, Food

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and Agriculture Organization, and the World Organization for Animal Health);

8. Timely coordination of bilateral and multilateral resource allocations; dedication of domestic resources (human and financial); improvements in public awareness; and development of economic and trade contingency plans;

9. Increased coordination and harmonization of preparedness, prevention, response and containment activities among nations, complementing domestics and regional preparedness initiatives, and encouraging where appropriate the development of strategic regional initiatives; and,

10. Actions based on the best available science.

Through the Partnership and other bilateral and multilateral initiatives, we will promote these principles and support the development of an international capacity to prepare for, detect, and respond to an influenza pandemic. Based on an overall public health analysis for pandemic flu, Libya requires assistance in detection, surveillance and other areas to manage and identify Avian Influenza.

Avian Influenza is a significant burden on neighboring countries of Libya. Egypt, for example, has consistently identified the H5N1 virus in poultry and humans resulting in human fatalities and the near decimation of its poultry industry. Other countries proximate to Libya which have reported human cases of H5N1 include Turkey, Iraq, and Azerbaijan. Sharing the same bird fly-ways and trading goods daily with many of its neighboring countries already affected by H5N1, Libya is at heightened risk. For these reasons, eligibility for this cooperative agreement is limited to the country of Libya.

Twenty-two years of sanctions has isolated Libya from the rest of the world and exacerbated the seriousness of the situation within Libya. The sanctions have prevented Libya from experiencing the benefits of medical training in state-of-the art practice and scientific collaborations leaving Libya vulnerable to an influenza pandemic.

Libya recently appointed its first Minister of Health and is in the early stages of developing a Ministry of Health. Previously, under the General People's Committee for Health and Environment of the Great Socialist People's Libyan Arab Jamahiriya, public health services did not in exist. With the control and governance of public health services now delegated to Libya's Ministry of Health, the Ministry of Health assumes responsibility for developing and building the capacity of the public health care system. Therefore, in accordance with the guidance presented here, and the demand to seek Ministers of Health of countries affected, the only eligible source for any efforts in building the capacity of the public health care system in the country of Libya is the Minister of Health.

2. Cost-Sharing or Matching

Although cost-sharing, matching funds, and cost participation are not a requirement of this agreement, preference may go to organizations that can leverage additional funds to contribute to program goals. If applicants receive funding from other sources to underwrite the same or similar activities, or anticipate receiving such funding in the next 12 months, they must detail how the disparate streams of financing complement each other.

3. Other - (If Applicable)

If an applicant requests a funding amount greater than the ceiling of the award range, HHS will consider the application non-responsive, and it will not enter into the review process. HHS will notify the applicant that the application did not meet the submission requirements.

IV. Application and Submission Information

1. Address To Request Application Package:

This Cooperative Agreement project uses the Application Form HHS Office of Public Health and Science (OPHS) OPHS–1, Revised 8/2004, enclosed in the application packet. Many different programs funded through the HHS Public Health Service (PHS) use this generic form. Some parts of it are not required; applicants must fill out other sections in a fashion specific to the program. Instructions for filling out OPHS–1, Revised 8/2004 will be included in the application packet. These forms are also available from the following sites by downloading from *https://egrants.osophs.dhhs.gov* and clicking on Grant Announcements, or *http://www.grants.gov/*; or by writing to Ms. Karen Campbell, Director, Office of Grants Management, Office of Public Health and Science, U.S. Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852; or by contacting the HHS/OPHS Office of Grants Management, at 1–(240) 453–8822. Please specify the HHS program(s) for which you are requesting an application kit.

ADDRESSES: Application kits may be requested from, and applications submitted to Karen Campbell, Director, Office of Grants Management, Office of Public Health and Science (OPHS), Department of Health and Human Services, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852.

2. Content and Form of Application Submission

Application Materials

A separate budget page is required for the budget year requested. Applicants must submit with the proposal a line-item budget (SF 424A) with coinciding justification to support each of the budget years. These forms will represent the full project period of Federal assistance requested. HHS will not favorably consider proposals submitted without a budget and justification for each budget year requested in the application. Specific instructions for submitting a detailed budget for this application appear in the application packet. If additional information and/or clarification are necessary, please contact the HHS/OPHS Office of Grants Management identified in Section VII of this announcement.

A Project Abstract submitted on 3.5 inch floppy disk must accompany all applications. The abstract must be typed, single-spaced, and not exceed two pages. Reviewers and staff will refer frequently to the information contained in the abstract, and therefore it should contain substantive information about the proposed projects in summary form. A list of suggested keywords and a format sheet for your use in preparing the abstract will be included in the application packet.

A Project Narrative must accompany all grant applications. In addition to the instructions provided in OPHS–1 (Rev 8/2004) for project narrative, the specific guidelines for the project narrative appear in the program guidelines. Format requirements are the same as for the Project Abstract Section; margins should be one inch at the top and one inch at the bottom and both sides; and typeset must be no smaller than 12 cpi, and not reduced. Applicants should type biographical sketches either on the appropriate form or on plain paper, and should not exceed two pages, with publications listed limited only to those that are directly relevant to this project.

Application Format Requirements

If applying on paper, the entire application may not exceed 80 pages in length, including theabstract, project and budget narratives, face page,

attachments, any appendices and letters of commitment and support. Applicants must number pages consecutively.

HHS/OGHA will deem as non-compliant applications submitted electronically that exceed 80 pages when printed and will return all non-compliant applications to the applicant without further consideration.

(a) *Number of Copies:* Please submit one (1) original and two (2) unbound copies of the application. Please do not bind or staple the application. Application must be single- sided.

(b) *Font:* Please use an easily readable serif typeface, such as Times Roman, Courier, or CG Times. Applicants must submit the text and table portions of the application in not less than 12-point and 1.0 line spacing. HHS/OGHA might return applications that do not adhere to 12-point font requirements.

(c) *Paper Size and Margins:* For scanning purposes, please submit the application on 8½″ x 11″ white paper. Margins must be at least one (1) inch at the top, bottom, left and right of the paper. Please left-align text.

(d) *Numbering:* Please number the pages of the application sequentially from page one (face page) to the end of the application, including charts, figures, tables, and appendices.

(e) *Names:* Please include the name of the applicant on each page.

(f) *Section Headings:* Please put all section headings flush left in bold type.

Application Format

An application for funding must consist of the following documents in the following order:

i. *Application Face Page:* Public Health Service (PHS) Application Form OPHS–1, provided with the application package. Prepare this page according to instructions provided in the form itself.

DUNS Number

An applicant organization is required to have a Data Universal Numbering System (DUNS) number in order to apply for a grant from the Federal Government. The DUNS number is a unique nine-character identification number provided by the commercial company, Dun and Bradstreet. There is no charge to obtain a DUNS number. Information about obtaining a DUNS number can be found at *https://www.dnb.com/product/eupdate/requestOptions.html* or call 1–866–705–5711. Please include the DUNS number next to the OMB Approval Number on the application face page. An application *will not* be reviewed without a DUNS number.

Additionally, the applicant organization will be required to register with the Federal Government's Central Contractor Registry (CCR) in order to do electronic business with the Federal Government. Information about registering with the CCR can be found at *http://www.hrsa.gov/grants/ccr.htm*.

Finally, an applicant applying electronically through Grants.gov is required to register with the Credential Provider for Grants.gov. Information about this requirement is available at *http://www.grants.gov/CredentialProvider*

An applicant applying electronically through the OPHS E-Grants System is required to register with the provider. Information about this requirement is available at *https://egrants.osophs.dhhs.gov*.

ii. *Table of Contents:* Provide a Table of Contents for the remainder of the application (including appendices), with page numbers.

iii. *Application Checklist:* Application Form OPHS–1, provided with the application package.

iv. *Budget:* Application Form OPHS–1, provided with the application package.

v. *Budget Justification:* The amount of financial support (direct costs) that an applicant is requesting from the Federal granting agency for the first year is to be entered on the Face Sheet of Application Form PHS 5161–1, Line 15a. The application should include funds for electronic mail capability unless access by Internet is already available. The amount of financial support (direct costs) entered on the SF 424 is the amount an applicant is requesting from the Federal granting agency for the project year.

Personnel Costs: Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percent full time equivalency, annual salary, and the exact amount requested.

Fringe Benefits: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plan, tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project.

Travel: List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. The budget should also reflect the travel expenses associated with participating in meetings and other proposed trainings or workshops.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the programs goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of computers and furniture items.

Supplies: List the items that the project will use. In this category, separate office supplies from medical and educational purchases. Office supplies could include paper, pencils, and the like; medical supplies are syringes, blood tubes, plastic gloves, *etc.*, and educational supplies may be pamphlets and educational videotapes. Remember, they must be listed separately.

Subcontracts: To the extent possible, all subcontract budgets and justifications should be standardized, and contract budgets should be presented by using the same object class categories contained in the Standard Form 424A. Provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables.

Other: Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, grantee rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.)

vi.*Staffing Plan and Personnel Requirements:* An applicant must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in Appendix B. Copies of biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be included in Appendix C.

vii. *Project Abstract:* Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed grant project including the needs to be addressed, the proposed services, and the population group(s) to be served.

Please place the following at the top of the abstract:

- Project Title;
- Applicant Name;
- Address;

• Contact Phone Numbers (Voice, Fax);
• E-Mail Address; and,
• Web site Address, if applicable.

The project abstract must be single-spaced and limited to two pages in length.

viii. *Program Narrative:* This section provides a comprehensive framework and description of all aspects of the proposed program. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Use the following section headers for the Narrative:

Introduction

This section should briefly describe the purpose of the proposed project.

Work Plan

Describe the activities or steps that will be used to achieve each of the activities proposed in the methodology section. Use a time line that includes each activity and identifies responsible staff.

Resolution of Challenges

Discuss challenges that are likely to be encountered in designing and implementing the activities described in the Work Plan, and approaches that will be used to resolve such challenges.

Evaluation and Technical Support Capacity

Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature.

Organizational Information

Provide information on the applicant agency's current mission and structure, scope of current activities, and an organizational chart, and describe how these all contribute to the ability of the organization to conduct the program requirements and meet program expectations.

ix. *Appendices:* Please provide the following items to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Be sure each appendix is clearly labeled.

1. *Appendix A:* Tables, Charts, *etc.*

To give further details about the proposal.

2. *Appendix B:* Job Descriptions for Key Personnel.

Keep each to one page in length as much as is possible. Item 6 in the Program Narrative section of the PHS 5161–1 Form provides some guidance on items to include in a job description.

3. *Appendix C:* Biographical Sketches of Key Personnel.

Include biographical sketches for persons occupying the key positions described in Appendix B, not to exceed two pages in length. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

4. *Appendix D:* Letters of Agreement and/or Description(s) of Proposed/Existing Contracts (project specific). Provide any documents that describe working relationships between the applicant agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverable. Letters of agreements must be dated.

5. *Appendix E:* Project Organizational Chart.

Provide a one-page figure that depicts the organizational structure of the project, including subcontractors and other significant collaborators.

6. *Appendix F:* Other Relevant Documents.

Include here any other documents that are relevant to the application, including letters of supports. Letters of support must be dated.

3. Submission Dates & Times

The Office of Public Health and Science (OPHS) provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of applications submitted using any of these mechanisms. Applications submitted to the OPHS Office of Grants Management after the deadlines described below will not be accepted for review. Applications which do not conform to the requirements of the grant announcement will not be accepted for review and will be returned to the applicant.

Applications may only be submitted electronically via the electronic submission mechanisms specified below. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, will not be accepted for review. While applications are accepted in hard copy, the use of the electronic application submission capabilities provided by the OPHS eGrants system or the Grants.gov Web site Portal is encouraged.

Electronic grant application submissions must be submitted no later than 5:00 p.m. Eastern Time on the deadline date specified in the **DATES** section of the announcement using one of the electronic submission mechanisms specified below. All required hard-copy original signatures and mail-in items must be received by the OPHS Office of Grants Management no later that 5 p.m. Eastern Time on the next business day after the deadline date specified in the **DATES** section of the announcement.

Applications will not be considered valid until all electronic application components, hard copy original signatures, and mail-in items are received by the OPHS Office of Grants Management according to the deadlines specified above. Application submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process, and to submit early on the due date or before. This will aid in addressing any problems with submissions prior to the application deadline.

Electronic Submissions Via the Grants.gov Web Site Portal

The Grants.gov Web site Portal provides organizations with the ability to submit applications for OPHS grant opportunities. Organizations must successfully complete the necessary registration processes in order to submit an application. Information about this system is available on the Grants.gov Web site, *http://www.grants.gov*.

In addition to electronically submitted materials, applicants may be required to submit hard copy signatures for certain Program related forms, or original materials as required by the announcement. It is imperative that the applicant review both the grant announcement, as well as the application guidance provided within the Grants.gov application package, to determine such requirements. Any required hard copy materials, or documents that require a signature, must be submitted separately via mail to the OPHS Office of Grants Management, and, if required, must contain the original signature of an individual authorized to act for the applicant agency and the obligations imposed by the terms and conditions of the grant award.

Electronic applications submitted via the Grants.gov Web site Portal must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. All

required mail-in items must received by the due date requirements specified above. Mail-In items may only include publications, resumes, or organizational documentation.

Upon completion of a successful electronic application submission via the Grants.gov Web site Portal, the applicant will be provided with a confirmation page from Grants.gov indicating the date and time (eastern time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is critical that the applicant print and retain this confirmation for their records, as well as a copy of the entire application package.

All applications submitted via the Grants.gov Web site Portal will be validated by Grants.gov. Any applications deemed ≥Invalid≥ by the Grants.gov Web site Portal will not be transferred to the OPHS eGrants system, and OPHS has no responsibility for any application that is not validated and transferred to OPHS from the Grants.gov Web site Portal. Grants.gov will notify the applicant regarding the application validation status. Once the application is successfully validated by the Grants.gov Web site Portal, applicants should immediately mail all required hard-copy materials to the OPHS Office of Grants Management to be received by the deadlines specified above. It is critical that the applicant clearly identify the Organization name and Grants.gov Application Receipt Number on all hard-copy materials.

Once the application is validated by Grants.gov, it will be electronically transferred to the OPHS eGrants system for processing. Upon receipt of both the electronic application from the Grants.gov Website Portal, and the required hard-copy mail-in items, applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of the application submitted using the Grants.gov Web site Portal.

Applicants should contact Grants.gov regarding any questions or concerns regarding the electronic application process conducted through the Grants.gov Web site Portal.

Electronic Submissions via the OPHS eGrants System

The OPHS electronic grants management system, eGrants, provides for applications to be submitted electronically. Information about this system is available on the OPHS eGrants Web site, *https://egrants.osophs.dhhs.gov*, or may be requested from the OPHS Office of Grants Management at (240) 453–8822.

When submitting applications via the OPHS eGrants system, applicants are required to submit a hard copy of the application face page (Standard Form 424) with the original signature of an individual authorized to act for the applicant agency and assume the obligations imposed by the terms and conditions of the grant award. If required, applicants will also need to submit a hard copy of the Standard Form LLL and/or certain Program related forms (*e.g.,* Program Certifications) with the original signature of an individual authorized to act for the applicant agency.

Electronic applications submitted via the OPHS eGrants system must contain all completedonline forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. The applicant may identify specific mail-in items to be sent to the Office of Grants Management separate from the electronic submission; however these mail-in items must be entered on the eGrants Application Checklist at the time of electronic submission, and must be received by the due date requirements specified above. Mail-in items may only include publications, resumes, or organizational documentation.

Upon completion of a successful electronic application submission, the OPHS eGrants system will provide the applicant with a confirmation page indicating the date and time (eastern time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission including all electronic application components, required hardcopy original signatures, and mail-in items, as well as the mailing address of the OPHS Office of Grants Management where all required hard copy materials must be submitted. As items are received by the OPHS Office of Grants Management, the electronic application status will be updated to reflect the receipt of mail-in items. It is recommended that the applicant monitor the status of their application in the OPHS eGrants system to ensure that all signatures and mail-in items are received.

Mailed or Hand-Delivered Hard Copy Applications

Applicants who submit applications in hard copy (via mail or hand-delivered) are required to submit an original and two copies of the application. The original application must be signed by an individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award.

Mailed or hand-delivered applications will be considered as meeting the deadline if they are received by the OPHS Office of Grant Management on or before 5 p.m. eastern time on the deadline date specified in the **DATES** section of the announcement. The application deadline date requirement specified in this announcement supersedes the instructions in the OPHS–1. Applications that do not meet the deadline will be returned to the applicant unread. Applicants should submit their applications to the following address: Director, Office of Grants Management, Office of Public Health and Science, U.S. Department of Health and Human Services, 1101 Wootten Parkway, Suite 550, Rockville, MD 20852.

4. Intergovernmental Review

This program is not subject to the review requirements of Executive Order 12372, Intergovernmental Review of Federal Programs.

5. Funding Restrictions

Allowability, allocability, reasonableness, and necessity of direct costs that may be charged are outlined in the following documents: OMB–21 (Institutes of Higher Education); OMB Circular A–122 (Nonprofit Organizations) and 45 CFR Part 74, Appendix E (Hospitals). Copies of these circulars are available on the Internet at the following address: *http://www.whitehouse.gov/omb*. No pre-award costs are allowed.

6. Other Submission Requirements

N/A.

V. Application Review Information

1. Criteria

The application will be screened by OGHA staff for completeness and for responsiveness to the program guidance. The applicant should pay strict attention addressing these criteria, as they are the basis upon which applications will be judged. An application judged to be non-responsive or incomplete will be returned to the applicant without review.

An application that is complete and responsive to the guidance will be evaluated for scientific and technical merit by an appropriate peer review group specifically convened for this solicitation and in accordance with HHS policies and procedures. As part of the initial merit review, all applications will receive a written critique. All applications recommended for approval

will be discussed fully by the ad hoc peer review group and assigned a priority score for funding. Eligible applications will be assessed according the following criteria:

(1) Technical Approach (40 Points)

- The applicant's presentation of a sound and practical technical approach for executing the requirements with adequate explanation, substantiation and justification for methods for handling the projected needs of the partner institution.
- The successful applicant must demonstrate a clear understanding of the scope and objectives of the cooperative agreement, recognition of potential difficulties that could arise in performing the work required, presentation of adequate solutions, and understanding of the close coordination necessary between the HHS/OGHA, the International Partnership on Avian and Pandemic Influenza, United Nations agencies, and the WHO Secretariat.
- Applicants must submit a strategic plan that outlines the schedule of activities and expected products of the Group's work with benchmarks at months six and 12. The strategic plan should specifically address the expected progress of the Quality of Care program.

(2) Personnel Qualifications and Experience (20 Points)

- Project Leadership— For the technical and administrative leadership of the project requirements, successful applicants must demonstrate documented training, expertise, relevant experiences, leadership/management skills, and the availability of a suitable overall project manager and surrounding management structure to successfully plan and manage the project. The successful applicant will provide documented history of leadership in the establishment and management of training programs that involve training of health-care professionals in countries other than the United States. Expertise in maternal and child health care, including documented training, expertise, relevant experience, leadership skills, and medical expertise specific to maternal and child health. Documented managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to manage successfully the project, including subcontractor and/or consultant efforts, if applicable, as evidence by the management plan and demonstrated by previous relevant experience.
- Partner Institutions and other Personnel—Applicants should provide documented evidence of availability, training, qualifications, expertise, relevant experience, education and competence of the scientific, clinical, analytical, technical and administrative staff and any other proposed personnel (including partner institutions, subcontractors and consultants), to perform the requirements of the work activities as evidenced by resumes, endorsements and explanations of previous efforts.
- Staffing Plan—Applicants should submit a staffing plan for the conduct of the project, including the appropriateness of the time commitment of all staff and partner institutions, the clarity and appropriateness of assigned roles, and lines of authority. Applicants should also provide an organizational chart for each partner institution named in the application showing relationships among the key personnel.
- Administrative and Organizational Framework—Adequacy of the administrative and organizational framework, with lines of authority and responsibility clearly demonstrated, and adequacy of the project plan, with proposed time schedule for achieving objectives and maintaining quality control over the implementation and operation of the project. Adequacy of back-up staffing and the evidence that they will be able to function as a team. The framework should identify the institution that will assume legal and financial responsibility and accountability for the use and disposition of funds awarded on the basis of this RFA.

(3) Experience and Capabilities of the Organization (30 Points)

- Applicant should submit documented relevant experience of the organization in managing projects of similar complexity and scope of the activities.
- Clarity and appropriateness of lines of communication and authority for coordination and management of the project. Adequacy and feasibility of plans to ensure successful coordination of a multiple-partner collaboration.
- Documented experience recruiting qualified medical personnel for projects of similar complexity and scope of activities.

(4) Facilities and Resources (10 Points)

- Documented availability and adequacy of facilities, equipment and resources necessary to carry out the activities specified under Program Requirements.

VI. Award Administration Information

1. Award Notices

HHS/OGHA does not release information about individual applications during the review process until we have made final funding decisions. When HHS/OGHA has made these decisions, we will notify applicants by letter regarding the outcome of their applications. The official document to notify an applicant HHS/OGHA has approved and funded an application is the Notice of Award, which specifies to the recipient the amount of money awarded, the purpose of the agreement, the terms and conditions of the agreement, and the amount of funding, if any, the recipient will contribute to the project costs.

2. Administrative and National Policy Requirements

The regulations set out at 45 CFR parts 74 and 92 are the U.S. Department of Health and Human Services (HHS) rules and requirements that govern the administration of grants. Part 74 is applicable to all recipients except those covered by part 92, which governs awards to State and Local governments. Applicants funded under this announcement must be aware of and comply with these regulations. The CFR volume that includes parts 74 and 92 are available from the following Internet address: *http://www.access.gpo.gov/nara/cfr/waisidx_03/45cfrv1_03.html.*

3. Reporting

The projects is required to have an evaluation plan, consistent with the scope of the proposed project and funding level that conforms to the project's stated goals and objectives. The evaluation plan should include both a process evaluation to track the implementation of project activities and an outcome evaluation to measure changes in knowledge and skills that can be attributed to the project. Project funds may be used to support evaluation activities.

In addition to conducting their own evaluation of projects, the successful applicant must be prepared to participate in an external evaluation, to be supported by OGHA/HHS and conducted by an independent entity, to assess efficiency and effectiveness for the project funded under this announcement.

Within 30 days following the end of each of quarter, submit a performance report no more than ten pages in length must be submitted to OGHA/HHS. A sample quarterly performance report will be provided at the time of notification of award. At a minimum,

quarterly performance reports should include:

- Concise summary of the most significant achievements and problems encountered during the reporting period, *e.g.* number of training courses held and number of trainees.
- A comparison of work progress with objectives established for the quarter using the grantee's implementation schedule, and where such objectives were not met, a statement of why they were not met.
- Specific action(s) that the grantee would like the OGHA/HHS to undertake to alleviate a problem.
- Other pertinent information that will permit monitoring and overview of project operations.
- A quarterly financial report describing the current financial status of the funds used under this award. The awardee and OGHA will agree at the time of award for the format of this portion of the report.

Within 90 days following the end of the project period a final report containing information and data of interest to the Department of Health and Human Services, Congress, and other countries must be submitted to OGHA/HHS. The specifics as to the format and content of the final report and the summary will be sent to successful applicants. At minimum, the report should contain:

- A summary of the major activities supported under the agreement and the major accomplishments resulting from activities to improve mortality in partner country.
- An analysis of the project based on the problem(s) described in the application and needs assessments, performed prior to or during the project period, including a description of the specific objectives stated in the grant application and the accomplishments and failures resulting from activities during the grant period.

Quarterly performance reports and the final report may be submitted to: Mr. DeWayne Wynn, Grants Management Specialist, Office of Grants Management, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852, phone (240) 453–8822.

A Financial Status Report (FSR) SF–269 is due 90 days after the close of each 12-month budget period and submitted to OPHS–Office of Grants Management.

VII. Agency Contacts

For assistance on administrative and budgetary requirements, please contact: Mr. DeWayne Wynn, Grants Management Specialist, Office of Grants Management, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852, phone (240) 453–8822.

For assistance with questions regarding program requirements, please contact the following: David Smith, PhD, Office of Global Health Affairs, U.S. Department of Health and Human Services, 5600 Fishers Lane, Suite 18–101, Rockville, MD 20857; Phone Number: 1–301–443–1774.

VIII. Tips for Writing a Strong Application

Include DUNS Number. You must include a DUNS Number to have your application reviewed. HHS/OGHA *will not* review applications without a DUNS number. To obtain a DUNS number, go to *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please include the DUNS number next to the OMB Approval Number on the application face page.

Keep your audience in mind. Reviewers will use only the information contained in the application to assess the application. Be sure the application and responses to the program requirements and expectations are complete and clearly written. Do not assume reviewers are familiar with the applicant organization. Keep the review criteria in mind when writing the application.

Start preparing the application early. Allow plenty of time to gather required information from various sources.

Follow the instructions in this guidance carefully. Place all information in the order requested in the guidance. If the applicant does not place information in the requested order, the application might receive a lower score.

Be brief, concise, and clear. Make your points understandable. Provide accurate and honest information, including candid accounts of problems and realistic plans to address them. If any required information or data is omitted, explain why. Make sure the information provided in each table, chart, attachment, *etc.*, is consistent with the proposal narrative and information in other tables.

Be organized and logical. Many applications fail to receive a high score because the reviewers cannot follow the thought process of the applicant or because parts of the application do not fit together.

Be careful in the use of appendices. Do not use the appendices for information that is required in the body of the application. Be sure to cross-reference all tables and attachments located in the appendices to the appropriate text in the application.

Carefully proofread the application. Misspellings and grammatical errors will impede reviewers in understanding the application. Be sure pages are numbered (including appendices), and follow page limits. Limit the use of abbreviations and acronyms, and define each one at its first use and periodically throughout the application.

Dated: September 26, 2006.

Sandra R. Manning,

Deputy Director for Operations, Office of Global Health Affairs, U.S. Department of Health and Human Services.

[FR Doc. E6–16181 Filed 9–29–06; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA) will hold a meeting. This meeting is open to the public. A description of the Council's functions is included with this notice.

DATES: October 16, 2006, 8 a.m. to 5 p.m., and October 17, 2006, 8 a.m. to 4 p.m.

ADDRESSES: Howard University, Armour J. Blackburn University Center, 2397 Sixth Street, NW., Washington, DC 20059.

FOR FURTHER INFORMATION CONTACT: Dana Ceasar, Program Assistant, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 733E, Washington, DC 20201; (202) 690–2470 or visit the Council's Web site at *http://www.pacha.gov.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to (a) promote effective prevention of HIV disease, (b) advance research on HIV and AIDS, and (c)