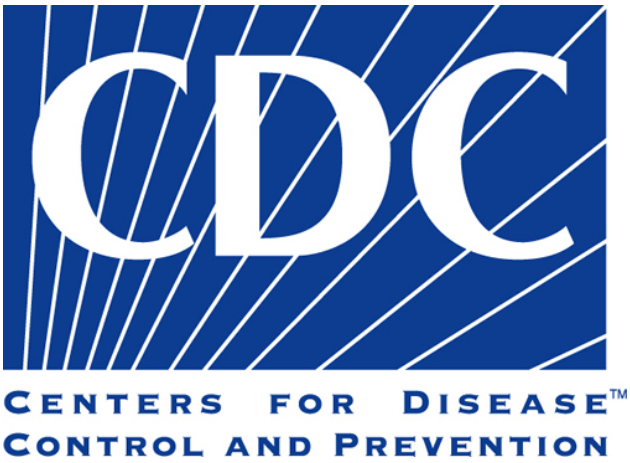


Centers for Disease Control and Prevention

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES

Surveillance and Response to Avian and Pandemic Influenza by National Health Authorities outside the United States

CDC-RFA-IP21-2101

Application Due Date: 05/04/2021

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Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-IP21-2101. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

Surveillance and Response to Avian and Pandemic Influenza by National Health Authorities outside the United States

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

New-Type 1

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-IP21-2101

E. Assistance Listings Number:

93.318

F. Dates:

1. Due Date for Letter of Intent (LOI):

NA

2. Due Date for Applications:
05/04/2021
11:59 p.m. U.S. Eastern Time, at www.grants.gov.

3. Due Date for Informational Conference Call:

3/23/2021 – 7:00 pm ET US; 3/24/2021 – 7:00 am ET US; 3/24/2021 – 10:00 am ET US

Zoom information for CDC-RFA-IP21-2101 calls is below:

March 23, 2021 - 7:00 pm ET US:
Join by Zoom Meeting:
https://cdc.zoomgov.com/j/1602552301?pwd=aFVGdDM1bGFvQmhJU3dzNDVNNXlMUT09
Meeting ID: 160 255 2301
Passcode: Y2WzxG=*

Join by phone:
Find your local number: https://cdc.zoomgov.com/u/aneWXnDPw
Meeting ID: 160 255 2301
Passcode: 83004646

Join by SIP:
1602552301@sip.zoomgov.com
Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 255 2301
Passcode: 83004646

March 24, 2021 - 7:00 am ET US:
Join by Zoom Meeting:
https://cdc.zoomgov.com/j/1604738847?pwd=UkhxSWRreXEvaTljSnh6TWdOT3JiUT09
Meeting ID: 160 473 8847
Passcode: 51bR%@3v

Join by phone:
Find your local number: https://cdc.zoomgov.com/u/adu47vB2r8
Meeting ID: 160 473 8847
Passcode: 22239399

Join by SIP:
1604738847@sip.zoomgov.com
Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 473 8847

Passcode: 22239399

March 24, 2021 - 10:00 am ET US:
Join by Zoom Meeting:
https://cdc.zoomgov.com/j/1609424763?pwd=QkcxTEI0Z2kyOWdsUWJPZ2FlSjc0Zz09
Meeting ID: 160 942 4763
Passcode: U@9ry5=D

Join by phone:
Find your local number: https://cdc.zoomgov.com/u/adzF8LfotM
Meeting ID: 160 942 4763
Passcode: 62330787

Join by SIP:
1609424763@sip.zoomgov.com
Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 942 4763
Passcode: 62330787

G. Executive Summary:

1. Summary Paragraph

This Notice of Funding Opportunity (NOFO) will support recipients to improve or maintain capacity to conduct routine influenza surveillance and detect and respond to pandemic influenza. A second intent is to ensure capacity to respond to highly pathogenic viruses transmissible among humans, including epidemiologic and virologic detection and to respond and monitor influenza virus changes, as well as identify outbreaks of severe respiratory illness syndromes. A third intent is to help strengthen connections between national institutions, especially National Influenza Centers (NIC), to fully participate in the WHO Global Influenza Surveillance and Response System (GISRS), and maintain capacity to share specimens, clinical and epidemiologic data related to influenza circulation.
Finally, this NOFO will support monitoring highly pathogenic viruses and bacteria transmissible to humans and identification of outbreaks of severe respiratory illness.
This program aligns with the Health and Human Services (HHS) Pandemic Influenza Operational Plan, the President's National Strategy for Pandemic Influenza, the principles of the International Partnership on Avian and Pandemic Influenza, the International Health Regulations (IHR) (2005) Joint External Evaluation Process (JEE), CDC Strategic Framework Priorities of "Securing Global Health and America's Preparedness", "Eliminating Disease" and "Ending Epidemics," and NCIRD's performance goal "Protect Americans from infectious diseases".

a. Eligible Applicants:
Open Competition

b. Funding Instrument Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards

60

d. Total Period of Performance Funding:
$ 120,000,000
Total period of performance funding: Up to $120,000,000

Component 1 (Influenza Core Activities): up to $85,000,000 (Component 1 estimated at $13,000,000 in Year One)

Component 2 (Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen activity): up to $10,000,000 (Component 2 is estimated at $1,000,000 in Year One)

Component 3 (Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies): Up to $15,000,000 (Component 3 is expected to be approved but unfunded). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for a designated public health threat, CDC can process applications and award funds in a timely manner. In the event that no designated public health threat is declared, no awards will be made.

Final award amounts may be less than requested. Funding is subject to the availability of appropriated funds.

e. Average One Year Award Amount:
$ 400,000
This announcement contains two separate annual components, and a third component aimed at providing a quick funding mechanism for pre-approved recipients faced with an identified public health threat.

The average Year One Award Amount refers to the two annual components:

Estimated Award Ranges:
Influenza Core Activities (Component 1): $50,000 to $200,000 award range

Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen (Component 2): $50,000 to $200,000 award range.

Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies (Component 3): Approved but Unfunded:
$20,000 - $1,000,000 award range**.** Funds will only be available if and when a public health emergency is declared.

Potential amounts are subject to the availability of funds.

f. Total Period of Performance Length:
5

g. Estimated Award Date:
August 31, 2021

h. Cost Sharing and / or Matching Requirements:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Spread of infectious diseases between countries remains a major global threat. Specifically, influenza epidemics are difficult to predict but recognized as recurring yearly events that can, and do, have serious global health and economic consequences. Influenza surveillance is essential in understanding the magnitude and impact of these annual influenza epidemics, to select influenza vaccine components, and to detect novel influenza viruses that may signal the start of a pandemic. Maintaining a worldwide surveillance network that systematically collects and analyzes data over time is an important step in addressing the potential risk of an influenza pandemic.

Since November 2005, when the United States (U.S.) National Strategy for Pandemic Influenza was announced and the HHS Pandemic Influenza Plan released, the U.S. Centers for Disease Control and Prevention (CDC) has leveraged global partnerships to increase preparedness and response capabilities around the world with the intent of stopping, slowing or otherwise limiting the spread of an influenza pandemic to the U.S..

For the last 16 years, CDC has worked with public health partners around the world to support and help establish or enhance countries' capacity to maintain virologic and epidemiologic influenza surveillance systems and gather strong baseline data that can be used to monitor disease severity and quickly identify outbreaks. Through cooperative agreements and technical and logistical support to countries, CDC's Influenza Division continues to work to increase worldwide capacity to detect, prevent and respond to global threats.

The importance of routine surveillance systems was recently emphasized during the COVID-19 pandemic in which components of influenza surveillance systems worldwide were utilized to detect, prevent, and respond to SARS-coronavirus-2. The rapid detection of pathogenic respiratory viruses with pandemic potential requires both a good routine surveillance system and pandemic preparedness. Additionally, the rapid spread of COVID-19 underscores the importance of routine surveillance and the connection between viruses in animals and their transmission to humans.

CDC will continue to support routine influenza surveillance and the development and maintenance of international capacity to detect and respond to identified influenza pandemics; support coordination and communication of the animal human interface facilitating the capacity to detect and monitor novel viruses occurring in animals; and support capacity development to detect and respond to the spread of non-influenza respiratory viruses and bacteria.

This NOFO has two annual components designed: 1) to build and/or maintain influenza surveillance and monitor novel viruses in animals (Influenza Activities); 2) to implement non-influenza pathogen surveillance (Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen). A third component is designed to support a response to a designated emergency event (Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies).

Applicants **must apply** for the Influenza Activities component and **may apply** for additional components. Applicants **must be approved for funding for Influenza Activities** to be considered for funding within other components.

The strategies and activities outlined in this NOFO directly support the mission of the National Center for Immunization and Respiratory Diseases (NCIRD) to prevent disease, disability, and death through immunization and by control of respiratory and related diseases.

b. Statutory Authorities
Section 307 of the Public Health Service Act, as amended (42 U.S.C. § 242l).

c. Healthy People 2030
This work contributes to accomplishing the following CDC Healthy People 2030 goals: Improve health by preventing, detecting, and responding to public health events worldwide. Healthy People 2030 focuses on increasing disease monitoring and prevention efforts and on improving global capacity to prevent, detect, and respond to public health threats including improvements in surveillance and laboratory systems.
Details can be found: https://health.gov/healthypeople/objectives-and-data/browse-objectives/global-health

d. Other National Public Health Priorities and Strategies
Measurable outcomes will support the HHS Pandemic Preparedness Operational plan, the President's National Strategy for Pandemic Influenza, the principles of the International Partnership on Avian and Pandemic Influenza, the CDC Strategic Priorities supporting global health preparedness and the National Center for Immunization and Respiratory Diseases (NCIRD) goal: Protect Americans from infectious diseases. Additionally, outcomes support the Global Health Security Agenda (https://ghsagenda.org) mandate to address priorities and gaps in efforts to build and improve country capacity and leadership in the prevention and early detection of, and effective response to, infectious disease threats.

e. Relevant Work
This NOFO continues work initiated in 2004 and continued under recent funding opportunities CDC-RFA-IP19-1902, CDC-RFA-IP16-1603. These agreements were developed to enhance the ability and capacity of foreign governments to conduct surveillance for seasonal influenza and to detect and respond to pandemic influenza threats. The proposed NOFO complements current global pandemic preparedness work and seeks to strengthen the capacity of national health authorities and partners to detect and respond more broadly to respiratory pathogen outbreaks like the response to the SARS-coronavirus-2 and other viral and bacterial pathogens utilizing systems developed to support surveillance for influenza.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

CDC-RFA-IP21-2101 Logic Model: Surveillance and Response to Avian and Pandemic Influenza by National Health Authorities outside the United States

The Logic Model shows the high-level strategies and activities, as well as short-term and long-term outcomes. Please see the Outcomes (ii) and Strategies and Activities (iii) sections below for more detailed information.

Bold indicates period of performance outcome

Component 1 – Influenza Core Activities

Strategies/Activities	Outputs	Short-Term Outcomes	Long-Term Outcomes
Strategy 1 - Infrastructure: Build/establish or maintain current integrated national influenza surveillance system Develop standard operating procedures	*Written and published strategic plan identifying national surveillance objectives ***Action items identified, and a plan developed** *** Documentation of human and financial resources needed** ***Establish mechanisms for the sharing of information about zoonoses between the ministries of health (MOH) and ministries of agriculture (MOA)**	***National surveillance objectives established and published** ***Improved communication between MOH and MOA**	***Established national influenza surveillance system** ***Country ownership of and sustainability of integrated surveillance system** ***Improved MOH and MOA coordination**
Strategies/Activities	**Outputs**	**Short-Term Outcomes**	**Long-Term Outcomes**
Strategy 2 - Epidemiological Surveillance: Establish/improve and/or maintain epidemiologic capacity Enhance	*Weekly reporting to WHO GISRS (FluID) *Estimate (numbers or rates) of respiratory illness or deaths due to influenza (burden of disease) *Use epidemiological	***Improved epidemiological surveillance system performance** *Improved stakeholder engagement and coordination	***Strong, capable data-driven surveillance workforce** *Robust quality data used for longitudinal analysis of influenza activity

epidemiological surveillance capacity Coordinate communication with MOA to implement or maintain Animal Human Interface/OneHealth surveillance system	data to build evidence base for influenza prevention and control policies	***Surveillance staff skilled in data collection, quality review, analysis and dissemination** ***Improved understanding of influenza activity** ***Zoonotic surveillance platform enhanced**	*Improved national and interconnected global networks ***Improved use of surveillance data to inform public health actions** ***Sustained ability to monitor the severity of epidemic and pandemic influenza associated illnesses** ***Improved awareness and response to zoonotic (novel) influenza human infections.**
Strategies/Activities	**Outputs**	**Short-Term Outcomes**	**Long-Term Outcomes**
Strategy 3 - Laboratory Surveillance: Maintain or improve laboratory capacity Enhance animal zoonotic influenza virus knowledge to support Animal Human Interface/OneHealth platform	*Documented analysis of existing capabilities and enhancement strategy *Consistent weekly reporting to WHO (FluNet and GISRS) *Shipments of influenza specimens received by designated WHO Collaborating Center (CC) *Influenza-positive samples available for use in vaccine strain selections	*** Improved testing capacity for influenza specimens, both quality and quantity** ***Improved or maintained acceptable performance on external quality assurance panels** ***Improved performance and consistent weekly influenza specimen testing** ***Timely notification to World Organization for**	*Well prepared and established laboratory testing and surveillance program ***Data available for analysis on influenza seasonality and severity and identification of novel viruses** *Achievement and/or improvement of WHO NIC testing functions and ability to respond to outbreak and pandemics ***Improved**

		Animal Health (OIE)	**international contribution of specimen data used for vaccine composition decision-making (VCM)** ***Increased capacity to identify new and emerging influenza viruses in animals and humans, and ability to identify pandemic threats**
Strategies/Activities	**Outputs**	**Short-Term Outcomes**	**Long-Term Outcomes**
Strategy 4 - Pandemic Preparedness: Develop and maintain preparedness plan	*Pandemic Plan created, reviewed and approved and published	***Improved awareness of pandemic influenza preparedness & response capacity** ***Improved adherence to the WHO Pandemic Influenza Preparedness (PIP) framework**	***Updated national pandemic preparedness and response plan** *Planned exercises used to test various components of plan, including monitoring

Component 2: Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable pathogens

Strategies/Activities	**Outputs**	**Short-Term Outcomes**	**Long-Term Outcomes**
Strategy 1 - Epidemiological Surveillance: Establish/improve or maintain epidemiologic capacity Evaluate the impact of interventions	*Strengths and gaps identified, and plan developed to address them *Weekly reporting to ministry of health	*Improved stakeholder engagement and coordination ***Surveillance staff skilled in data collection, data quality review, and data dissemination skills**	***Strong and capable data-driven surveillance workforce** ***Weekly and annual national publicly available surveillance report** *Robust quality data ***Functioning early**

			warning systems to detect emerging pathogens
Strategies/Activities	**Outputs**	**Short-Term Outcomes**	**Long-Term Outcomes**
Strategy 2: Laboratory Surveillance Enhancement of laboratory testing and quality management systems Expand laboratory testing capacity	*Documented analysis of existing capabilities and enhancement strategy *Consistent weekly reporting and timely shared reports *Shipments of viable specimens received by CDC in a timely manner	***Achievement of/or improved performance of laboratory functions** ***Improved timeliness and representativeness of shipments of specimens sent to CDC** *Identification of newly emerging pathogens ***Improved skill among laboratory staff** ***Improved proficiency panel performance**	***Improved availability of indicator results to measure testing and frequency** ***Increased number of specimens tested** ***Increased and improved quality measures** ***Enhanced ability to detect and characterize various pathogens** ***Data available for seasonal analysis of non-influenza respiratory viruses**
Strategy 3: Viral Respiratory Pathogen Surveillance Leverage NCIRD surveillance platforms to improve surveillance capacity Strengthen existing laboratory networks		***Enhanced sentinel surveillance including event-based surveillance** *Established standard data management systems ***Enhanced detection and reporting of viral respiratory illness** *Enhanced genetic characterization of circulating viruses	***Enhanced sentinel surveillance** *Improved data management ***Validated pandemic preparedness and response plans** *Integration of laboratory testing procedures for respiratory surveillance ***Improved competency for specimen collection, testing, and reporting**

Component 3: Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies

Strategies/Activities	**Short-Term Outcomes**	**Long-Term Outcomes**

Emergency Response: Respond to a declared public health emergency or identified highly infectious disease outbreaks	***Rapid identification of and response to highly infectious disease outbreaks** ***Strengthened coordination and robust emergency preparedness and response capacities** *Improved identification of cases and conducting appropriate outbreak investigations ***Increased awareness, knowledge, and support for local disease outbreak response and prevention**	***Achieve timely outbreak response** *Reduced time to reinvigorate public health activities ***Increased capacity of countries for early warning, risk reduction and management of national and global health risks** *Prevention of spread of the outbreak

i. Purpose

This NOFO supports building capacity for routine influenza and other respiratory disease surveillance systems to monitor, detect, respond and mitigate transmission; enabling national institutions to maintain their laboratory; participating fully in the Global Influenza Surveillance and Response System (GISRS); enabling influenza surveillance platforms or other existing surveillance platforms to be expanded and utilized for response to outbreaks of pathogens that are of public health importance and utilizing data collected by ministries of health for healthcare policy decisions.

ii. Outcomes

Component 1: Influenza Core Activities

<u>Strategy 1: Infrastructure</u>

Short-Term Outcomes

- National surveillance objectives established and published
- Improved communication between ministries of health and agriculture/animal health via established mechanisms for the daily or weekly sharing of information about zoonoses between the MOH and MOA
    - Establish mechanisms for sharing of zoonoses information between the MOH and MOA

Long-Term Outcomes

- Established national influenza surveillance system with integrated laboratory and epidemiological data tracking
- Country ownership and sustainability of integrated surveillance system
    - Support from government for long-term sustainability
- MOH and MOA coordination to ensure knowledge, awareness, and coordinated response and control of disease circulation within and between humans and animals

Strategy 2: Epidemiological Surveillance

Short-Term Outcomes

- Improved epidemiological surveillance system performance
- Surveillance staff skilled in data collection, data quality review, and data dissemination skills
- Improved understanding of influenza activity to properly inform MOH and other public health officials on virus' transmissibility and severity
- Zoonotic surveillance platform enhanced to include tracking of virus transmission from animals to humans and potential transmission from humans to animals

Long-Term Outcomes

- Strong and capable data-driven surveillance workforce
    - Improved reporting and improved situational awareness in country and globally
- Improved utilization of surveillance to inform public health action and support preparedness, response and recovery measures.
- Sustained ability to monitor the severity of epidemic and pandemic influenza-associated illnesses (PISA)
    - Ability to use collected epidemiological data as an evidence base to support the implementation of influenza prevention and control policies for specific at-risk groups
- Improved awareness and response to zoonotic (novel) influenza human infections

Strategy 3: Laboratory Surveillance

Short-Term Outcomes

- Improved testing capacity for influenza specimens, both quality and quantity
- Improved or maintained acceptable performance on external quality assurance panels
- Improved international contribution of specimen data used for vaccine composition decision-making (VCM)
- Improved performance and consistent weekly influenza specimen testing
    - Timely contribution of influenza positive respiratory specimens to CC for VCM and provide in-depth information about circulating strains
- Timely notification to World Organization for Animal Health (OIE) regarding animal influenza outbreaks and/or zoonotic transmission to humans

Long-Term Outcomes

- Data available for analysis on influenza seasonality and severity and identification of novel viruses within the country
- Improved international contribution of specimen data used for vaccine composition decision-making (VCM)
-
    - Identification of novel viruses within the country per WHO IHR guidelines

    - Established stable routine testing of a defined number of specimens each week based on local capacity

- Increased capacity to identify new and emerging influenza viruses in animals and humans, and ability to identify pandemic threats

Strategy 4: Pandemic Preparedness

Short-Term Outcomes

- Improved awareness of pandemic influenza preparedness & response capacity
- Improve adherence to the WHO Pandemic Influenza Preparedness (PIP) framework
    - Immediate sharing of influenza viruses with pandemic potential IVPP with a WHO CC

Long-Term Outcomes

- Updated national pandemic preparedness and response plan that meets country needs, global standards, WHO guidance
    - Pandemic Plans planned exercises used to test various components for appropriateness and usability and inclusion of a monitoring system with a set testing schedule defined.

Component 2: Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen

Strategy 1: Epidemiological Surveillance

Short-Term Outcomes

- Surveillance staff skilled in data collection, data quality review, and data dissemination skills leading to improved data quality and outputs

Long-Term Outcomes

- Strong and capable data-driven surveillance workforce, improved reporting and situational awareness in country and globally
- Weekly and annual national publicly available surveillance report
    - Includes accurate summaries of epidemiologic and laboratory data generated from all laboratories and sentinel sites

- Countries have functioning early warning systems to detect emerging pathogens

Strategy 2: Laboratory Surveillance

Short-Term Outcomes

- Achievement of/or improved performance of laboratory functions
- Improved timeliness and representativeness of shipments of specimens received by CDC
- Improved skill among laboratory staff for non-influenza pathogen characterization and testing
- Increase in proficiency panel performance

Long-Term Outcomes

- Improved availability of indicator results to measure testing and frequency

- Increase the annual number of specimens tested
- Increased and improved quality measures
- Enhanced ability to detect and characterize various pathogens
- Data available for analysis of seasonality of non-influenza respiratory and vaccine-preventable pathogens

Strategy 3: Viral Respiratory Pathogen Surveillance
Short-Term Outcomes

- Enhanced sentinel surveillance including event-based surveillance where utilized
- Enhanced detection and reporting of viral respiratory illness

Long-Term Outcomes

- Enhanced sentinel surveillance to provide timely data about viral respiratory pathogens activity
- Validated pandemic preparedness and response plans
- Improved competency for specimen collection, testing, serologic methods as well as reporting

Component 3: Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies
Short-Term Outcomes

- Rapid identification of and containment of highly infectious disease outbreaks
- Strengthened coordination and robust emergency preparedness and response capacities
- Increased awareness, knowledge, and support for local disease outbreak response and prevention efforts at the community level

Long-Term Outcomes

- Achieve timely outbreak and epidemic/pandemic control
- Increased capacity of countries for early warning, risk reduction and management of national and global health risks

iii. Strategies and Activities
Component 1 – Influenza Core Activities
<u>Strategy 1: Infrastructure –</u>

- Build/establish or maintain current integrated national influenza surveillance system
    - Assessment of entire influenza surveillance system with documentation of overall surveillance objectives, including the strengths and weaknesses for all laboratory, epidemiologic objectives and sentinel performance
        - Specifically assess staffing capacity and identify needs to support comprehensive influenza program including overall grant and project management

- Develop a sustainability plan for the national influenza surveillance system including budget needed to maintain the system and optimize national integration
  - Analyze the costs of the surveillance system and determine a budget to sustain and optimize a base level national integrated surveillance system
- Develop a plan to address organizational capacity, communications, partnerships, and program evaluation

- Develop standard operating procedures for the prompt sharing of information about potential outbreaks of consequence to animal and/or human populations with IHR defined timelines
  - Develop work plans outlining routine communications between Ministries of Health and Agriculture about animal influenza outbreaks and/or human cases of zoonotic (novel) influenza virus
    - Include information on current Animal Human Interface (AHI)/OneHealth activities and plans to either initiate or continue activities to ensure strong connection to and communication with the Ministry of Agriculture (MOA)

Strategy 2: Epidemiological Surveillance

- Establish/improve or maintain epidemiologic capacity to monitor seasonal influenza activity and identify potential pandemic outbreak
  - Conduct critical review/assessment of surveillance system including program costs, identification of data quality indicators, identification of gaps and develop plan to address
  - Identify, clearly define and document long-term national surveillance objectives
  - Develop revised protocol/standard operating procedures (SOPs) for sentinel surveillance
    - Utilize tools such as the Joint External Evaluation (JEE) 2.0 framework (https://www.cdc.gov/globalhealth/healthprotection/ghs/ihr/index.html) to identify gaps and prepare plan for addressing them
  - Convene annual surveillance meeting with all surveillance staff and key stakeholders
    - Epidemiologic, Laboratory and AHI/OneHealth teams should be included in the meeting

- Enhance epidemiological surveillance capacity to monitor influenza activity year-round and to establish >3-year baseline influenza activity
  - Develop, improve and maintain data management and analysis skills including integration of epidemiologic and laboratory data linkages and reporting.
    - Include reporting SOP for links to AHI/OneHealth
  - Design weekly and annual reporting systems, contributing to national and global situational awareness
  - Conduct a data quality assessment of established influenza like illness (ILI) and/or severe acute respiratory illness (SARI) sentinel sites with at least 3 years of data collected.

- Develop surveillance data triggers for public health actions and guidance for non-pharmaceutical interventions, antiviral use, and influenza vaccination.
    - Conduct enhanced surveillance to identify populations at high risk for severe influenza disease or groups that may be priority for targeted vaccination, antiviral treatment, or other non-pharmaceutical interventions (NPI)
- Enhance existing capacity or expand sources of surveillance to establish national indicators of influenza transmission, disease severity, and impact
    - Develop and disseminate weekly reports of Pandemic Influenza Severity Assessment (PISA)

- Coordinate and communicate with the MOA to implement or maintain Animal Human Interface/OneHealth surveillance system to actively monitor animal and zoonotic viruses
    - Outbreak investigations of zoonotic (novel) transmission events among humans
    - Develop or revise plans to conduct surveillance among humans potentially exposed to influenza viruses circulating in animal populations.
        - Include information on current links to AHI/OneHealth group and identified strengths and weaknesses (if available)

Strategy 3: Laboratory Surveillance

- Maintain or improve laboratory capacity to monitor and test samples and strengthen participation in WHO Global Influenza Surveillance and Response System (GISRS) and contribution to VCM
    - Assess capacity of national reference and provincial laboratories, identify training needs and develop a working plan to improve influenza detection and ensure consistent timely reporting to WHO FluNet
        - Utilize data to document and prepare plan to improve laboratory performance and personnel skill
    - Develop a working plan to improve influenza detection
    - Timely and routine submission of specimens to WHO CC
    - Maintain influenza testing capacity through external quality review
        - Participation in external quality proficiency panels and needs identified to improve influenza specimen testing
        - Train laboratory staff and implement new or enhanced testing capabilities
        - Identify areas where quality control measures could be implemented to improve testing results and validity (i.e., monitoring of sample CT values)
        - Assess influenza laboratory manuals (i.e., Biosafety/Biosecurity) and protocols (i.e., Standard Operating Procedure for RT-PCR) that require regular updating
        - Develop plan to ensure ongoing updates and relevance of manuals is maintained
    - Monitor or establish inventory levels for influenza laboratory reagents and supplies

        - Develop a national plan for the procurement of reagents and supplies for influenza virus characterization and testing
    - Develop and disseminate routine and timely reports of circulating influenza viruses identified through molecular diagnostics to WHO Global Influenza Surveillance and Response Systems (GISRS)

- Enhance animal zoonotic influenza virus knowledge to support Animal Human Interface/OneHealth platform
    - Develop and/or maintain testing algorithms and protocols evaluating clinical presentation of individuals with zoonotic influenza viruses and risk factors for human to human transmission.

<u>Strategy 4: Pandemic Preparedness</u>

- Develop and maintain preparedness plan for an influenza outbreak or pandemic
    - Establish group of national/ international stakeholders to evaluate country-level pandemic preparedness including coordination with animal health surveillance and either draft a new or update the current national pandemic preparedness and response plan
        - If necessary, update the national pandemic preparedness and response plan to meet country needs, global standards, WHO guidance including consideration of challenges experienced during the 2020 COVID-19 pandemic.
        - Consider including AHI/OneHealth linkages and include AHI group in ongoing surveillance discussions
    - Test preparedness and response plans by conducting tabletop outbreak and response exercises and responding to real events
        - Create after action report to summarize strengths and weaknesses identified during tabletop exercises
    - Monitor pandemic preparedness levels and capacity through evaluation tools, training, outbreak reviews

Component 2: Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable pathogens

Strategy 1: Epidemiological Surveillance

- Establish/improve or maintain epidemiologic capacity to monitor seasonal activity and identify potential outbreaks
    - Conduct critical review/assessment of surveillance system identifying gaps and develop plan to address
    - Convene annual surveillance meeting with all surveillance staff and key stakeholders
    - Enhance early warning capacity for emerging and re-emerging pathogens by promoting integrated surveillance and strengthening event-based surveillance

- Evaluate the impact of interventions on reducing the burden of diseases caused by pathogens
    - Develop, improve and maintain data management and analysis skills including integration of epidemiologic and laboratory data linkages and reporting
    - Design efficient weekly and annual reporting systems, contributing to national and global situational awareness

Strategy 2: Laboratory Surveillance

- Enhancement of laboratory testing and quality management systems
    - Perform laboratory capacity reviews across Member States in conjunction with external collaborators (i.e., WHO, WHO RO and CDC) and follow up with recommendations
    - Sharing of non-influenza pathogens with CDC

- Expand laboratory testing capacity to identify a broader range of pathogens
    - Training consultations or workshops in conjunction with external collaborators (i.e, WHO, WHO Regional Office, and CDC) to strengthen laboratory capacity at Regional and national levels.
    - Train and certify medical technologists through laboratory trainings and participation in regional workshops/networks

Strategy 3: Viral Respiratory Pathogen Surveillance

- Leverage NCIRD led surveillance platforms to improve surveillance capacity for viral respiratory pathogens with pandemic potential
    - Identify gaps in viral respiratory surveillance and laboratory capacity
    - Expand epidemiologic and virologic capacity detection of viral respiratory pathogens
    - Providing training, technical and analytical support to improve or maintain data management systems,
    - Develop standardized approaches

- Promote early detection and surveillance of respiratory pathogens with epidemic potential by strengthening existing laboratory networks
    - Provide training for specimen collection, testing with the multiplex RT-PCR and serologic methods
    - Conduct survey of ongoing surveillance to assess the scope of current activities in WHO VPD Laboratories, identify gaps and describe best practices used

Component 3: Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies

- Respond to a declared public health emergency or identified highly infectious disease outbreaks
    - Intensify active surveillance, case finding, contact tracing, monitoring and other outbreak response measures at national and local levels

- Strengthen capabilities for epidemiologic and laboratory analysis and program evaluation
- Intensify social mobilization, community and professional education and engagement
- Improve outbreak contact tracing management and infection control
- Increase security and logistics for local responders

1. Collaborations

a. With other CDC programs and CDC-funded organizations:
Recipients should make every effort to coordinate work with other CDC implementing partners (if known), including non-governmental organizations, universities, Ministry of Health and other host governmental bodies and multi-lateral organizations that receive CDC funds. The recipient should ensure their proposed activities are not duplicating activities already implemented by other CDC-funded organizations.

Applicants supported by CDC's Global Health Security Agenda (GHSA) are encouraged to collaborate with GHSA counterparts and must describe how they plan to ensure activities conducted for this NOFO complement, without duplicating or supplanting, broader respiratory surveillance packages supported by GHSA.

b. With organizations not funded by CDC:
In collaboration with WHO, WHO regional offices, and country offices, Recipients should submit weekly reporting to WHO FluNet and WHO FluID, which supports the monitoring of circulating influenza viruses and allows rapid identification of an increase in reported influenza cases worldwide.

Shipment of viruses by Recipients to a WHO Collaborating Center (CC) is requested per the guidance of the designated WHOCC up to four times a year.

If CDC is not the routine WHO CC for shipments, recipients are encouraged to ship an additional package of positive original clinical specimens to CDC. Shipments of viruses to WHO CC and/or CDC prior to the annual Vaccine Composition meetings (held in February/September) informs recommendations made on the composition of the influenza vaccines for the following influenza season.

Recipients are expected to participate fully in the WHO Global Influenza Surveillance and Response System (GISRS). Recipients are also expected to adhere to applicable provisions within the International Health Regulations (2005) (IHR). Specifically, countries should have the ability to:

- **Detect:** Make sure surveillance systems and laboratories can detect potential threats
- **Assess:** Work together with other countries to make decisions in public health emergencies
- **Report:** Report specific diseases, plus any potential international public health emergencies, through participation in a network of National Focal Points
- **Respond:** Respond to public health events

In addition, recipients will be expected to work with other stakeholders in country and at the global level including but not limited to other government entities, non-governmental organizations, civil society, the private sector, and other USG agencies.

CDC serves as one of six World Health Organization Collaborating Centers for Influenza (WHOCC). One of CDC's long-standing terms of reference and responsibilities as a collaborating center is to provide technical support and develop capacity in laboratory and influenza surveillance with global ministries of health. As a result, the CDC Influenza Program works with MOHs to build the capacity of their national laboratory and influenza surveillance systems, and to maintain capacities gained with increased national ownership and to provide a mechanism for emergency fund distribution in case of a worldwide pandemic.

Through CDC's role as a WHO Collaborating Center for Influenza, CDC works to support country participation in the Global Influenza Surveillance and Response System (GISRS). The GISRS is the only global influenza surveillance system and is responsible for conducting surveillance and collecting specimens and data that contribute to twice annual vaccine strain selection decisions for the world. These updated recommendations are used globally to make new influenza vaccine formulation recommendations every six months. The GISRS is entirely dependent on National Governments and MOHs to collect the specimens and submit data. National governments and MOHs are the only entities eligible to designate their laboratories as National Influenza Centers. The entire GISRS system is made up of and supported by countries with capacity to conduct influenza surveillance.

This NOFO targets qualified entities (national governments and their MOHs) uniquely positioned to contribute to the Global Influenza Surveillance and Response System through designated National Influenza Centers that share viruses within the GISRS, thereby contributing to the Centers for Disease Control and Prevention's support for international effort to contain and mitigate the spread of an influenza pandemic or other highly pathogenic respiratory viruses. By increasing preparedness and response capabilities around the world, the United States will be much better positioned to protect the health of its citizens.

This NOFO targets countries designated by the World Bank as countries in the low- and middle-income category. These countries need both technical and financial assistance to strengthen surveillance systems, including increasing laboratory capacity to identify and monitor pathogenic viruses. The current list of countries designated as such by the World Bank is attached for review.

2. Target Populations

The target populations for this NOFO include but are not limited to those people from countries designated by the World Bank as low- and middle-income whose populations are infected and affected by infectious diseases or other public health emergencies, at risk for becoming infected by an infectious disease, as well as health care workers. In addition, the work under this NOFO will target increased capacity within countries at the national and sub-national level to implement and achieve outbreak/epidemic/pandemic control in line with the recipient's and USG strategies. The recipient should particularly work to identify WHO-recommended at-risk populations for influenza prevention and other relevant infectious diseases or public health threats and may propose additional target populations based on relevant evidence-based criteria

in order to achieve and sustain epidemic control. Recipients are expected to use epidemiologic, social determinants, and linked laboratory surveillance data to identify communities disproportionately affected by influenza or other infectious respiratory diseases in the target areas to ensure that program activities appropriately cover these populations.

a. Health Disparities

Implementation of strategies and activities within this NOFO will support establishment of surveillance systems that provide a representative sample of the country population, geographically, socio-demographically, including those populations identified as high-risk for morbidity from respiratory infections. Identification of the burden of disease, through use of surveillance data, will assist countries to plan and implement public health information campaigns and equitable vaccination programs.

iv. Funding Strategy

This funding opportunity announcement will support countries designated by the World Bank Income Designation (January 7, 2021) as Low- & Middle-Income Countries: Afghanistan; Albania: Algeria: American Samoa; Angola; Argentina; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Benin; Bhutan; Bolivia; Bosnia and Herzegovina; Botswana; Brazil; Bulgaria; Burkina Faso; Burundi; Cabo Verde; Cambodia; Cameroon; Central African Republic; Chad; China; Colombia; Comoros; Congo Dem. Republic; Congo, Republic; Costa Rica; Cote d'Ivoire; Cuba; Djibouti; Dominica, Dominican Republic; Ecuador; Egypt, Arab Republic; El Salvador; Equatorial Guinea; Eritrea; Eswatini; Ethiopia; Fiji; Gabon; Gambia, The; Georgia; Ghana; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; India; Indonesia; Iran; Islamic Republic; Iraq; Jamaica; Jordan; Kazakhstan; Kenya; Kiribati; Korea, Dem. People's Rep.; Kosovo; Kyrgyz Republic; Lao PDR; Lebanon; Lesotho; Liberia; Libya; Madagascar; Malawi; Malaysia; Maldives; Mali; Marshall Islands; Mauritania; Mexico; Micronesia, Fed. Sts.; Moldova; Mongolia; Montenegro; Morocco; Mozambique; Myanmar; Namibia; Nepal; Nicaragua; Niger; Nigeria; North Macedonia; Pakistan; Papua New Guinea; Paraguay; Peru; Philippines; Russian Federation; Rwanda; Samoa; Sao Tome and Principe; Senegal; Serbia; Sierra Leone; Solomon Islands; Somalia; South Africa; South Sudan; Sri Lanka; St. Lucia; St. Vincent and the Grenadines; Sudan; Suriname; Syrian Arab Republic; Tajikistan; Tanzania; Thailand; Timor-Leste; Togo; Tonga; Tunisia; Turkey; Turkmenistan; Tuvalu; Uganda; Ukraine; Uzbekistan; Vanuatu; Venezuela, RB; Vietnam; West Bank and Gaza; Yemen, Rep.; Zambia; Zimbabwe

There are three funding components for this NOFO. Applicants must apply for Component 1 (Influenza Activities). Additionally, applicants can choose to apply for Component 2 and/or Component 3.

Applicants must submit a single application with a clearly marked budget, and work plan for each proposed component and strategy. Clearly mark all work plans and budgets indicating Component name. Each component will be reviewed and scored separately. Please note: Components and strategies not outlined in this initial application cannot be added to work plans in subsequent years. The initial project application should contain a detailed Year 1 plan and a projection of strategies and activities to be accomplished in later years.

Applicants should be designated by the World Bank as a low- or middle-income category

country.

Final decision on which countries and activities to be funded will be made after application review. CDC can fund out of rank order in order: 1) to align with USG and/or agency prioritized technical areas and activities; 2) to ensure maximum coverage of activities geographically; 3) to avoid duplication of activities in other CDC funding mechanisms; or 4) to respond to an unforeseen public health emergency of an international concern. Decisions will be documented.

Applicants selected to receive funding for Component 1 (Influenza Activities) will be considered for funding for any additional Components included as part of the application.

Component 1 (Influenza Activities) within this NOFO are intended to be funded on an annual basis. Future year funding levels will be dependent on funding availability and satisfactory progress. Satisfactory progress will be determined by successful completion of workplan activities and evaluation metrics agreed to and finalized in discussions with appropriate Influenza Program staff during the first 6 months of Year 1.

Component 2 - Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen

Component 2 activities are intended to be funded on an as needed basis within those countries approved for funding under Component 1 (Influenza activities). Funding will occur when specific public health activities are identified.

Component 3 – Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies

This is intended to be approved but unfunded (ABU) as a baseline practice. It would be funded to support additional activities needed when a disease outbreak or other public health emergency reaches a scale that requires a substantial response.

Final decision on which countries and activities to be funded will be made at the time of award. There are clearly identified definitions of what constitutes an emergency (see below for specifics).

Emergency Funding

The ability to respond rapidly and effectively to public health emergencies is a key component of global health security. International public health emergencies including humanitarian crises are by nature unpredictable, requiring fulfilment of changing and often unpredictable needs that vary widely according to context. Consequently, funding for public health emergencies is also unpredictable and based on external factors. In recent years, there has been a sharp rise in the number of people living in regions of the world affected by public health emergencies, including humanitarian emergencies, which has often led to additional funding resources from the USG to respond to these threats. Given this unpredictability and the resulting need for rapid, flexible, and efficient process to award funding under an emergency situation, recipients that are selected for

funding under this NOFO may be eligible to receive additional supplemental funding when a public health emergency occurs to scale up activities included within the scope of work of this NOFO.
Definition of public health emergency:
1. When UN or WHO classifies the emergency as a Level 3 (L3)
2. When the US Congress appropriates funding for an international response related to humanitarian or public health crisis with the words containing "emergency" in the program title. The appropriated funding could be for CDC directly or is transferred to CDC through an Interagency Agreement (IAA) by HHS or another USG agency
3. When the US government (Congress, White House, National Security Council etc.) declares a public health emergency as national security priority
4. When HHS Secretary declares an emergency
5. When the CDC Director activates Emergency Operation Center (EOC) in response to an international public health threat
6. When Department of State or U.S. Agency for International Development (USAID) transfer funds to CDC to respond to an international disaster or humanitarian assistance under 2 FAM 060 (International Disaster and Humanitarian Assistance)
If a public health emergency situation meets any one criterion listed above, then selected recipients under this NOFO may be eligible to receive supplemental emergency funding to scale up public health activities included in the scope of work of this NOFO on a single-source basis, i.e., without additional competition. There is no limit on the number of emergency supplemental funding that a recipient may receive within a period of performance, however, emergency funding requests cannot exceed a recipient's budget period or period of performance. In addition, all reporting requirements listed under this NOFO still apply to any emergency supplemental funding.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data;

data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

c. Organizational Capacity of Recipients to Implement the Approach

Applicant must be able to manage program performance, evaluation, performance monitoring, financial reporting, and must have capacity to manage the required funds in accordance with the HHS Grants Policy Statement.

Applicants should clearly document and demonstrate experience or institutional capacity (both technical and administrative to achieve the outcomes outlined in the logic model including evidence of strong administration and information management systems to support the proposed activities and to manage the resources of the project, prepare reports, monitor and evaluate activities, audit expenditures, and produce, collect, and analyze performance and surveillance data. Applications should include description of the ability to develop or maintain the following: support of the ministry of health in the country where work is proposed, conduct routine influenza surveillance and the capacity to contain highly pathogenic virus transmissible among humans and between humans and animals; epidemiologic, virologic, and related capacity to detect, respond to, and monitor changes in influenza viruses and identify respiratory outbreaks; strengthen connections and participate in the WHO Global Influenza Surveillance and Response System (GISRS), and capacity to share specimens and clinical and epidemiologic data about influenza and other respiratory pathogens with epidemic and pandemic potential. Additionally, applicants should describe the existence of or plans to establish partnerships needed to accomplish stated objectives and describe collaborations with other international organizations, other national health agencies i.e., ministry of agriculture), as well as national Government authorities responsible for public health emergency preparedness and animal health. Finally, applications should describe any experience managing prior awards, experience implementing sentinel surveillance sites, influenza or other respiratory disease surveillance experience, laboratory testing capacity, knowledge of International Health Regulations (IHR) as well as documentation of country government support for the proposed activities.

Additionally, information on the financial and procurement systems available to support any potential award should be provided. Language skills, specifically the ability to understand and converse in English should be described. All applicants should document their working

relationship with the country ministry of health and provide letters of support.

The applicant should provide as part of their appendix the following documents:
1) Curricula Vitae (CVs)/Resumes for positions related to Principal Investigator, Project Director, Business Official, and other key staff related to program planning and implementation, finance, and monitoring and evaluation.
2) Job descriptions (maximum 1 page per job description) for key positions including: Principal Investigator, Project Director, Business Official, and other key staff related to program planning and implementation, finance, and monitoring and evaluation. Clearly identify percent (%) of time spent on activities supporting the proposed project.
3) Organizational chart (maximum 1 page)
4) Capacity summary statement to be able to implement the activities proposed under this NOFO (maximum 1 page).
5) MOH letter of support and cooperation including specific surveillance goals at the national level and local level for epidemiological and laboratory-based goals.
6) MOU between all teams associated with implementation and ongoing maintenance of a surveillance system. This would include but not be limited to the epidemiological team, the laboratory team, the veterinary team, and others as needed
7) Financial management statement that demonstrates experience in managing USG or CDC funds that are similar in size and scope to this NOFO (maximum 1 page)

- Details of required procurement process
- Details of internal monetary movement

Applicants must title these documents in their appendix as follows: "CVs/Resumes," "Job Descriptions," "Organizational Chart," "Capacity Summary," "MOH Support," "MOU," "Financial Statement," and upload as attachments to the application at www.grants.gov.

d. Work Plan
The applicant must submit one application with clearly marked separate budget and work plan for each component within their application. Components not included in the initial application are not eligible to be added or funded in subsequent budget years.

- Component 1: Influenza Core Activities
- Component 2: Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable pathogens
- Component 3: Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies

The work plan should demonstrate how the outcomes, strategies, activities, timelines, and staffing will take place over the course of the award.

Applicants must submit a detailed work plan for the first year of the project, and a high-level work plan in subsequent years.

Please note that only one application with clearly marked separate work plan and budget for each

component will be accepted.

An example work plan is shown below. Applicants are not required to use this format; however, they must include the required information.

Period of Performance Outcome:		Outcome Measure:	
Strategy and Activities:	Process Measure:	Responsible Position/Party	Completion Date
1.			
2.			
3.			
4.			
5.			

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

The following data sources will be utilized to monitor performance of Recipients:

- Payment Management System (PMS) will be reviewed to ensure timely utilization of funds in support of project activities as well as timely reporting of fund use.
- WHO FluNet and FluID will be used to monitor timely reporting of influenza virus identification and testing.

- Shipments to WHO CC (up to four shipments to a CC per year are recommended – 1 at season start, 1 to support bi-annual Vaccine Strain Selection meeting (February/September), 1 mid-season and 1 at end of the season) will be used to monitor participation in GISRs and Vaccine Composition.
- WHO annual External Quality Assessment Project (EQAP) participation will be used to monitor capability to identify influenza circulating viruses. A sustained score of 80% or higher for established National Influenza Centres (NICs) will be used as minimally acceptable.
- Federal Financial Reports (FFR) will be reviewed and tracked for timely and accurate reflection of the cooperative agreement funds. Annual FFRs are due 90 days following the end of the designated Budget Period. Reports are required to be submitted within the Payment Management System.
- Administrative accountability will be measured by use of and maintaining access to the Grant Solutions system and timely submissions of prior approval amendments and other requested information as required within the cooperative agreement.

The recipient(s) will be required to collaborate with CDC headquarters (HQ) for technical oversight of project activities to be implemented under this NOFO. In addition to the Project Officer, the recipient will collaborate with CDC in-country or HQ contacts, Subject Matter Experts (SMEs) and technical leads. The Project Officer for this award will provide relevant contacts of CDC staff and coordinate discussions with the award recipients.

Annual performance will be reviewed and may determine future funding decisions. Future funding for this cooperative agreement is based on satisfactory progress.

B. Award Information

1. Funding Instrument Type:
CA (Cooperative Agreement)
CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism:
U51

3. Fiscal Year:
2021

4. Approximate Total Fiscal Year Funding:
$ 30,000,000

5. Total Period of Performance Funding:
$ 120,000,000
This amount is subject to the availability of funds.

Total period of performance funding: Up to $120,000,000

Component 1 (Influenza Core Activities): up to $85,000,000 (Component 1 estimated at $13,000,000 in Year One)

Component 2 (Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen activity): up to $10,000,000 (Component 2 is estimated at $1,000,000 in Year One)

Component 3 (Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies): Up to $15,000,000 (Component 3 is expected to be approved but unfunded). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for a designated public health threat, CDC can process applications and award funds in a timely manner. In the event that no designated public health threat is declared, no awards will be made.

Final award amounts may be less than requested. Funding is subject to the availability of appropriated funds.

Estimated Total Funding:
$ 120,000,000

6. Total Period of Performance Length:

5 year(s)

7. Expected Number of Awards:

60

8. Approximate Average Award:

$ 400,000
Per Budget Period

This announcement contains two separate annual components, and a third component aimed at providing a quick funding mechanism for pre-approved recipients faced with an identified public health threat.

The average Year One Award Amount refers to the two annual components:

Estimated Award Ranges:
Influenza Core Activities (Component 1): $50,000 to $200,000 award range

Non-Influenza Viral and Bacterial Respiratory and Vaccine-preventable Pathogen (Component 2): $50,000 to $200,000 award range.

Rapid Response to Infectious Disease Outbreaks or other Public Health Emergencies (Component 3): Approved but Unfunded:
$20,000 - $1,000,000 award range**.** Funds will only be available if and when a public health emergency is declared.

Potential amounts are subject to the availability of funds.

9. Award Ceiling:
$ 0 Per Budget Period

This amount is subject to the availability of funds.

There is no award ceiling for this NOFO

10. Award Floor:
$ 0 Per Budget Period

There is no award floor for this NOFO

11. Estimated Award Date:
August 31, 2021

12. Budget Period Length:
12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance
Direct Assistance (DA) is not available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

Additional Eligibility Category:

Other

Ministries of Health

2. Additional Information on Eligibility

Other: Ministries of Health or their bona-fide agents in World Bank low- and middle- income designated countries

This Notice of Funding Opportunity Announcement will support foreign governments through their Ministries of Health, other responsible Ministries for human health or public-health emergency preparedness or bona fide agents working on behalf of these ministries. Countries must be designated by the World Bank as low or middle-income.
Ministries of Health are uniquely qualified to set country health priorities and to impact and strengthen health systems on a national scale. They are the entities within their countries responsible for administering and enforcing laws, rules, or regulations on collecting and reporting of influenza surveillance data. Ministries also have the authority to mobilize and respond to outbreaks nationally, gather and report notifiable disease data, improve surveillance and laboratory systems, and build human resource capacity.

Countries designated by the World Bank Income Designation (January 7, 2021) as Low- & Middle-Income Countries: Afghanistan; Albania: Algeria: American Samoa; Angola; Argentina; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Benin; Bhutan; Bolivia; Bosnia and Herzegovina; Botswana; Brazil; Bulgaria; Burkina Faso; Burundi; Cabo Verde; Cambodia; Cameroon; Central African Republic; Chad; China; Colombia; Comoros; Congo Dem. Republic; Congo, Republic; Costa Rica; Cote d'Ivoire; Cuba; Djibouti; Dominica, Dominican Republic; Ecuador; Egypt, Arab Republic; El Salvador; Equatorial Guinea; Eritrea; Eswatini; Ethiopia; Fiji; Gabon; Gambia, The; Georgia; Ghana; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; India; Indonesia; Iran; Islamic Republic; Iraq; Jamaica; Jordan; Kazakhstan; Kenya; Kiribati; Korea, Dem. People's Rep.; Kosovo; Kyrgyz Republic; Lao PDR; Lebanon; Lesotho; Liberia; Libya; Madagascar; Malawi; Malaysia; Maldives; Mali; Marshall Islands; Mauritania; Mexico; Micronesia, Fed. Sts.; Moldova; Mongolia; Montenegro; Morocco; Mozambique; Myanmar; Namibia; Nepal; Nicaragua; Niger; Nigeria; North Macedonia; Pakistan; Papua New Guinea; Paraguay; Peru; Philippines; Russian Federation; Rwanda; Samoa; Sao Tome and Principe; Senegal; Serbia; Sierra Leone; Solomon Islands; Somalia; South Africa; South Sudan; Sri Lanka; St. Lucia; St. Vincent and the Grenadines; Sudan; Suriname; Syrian Arab Republic; Tajikistan; Tanzania; Thailand; Timor-Leste; Togo; Tonga; Tunisia; Turkey; Turkmenistan; Tuvalu; Uganda; Ukraine; Uzbekistan; Vanuatu; Venezuela, RB; Vietnam; West Bank and Gaza; Yemen, Rep.; Zambia; Zimbabwe

If an organization applies as a bona fide agent on behalf of the Ministry of Health, a letter from the ministry of health is required as documentation of the agreement.

- MOH letter of agreement indicating designation as bona-fide agent to support surveillance goals at the national level and local level for epidemiological and laboratory-based goals.

The above referenced document should be titled as follows: "MOH Letter of Support"; and uploaded as attachments to the application at www.grants.gov.

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System:
All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.
The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number will be provided at no charge.
If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):
The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at https://www.sam.gov/SAM/.

c. Grants.gov:
The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.
All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/ and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

NA

b. Application Deadline

05/04/2021
11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Due Date for Information Conference Call

3/23/2021 – 7:00 pm ET US; 3/24/2021 – 7:00 am ET US; 3/24/2021 – 10:00 am ET US

Zoom information for CDC-RFA-IP21-2101 calls is below:

March 23, 2021 - 7:00 pm ET US:
Join by Zoom Meeting:
https://cdc.zoomgov.com/j/1602552301?pwd=aFVGdDM1bGFvQmhJU3dzNDVNNXlMUT09
Meeting ID: 160 255 2301
Passcode: Y2WzxG=*

Join by phone:
Find your local number: https://cdc.zoomgov.com/u/aneWXnDPw
Meeting ID: 160 255 2301
Passcode: 83004646

Join by SIP:
1602552301@sip.zoomgov.com
Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 255 2301
Passcode: 83004646

March 24, 2021 - 7:00 am ET US:
Join by Zoom Meeting:
https://cdc.zoomgov.com/j/1604738847?pwd=UkhxSWRreXEvaTljSnh6TWdOT3JiUT09
Meeting ID: 160 473 8847
Passcode: 51bR%@3v

Join by phone:
Find your local number: https://cdc.zoomgov.com/u/adu47vB2r8
Meeting ID: 160 473 8847
Passcode: 22239399

Join by SIP:
1604738847@sip.zoomgov.com
Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 473 8847
Passcode: 22239399

March 24, 2021 - 10:00 am ET US:
Join by Zoom Meeting:
https://cdc.zoomgov.com/j/1609424763?pwd=QkcxTEI0Z2kyOWdsUWJPZ2FlSjc0Zz09
Meeting ID: 160 942 4763
Passcode: U@9ry5=D

Join by phone:
Find your local number: https://cdc.zoomgov.com/u/adzF8LfotM
Meeting ID: 160 942 4763
Passcode: 62330787

Join by SIP:
1609424763@sip.zoomgov.com
Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 942 4763
Passcode: 62330787

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award

Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

LOI is not requested or required as part of the application for this NOFO

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the “Table of Contents” for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include **all** of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see http://www.hhs.gov/ ocio/policy/collection/.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub

accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

15. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS

identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

16. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:
https://www.cdc.gov/grants/additionalrequirements/ar-25.html

18. Other Submission Requirements

a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t= Get_Started%2FGet_Started. htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry

2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

   If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements

i. Approach **Maximum Points:** 40

Evaluate the extent to which the applicant:

a. Describes the background and workplan to justify the need for the proposed project to enhance or expand human influenza surveillance networks in the country, and to implement other associated activities as part of the national effort to contain the emergence of a new pandemic virus and to prepare for pandemic influenza. Does the applicant show that proposed use of funds is an efficient way to implement the strategies and activities and attain the period of performance outcomes and does the applicant provide information on collaboration and support of the MOH in the country where work is proposed. (10 points)
b. Proposes activities that optimally address the critical goal of building or maintaining capacity to conduct routine influenza surveillance, and to detect and respond to seasonal and pandemic influenza. If the applicant has an existing surveillance system, the extent

to which the applicant describes appropriate institutional counter parts including any targeted geographical area(s) and its (their) demographics and describes identified strengths and gaps of the current activities and system. (10 points)

c. Describes specific strategies of the proposed project consistent with the purpose and logic model of this NOFO that are measurable, achievable, time phased and evidenced based. Presents a work plan that is aligned with the strategies/activities, outcomes and performance measures in the approach and is consistent with the content and format proposed by CDC (10 points)
d. Describes appropriate collaborations with other health agencies, as well as national Government authorities responsible for public-health emergency preparedness and animal health, during various phases of the project and describes linkages, as appropriate, with programs funded to establish human disease-surveillance networks among non-governmental and private-sector institutions. (5 points)
e. Does the applicant clearly identify specific persons responsible for each key activity? Does the plan clearly describe the applicant's technical approach/methods for developing and conducting the proposed activities, and does it appear feasible and adequate to accomplish the objectives? Does the applicant describe funding received or anticipated from other sources to perform the same or similar activities? (5 points)

ii. Evaluation and Performance Measurement **Maximum Points:** 25

Evaluate the extent to which the applicant:

a. Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities, as well as to address necessary adjustment of program activities based on monitoring information? Shows/affirms the ability to collect data on the process and outcome performance measures specified by CDC in the project description and presented by the applicant in their approach. (10 points)
b. Describes how performance measurement and evaluation findings will be reported and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement. Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base. (5 points)
c. Clearly and appropriately addresses all proposed activities? Does the applicant describe specific objectives consistent with the purpose and measurable outcomes of this announcement, and which are specific and measurable? Describes any evaluation studies they are to undertake. Describe in sufficient detail to identify the key evaluation questions, and data sources and analysis methods. (10 points)

iii. Applicant's Organizational Capacity to Implement the Approach **Maximum Points:** 35

Evaluate the extent to which the applicant:

a. Clearly documents and demonstrates experience or institutional capacity (both technical and administrative) to achieve the outcomes outlined in the NOFO and logic model?

Does the applicant clearly document experience building strong administration and information management systems to support the proposed activities and to manage the resources of the project, prepare reports, monitor and evaluate activities, audit expenditures, and produce, collect, and analyze performance and surveillance data as evidenced by the CVs of key staff? Is the management structure for the project, as documented by CVs or other documents, sufficient to ensure implementation of the project? (15 points)

b. Develop/maintain capacity and authority to conduct routine influenza surveillance and capacity to contain highly pathogenic virus transmissible among humans and between humans and animals; develop/maintain epidemiologic, virologic, and related capacity to detect, respond to, and monitor changes in influenza viruses and identify respiratory outbreaks; and strengthen connections and authority to participate in the WHO Global Influenza Surveillance and Response System (GISRS), and more capable of sharing timely specimens and clinical and epidemiologic data about influenza and other respiratory pathogens with epidemic and pandemic potential (10 points)
c. Describe the existence of or plans to establish partnerships needed to accomplish objectives? Does the applicant describe adequate and appropriate collaborations with other international organizations, other national health agencies i.e., ministry of agriculture), as well as national Government authorities responsible for public health emergency preparedness and animal health? (5 points)
d. Provide documentation of experience managing prior awards, experience implementing sentinel surveillance sites, influenza or other respiratory disease surveillance experience, laboratory testing capacity, knowledge of International Health Regulations (IHR) 2005 as well as documentation of country government support for proposed activities? (5 points)

Budget **Maximum Points:** 0

Presentation of a reasonable budget that is consistent with the stated objectives and planned project activities.
The budget will not be scored but will be reviewed.

a. Is the itemized budget for conducting the project, along with justification, reasonable and consistent with stated objectives and planned program activities?
b. Is the budget itemized, well justified and consistent with the goals of the NOFO?

If applicable, did the Applicant clearly indicate activities and budget for each component in their submitted workplan?

c. Phase III Review

An Objective Review Panel will be convened.

In addition to direct consideration of findings from the Objective Review Panel, funding under this award will be subject to several preferences based on cost-effectiveness, geography, programmatic needs and country strategic priorities. . CDC can fund out of rank order in order: 1) to align with USG and/or agency prioritized technical areas and activities; 2) to ensure maximum coverage of activities geographically; 3) to avoid duplication of activities in other CDC funding mechanisms; 4) to respond to an unforeseen public health emergency of an international concern.

Only one application per country will be funded.

Funding will differ based on the component applied for, demonstration of need and justification; geography; and availability of funds.
Countries with funding priority are countries designated by the World Bank Income Designation (January 7, 20211) as Low- & Middle-Income Countries: Afghanistan; Albania: Algeria: American Samoa; Angola; Argentina; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Benin; Bhutan; Bolivia; Bosnia and Herzegovina; Botswana; Brazil; Bulgaria; Burkina Faso; Burundi; Cabo Verde; Cambodia; Cameroon; Central African Republic; Chad; China; Colombia; Comoros; Congo Dem. Republic; Congo, Republic; Costa Rica; Cote d'Ivoire; Cuba; Djibouti; Dominica, Dominican Republic; Ecuador; Egypt, Arab Republic; El Salvador; Equatorial Guinea; Eritrea; Eswatini; Ethiopia; Fiji; Gabon; Gambia, The; Georgia; Ghana; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; India; Indonesia; Iran; Islamic Republic; Iraq; Jamaica; Jordan; Kazakhstan; Kenya; Kiribati; Korea, Dem. People's Rep.; Kosovo; Kyrgyz Republic; Lao PDR; Lebanon; Lesotho; Liberia; Libya; Madagascar; Malawi; Malaysia; Maldives; Mali; Marshall Islands; Mauritania; Mexico; Micronesia, Fed. Sts.; Moldova; Mongolia; Montenegro; Morocco; Mozambique; Myanmar; Namibia; Nepal; Nicaragua; Niger; Nigeria; North Macedonia; Pakistan; Papua New Guinea; Paraguay; Peru; Philippines; Russian Federation; Rwanda; Samoa; Sao Tome and Principe; Senegal; Serbia; Sierra Leone; Solomon Islands; Somalia; South Africa; South Sudan; Sri Lanka; St. Lucia; St. Vincent and the Grenadines; Sudan; Suriname; Syrian Arab Republic; Tajikistan; Tanzania; Thailand; Timor-Leste; Togo; Tonga; Tunisia; Turkey; Turkmenistan; Tuvalu; Uganda; Ukraine; Uzbekistan; Vanuatu; Venezuela, RB; Vietnam; West Bank and Gaza; Yemen, Rep.; Zambia; Zimbabwe

In addition, the following factors may affect funding decision:

Funding Preferences

Funding Preference 1 (5 Points)
Preference to organizations supporting laboratory and epidemiology teams that consistently provide reports to WHO FluNet and WHO FluID respectively.

Deliverable 1: Documentation from WHO FluMart of performance for influenza seasons for the 2 years prior to application submission date.
Label for Deliverable 1: Funding Preference - Reporting Performance

Acceptable performance by applicants is defined by:

- Reporting of virologic and epidemiologic data to WHO FluNet and WHO FluID respectively
    - Reporting submitted during country's defined influenza season.
    - Shipment of specimens to a WHO CC per WHO guidelines

Funding Preference 2 (5 Points)
Preference to organizations whose laboratories have participated in the WHO annual proficiency panel (EQAP)
Deliverable 2: Documentation of results of prior 2 years EQAP scores.
Label for Deliverable 2: Funding Preference – Testing Status

Acceptable performance by applicants is defined by:

- Participation in the annual proficiency panel during the previous 2 years
- Panel score of >= 80% score on panels submitted

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

9/30/2021

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-14: Accounting System Requirements
AR-25: Data Management and Access

AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020
AR-27: Conference Disclaimer and Use of Logos

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Federal Financial Reporting Forms	90 days after the end of the budget period	Yes
Final Performance and Financial Report	90 days after end of period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken

as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

• Performance measures and targets
• The frequency that performance data are to be collected.
• How performance data will be reported.
• How quality of performance data will be assured.
• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
• Dissemination channels and audiences.
• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).
• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publically available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)
The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).

- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
    - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
    - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
    - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.
- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs.
    - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
    - Indirect Cost Rate Agreement.

For year 2 and beyond of the award, recipients may request that as much as 75% of their estimated unobligated funds be carried over into the next budget period. Recipients must include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a single, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances);
- and Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The recipients must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

N/A

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:
"Commodity" means any material, article, supplies, goods, or equipment;
"Foreign government" includes any foreign government entity;
"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;
b. contact name with phone, fax, and e-mail;
c. agreement number(s) if reporting by agreement(s);
d. reporting period;
e. amount of foreign taxes assessed by each foreign government;
f. amount of any foreign taxes reimbursed by each foreign government;
g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Pamela Kennedy
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

1600 Clifton Road, NE
Atlanta, GA 30333

Telephone:
(404) 639-3998
Email:
iux5@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance,** contact:

Nicole Comick
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

2939 Flowers Road, South
Atlanta, GA 30341

Telephone:
(404) 718-5907
Email:
ktv6@cdc.gov
For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:
Resumes / CVs

Position descriptions

Organization Charts

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Indirect Cost Rate, if applicable

Project Narrative - an additional 20 pages may be attached to include Component 2 and Component 3 information

Documentation of connection with and support of the ministry of health or country government to support public health work in the country.
Documentation of WHO EQAP participation for the 2 years prior to this application
Documentation of reporting to WHO FluNet and WHO FluId
Other required documents:
CD/Resume; Job Descriptions; Organizational Chars; Capacity Summary Statement; Financial Statement

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see http:// www.cdc.gov/ grants/ additional requirements/ index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings: A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http:// www.cdc.gov /grants /additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and

specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher

educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance –formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

NOFO-specific Glossary and Acronyms

FluID, FluNet, FluMart – WHO supported reporting systems and repositories of influenza surveillance data.

Acronyms:
AHI – Animal Human Interface
CDC - Centers for Disease Control and Prevention
GHSA – Global Health Security Agenda
GISRS – Global Influenza Surveillance and Response System
HHS – Health and Human Services
IHR – International Health Regulation
ILI – Influenza-like-illness
JEE – Joint External Evaluation
MOA – Ministry of Agriculture
MOH – Ministry of Health
NCIRD – National Center for Immunization and Respiratory Diseases
NIC – National Influenza Centre
NOFO – Notice of Funding Opportunity
OIE – World Organization for Animal Health
PIP – Pandemic Influenza Preparedness
PISA – Pandemic Influenza Severity Assessment
RT-PCR – Revers Transcription – Polymerase Chain Reaction
SARI – Severe Acute Respiratory Infections

U.S. – United States of America
VCM – Vaccine Composition Meeting
WHO – World Health Organization
WHO CC – World Health Organization Collaborating Centre