

Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases

Global Healthcare Detection and Response

CDC-RFA-CK21-2104

06/28/2021

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Part I. Overview

Applicants must go to the synopsis page of this announcement at <u>www.grants.gov</u> and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-CK21-2104. Applicants also must provide an e-mail address to <u>www.grants.gov</u> 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:

Global Healthcare Detection and Response

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 <u>https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf</u>. Guidance on how CDC interprets the definition of research in the context of public health can be found at <u>https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html</u> (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-CK21-2104

E. Assistance Listings Number:

93.318

F. Dates:

1. Due Date for Letter of Intent (LOI): 5/27/2021

2. Due Date for Applications:

06/28/2021

11:59 p.m. U.S. Eastern Standard Time, at <u>www.grants.gov</u>.

3. Due Date for Informational Conference Call:

• Informational Call/Webinar I – May 18, 2021, 9 – 11 AM

Join ZoomGov Meeting https://cdc.zoomgov.com/j/1608908023?pwd=ZHhuU0hXU3RSUEhJelBvNmtYUTZtdz09 Meeting ID: 160 890 8023: Passcode: ++YeX8F& One tap mobile +16692545252,,1608908023#,,*77201071# US (San Jose) +16468287666,,1608908023#,,*77201071# US (New York)

• Informational Call/Webinar II – May 20, 2021, 7 – 9 PM

Join ZoomGov Meeting https://cdc.zoomgov.com/j/1614726088?pwd=UFZyZ1I5aD15dmtsdmhGVWp6OUtTQT09 Meeting ID: 161 472 6088 Passcode: B#hR4F!D One tap mobile +16692545252,,1614726088#,,,,*23626182# US (San Jose) +16468287666,,1614726088#,,,,*23626182# US (New York)

G. Executive Summary:

1. Summary Paragraph

This Notice of Funding Opportunity (NOFO) intends to enhance detection and response to infectious disease threats globally by developing networks to implement prevention and containment strategies at local, national, and regional levels. Interventions to prevent, detect, and respond to infectious disease threats in healthcare, including antimicrobial resistance (AMR), healthcare-associated infections (HAIs), and COVID-19, will be developed and implemented within networks. Additionally, this NOFO aims to improve the detection of emerging AMR threats and identify AMR risk factors and prevention strategies across healthcare and the community to inform global AMR containment efforts.

The main outcomes are to: 1). reduce HAI's and deliver safe healthcare; 2). ensure facilities and countries are better prepared to respond to emerging AMR threats in healthcare; 3). countries and regions better understand AMR in enteric pathogens, fungal pathogens, invasive bacterial and respiratory pathogens, and *N. gonorrhoeae*; and 4). control and prevent outbreaks and emergencies in healthcare facilities and affected communities.

a. Eligible Applicants:
Open Competition
b. Funding Instrument Type:
CA (Cooperative Agreement)
c. Approximate Number of Awards 40

d. Total Period of Performance Funding:

\$150,000,000

e. Average One Year Award Amount:

\$ 800,000

Funding amount may vary by Component.

f. Total Period of Performance Length:

5

g. Estimated Award Date:

September 30, 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

Around the world, fighting emerging infections, antibiotic resistance, and delivering essential medical care depend on a safe and functional healthcare system. The COVID-19 pandemic has demonstrated the importance of protecting healthcare facilities during outbreaks, and the critical role of hospitals to actively detect, monitor, and respond to emerging infectious disease threats. Protecting healthcare workers and patients, and maintaining essential services through safe delivery of care, is a critical priority to reducing morbidity and mortality from COVID-19 infection.

The pandemic has also exposed critical weaknesses in healthcare, which have led to large numbers of COVID-19 infections in healthcare workers, healthcare-associated outbreaks of COVID-19, and the emergence of antibiotic resistant healthcare-associated infections (HAIs). Studies have found that 1 in 7 hospitalized patients with COVID-19 has acquired a secondary bacterial infection, and 50% of those patients who died had an antibiotic resistant HAI. It is possible that the COVID-19 pandemic will lead to an increased burden of antimicrobial resistance (AMR), which in turn could lead to higher levels of AMR infections in both community and healthcare settings and result in worse outcomes in hospitalized patients, including those with COVID-19.

Improving infection prevention and control (IPC) in healthcare facilities can prevent the transmission of emerging infectious diseases, including COVID-19 and HAIs caused by pathogens exhibiting AMR, and contain outbreaks of these diseases before they spread widely within the facility and into the community. Conducting assessments to better understand the burden, risk factors, and prevention strategies for AMR in both healthcare and community settings will inform local, regional, and global responses to contain the emergence of concerning AMR.

Globally and regionally, healthcare facilities confront similar challenges when detecting and responding to new threats, including COVID-19 and emerging AMR in many pathogens. Therefore, supporting rapid local analysis and exchange of prevention strategies will be pivotal to collectively build response capacity at national, regional, and global levels. Countries and facilities across the globe can accelerate progress toward safeguarding the health system by working together on common priorities of improving healthcare settings and containing AMR through detection and response of emerging threats.

The NOFO will have three components to support this approach. Component One: Detect and Respond to Infectious Disease Threats in Healthcare Facilities, creates collaborative networks to prevent transmission of infections in healthcare settings and contain emerging AMR threats. Component Two: Improve Capacity to Detect and Monitor Antimicrobial Resistance, aims to improve detection and monitoring of AMR in pathogens commonly found in healthcare settings and the community. Component Three: Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities, supports efforts to effectively respond to outbreaks in healthcare facilities, keeping them from becoming amplifiers of disease transmission.

The strategies and activities outlined in this funding opportunity directly support the mission of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) to prevent disease, disability, and death caused by a wide range of infectious agents.

b. Statutory Authorities

This program is authorized under Public Health Service Act, Sections 301(a), 307 and 317, as amended [42 U.S.C. Sections 241(a), 2421, and 247b]. Authority may also stem from an applicable emergency supplemental appropriation; such appropriation and any requirements and/or limitation associated with that emergency supplemental will be added to the notice of award.

Possible applicable supplemental appropriations include, but may not be limited to: P.L. 116-123 - Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 [March 6, 2020] P.L 116–136 - Coronavirus Aid, Relief, and Economic Security Act (CARES Act) [March 27, 2020].

c. Healthy People 2030

This project supports the following Healthy People 2030 goals and objectives:

Goal: Improve health by preventing, detecting, and responding to public health events worldwide.

- Increase the number of globally important public health events that are tracked and reported.
- Increase the number of individuals trained globally to prevent, detect, or respond to public health threats.
- Increase laboratory diagnostic testing capacity, surveillance, and reporting globally.

Global Health - Healthy People 2030 | health.gov

d. Other National Public Health Priorities and Strategies

Activities funded through this cooperative agreement must align with the following USG and HHS/CDC strategies and policies:

- National Strategy for Combating Antibiotic-Resistant Bacteria <u>https://www.cdc.gov/drugresistance/pdf/carb_national_strategy.pdf</u>
- National Health Security Strategy
- <u>https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf</u>
- CDC's strategy for improving global health security (GHS), based on three concepts to protect public health worldwide: 1) Prevent 2) Detect 3) Respond https://www.cdc.gov/globalhealth/security/index.htm
- The Department of Health and Human Services' (HHS) Global Health Strategy <u>https://www.hhs.gov/about/agencies/oga/about-oga/why-hhs-works-globally/hhs-global-strategy/index.html</u>

e. Relevant Work

This NOFO supports the Division of Healthcare Quality Promotion's (DHQP) priority of protecting patients and healthcare personnel globally. DHQP works with partners to implement IPC programs, identify and refine best practices, and promote innovative solutions for preventing infections and controlling AMR in healthcare settings and communities. DHQP collaborates with partners through NOFOs including CK18-1801 and GH20-2110.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

The Logic Model shows the high-level strategies and activities, as well as short-term and longterm outcomes. The Outcomes section has the descriptions of short- and long-term outcomes **bolded** in the logic model. The Strategies and Activities section includes the full descriptions of strategies/activities listed in the logic model.

Strategies & Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Strategy 1: Prevent Transmission of Infections in Healthcare	Healthcare workers increase collection and use of HAI Surveillance and IPC monitoring data		HAIs are reduced and safe healthcare is delivered
Facilities	Healthcare workers increase knowledge of IPC interventions and approaches to prevent HAIs Healthcare facilities increase	Healthcare workers use HAI surveillance, IPC monitoring, and AMR data to inform, monitor, and	Facilities and countries are better prepared to respond to infectious

Component 1 – Detect and Respond to Infectious Disease Threats in Healthcare Facilities

	implementation of IPC strategies to prevent transmission of infectious disease threats	improve prevention interventions Supportive systems for IPC, HAI prevention, and AMR containment are	disease threats in healthcare, including emerging AMR Spread of
Strategy 2: Detect and Respond to Emerging Antimicrobial Resistance in	Clinical and reference laboratory staff increase ability to detect emerging AMR Healthcare workers increase collection and use of AMR	improved	infectious disease threats is decreased within communities and across borders
Healthcare Facilities	data		Emerging AMR threats are contained at regional and global levels

<u>Component 2 – Improve Capacity to Detect and Monitor Emerging Antimicrobial</u> <u>Resistance</u>

Strategies & Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Strategy 1: Assess Antimicrobial Resistance in Healthcare	Clinical and reference laboratory staff increase ability to detect emerging AMR in relevant settings or	threats in relevant settings or pathogens are identified	Countries and regions better understand AMR in relevant settings or pathogens
Settings Strategy 2: Assess Antimicrobial Resistance in Enteric Pathogens	pathogens Methods developed to collect epidemiologic data to monitor emerging AMR in relevant settings or pathogens	Risk factors driving the emergence of AMR threats in	Emerging AMR threats in relevant settings or pathogens are contained and AMR drivers are reduced at country, regional, and global levels
Strategy 3: Assess Antimicrobial Resistance in Fungal Pathogens Strategy 4:		<u>Strategy 5</u> <u>ONLY:</u> Molecular assays to detect AMR in <i>N. gonorrhoeae</i> are developed and deployed	

Assess Antimicrobial Resistance in		
Invasive Bacterial and		
Respiratory		
Pathogens		
Strategy 5:		
Assess		
Antimicrobial		
Resistance in N.		
gonorrhoeae		

<u>Component 3 – Rapid Response to Infectious Disease Outbreaks or Other Public Health</u> <u>Emergencies in Healthcare Facilities</u>

Strategies and	Short-term Outcomes	Intermediate	Long-Term
Activities		Outcomes	Outcomes
Strategy 1: Improve Infection Prevention and Control to Prevent Transmission in Healthcare Facilities	Healthcare workers increase knowledge of IPC in the context of outbreaks and emergency responses Local, national, and regional partners increase ability to respond to outbreaks and emergencies in healthcare facilities	IPC in the context of outbreaks and emergencies in healthcare facilities is improved	Outbreaks and emergencies in healthcare facilities and affected communities are controlled and prevented

i. Purpose

This NOFO will enhance detection and response to infectious disease threats in healthcare facilities globally by developing networks to implement prevention and containment strategies at local, national, and regional levels. Interventions to prevent, detect, and respond to infectious disease threats in healthcare, including AMR, HAIs, and COVID-19, will be developed and implemented within networks. The NOFO will also improve the detection of emerging AMR and identify AMR risk factors and prevention strategies across healthcare and the community to inform global AMR containment efforts.

ii. Outcomes

Component 1 – Detect and Respond to Infectious Disease Threats in Healthcare Facilities

Strategy 1: Prevent Transmission of Infections in Healthcare Facilities Short-Term Outcomes

- Healthcare workers increase collection and use of HAI surveillance and IPC monitoring data
- Healthcare workers increase knowledge of IPC interventions and approaches to prevent HAIs
- Healthcare facilities increase implementation of IPC strategies to prevent transmission of infectious disease threats

Intermediate Outcomes

- Infectious disease threats are identified and contained in healthcare facilities
- Healthcare workers use HAI surveillance and IPC monitoring data to inform, monitor, and improve prevention interventions

Long-Term Outcomes

• HAIs are reduced and safe healthcare is delivered

Strategy 2: Detect and Respond to Emerging Antimicrobial Resistance in Healthcare Facilities Short-Term Outcomes

- Clinical and reference laboratory staff increase ability to detect emerging AMR
- Healthcare workers increase collection and use of AMR data

Intermediate Outcomes

- Emerging AMR threats are identified and contained within healthcare facilities
- Healthcare worker use AMR data to inform, monitor, and improve prevention interventions
- Supportive systems for AMR containment are improved

Long-Term Outcomes

• Facilities and countries are better prepared to respond to emerging AMR threats in healthcare

<u>Component 2 – Improve Capacity to Detect and Monitor Emerging Antimicrobial</u> <u>Resistance</u>

Strategy 1: Assess Antimicrobial Resistance in Healthcare Settings

Short-Term Outcomes

- Clinical and reference laboratory staff increase ability to detect emerging AMR in clinical isolates
- Methods developed to collect epidemiologic data to monitor emerging AMR in healthcare

Intermediate Outcomes

- Emerging AMR threats in healthcare settings are identified
- Risk factors driving the emergence of AMR threats in healthcare settings are identified

Long-Term Outcomes

• Countries and regions better understand AMR in healthcare settings

Strategy 2: Assess Antimicrobial Resistance in Enteric Pathogens

Short-Term Outcomes

- Clinical and reference laboratory staff increase ability to detect emerging AMR in enteric pathogens
- Methods developed to collect epidemiologic data and/or set up surveillance for emerging AMR in enteric pathogens

Intermediate Outcomes

- Emerging AMR threats in enteric pathogens are identified
- Risk factors driving the emergence of AMR threats in enteric pathogens are identified

Long-Term Outcomes

• Countries and regions better understand AMR in enteric pathogens

Strategy 3: Assess Antimicrobial Resistance in Fungal Pathogens

Short-Term Outcomes

- Clinical and reference laboratory staff increase ability to detect emerging AMR in fungal pathogens
- Methods developed to collect epidemiologic data and/or set up surveillance for emerging AMR in fungal pathogens

Intermediate Outcomes

- Emerging AMR threats in fungal pathogens are identified
- Risk factors driving the emergence of AMR threats in fungal pathogens are identified

Long-Term Outcomes

• Countries and regions better understand AMR in fungal pathogens

Strategy 4: Assess Antimicrobial Resistance in Invasive Bacterial and Respiratory Pathogens Short-Term Outcomes

- Clinical and reference laboratory staff increase ability to detect emerging AMR in invasive bacterial and respiratory pathogens
- Methods developed to collect epidemiologic data and/or set up surveillance for emerging AMR in invasive bacterial and respiratory pathogens

Intermediate Outcomes

- Emerging AMR threats in invasive bacterial and respiratory pathogens are identified
- Risk factors driving the emergence of AMR threats in invasive bacterial and respiratory pathogens are identified

Long-Term Outcomes

 Countries and regions better understand AMR in invasive bacterial and respiratory pathogens

Strategy 5: Assess Antimicrobial Resistance in N. gonorrhoeae

Short-Term Outcomes

- Clinical and reference laboratory staff increase ability to detect emerging AMR in *N. gonorrhoeae*
- Methods developed to identify novel strains/isolates, collect epidemiologic data, and/or set up surveillance for emerging AMR in *N. gonorrhoeae*

Intermediate Outcomes

- Emerging AMR threats in *N. gonorrhoeae* are identified
- Molecular assays to detect AMR in *N. gonorrhoeae* are developed and deployed
- Risk factors driving the emergence of AMR threats in *N. gonorrhoeae* are identified

Long-Term Outcomes

• Countries and regions better understand AMR in *N. gonorrhoeae*

<u>Component 3 – Rapid Response to Infectious Disease Outbreaks or Other Public Health</u> <u>Emergencies in Healthcare Facilities</u>

Strategy 1: Improve Infection Prevention and Control to Prevent Transmission in Healthcare Facilities

Short-Term Outcomes

- Healthcare workers increase knowledge of IPC in the context of outbreaks and emergency responses
- Local, national, and regional partners increase ability to respond to outbreaks and emergencies in healthcare facilities

Intermediate Outcomes

• IPC in the context of outbreaks and emergencies in healthcare facilities is improved

Long-Term Outcomes

• Outbreaks and emergencies in healthcare facilities and affected communities are controlled and prevented

iii. Strategies and Activities <u>Component 1 – Detect and Respond to Infectious Disease Threats in Healthcare Facilities</u>

Strategy 1: Prevent Transmission of Infections in Healthcare Facilities

- Create and coordinate a network of at least three (3) hospitals with adequate laboratory and IPC capacity in a country or countries to participate in a CDC-organized global "network of networks" focused on harmonized HAI data collection linked to evidence-based and data-driven HAI prevention efforts and innovation to improve the science of HAI prevention.
 - Network coordinators should provide additional IPC support to participating hospitals or identify a partner who can do so.

- Priority activities for network coordinators include:
 - Engage with global network coordinators at CDC to develop surveillance and prevention protocols to implement across network hospitals, with an initial focus on healthcare-associated bloodstream infections (HA-BSI) and healthcare-associated transmission of COVID-19
 - Facilitate communication and coordination between network hospitals and partners to support HAI data collection and prevention activities
 - Coordinate trainings and meetings of network hospitals and partners and provide feedback to network hospitals to ensure standardized implementation of network activities
 - Collect and share relevant and agreed upon data pertaining to facility and/or network-level HAI surveillance and prevention activities within the network and with CDC using the global network reporting system on an ongoing and routine schedule
 - A commitment to data sharing is necessary for network participation
 - Adhere to patient privacy and data storage standards as set forth by global, national, and local standards
 - Adapt information technology (IT) infrastructure to align with CDC reporting requirements and the global network reporting system
 - Participate in monitoring and evaluation of network performance
 - Participate in meetings of CDC's steering group for global network activities
 - Adapt networks over time to add new HAI surveillance and prevention activities across the global network and/or network-specific discretionary activities in collaboration with CDC's global network coordinators
 - Use the network's expertise to support other hospitals in the region, including provision of technical assistance, mentoring, and/or training in HAI surveillance and prevention techniques
- Priority activities to be implemented by network hospitals include:
 - Validated collection of HAI data to address network priorities (e.g., HA-BSI and COVID-19, initially). Data collection activities must be harmonized across network hospitals. These activities may include:
 - Regular periodic HAI point prevalence surveys (PPS) using standardized methods, harmonized definitions, and standardized presentation of results across the network
 - Continuous, outcome-based HAI surveillance utilizing methods that assure within-site comparability of results over time (e.g., trend analysis)
 - Practice-based IPC monitoring activities using methods that assure withinsite comparability of results over time (e.g., trend analysis)
 - Development and support of evidence-based HAI prevention programs to address network priorities (e.g., HA-BSI and COVID-19, initially) and sharing of strategies and experiences with CDC and global network collaborators. These activities may include:

- Implementation of core prevention strategies (based on scientific evidence and demonstrated feasibility) for targeted HAIs using standardized methods
- Development of new initiatives for supplemental prevention strategies (based on some scientific evidence and variable levels of feasibility) or novel supplemental strategies based on patient population and health system context
- Implementation of additional, network-specific discretionary activities in collaboration with CDC's global network coordinators. Initial discretionary activities may include:
 - Response to healthcare-associated outbreaks using standardized methods and collaboration across the network
 - Validation and/or feasibility assessments of novel HAI surveillance methods or definitions
 - Pilot implementation of novel IT or information systems to support and enhance HAI surveillance
- Priority activities for the network-level IPC team include:
 - Participate in trainings and meetings with network coordinators to ensure standardized implementation of network activities
 - Provide training and technical assistance to IPC teams at network hospitals to implement HAI surveillance and prevention activities
 - Facilitate communication between IPC teams at hospitals across the network

Strategy 2: Detect and Respond to Emerging Antimicrobial Resistance in Healthcare Facilities

- Create and coordinate a network of at least three (3) hospitals within a country or countries and at least one (1) reference laboratory within 18 months to participate in a CDC-organized global "network of networks" focused on the rapid identification, confirmation, response to, and containment of emerging AMR threats in healthcare settings.
 - Network coordinators should provide additional IPC support to participating hospitals or identify a partner who can do so.
- Priority activities for network coordinators include:
 - Identify priority pathogens and AMR profiles to target for the network's AMR containment response activities with global network coordinators at CDC and partners based on local epidemiology
 - Facilitate communication and coordination between network hospitals, laboratories, and partners to support AMR detection activities and containment responses
 - Coordinate trainings and meetings of network hospitals, laboratories, and partners and provide feedback to network hospitals and laboratories to ensure standardized implementation of network activities
 - Facilitate procurement of supplies and reagents and shipping of isolates between network hospitals and laboratories

- Collect and share relevant and agreed upon data pertaining to laboratory results and containment responses with CDC using the global network reporting system routinely
 - A commitment to data sharing is necessary for network participation
- Adhere to patient privacy and data storage standards as set forth by global, national, and local standards
- Adapt and implement IT infrastructure to align with CDC reporting requirements and the global network reporting system
- Participate in monitoring and evaluation of network performance
- Participate in meetings of CDC's steering group for global network activities
- Adapt networks over time to add new priority AMR threats, laboratory methods, data collection tools and systems, and IPC strategies
- Use the network's expertise to support other hospital laboratories and IPC teams in the region, including provision of technical assistance, mentoring, and/or training in detection and containment of emerging AMR threats
- Priority activities for network hospital clinical laboratories include:
 - Test priority pathogen isolates obtained from routine hospital clinical and surveillance cultures to determine if they meet criteria for referral or containment response according to network protocols
 - Refer all isolates meeting referral criteria and supporting documentation to the network's reference laboratory within 24 hours for additional characterization if not performed in the hospital laboratory
 - Store all isolates meeting network referral criteria at -20°C or -70°C for a period of at least 6 months and refer isolates to a supporting national, regional, or global reference laboratory, if needed or requested
 - For isolates meeting the containment response criteria, report laboratory results to the network's alert reporting system within 24 hours of detection, and engage appropriate network partners
 - Share agreed-upon laboratory results and other relevant data to the global network reporting system for all isolates tested as part of network activities on at least a monthly basis
 - A commitment to data sharing is necessary for network participation
 - Test colonization screening specimens collected during network containment response activities according to network protocols using validated methods
 - Participate in trainings and meetings to ensure standardized implementation of network activities
 - Pilot innovative laboratory testing methods in concert with network partners and CDC and share results with global network collaborators
- Priority activities for network reference laboratories include:
 - Monitor the network's alert reporting system daily, assist with assessment of any alerts, and coordinate isolate transportation for additional characterization if needed

- Test clinical isolates and colonization screening specimens referred from network hospitals according to network protocols
- Support network hospitals to test colonization screening specimens using targeted gene testing or other methodology according to network protocols and strengthen colonization screening testing capacity at the hospital laboratories
- Store isolate- and specimen-level laboratory results for all isolates tested for the network for a period of at least 2 years after receiving the specimen
- Store all isolates received from network hospitals or other laboratories that meet criteria at -70°C for a period of at least 2 years and refer isolates to a supporting national, regional or global reference laboratory, if needed or requested
- Ship select isolates to the regional or global reference laboratory for routine confirmatory testing and participate in proficiency testing activities based on methods and timelines developed in collaboration with CDC
- Routinely deposit whole genome sequencing data to an agreed upon accessible repository, if performed
- Participate in trainings and meetings to ensure standardized implementation of network activities
- Pilot innovative reference testing methods in concert with network partners and CDC and share results with global network collaborators
- Priority activities for network hospital IPC teams include:
 - Monitor the network's alert reporting system for the facility daily and initiate containment activities for isolates requiring a containment response within 24 hours of receiving the alert
 - When isolates requiring a containment response are identified, conduct containment activities, including (but not limited to) laboratory data reviews, patient screening, point prevalence surveys, and IPC assessments, according to network protocols with adaptation to the facility's resources and infrastructure as needed
 - Collect colonization screening specimens as indicated according to network containment protocols
 - Report relevant and agreed-upon containment response data to the global network reporting system and key stakeholders at least quarterly
 - A commitment to data sharing is necessary for network participation
 - Report data for predefined performance measures/metrics for network containment activities annually
 - Participate in trainings and meetings to ensure standardized implementation of network containment activities
 - Pilot innovative IPC strategies in concert with network partners and CDC and share experiences and results with global network collaborators
- Priority activities for the network-level IPC team include:
 - Monitor the network's alert reporting system daily and proactively reach out to network hospitals reporting alerts to offer assistance within 24 hours
 - Assist IPC teams at network hospitals to implement containment activities according to network protocols upon request

- Monitor and evaluate network containment alerts for patterns in emerging AMR threats across hospitals in the network in collaboration and engage relevant partners
- Facilitate communication between IPC teams at hospitals across the network
- Coordinate containment responses across hospitals when an outbreak involves multiple hospitals in the network
- Participate in trainings and meetings to ensure standardized implementation of network containment activities

<u>Component 2 – Improve Capacity to Detect and Monitor Emerging Antimicrobial</u> <u>Resistance</u>

Activities within this component aim to assess AMR at the interface of healthcare and community settings outside of the United States and may be performed within or outside of an existing network of healthcare facilities and/or community sites, as appropriate. Applicants may propose activities to support a single strategy or multiple strategies.

Strategy 1: Assess Antimicrobial Resistance in Healthcare Settings

- Prioritized activities may include the following:
 - Design and implement projects to inform, implement, and/or evaluate AMR prevention and control strategies in healthcare settings
 - Develop strategies to better estimate the burden of AMR in healthcare settings and its associated costs and/or cost-effectiveness of AMR prevention interventions (e.g., antimicrobial stewardship, IPC programs, etc.) in healthcare settings
 - Develop and implement projects to address the limitations of passive, isolate-based AMR surveillance in healthcare settings, including studies to improve diagnostic stewardship and clinicians' use of microbiology services and surveillance studies using case-based approaches
 - Improve antimicrobial stewardship in healthcare settings and develop effective, resource-appropriate methods for monitoring antimicrobial use in low- and middle-income countries
 - Support implementation science-based approaches to improving AMR prevention interventions (e.g., antimicrobial stewardship, IPC programs, etc.) in healthcare settings
 - Design and implement projects to improve the monitoring of emerging AMR and assess relationships between AMR in healthcare settings, the community, and the environment
 - Perform whole genome sequencing of isolates exhibiting AMR to describe the molecular epidemiology of AMR in a region, describe the resistome of isolates, or evaluate transmission of AMR in a geographic area (e.g., hospital, community, or region)
 - Assess risk factors for development of AMR infections in patients with and without exposures to healthcare settings, including colonization with organisms exhibiting AMR

• Examine potential relationships between environmental risk factors (e.g., effluent from healthcare facilities, etc.) and AMR infections in humans

Strategy 2: Assess Antimicrobial Resistance in Enteric Pathogens

- Prioritized activities may include the following:
 - Build whole genome sequencing (WGS) capacity among PulseNet International (PNI) participants including the 12-country PulseNet Africa (PNAFR) region, the 16-country PulseNet Latin America and the Caribbean (PNLAC) region, the 13country PulseNet Asia Pacific (PNAP) region, the 13-country PulseNet Middle East (PNME) region, and the country of Georgia to improve detection and surveillance of emerging multidrug-resistant (MDR) enteric bacteria and ensure that data are comparable across countries in these surrounding regions.
 - Develop action plans in collaboration with existing PulseNet (PN) members in the country/region and laboratory and epidemiology teams to implement and validate WGS as a subtyping method and tool to monitor emerging antibiotic resistance mechanisms
 - Build laboratory, analysis, and bioinformatics capacities by providing training and technical assistance for PNI countries and laboratory scientists in PNI countries/regions
 - Launch pilot project to demonstrate the value of using WGS to characterize emerging MDR enteric bacteria and strengthen communication between laboratory scientists and epidemiologists in the PNI countries/regions
 - Use data generated from improved laboratory and/or epidemiology capacity to inform, implement, and/or evaluate strategies to prevent spread of AMR in enteric pathogens
 - Build or enhance capacity to isolate, identify, and conduct antimicrobial susceptibility testing and/or whole genome sequencing for enteric/diarrheal infections, measure exposure risk from potential sources (human, animal, environment), and implement and/or evaluate effectiveness of conventional and non-conventional treatments and prevention strategies, with a focus on regions/countries where enteric pathogens are endemic including: Middle East (Lebanon, Saudi Arabia), Africa (Kenya, Tanzania, Mozambique, Ethiopia, Zambia, Uganda), Asia (Pakistan, Bangladesh), and the Americas and Caribbean (Haiti, Guatemala).
 - Detect emerging resistance to entering pathogens to treatment drugs of choice, including fluoroquinolones, 3rd generation cephalosporins, azithromycin, and carbapenems
 - Assist regions with the development of protocols to assure that similar laboratory and analytic methods are used and the same nomenclature is applied so that strains with emerging resistance can be tracked regionally and globally
 - Build surveillance capacity to collect epidemiological (e.g., demographics, exposures) and clinical (e.g., severity, outcomes) data on patients infected

with antibiotic resistant enteric bacteria to determine exposures (e.g., food, animal, environment), risk factors, and clinical outcomes of infection

- Build capacity to strengthen data systems for surveillance and outbreak investigations and build communication systems for relaying results of investigations to partners
- Build capacity to investigate and prevent outbreaks of antibiotic-resistant enteric illness linked to food, animals, animal feed, or the environment
- Obtain samples from food, animals, animal feed, and the environment, and associated epidemiologic information, to detect and prevent antibiotic-resistant enteric bacteria
- Detect and characterize AMR bacteria in drinking water sources and other water types (e.g., surface water, wells) used for household activities (e.g., washing, cooking)
- Implement AMR testing of pathogenic isolates collected from water sources (e.g., taps, surface water, springs) known or suspected to be associated with a disease outbreak
- Institute testing or regular monitoring of AMR organisms in wastewater or fecal sludge (e.g. rapid screening of extended-spectrum beta-lactamase-producing E. coli via modified conventional water testing)
- Assess the survival and dissemination of AMR bacteria in wastewater or fecal sludge in low sanitation settings (e.g., retention ponds, open drains, latrines)
- Assess the impact that inadequate population coverage with safely managed sanitation and drinking water has on creating an environment that facilitates emergence and transmission of new highly resistant enteric pathogens
- Assess adult and/or pediatric exposure risks for AMR-specific organisms from poor water, sanitation, and hygiene facilities
- Strengthen surveillance of *Salmonella Typhi* and invasive non-Typhi *Salmonella* clinical specimens to help target and prioritize typhoid vaccination and prevention strategies in endemic countries
- Conduct clinical studies on the effectiveness of different antimicrobial regimens to cure acute episodes of extensively drug-resistant (XDR) typhoid fever and to eliminate carriage of XDR Typhi strains from chronic carriers
- Evaluate non-conventional treatment agents for diarrheal diseases that would reduce the demand for antimicrobial treatment (for example, Pepto-Bismol or its active ingredient, bismuth subsalicylate)

Strategy 3: Assess Antimicrobial Resistance in Fungal Pathogens

- Prioritized activities may include the following:
 - Increase support and capabilities for identification, surveillance, and response to known and emerging antifungal resistant threats (i.e. C. auris, Azole-resistant aspergillus), specifically in the following regions/countries: South and Central American countries, Pacific island countries (including Guam), Dominican

Republic, Southeast Asian countries (including Pakistan, Bangladesh, Indonesia), India, Japan, East African countries (including Tanzania, Kenya), South Africa, Middle East countries (including United Arab Emirates).

- Build focused and detailed epidemiology, laboratory, and bioinformatics capacity for antifungal resistant diseases and outbreaks
- Engage frontline personnel and lead training in CDC best practices for the broader workforce supporting the prevention and control of antifungal resistant pathogens
- Target guidance and tools to better reach communities and populations at increased risk for antifungal resistant diseases and reduce antifungal resistant disease spread in targeted healthcare facilities or high-risk settings
- Monitor and evaluate the impact and effectiveness of implemented strategies for improved antifungal resistant infection prevention and control practices

Strategy 4: Assess Antimicrobial Resistance in Invasive Bacterial and Respiratory Pathogens

- Prioritized activities may include the following:
 - Build or enhance bacterial culture capacity, molecular AMR testing capacity, and/or whole genome sequencing capacity in sites conducting surveillance for meningitis, *S. pneumoniae*, Group B Streptococcus, or Group A Streptococcus, specifically in the following countries: Burkina Faso, Niger, Mali, Togo, Benin, Senegal, Ghana, South Africa, Kenya, Mozambique, India, Indonesia, Thailand, Haiti, El Salvador, Costa Rica, and Brazil
 - Enhance *B. pertussis* laboratory-based surveillance and evaluate macrolide resistance in nasopharyngeal specimens of patients tested positive for pertussis, focusing on participating sites of established platform for culture diagnostics and PCR capacity in the following countries: Mexico, Panama, Colombia, Brazil, Argentina, and Chile
 - Use data generated from improved laboratory and/or epidemiology capacity to inform, implement, and/or evaluate vaccine efficacy and improvement and other strategies to prevent spread of AMR in invasive bacterial and respiratory pathogens

Strategy 5: Assess Antimicrobial Resistance in N. gonorrhoeae

- Prioritized activities may include the following:
 - Expand Enhanced Gonococcal Antimicrobial Surveillance Programme (EGASP) activities and capabilities at sites where this work has already begun (Thailand, Philippines), and implement EGASP, per established protocol, in new regions/countries, prioritizing areas with little to no data on gonococcal infection rates and/or antimicrobial resistance levels, with known or suspected high levels of AMR among gonococcal infections, or with existing gonococcal laboratory and/or surveillance capacities, specifically in the following regions/countries: Africa (South Africa, Côte d'Ivoire, Kenya, Zambia, Uganda), South America

(Brazil, Argentina, Peru), Eastern Mediterranean (Georgia), Southeast Asia (India), Western Pacific (Cambodia, Vietnam)

- Use data generated from improved laboratory and/or epidemiology capacity to inform, implement, and/or evaluate strategies to prevent the spread of AMR in *N. gonorrhoeae*
- Build focused and detailed epidemiology, laboratory, and data sharing capacity for tracking spread of and risk factors for AMR *M. genitalium*

<u>Component 3 – Rapid Response to Infectious Disease Outbreaks or Other Public Health</u> <u>Emergencies in Healthcare Facilities</u>

Strategy 1: Improve Infection Prevention and Control to Prevent Transmission in Healthcare Facilities

- Develop outbreak-specific IPC policies, procedures, guidelines, and trainings in collaboration with government and non-government partners
- Identify and train IPC focal persons responsible for implementation of IPC practices at priority healthcare facilities
- Provide on-site supportive supervision and mentorship to improve implementation of IPC practices at priority healthcare facilities
- Improve screening and triage at healthcare facilities to rapidly identify, isolate, and refer suspect cases for treatment
- Implement enhanced surveillance of healthcare workers and inpatients at healthcare facilities

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

Recipients are encouraged to work with CDC and other CDC implementing partners, including Ministries of Health, other host government agencies, multilateral organizations, non-governmental organizations, academic institutions, and other entities that receive CDC funds in the country or countries where they implement strategies and activities. Recipients should ensure their proposed activities are not duplicating activities already implemented by other CDC-funded organizations.

b. With organizations not funded by CDC:

Recipients are encouraged to build and sustain strategic partnerships and collaborations with regional, national, and local agencies and organizations that have a role in supporting the implementation of a recipient's proposed work plan/activities and achieving expected outcomes. Partners and collaborators may include government agencies, academic institutions, non-governmental organizations, and healthcare facilities and laboratories.

Applicants to Component One must implement activities within a network of hospitals, IPC support partner, and/or reference laboratories. Applicants to Component One must submit letters of support from all hospitals, IPC support partners, and/or reference laboratories proposed in their network that demonstrate their willingness to collaborate in a network.

Applicants to all components may also provide letters of support from host government agencies and other collaborating organizations. Applicants should combine all letters of support into a single document, name the file "Letters of Support," and upload the file as a pdf at <u>www.grants.gov</u>. A maximum of 15 letters of support per component are allowed.

2. Target Populations

The target population includes, but is not limited to, those individuals affected and infected by infectious diseases or at risk for becoming infected by an infectious disease. This may also include at-risk populations for non-communicable diseases and/or other public health emergencies.

a. Health Disparities

Epidemic diseases affect the connectivity within societies, and their impacts may be exacerbated by social divides, economic disparities, and injustices that lead to inequities in healthcare. Given that it is possible the COVID-19 pandemic will lead to increased AMR infections in both community and healthcare settings, and result in worse outcomes in hospitalized patients, including COVID-19 patients, these affects will be more pronounced for disproportionately burdened populations, disproportionately burdened healthcare facilities, and healthcare workers working in workplace environments with disproportionate risk. Applicants are encouraged to describe how health disparities will be addressed in their proposals. Applicants may propose evidence-based strategies to better understand the burden, risk factors, and prevention strategies for AMR in both healthcare and community settings and how they will inform local, regional, and global responses to contain the emergence of concerning AMR for populations disproportionately burdened populations.

iv. Funding Strategy

This NOFO is divided into three components – the applicant is required to propose work in a country or region with a clearly marked budget and work plan for each component. The NOFO has two core components: **Component One: Detecting and Responding to Infectious Disease Threats in Healthcare Facilities** and **Component Two: Improve Capacity to Detect and Monitor Emerging Antimicrobial Resistance**. Component Three is designed to support a response to a designated emergency event (**Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities**).

Applicants may apply for one or multiple components; a separate application must be submitted for each component. Only recipients selected to receive funding for Component One, Component Two, or both will be considered for funding for Component Three.

Applicants may propose activities to support a single strategy or multiple strategies within each component. Applicants must clearly specify the strategies they plan to support and the activities within each strategy that they plan to implement within a clearly marked budget and work plan.

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 One plan and projection of strategies and activities to be accomplished in later years.

Component One (Detecting and Responding to Infectious Disease Threats in Healthcare Facilities) within this NOFO is intended to be funded on an annual basis. The estimated Year

One funding level \$10,000,000. Future year funding levels will be dependent on funding availability.

Component Two (Improve Capacity to Detect and Monitor Emerging Antimicrobial Resistance) within this NOFO is intended to be funded on an annual basis. The estimated Year One funding level \$3,000,000. Future year funding levels will be dependent on funding availability.

The final decision on which components and strategies will be funded will be made at the time of award. Applications will be rank ordered. Program will use a separate rank ordered listing for each Component. CDC can fund out of rank order in order: 1) to align with USG and/or agency prioritized technical areas and activities; 2) to align with funding availability for a geographic area at the time of the award; 3) to ensure maximum coverage of activities geographically; 4) to avoid duplication of activities in other CDC funding mechanisms; or 5) to respond to an unforeseen public health emergency of an international concern.

There is no minimum number of countries/regions an applicant can apply for. However, CDC seeks to maximize coverage of activities geographically and can fund out of order in order to ensure maximum coverage exists (based on funding availability for those countries/regions at the time of award).

Component Three (Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities) is intended to be approved but unfunded (ABU) as a baseline practice. It would be funded to support additional activities needed within a budget period when a disease outbreak or other public health emergency reaches a scale that requires a moderate response. Estimated planning level is \$10,000,000.

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.

Awards made under this NOFO may utilize funds made available through legislation supporting the response to the Coronavirus Disease 2019 (COVID-19) pandemic. Additional guidance for awards made using these funds is outlined below:

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); and/or the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory reporting guidance is posted at: <u>https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-</u>

guidance.pdf.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such sub-award.

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.

Applicants must provide the following information as part of their Evaluation and Performance Measurement Plan:

- 1. Describe a data collection plan that specifies the data sources and feasibility of collecting the appropriate data needed for the process and outcome performance measures. Plans for data collection should include the method and frequency of data collection and describe responsible parties who will assure that data collection activities are implemented.
- 2. Describe how process and outcome performance measure findings will be used to assess project progress, identify performance gaps, and identify new interventions and activities to address performance gaps and continuously improve project quality.
- 3. Documentation of their willingness to share agreed-upon data with CDC and a description of any anticipated challenges in sharing evaluation and performance measurement data with CDC or storing performance measurement data on CDC data systems due to local or national guidelines, standards, or regulations.

c. Organizational Capacity of Recipients to Implement the Approach

Applicants must demonstrate existing or forthcoming organizational capacity to successfully execute the project strategies and activities, including willingness to share relevant and agreed upon de-identified data with CDC. Organizational capacity includes technical, management, and administrative skillsets required to implement the award, such as program management, epidemiological and/or clinical expertise, data management and analysis, performance monitoring, evaluation, and financial management.

Applicants must provide a project management structure and staffing plan that will be sufficient to achieve project outcomes which clearly defines staff roles. Applicants must describe their experience and capacity to implement the Evaluation and Performance Measurement Plan.

Applicants should also describe fiscal, administrative, support, and personnel services responsible for supporting project activities and personnel. Applicants must also have the capacity to manage award funds in accordance with HHS Grants Policy Statement, which can be found at <u>https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html</u>.

Component One – Detect and Respond to Infectious Disease Threats in Healthcare Facilities

Networks proposed by applicants to support either strategy in Component One should consist of hospitals, IPC support partners, and reference laboratories that meet or exceed the specifications described below.

Applicants to Component One must submit letters of support from all hospitals, reference laboratories, and partners providing additional IPC support to proposed network laboratories or hospitals. These letters should describe the hospital, reference laboratory, or IPC support partner's ability to meet these specifications and demonstrate their willingness to collaborate in a network. Additional information about letters of support is provided in the "Collaborations"

section of this NOFO.

Specifications for network hospitals:

- Support from appropriate hospital authorities to participate in activities proposed in the network (for example, implementation of systematic data collection for HAI surveillance and ability to address IPC deficiencies to meet network standards in Strategy 1 and/or implementation of emerging AMR threat detection and containment response activities in Strategy 2)
- Access to a hospital microbiology laboratory with capacity for bacterial culture, organism identification, and antimicrobial susceptibility testing with demonstrated participation in external quality assessment programs and documented internal quality control programs
 - For hospitals proposed in networks supporting Strategy 1, access to COVID-19 testing is necessary
 - For hospitals proposed in networks supporting Strategy 2, access to additional phenotypic and genotypic testing capacities for advanced detection of emerging known and potentially novel AMR are not necessary but would be advantageous (for example, other phenotypic or genotypic methods to detect priority AMR genes and/or short-read whole genome sequencing)
- Experience with shipping bacterial and/or viral isolates to reference laboratories within and outside of the country for confirmatory testing or additional characterization, as needed
- Active and functional IPC program with a dedicated and trained team currently engaged in longitudinal outcome or process-based HAI surveillance, implementing HAI and multidrug-resistant organism prevention activities, and responding to outbreaks
- Information technology infrastructure that allows for reporting to CDC's global network data reporting system (e.g., reliable internet access for clinical, laboratory, and epidemiologic data entry) and operational health information system with the ability to link electronic clinical data with laboratory information system data
- Willingness to establish or maintain existing collaborations with the network organizers and their designated partners
- Willingness to share relevant and agreed upon de-identified data required to meet global network objectives

Specifications for IPC support provided by network coordinators and/or partners:

- Support from appropriate authorities to participate in activities proposed in the network (for example, assisting network hospitals to conduct HAI prevention and/or AMR containment activities, as needed)
- Expertise in implementing HAI prevention strategies, prevention of multi-drug resistant organisms, and/or response to outbreaks at the hospital level
- Willingness to establish or maintain existing collaborations with network hospital IPC teams to support network HAI prevention and AMR containment activities, as needed

- Information technology (IT) infrastructure, including reliable Internet access, for IPC response data entry to the global network reporting system, and willingness to align with network IT standards
- Willingness to establish or maintain existing collaborations with network organizers and their designated partners
- Willingness to share relevant and agreed upon de-identified data pertaining to HAI prevention and AMR containment activities to meet global network objectives

Specifications for network reference laboratories (only relevant for Strategy 2):

- Support from appropriate authorities to participate in activities proposed in the network (for example, implementation of network testing protocols for emerging AMR threat confirmation from network hospitals)
 - Reference laboratories may include, but are not limited to, government reference laboratories (e.g., national reference laboratories), university or academic laboratories, or research laboratories
- Capacity for bacterial culture, organism identification, antimicrobial susceptibility testing, molecular detection techniques for emerging known and potentially novel AMR (for example, phenotypic and genotypic testing for priority AMR genes), with demonstrated participation in external quality assessment programs and documented internal quality control activities.
 - Short-read whole genome sequencing capacity is desired, but not required
- Capacity to test large numbers of specimens with rapid turnaround time and feedback to referring hospitals and/or laboratories
- Willingness to establish or maintain existing collaborations with network hospital laboratories to support specialized testing and characterization of priority AMR isolates and surge test capacity for AMR threat detection and response
- Experience with shipping bacterial isolates reference laboratories within or outside of the country for surge test capacity and additional characterization, as needed
- Information technology (IT) infrastructure, including reliable Internet access, for laboratory and containment data entry to the global network reporting system, and willingness to align with network IT standards
- Willingness to establish or maintain existing collaborations with network organizers and their designated partners
- Willingness to share relevant and agreed upon de-identified data pertaining to selected isolates and containment response activities to meet global network objectives

Component Two – Improve Capacity to Detect and Monitor Antimicrobial Resistance Applicants to Component Two should:

• Describe a previous track record of successful work supporting detection, response, containment, and/or prevention of specified priority AMR pathogens in international settings

- Propose work with laboratories demonstrating proficiency in basic testing techniques according to internationally accepted protocols and capable of assisting with appropriate specimen collection
- Describe laboratories' ability to successfully ship and store specimens/isolates and ongoing maintenance of equipment and supplies
- Collaborate with laboratories implementing a complete and effective Quality Management System with reporting protocols already in place, per accepted capacity assessment and QMS tools
- Describe established connections with clinical sites that produce high volumes of specimens of interest
- Describe the ability to collect and link clinical, laboratory, and epidemiologic data from relevant sites
- Describe the necessary expertise and capacity to facilitate development of action plans, as well as provide and support training and technical assistance within specified regions/countries
- Describe established partnerships within region/country(s) with leadership, networks, and/or programs relevant to the specific AMR focus
- Describe initial work underway on specified pathogens and AMR characterization within specified regions/countries and as part of already existing networks needing additional support and expansion
- Describe existing mechanisms and abilities to share data across laboratory, epidemiology, clinical, and/or environmental spaces where relevant and willingness to work across partners to improve data sharing capacities and communications

Component Three - Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities

Applicants to Component Three should:

- Describe a previous track record of successful work supporting outbreak responses in healthcare settings inside or outside of the United States, including but not limited to outbreaks of pathogens exhibiting AMR and other diseases of public health concern (*e.g., COVID-19, viral hemorrhagic fevers, etc.*)
- Describe subject matter expertise with IPC practices relevant for outbreak responses in healthcare settings (*e.g., isolation and transmission-based precautions, etc.*) and their application outside of the United States
- Have experience training, mentoring, and/or supervising IPC staff and/or frontline healthcare workers in the identification of and response to outbreaks in healthcare settings

For all components, applicants should provide the following documents in their appendix:

- Curricula vitae (CVs) or Resumes for staff positions including Principal Investigator, Project Director, Business Official, and other key staff related to program planning and implementation, finance, and monitoring and evaluation
- Job Descriptions (*maximum 1 page per job description*) for staff positions including Principal Investigator, Project Director, Business Official, and other key staff related to program planning and implementation, finance, and monitoring and evaluation

- Organizational Chart (*maximum 1 page*)
- 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*)
- Letters of Support Required for Component One; Optional for Components Two and Three (*maximum 15 pages*)

Applicants must title these documents in the appendix as follows: "CVs/Resumes," "Job Descriptions," "Organizational Chart," "Financial Statement," "Letters of Support," and upload at <u>www.grants.gov</u>.

d. Work Plan

Applicants must submit a separate work plan as part of their application for each component applied to. The work plan must provide a high-level overview of the entire five-year period of performance and a detailed description of the first year of the award. The work plan should clearly state the NOFO strategies and activities that the applicant plans to support and should explain how all proposed activities align with the logic model, outcomes, and indicators from the Evaluation and Performance Measurement section of this NOFO.

Post-award, the proposed work plan and activities may be adjusted in collaboration with CDC to better address the overarching goals of the NOFO.

Period of Performa	nce Outcome:	Outcome Measure:	
Strategies and Activities	Process Measure	Responsible Position/Party	Completion Date
1.			
2.			
3.			
4.			

An example work plan template follows below; applicants may use any format that links proposed activities to outcomes.

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.

For any set of activities funded under this NOFO, recipients should collaborate closely with Project Officers from CDC's Division of Healthcare Quality Promotion providing funds for technical and administrative oversight of project activities under the award. The Project Officer for the award will provide relevant contacts of CDC staff and coordinate discussions with award recipients.

Additional routine monitoring activities may include:

- Reviewing and approving the recipient's annual work plan and detailed budget
- Reviewing as necessary to the process used by the recipient to select key personnel and/or sub-recipients used in the activities performed under this agreement
- Providing administrative support to help the recipient meet U.S. Government financial and reporting requirements
- Organizing regular calls and meetings with the recipient to monitor project implementation progress
- Organizing regular calls and meetings with the recipient to assess expenditure in relation to approved work plan and to modify as necessary

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:

U3H

3. Fiscal Year:
2021
4. Approximate Total Fiscal Year Funding: \$ 15,000,000

5. Total Period of Performance Funding:

\$ 150,000,000

This amount is subject to the availability of funds.

Estimated Total Funding:

\$ 150,000,000

6. Total Period of Performance Length:

5 year(s)

7. Expected Number of Awards:40

8. Approximate Average Award:

\$ 800,000 Per Budget Period

Funding amount may vary by Component.

9. Award Ceiling:\$ 0Per 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: September 30, 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")

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

Territorial governments or their bona fide agents in 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

State controlled institutions of higher education

Local governments or their bona fide agents

Other

Ministries of Health

2. Additional Information on Eligibility

N/A

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 <u>www.grants.gov</u>.

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 <u>http:// fedgov.dnb. com/ webform/ displayHomePage.do</u>. 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 <u>www.grants.gov</u>, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at <u>www.grants.gov</u>.

All applicant organizations must register at <u>www.grants.gov</u>. 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)	 Click on <u>http://</u> fedgov.dnb.com/ webform Select Begin DUNS search/request process Select your country or territory and follow the instructions to obtain your DUNS 9-digit # Request appropriate staff member(s) to obtain DUNS 	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (<u>http://</u> fedgov.dnb.com/ webform) or

		number, verify & update information under DUNS number		call 1-866-705- 5711
2	Award Management (SAM) formerly Central Contractor Registration	 Retrieve organizations DUNS number Go to <u>https://www.sam.gov/SAM/</u> 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) 	be renewed once a year	For SAM Customer Service Contact <u>https://fs</u> <u>d.gov/ fsd-gov/</u> <u>home.do</u> Calls: 86 6-606-8220
3	Grants.gov	2. Once the account is set up the E-BIZ POC will be notified via	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	Register early! Log into grants.gov and check AOR status

2. Request Application Package

Applicants may access the application package at <u>www.grants.gov</u>.

3. Application Package

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

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)

5/27/2021

b. Application Deadline

06/28/2021

11:59 pm U.S. Eastern Standard Time, at <u>www.grants.gov</u>. 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

• Informational Call/Webinar I – May 18, 2021, 9 – 11 AM

Join ZoomGov Meeting https://cdc.zoomgov.com/j/1608908023?pwd=ZHhuU0hXU3RSUEhJelBvNmtYUTZtdz09 Meeting ID: 160 890 8023: Passcode: ++YeX8F& One tap mobile +16692545252,,1608908023#,,*77201071# US (San Jose) +16468287666,,1608908023#,,*77201071# US (New York)

• Informational Call/Webinar II – May 20, 2021, 7 – 9 PM

Join ZoomGov Meeting https://cdc.zoomgov.com/j/1614726088?pwd=UFZyZ1I5aD15dmtsdmhGVWp6OUtTQT09 Meeting ID: 161 472 6088 Passcode: B#hR4F!D One tap mobile +16692545252,,1614726088#,,,,*23626182# US (San Jose) +16468287666,,1614726088#,,,,*23626182# US (New York)

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 <u>https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf</u>, 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 <u>https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf</u>, 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 <u>www.grants.gov</u>.

7. Letter of Intent

Letter of Intent is requested, but optional.

The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

LOI should be sent via email to: Sajata Outin/Paul Malpiedi CDC/NCEZID 1600 Clifton Road, NE, Atlanta, GA 30329 Email: <u>RFA-CK21-2104@cdc.gov</u>

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 <u>www.grants.gov</u>.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at <u>www.grants.gov</u>. 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 <u>www.grants.gov</u>.

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 <u>www.grants.gov</u>. 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 evidencebased 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 gualified 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 <u>www.grants.gov</u>. 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 <u>www.grants.gov</u>.

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 <u>Additional Requirement (AR) 12</u> for detailed guidance on this prohibition and <u>additional guidance on lobbying for CDC recipients</u>.
- 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.

Indirect Costs for Foreign Organizations

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. Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities). All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign recipients for currency exchange fluctuations through the issuance of supplemental awards.

Public Financial Management Clause

The Parties acknowledge that HHS/CDC has the authority to assess the recipient's systems required to manage the activities supported with US Government funds under this Agreement and that this NOFO is expressly conditioned upon that assessment, as well as any measures, mitigation or means by which the recipient has or will address the vulnerabilities or weaknesses, if any, found in that assessment. The recipient agrees to take the necessary action(s) to address the recommendations or requirements of the assessment as agreed separately in writing with HHS/CDC in accordance with an action plan to be jointly developed to address such recommendations or as otherwise contained in this agreement.

Conference Costs and Fees

U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by CDC in writing.

- Definitions:
 - A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc
 - A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations

Trafficking in Persons Provision

- No contractor or sub-recipient under this Agreement that is a private entity may, during the period of time that the award is in effect:
 - engage in trafficking in persons, as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime;
 - procure any sex act on account of which anything of value is given to or received by any person;
 - o or use forced labor in the performance of this award.
- If HHS/CDC determines that there is a reasonable basis to believe that any private party contractor or subrecipient has violated paragraph 1 of this section or that an employee of the contractor or subrecipient has violated such a prohibition where that the employee's conduct is associated with the performance of this award or may be imputed to the contractor or subrecipient, HHS/CDC may, without penalty, (i) require the Recipient to

terminate immediately the contract or subaward in question or (ii) unilaterally terminate this Agreement in accordance with the termination provision.

- For purposes of this provision, "employee" means an individual who is engaged in the performance in any part of the Project as a direct employee, consultant, or volunteer of any private party contractor or subrecipient.
- The Applicant must include in all sub-agreements, including sub-awards and contracts, a provision prohibiting the conduct described in subsection a by private party subrecipients, contractors, or any of their employees.

Prohibition on Assistance to Drug Traffickers

- HHS/CDC reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by HHS/CDC who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.
- The Applicant agrees not to disburse, or sign documents committing the Applicant to disburse funds to a sub-recipient designated by HHS/CDC ("Designated Sub-recipient") until advised by HHS/CDC that: (1) any USG review of the Designated Sub-recipient and its key individuals has been completed; (2) any related certifications have been obtained; and (3) the assistance to the Designated Sub-recipient has been approved.
- The Applicant shall insert the following clause, or its substance, in its agreement with the Designated Sub-recipient:
- The Applicant reserves the right to terminate this Agreement or take other appropriate measures if the [Sub-recipient] or a key individual of the [Sub-recipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140.

Financing of Terrorism

Consistent with numerous United Nations Security Council resolutions, including UNSCR 1267 (1999) (http://www.undemocracy.com/S-RES-1269(1999).pdf), UNSCR 1368 (2001) (http://www.undemocracy.com/S-RES-1368(2001).pdf), UNSCR 1373 (2001) (http://www.undemocracy.com/S-RES-1373(2001).pdf), and UNSCR 1989 (2011), both HHS/CDC and the applicant are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities associated with terrorism. In accordance with this policy, the Applicant agrees to use reasonable efforts to ensure that none of the HHS/CDC funds provided under this Agreement are used to provide support to individuals or entities associated with terrorism, including those identified on the U.S. Department of Treasury Office of Foreign Assets Control Specially Designated Nationals List. This provision must be included in all sub-agreements, including contracts and sub-awards, issued under this award.

Restriction on Assistance for Military or Paramilitary Purposes or for Police and Prisons

No funds or other support provided under the award may be used for support to any military or paramilitary force or activity, or for support to any police, prison authority, or other security or law enforcement forces without the prior written consent of HHS/CDC.

UN Security Council Sanctions List

It is the policy of HHS/CDC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities designated for United Nations Security Council sanctions. In accordance with this policy, the applicant agrees to use reasonable efforts to ensure that none of the funds provided under this grant are used to provide support of individuals or entities designated for UN Security Council sanctions (compendium of Security Council Targeted Sanctions Lists at: http://www.un.org/sc/committees/list_compend.shtml). This provision must be included in all sub-agreements, including contracts and sub-awards, issued under this award.

Worker's Rights

No funds or other support provided hereunder may be used for any activity that contributes to the violation of internationally recognized workers' rights of workers in the recipient country. In the event the Applicant is requested or wishes to provide assistance in areas that involve workers' rights or the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.

The Applicant must ensure that all employees and subcontractors and sub-recipients providing employment-related services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder. The term "internationally recognized worker rights" includes-- the right of association; the right to organize and bargain collectively; a prohibition on the use of any form of forced or compulsory labor; a minimum age for the employment of children, and a prohibition on the worst forms of child labor; and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health.

The term "*worst forms of child labor*" means-- all forms of slavery or practices similar to slavery, such as the sale or trafficking of children, debt bondage and serfdom, or forced or compulsory labor, including forced or compulsory recruitment of children for use in armed conflict; the use, procuring, or offering of a child for prostitution, for the production of pornography or for pornographic purposes; the use, procuring, or offering of a child for illicit activities in particular for the production and trafficking of drugs; and work which, by its nature or the circumstances in which it is carried out, is likely to harm the health, safety, or morals of children, as determined by the laws, regulations, or competent authority of the country.

Investment Promotion

No funds or other support provided hereunder may be used to provide a financial incentive to a business enterprise currently located in the United States for the purpose of inducing such an enterprise to relocate outside the United States if such incentive or inducement is likely to reduce the number of employees of such business enterprise in the United States because United States production is being replaced by such enterprise outside the United States.

In the event the Applicant requires clarification from HHS/CDC as to whether the activity would be consistent with the limitation set forth above, the Applicant must notify HHS/CDC and

provide a detailed description of the proposed activity. The Applicant must not proceed with the activity until advised by HHS/CDC that it may do so.

The Applicant must ensure that its employees and subcontractors and sub-recipients providing investment promotion services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all subcontracts and other sub-agreements entered into hereunder.

Contract Insurance Requirement

To the extent that a host government partner enters into contracts expressly approved by the U.S. government, the host country government partner shall ensure that its contractors or subcontractors (a) provide, before commencing performance under any contracts or subcontracts funded under this agreement, such workers' compensation insurance or security as required by HHS/CDC and (b) continue to maintain such insurance until performance is completed. The host country government partner shall insert, in all contracts and subcontracts under this agreement, a clause similar to this clause (including this sentence) imposing upon those contractors and subcontractors the obligation to obtain workers' compensation insurance or security as required by HHS/CDC.

Source and Nationality and Other Procurement Restrictions

Disbursements will be used exclusively to finance the costs of goods and services required for this Agreement [in accordance with 22 CFR 228, and] having their source and nationality in countries [included in Geographic Code [937 or 935]] OR [identified in subsection 6 below], except as HHS/CDC may otherwise agree in writing and as follows:

- Ocean transportation costs must be financed under the Agreement only on vessels under flag registry of [countries included in Code 935] OR [the following countries: LIST. Also see subsection 7 below on use of U.S.-flag vessels.
- Any motor vehicles financed under the Agreement will be of United States manufacture, except as HHS/CDC may otherwise agree in writing.
- The nationality of the contractor providing ocean and air shipping services will be deemed to be the ocean vessel's or aircraft's country of registry at the time of shipment.
- Provisions concerning restricted and ineligible goods and services may be provided in subsequent written communications between the parties. Special procurement rules apply to agricultural commodities, pharmaceuticals, pesticides, and fertilizer, none of which may be procured without advance written consent of HHS/CDC.
- Transportation by air of property or persons financed under this agreement will be on carriers holding United States certification to the extent service by such carriers is available under the Fly America Act. This requirement may be further described by HHS/CDC in subsequent written communications between the parties.
- Eligibility Date. No goods or services may be financed under the Agreement which are procured pursuant to orders or contracts firmly placed or entered into prior to the date of this Agreement, except as the Parties may otherwise agree in writing.
- Eligible countries for procurement: HHS/CDC to identify for specific agreement.
- Transportation
 - In addition to the requirements in subsection 1 above, costs of ocean or air transportation and related delivery services may not be financed under this

Agreement, if the costs are for transportation under an ocean vessel or air charter which has not received prior HHS/CDC approval.

- Unless HHS/CDC determines that privately owned U.S. -flag commercial ocean vessels are not available at fair and reasonable rates for such vessels, or otherwise agrees in writing:
 - At least fifty percent (50%) of the gross tonnage of all goods (computed separately for dry bulk carriers, dry cargo liners and tankers) financed by HHS/CDC which may be transported on ocean vessels will be transported on privately owned U.S.-flag commercial vessels; and
 - At least fifty percent (50%) of the gross freight revenue generated by all shipments financed by HHS/CDC and transported to the territory of the Recipient on dry cargo liners shall be paid to or for the benefit of privately owned U.S.-flag commercial vessels. Compliance with the requirements of (1) and (2) of this subsection must be achieved with respect to both any cargo transported from U.S. ports and any cargo transported from non-U.S. ports, computed separately.

Monitoring and Evaluation Section

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, must require a provision to this effect in all sub-awards or contracts financed by funds under this Agreement.

Monitoring Reporting and Evaluation

CDC programs must ensure that recipient's Evaluation and Performance Measurement Plan is aligned with the guidance established by HHS/CDC and CDC's Data for Partner Monitoring Program (DFPM). All evaluations conducted must submit an evaluation report using a format agreed upon by HHS/CDC.

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 <u>www.grants.gov</u> 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 <u>www.grants.gov</u> 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 <u>www.grants.gov</u>. A second e-mail message to applicants will then be generated by <u>www.grants.gov</u> 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 <u>www.grants.gov</u>. 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 <u>www.grants.gov</u>, applicants should contact Customer Service at <u>www.grants.gov</u>. 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 <u>support@grants.gov</u>. 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 <u>www.grants.gov</u>, applicants should call the <u>www.grants.gov</u> Contact Center at 1-800-518-4726 or e-mail them at <u>support@grants.gov</u> 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 <u>www.grants.gov</u> case number assigned to the inquiry
- 2. Describe the difficulties that prevent electronic submission and the efforts taken with the <u>www.grants.gov</u> 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. <u>Non-responsive applications will not advance to Phase II review</u>. 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: 35 Component 1 – Detect and Respond to Infectious Disease Threats in Healthcare Facilities

- To what extent does the applicant illustrate and justify the public health need for the proposed project consistent with the purpose and objectives of this NOFO? (5 points)
- To what extent does the applicant describe an overall strategy and activities consistent with the logic model and outcomes? (10 points)
- To what extent does the applicant describe specific activities to be implemented by hospitals, reference laboratories, and/or IPC support partners within their proposed network and demonstrate how they will achieve project outcomes? (10 points)
- To what extent does the applicant present a work plan consistent with the content and format proposed by CDC and aligned with NOFO strategies and activities, outcomes, and performance measures described in the approach? (5 points)
- Has the applicant provided estimated timelines for completion of work plan activities that are reasonable and within the period of performance? (5 points)

Component 2 - Improve Capacity to Detect and Monitor Antimicrobial Resistance

- To what extent does the applicant illustrate and justify the public health need for the proposed project consistent with the purpose and objectives of this NOFO? (5 points)
- To what extent does the applicant describe an overall strategy and activities consistent with the logic model and outcomes? (10 points)
- To what extent does the applicant describe specific activities to be implemented within the proposed strategies and demonstrate how they will achieve project outcomes? (10 points)
- To what extent does the applicant present a work plan consistent with the content and format proposed by CDC and aligned with NOFO strategies and activities, outcomes, and performance measures described in the approach? (5 points)
- Has the applicant provided estimated timelines for completion of work plan activities that are reasonable and within the period of performance? (5 points)

Component 3 - Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities

- To what extent does the applicant illustrate and justify the public health need for the proposed project consistent with the purpose and objectives of this NOFO? (5 points)
- To what extent does the applicant describe an overall strategy and activities consistent with the logic model and outcomes? (10 points)
- To what extent does the applicant describe activities that are evidence-based, realistic, and achievable to meet the objectives of this NOFO? (10 points)
- To what extent does the applicant present a work plan consistent with the content and format proposed by CDC and aligned with NOFO strategies and activities, outcomes, and performance measures described in the approach? (10 points)

ii. Evaluation and Performance MeasurementMaximum Points: 25Component 1 – Detect and Respond to Infectious Disease Threats in Healthcare Facilities

- To what extent does the applicant describe specific objectives and activities of the proposed project that are consistent with the purpose and measurable outcomes of this NOFO? (10 points)
- To what extent does the applicant's evaluation and performance measurement plan include and adequately describe quantitative and qualitative process and outcome measures and a data management plan? (5 points)
- To what extent does the applicant describe available data systems and feasibility of collecting appropriate evaluation and performance measurement data? (5 points)
- To what extent does the applicant demonstrate local experience and capacity to implement evaluation and performance measurement activities? (5 points)

Component 2 - Improve Capacity to Detect and Monitor Antimicrobial Resistance

• To what extent does the applicant describe specific objectives and activities of the proposed project that are consistent with the purpose and measurable outcomes of this NOFO? (10 points)

- To what extent does the applicant's evaluation and performance measurement plan include and adequately describe quantitative and qualitative process and outcome measures and a data management plan? (5 points)
- To what extent does the applicant describe available data systems and feasibility of collecting appropriate evaluation and performance measurement data? (5 points)
- To what extent does the applicant demonstrate local experience and capacity to implement evaluation and performance measurement activities? (5 points)

Component 3 – Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities

- To what extent does the applicant describe specific objectives and activities of the proposed project that are consistent with the purpose and measurable outcomes of this NOFO? (10 points)
- To what extent does the applicant's evaluation and performance measurement plan include and adequately describe quantitative and qualitative process and outcome measures and a data management plan? (5 points)
- To what extent does the applicant describe available data systems and feasibility of collecting appropriate evaluation and performance measurement data? (5 points)
- To what extent does the applicant demonstrate local experience and capacity to implement evaluation and performance measurement activities? (5 points)

iii. Applicant's Organizational Capacity to Implement the Approach Maximum Points: 40

Component 1 – Detect and Respond to Infectious Disease Threats in Healthcare Facilities

- To what extent does the applicant demonstrate the ability to create a network of hospitals meeting specifications described in this NOFO? (15 points)
- To what extent does the applicant demonstrate the ability to include IPC support partners (for activities proposed in Strategy 1 or 2) and reference laboratories (for activities proposed in Strategy 2) meeting specifications described in this NOFO? (5 points)
- To what extent does the applicant demonstrate the ability to effectively implement and coordinate activities within the proposed network of hospitals, IPC support partners, and/or reference laboratories and collaborate with CDC as described in this NOFO? (5 points)
- To what extent does the applicant describe its past experience with and current readiness to begin immediate implementation of HAI prevention and/or AMR detection and response activities? (5 points)
- Does the applicant include qualified staff with appropriate technical expertise and context-appropriate local experience to effectively implement proposed activities? Does the applicant include a clear organizational chart and CVs/resumes for key personnel? (5 points)
- Does the applicant's proposed management structure for the project demonstrate a clear plan and capacity for administration and management of proposed activities, management of program resources, preparation of required reports, implementation of

monitoring and evaluation activities, and collection and analysis of performance measurement data? (5 points)

Component 2 - Improve Capacity to Detect and Monitor Antimicrobial Resistance

- To what extent does the applicant describe its past experience with and current readiness to begin immediate implementation of AMR detection, response, containment, and/or prevention activities outside of the United States? (5 points)
- To what extent does the applicant demonstrate the ability to implement the proposed activities in laboratories proficient in basic AMR detection techniques (e.g., pathogen isolation, identification, and susceptibility testing) with complete implementation of quality management systems? (10 points)
- To what extent does the applicant demonstrate the ability to collaborate with clinical, community, and/or environmental sites generating specimens for AMR laboratory testing? (5 points)
- To what extent does the applicant demonstrate its access to and ability to link clinical, laboratory, and/or environmental data to better understand the epidemiology of AMR? (5 points)
- To what extent does the applicant describe established partnerships with regional, national, and/or local partners, networks, and/or programs working on AMR detection, response, containment, and/or prevention activities? (5 points)
- Does the applicant include qualified staff with appropriate technical expertise and context-appropriate local experience to effectively implement proposed activities? Does the applicant include a clear organizational chart and CVs/resumes for key personnel? (5 points)
- Does the applicant's proposed management structure for the project demonstrate a clear plan and capacity for administration and management of proposed activities, management of program resources, preparation of required reports, implementation of monitoring and evaluation activities, and collection and analysis of performance measurement data? (5 points)

Component 3 – Rapid Response to Infectious Disease Outbreaks or Other Public Health Emergencies in Healthcare Facilities

- To what extent does the applicant demonstrate its previous experience supporting outbreak responses in healthcare settings outside of the United States? (10 points)
- To what extent does the applicant demonstrate its IPC subject matter expertise and ability to provide mentorship and supervision to healthcare workers in the context of outbreak responses in healthcare settings? (10 points)
- Does the applicant include qualified staff with appropriate technical expertise and context-appropriate local experience to effectively implement proposed activities? Does the applicant include a clear organizational chart and CVs/resumes for key personnel? (10 points)
- Does the applicant's proposed management structure for the project demonstrate a clear plan and capacity for administration and management of proposed activities, management of program resources, preparation of required reports, implementation of

monitoring and evaluation activities, and collection and analysis of performance measurement data? (10 points)

Budget

Maximum Points: 0

The applicant's budget for each component will be reviewed but not scored. Budget review questions include:

- Is the budget itemized, well justified, and consistent with the goals of the NOFO?
- Is the itemized budget and its justification reasonable and consistent with stated objectives and planned activities?

c. Phase III Review

All applicants will be subject to CDC's standard objective review process using the criteria described above. The final decision on which components and strategies will be funded will be made at the time of award.

Applications will be rank ordered. CDC may fund out of rank order using the following criteria: 1) to align with USG and/or agency prioritized technical areas and activities; 2) to align with funding availability for a geographic area at the time of the award; 3) to ensure maximum coverage of activities geographically; 4) to avoid duplication of activities in other CDC funding mechanisms; or 5) to respond to an unforeseen public health emergency of an international concern.

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 OMBdesignated 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

September 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 <u>http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17</u>.

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

Generally Applicable ARs:

- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2030
- AR-12: Lobbying Restrictions (June 2012)
- AR-14: Accounting System Requirements
- AR-25: Data Management and Access
- AR-27: Conference Disclaimer and Use of Logos
- AR-35: Protecting Life in Global Health Assistance
- AR-37: Prohibition of Certain Telecommunications and Video Surveillance Services or Equipment for all Awards Issued on or after August 31, 2020

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

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	No later than 6 months into award	Yes
Performance		
Measurement		
Plan, including Data		
Management Plan		
(DMP)		
Annual Performance	No later than 120 days before end of budget	Yes
Report (APR)	period. Serves as yearly continuation application.	

Data on Performance Measures	60 days after the end of the first 6 months of the award year and as part of the APR	Yes
Audit, Books, and Records	When applicable, within 30 days of completion of the audit and no later than 9 months after the end of the period under audit	Yes, as applicable
Expenditure Report	Financial reports due to CDC for each country/program under this NOFO	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 <u>www.Grantsolutions.gov</u> 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.

The recipients must submit the Annual Performance Report via <u>www.Grantsolutions.gov</u> 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.

Recipients must report on performance measures as part of their Annual Performance Report, as described in the Annual Performance Report section of this NOFO, and submit a mid-year performance measure report within 60 days of the end of the first six months of the award year.

The mid-year performance measure report must include brief information on each of the following:

- A comparison of actual accomplishments with the goals and objectives previously established for the reporting period, including metrics outlined in the evaluation and performance management plan and other monitoring and evaluation activities conducted by the recipient
- Reasons why established goals for the reporting period were not met, if appropriate
- Developments that have a significant impact on or adverse conditions which materially impair activities supported under the award

Audit, Books, and Records Clause (required): A. Reports and Information. The recipient must furnish HHS/CDC accounting records and such other information and reports relating to the Agreement as HHS/CDC may reasonably request.

B. The Recipient Agreement Books and Records. The recipient must maintain accounting books, records, documents and other evidence relating to the Agreement, adequate to show, without limitation, all costs incurred by the recipient, the receipt and use of goods and services acquired by the recipient, agreed-upon cost sharing requirements, the nature and extent of solicitations of prospective suppliers of goods and services acquired by the recipient, the basis of award of recipient contracts and orders, and the overall progress of the Agreement toward completion ("Agreement books and records"). The recipient must maintain Agreement books and records in accordance with generally accepted accounting principles prevailing in the United States, or at the recipient's option, with approval by HHS/CDC, other accounting principles, such as those (1) prescribed by the International Accounting Standards Committee (an affiliate of the International Federation of Accountants), or (2) prevailing in the country of the recipient. Agreement books and records must be maintained for at least three years after the date of last disbursement by HHS/CDC or for such longer period, if any, required to resolve any litigation, claims or audit findings.

C. Partner Government Audit. If \$300,000 or more of USG funds are expended by the recipient in its fiscal year under the Agreement, the recipient must have financial audits made of the

expenditures in accordance with the following terms, except as the Parties may otherwise agree in writing: i. The recipient must use its Supreme Audit Institution (SAI), if the SAI is approved by HHS/CDC, or select an independent auditor to perform the audit in accordance with the guidelines issued by HHS/CDC. ii. The audit must determine whether the receipt and expenditure of the funds provided under the Agreement are presented in accordance with generally accepted accounting principles agreed to in Section 2 above and whether the recipient has complied with the terms of the Agreement. Each audit must be submitted to HHS/CDC no later than nine months after the close of the recipient's year under audit.

D. Sub-recipient Audits. The recipient, except as the Parties may otherwise agree in writing, must ensure that "covered" sub-recipients, as defined below, are audited, and submit to HHS/CDC, no later than the end of the recipient's year under audit, in form and substance satisfactory to HHS/CDC, a plan for the audit of the expenditures of "covered" sub-recipients, as defined below, that receive funds under this Agreement pursuant to a direct contract or agreement with the recipient. i. "Covered" sub-recipient is one who expends \$300,000 or more in its fiscal year in "US Government awards" (i.e. as recipients of US Government cost reimbursable contracts, grants or cooperative agreements). ii. The plan must describe the methodology to be used by the recipient to satisfy its audit responsibilities for covered subrecipients. The recipient may satisfy such audit responsibilities by relying on independent audits of the sub-recipients; expanding the scope of the independent financial audit of the recipient to encompass testing of sub-recipients' accounts; or a combination of these procedures. iii. The plan must identify the funds made available to sub-recipients that will be covered by audits conducted in accordance with audit provisions that satisfy the recipient's audit responsibilities. iv. The recipient must ensure that covered sub-recipients under direct contracts or agreements with the recipient take appropriate and timely corrective actions; consider whether sub-recipients' audits necessitate adjustment of its own records; and require each such sub-recipient to permit independent auditors to have access to records and financial statements as necessary.

E. Audit Reports. The recipient must furnish or cause to be furnished to HHS/CDC an audit report for each audit arranged for by the recipient in accordance with this Section within 30 days after completion of the audit and no later than nine months after the end of the period under audit.

F. Cost of Audits. Subject to HHS/CDC approval in writing, costs of audits performed in accordance with the terms of this Section may be budgeted for, and charged to, the Agreement so long as such costs are allowable, allocable, and reasonable as defined in the Cost Allowability section of this Agreement.

G. Audit by HHS/CDC. HHS/CDC retains the right to perform the audits required under this Agreement on behalf of the recipient conduct a financial review, or otherwise ensure accountability of organizations expending US Government funds regardless of the audit requirement.

H. Opportunity to Audit or Inspect. The recipient must afford authorized representatives of HHS/CDC the opportunity at all reasonable times to audit or inspect activities financed under the Agreement, the utilization of goods and services financed by HHS/CDC, and books, records and

other documents relating to the Agreement.

I. Sub-recipient Books and Records. The recipient will incorporate paragraphs (A), (B), (D), (E), (F), (G) and (H) of this provision into all sub-agreements with non-U.S. organizations which meet the \$300,000 threshold of paragraph (C) of this provision. Sub-agreements with non-U.S. organizations, which do not meet the \$300,000 threshold, must, at a minimum, incorporate paragraphs (G) and (H) of this provision. Sub-agreements with U.S. organizations must state that the U.S. organization is subject to the audit requirements contained in 2 CFR 200 and 45 CFR 75.

Expenditure Report (required): Recipients is required to report quarterly on program expenditures. The quarterly report must report on funds expended by the recipient at the country and program/activity-level.

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, <u>http://www.USASpending.gov</u>.

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,
- <u>https://www.fsrs.gov/documents/ffata_legislation_110_252.pdf</u>
- 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:

Sajata Outin-Blenman Project Officer Department of Health and Human Services Centers for Disease Control and Prevention

Address: 1600 Clifton Road, NE, Atlanta, GA 30329

Telephone: (404) 639-0256 Email: soutin@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

Address: 2939 Flowers Road, South, Atlanta, GA 30341

Telephone: (404) 718-5907 Email: ktv6@cdc.gov For assistance with **submission difficulties related to** <u>www.grants.gov</u>, 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 <u>www.grants.gov</u>. 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

Organization Charts

Letters of Support

Position descriptions

Indirect Cost Rate, if applicable

Non-profit organization IRS status forms, if applicable

- Financial Management Statement
- Letters of Support (Required for Component 1, Optional for Components 2 and 3)

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 <u>http://www.cdc.gov/grants/additional requirements/index.html</u>. 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. <u>http:// www.cdc.gov/grants/additionalrequirements/index.html</u>.

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 <u>www.USAspending.gov</u>.

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 <u>www.grants.gov</u>.

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 <u>http://www.phaboard.org</u>.

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 <u>www.grants.gov</u> 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

AMR - Antimicrobial Resistance
BSI - Bloodstream Infections
EGASP - Enhanced Gonococcal Antimicrobial Surveillance Programme
HAI - Healthcare-Associated Infection
IPC - Infection Prevention and Control
MDR - Multidrug-resistant
PNI - PulseNet International
PPS - Point Prevalence Survey
WGS - Whole Genome Sequencing
XDR - Extensively Drug-resistant