Centers for Disease Control and Prevention

National Center for Immunization and Respiratory Diseases Extramural Research Program Office

Enhanced Surveillance for New Vaccine Preventable Diseases
RFA-IP-16-004
Application Due Date: 01/15/2016
Enhanced Surveillance for New Vaccine Preventable Diseases
RFA-IP-16-004

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## Part 1. Overview Information

### Participating Organization(s)
Centers for Disease Control and Prevention

### Components of Participating Organizations
National Center for Immunization and Respiratory Diseases Extramural Research Program Office (NCIRD ERPO)
National Center for Immunization and Respiratory Diseases (NCIRD)

### Funding Opportunity Announcement (FOA) Title
Enhanced Surveillance for New Vaccine Preventable Diseases

### Activity Code
U01 Research Project Cooperative Agreements

### Funding Opportunity Announcement Type
New

### Funding Opportunity Announcement Number
RFA-IP-16-004

### Catalog of Federal Domestic Assistance (CFDA) Number(s)
93.185

### Category of Funding Activity:
Health

### FOA Purpose
The purpose of this announcement is to solicit applications for a research cooperative agreement that will fund a network of pediatric medical institutions conducting prospective, active surveillance for acute gastroenteritis (AGE) and acute respiratory illnesses (ARI) in inpatient and emergency department clinical settings, and among asymptomatic healthy controls. Funded activities for this Core Component award will include the provision of a US pediatric vaccine-preventable (and potentially vaccine preventable) disease surveillance system for a wide variety of AGE and ARI pathogens, evaluations of vaccine effectiveness for licensed vaccines including rotavirus and influenza, burden and natural history of disease for pathogens having upcoming and/or new vaccines, pediatric infectious disease transmission dynamics, informing vaccination/therapeutic policy and development, vaccine impacts for targeted and vulnerable populations, and socioeconomic and microbiological environments potentially relevant to these public health interventions. A second purpose of this announcement is to prospectively follow a birth cohort to the second birthday to incorporate a natural history study of pathogens and immunologic factors related to symptomatic and asymptomatic infection in US infants/young children. This second purpose/activity will be a separate Optional Component of the application, independently scored, that will be awarded to an applicant that has been competitively awarded a Core Component award.

### Key Dates

<table>
<thead>
<tr>
<th>Publication Date</th>
<th>To receive notification of any changes to RFA-IP-16-004, return to the synopsis page of this announcement at <a href="http://www.grants.gov">www.grants.gov</a> and click on the &quot;Send Me Change Notification Emails&quot; link. An email address is needed for this service.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Letter of Intent Due Date</th>
<th>[Insert 30 days from date of publication]</th>
</tr>
</thead>
</table>
Application Due Date: 01/15/2016

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 03/31/2016
Secondary Review: 04/28/2016
Estimated Start Date: 09/30/2016
Expiration Date: 01/16/2016

Due Dates for E.O. 12372: Due no later than 60 days after the application receipt date.

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Page Limitations


Optional Component: The Research Strategy section of the Research Plan must not exceed 15 pages.

Executive Summary

- **Purpose.** This FOA will fund a network of pediatric medical institutions throughout the US conducting prospective, active surveillance for acute gastroenteritis (AGE) and acute respiratory illnesses (ARI) in inpatient and emergency department clinical settings, and among asymptomatic healthy controls.

- **Mechanism of Support.** Cooperative Agreement

- **Funds Available and Anticipated Number of Awards.** Estimated total funding available, to include direct and indirect costs for the entire project period, is $38,600,000. The project period for the Core Component awards will be five (5) years and there will be up to seven (7) awards. The project period for the Optional Component award will be three (3) years and there will be one (1) award. The awards issued under this FOA are contingent upon availability of funds and the total number of meritorious applications received.

- **Budget and Project Period.** The estimated funding (direct and indirect) for each Core Component award for the first year (12 month budget period) will be $1,000,000. An estimated $5,000,000 total funding (direct and indirect) will be available for each Core Component award for the entire five (5) year project period, with a maximum award of $1,000,000 per year. The project period will run from 9/30/2016 to 9/29/2021. An additional $1,200,000 per year, for up to three (3) years will be available to one of the Core Component awardees to conduct an Optional Component longitudinal cohort study.
Application Research Strategy Length: Page limits for the Research Strategy component of the Research Plan are clearly specified in Section IV. "Application and Submission Information" of this announcement.

Eligible Institutions/Organizations. Institutions/organizations listed in Section III.1 of this announcement are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

Number of PDs/PIs. Applications may name more than one PD/PI; however, one PD/PI must be designated as the contact person for all correspondence related to the application AND all PD/PIs must include their eRA Commons identification in the credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package.

Number of Applications. Each eligible applicant institution may submit only one application. The application must include one Core Component and may include one Optional Component.

Application Type. New.

Special Date(s). Not applicable.

Application Materials. See Section IV.1 for application materials. Please note that Form C is to be used when downloading the application package: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority
Public Health Service Act 42 U.S.C. 247b(k)(1).

1. Background and Purpose

This cooperative agreement will fund a network of US pediatric medical institutions (the New Vaccine Surveillance Network [NVSN]) conducting prospective, active surveillance for acute gastroenteritis (AGE) and acute respiratory illnesses (ARI) in inpatient and emergency department clinical settings, and among asymptomatic healthy controls. Funded activities will provide a principal US pediatric disease surveillance system, to include actively assessing a wide spectrum of AGE and ARI pathogens, evaluations of vaccine effectiveness for licensed vaccines including rotavirus and influenza, burden and natural history of disease for pathogens having upcoming and/or new vaccines, pediatric infectious disease transmission dynamics, informing vaccination/therapeutic policy and development, vaccine impacts for targeted and vulnerable populations, and socioeconomic and microbiological environments potentially relevant to these public health interventions.

Healthy People 2020 and other National Strategic Priorities

This FOA is aligned with the following CDC Public Health Priorities:

- Excellence in surveillance, epidemiology, and laboratory science and services
- Advance evidence-based health policies (e.g., vaccination)
- Prevent illness, injury, disability, and premature death (e.g., infectious diseases)

This FOA is aligned with the HP2020 focus areas of: Immunization and Infectious Diseases: http://www...
Public Health Impact
Funded activities will provide a principal US pediatric disease surveillance system, to include: actively assessing a wide spectrum of AGE and ARI pathogens, evaluations of vaccine effectiveness for licensed vaccines, burden and natural history of disease for pathogens having upcoming and/or new vaccines, pediatric infectious disease transmission dynamics, informing vaccination/therapeutic policy and development, vaccine impact for targeted and vulnerable populations, and socioeconomic and microbiological environments potentially relevant to these public health interventions.

Relevant Work


Weinberg, GA, Hall CB, Poehling KA, et al. Parainfluenza virus infection of young children:


2. Approach

Whenever possible, applications should include objectives written in the SMART format (e.g., Specific, Measurable, Achievable, Realistic and Time-bound).

Objectives/Outcomes

Outcomes:

1. To evaluate the effectiveness and impact(s) of current or upcoming vaccines and other immunoprophylaxis strategies, and inform pediatric vaccine-related policies;
2. To actively assess the burden of acute gastroenteritis and acute respiratory illness (including illness with laboratory-confirmed influenza, respiratory syncytial virus [RSV], and other pathogens) in the pediatric population;
3. To establish the natural history of disease for pediatric infectious diseases, transmission dynamics, vaccine impacts for targeted and vulnerable populations, and socioeconomic and microbiological environments potentially relevant to public health interventions.

Objectives:

A. Core Component (Mandatory)

Establish and operate a network of pediatric disease surveillance sites at US medical institutions.

Each site must be able to conduct the following surveillance activities:

1) Establish a surveillance site with a defined pediatric catchment population in a geographically-defined area, in order to conduct year-round surveillance activities. Establishing population-based surveillance is desirable. A minimum population-base of approximately 500,000 persons of all ages in the catchment area is expected to be sufficient to accomplish the objectives of certain New Vaccine Surveillance Network (NVSN) activities.

   a. Provide detailed description(s) of each proposed participating medical institution where patients will be enrolled (e.g., physical description, patient volume, number of pediatric hospital beds, etc.) and a demonstration of institutional support regarding patient enrollment (e.g., access to admissions data and other relevant data sources for screening and enrollment, successful navigation of institutional review board approvals for pediatric surveillance and clinical research, etc.).

   b. A timeline and explanation should be included to describe how surveillance activities will begin no later than November 1, 2016.

Applications should include the following information relevant to core surveillance activities:

- Methodology for conducting surveillance for the appropriate disease targets among patients at hospitals and emergency departments within the surveillance area.
- Estimated proportion of children in the catchment area who would be captured by the medical institution’s emergency department (ED).
- Methodology for conducting rotavirus and influenza vaccination data with accuracy and completeness (dose, type, dates of administration, vaccine manufacturer) that will enable accurate vaccine effectiveness evaluations and coverage for enrolled subjects in the population.
- Methodology for vaccine effectiveness assessments.
- Ability to conduct AGE, ARI, and influenza surveillance.
- Methodology for enrollment and data/specimen collection of healthy control subjects, comparable to subject cases.
Experience in conducting surveillance activities in pediatric populations and demonstrated surveillance data for the pre-licensure and post-licensure vaccine eras.  
Letters of Support from participating agencies, institutions, organizations, laboratories, consultants, etc. indicated in the application’s operational plan.  
The geographic area and population base in which the surveillance site will operate, including population denominators for calculating disease rates.  
Description of the demographics of the proposed population base, including a description of various special populations as they relate to the proposed activities of the site.

2) The application should detail how surveillance activities would be conducted, including screening subjects for eligibility, enrolling consenting subjects, collecting epidemiological and clinical data from subjects, obtaining specimens for testing, and verifying vaccination status for the subjects. Further details on these surveillance activities follow (see Table 1):

a. Conduct active, prospective surveillance consistent with previous methods (applicants can refer to publications and websites from the NVSN) for all children with AGE in surveillance hospitals for children aged <18 years, and for children aged <5 years with AGE in surveillance emergency departments year-round.

b. Conduct active, prospective surveillance consistent with previous methods (applicants can refer to publications and websites from the NVSN) for all children with ARI in surveillance hospitals for children aged <18 years, and for children aged <5 years with ARI in surveillance emergency departments during October 1–May 31 of the following year throughout the period of performance.

- In addition, during July 1–November 30 of each year throughout the period of funding, expand active, prospective surveillance to include all children aged <18 years with ARI in surveillance hospitals and emergency departments (EDs), for the purpose of capturing ARI caused by rhinoviruses/enteroviruses, including EV-D68.

c. Conduct active, prospective surveillance of asymptomatic healthy controls aged <11 years at well-child visits.

Table 1. Summary of surveillance enrollment activities

<table>
<thead>
<tr>
<th>Subject group (by illness)</th>
<th>Targeted Pathogen</th>
<th>Enrollment period</th>
<th>Age group (years)</th>
<th>Clinical setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>AGE pathogens</td>
<td>Year-round</td>
<td>&lt;18</td>
<td>ED and Inpatient</td>
</tr>
<tr>
<td>ARI</td>
<td>Influenza</td>
<td>Oct. 1–May 31</td>
<td>&lt;18</td>
<td>Inpatient</td>
</tr>
<tr>
<td>Non-influenza ARI pathogens</td>
<td>July 1–Nov. 30</td>
<td>&lt;18</td>
<td>ED and Inpatient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dec. 1–May 31</td>
<td>&lt;5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthy controls</td>
<td>AGE and ARI pathogens</td>
<td>Year-round</td>
<td>&lt;11</td>
<td>Well-child clinics</td>
</tr>
</tbody>
</table>
d. Screen admissions and systematically enroll inpatient children with AGE and/or ARI at least 5 days per week during the enrollment period. Screen admissions and enroll children visiting the emergency department with AGE and/or ARI at least 4 days per week during the enrollment period.

e. Collect stool specimens from children enrolled in AGE surveillance and respiratory (nasal and throat swabs) specimens from children enrolled in ARI surveillance, and both specimen types from healthy controls. Describe the ability to process, store and ship duplicate aliquots of specimens to CDC for further characterization.

- Describe willingness and capability to collect any scavenged whole blood, sera, or plasma specimens that had been already collected from the enrolled subject by the medical institution for clinical purposes (i.e. collected independently of this surveillance activity) after clinically indicated testing is completed, for further testing. If this would be only possible for a subset of those enrolled, please describe any limitations, as well as any conditions placed upon their use.

f. For children aged <5 years, describe the ability to perform timely, sensitive nucleic acid-based diagnostics for influenza (see section B.3. of Core Component Objectives for details) and non-influenza respiratory pathogens including, but not limited to RSV, parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses, and adenoviruses on a large volume of collected samples (CDC will work with awarded sites to perform testing for EV-D68).

- During July 1–November 30 of each year, in addition to testing children aged <5 years as outlined above, describe strategies and capabilities to perform timely, sensitive nucleic acid-based diagnostics for non-influenza respiratory pathogens focusing on (but not limited to) rhinoviruses/enteroviruses on collected samples from either all enrolled children aged 5–17 years or a systematic sample of that same age group. (CDC will work with awarded sites to perform testing for EV-D68.)

- Participate in CDC-sponsored proficiency testing and ongoing quality control monitoring among sites (e.g., circulating a sample of specimens among sites for testing).

g. Describe the ability to store specimens locally including multiple aliquots of ARI specimens (original, lysis buffer, extracted sample) with a system for tracking inventory of aliquots; ship samples in a timely way to other laboratories and CDC as needed for testing in accordance with NVSN guidance.

h. Collect information on epidemiologic and clinical factors, including but not limited to admission and discharge diagnoses, vaccination history, risk factors, markers for the course and severity of disease, treatments such as use of antiviral drugs, clinical radiographic and laboratory results including virologic testing (for comparison to research testing).

i. Conduct quality control activities and demonstrate the ability to enroll at least 70% of inpatient subjects found to be eligible for surveillance during the dates of active surveillance and collect at least 70% of stool and ARI specimens from enrolled subjects. Provide summary tables at regular intervals (e.g., every 2 weeks) about patient screening and enrollment using information that includes patient counts along with key demographic information such as age group.

j. Develop projects and protocols collaboratively and in coordination with CDC. Allow compatible variables to be integrated across the surveillance network, following a standardized manual of operations and federal data safety standards. Initiate and allow publishable works to be developed jointly using the network-wide data. Sharing a set of all specimens collected and consented for testing with CDC for further laboratory analyses.

3) Assess influenza vaccine effectiveness (VE) in preventing laboratory-confirmed influenza infections among hospitalized children with ARI <18 years of age. Enrolled subjects admitted to the hospital with ARI
aged 6 months to 17 years will be included in influenza VE analyses. Specimens will be collected and tested for influenza A subtypes and B lineages. Patients with influenza positive specimens will be “cases” and those testing negative for influenza, or positive for other respiratory viruses, will be “controls”. Information on underlying conditions, medical outcomes, antiviral use, and vaccination will be collected. Data will be shared with CDC and aggregated data from the participating sites will be used to estimate VE using a test-negative study design (influenza positive patients are cases and influenza negative patients are controls) for each influenza season. Applicants must include, at a minimum, details to address all of the following in their application.

a. Document study resources, capabilities and proposed activities to achieve the minimal acceptable study sample size enrollment each influenza season (approximately 500-550 enrollees aged 6 months to 17 years with ARI during the influenza season; see shaded numbers in Table 2).

Sample size: For planning purposes, the following conservative assumptions were used to estimate sample size populations:

- Influenza detection in 7% of hospitalized children with ARI;
- VE = 60% and vaccine coverage = 40% (alternatively, 55% and 50%, respectively);
- Enrollees missing vaccine data: 10%;
- At least 5 sites, up to 4 strata for analysis (e.g., influenza A subtype- and B lineage-specific VE or up to 4 age groups);
- Alpha = 0.05, Power = 0.80.

Table 2. Number of enrollees (children 6 mos to 17 yrs) needed per site to determine influenza VE (calculated for n=5 sites).

<table>
<thead>
<tr>
<th>Vaccine Coverage</th>
<th>50%</th>
<th>55%</th>
<th>60%</th>
<th>65%</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>1017</td>
<td>796</td>
<td>633</td>
<td>508</td>
</tr>
<tr>
<td>40%</td>
<td>817</td>
<td>633</td>
<td>496</td>
<td>393</td>
</tr>
<tr>
<td>50%</td>
<td>717</td>
<td>548</td>
<td>424</td>
<td>331</td>
</tr>
</tbody>
</table>

Overall, each of at least 5 awardee institutions will enroll approximately 500-550 enrollees aged 6 months to 17 years with ARI (2500–2750 total enrollees) to identify a total of 225-250 influenza positive cases. Sites able to enroll more than 500 patients should specify this in the application. We recognize that the frequencies of virus (sub)type circulation varies yearly and geographically and that age group or subtype specific VE estimates may not be possible every year.

Note: Sample size is likely to vary. For example, with lower VE and vaccine coverage of 55% and 40%, respectively, approximately 3200 enrollees (approximately 635 per site) would be needed to provide 290 influenza positive cases; whereas for a higher VE of 65% and vaccine coverages ranging from 30-50%, the enrollment numbers would be fewer per site.

b. Provide descriptions of previous experience in enrollment of hospital patients (e.g., ability to screen and enroll patients and to meet target enrollment and patient participation (number enrolled/number eligible).

c. Describe ability to use local influenza surveillance data to assess onset of influenza season and trigger enrollment (i.e., with local enrollment triggered by 2 consecutive weeks of increasing detection of influenza viruses by molecular diagnostic assays conducted as part of pre-enrollment surveillance).
d. Describe the influenza molecular diagnostic assays (nucleic acid-based influenza assays) that will be used to detect influenza viruses, including influenza A virus subtypes and influenza B lineage. Include relevant published reports and information from product package insert identifying test sensitivity and specificity and the ability to detect influenza types A and B, as well as A subtypes A(H3N2) and A(H1N1)pdm09 and B lineage (Yamagata and Victoria) viruses. Include algorithm to perform additional testing using CDC RT-PCR assays on unsubtypeable and indeterminate samples.

- Provide evidence of competency in the use of these methods or evidence that the contracting laboratory performing the testing has expertise with these methods, both before study enrollment begins and with ongoing monitoring (e.g., number of the assays run/year; comparisons to other assays or results from validation studies, other measures of proficiency; letters of support; and publications).
- Provide a statement of agreement to participate in CDC-sponsored proficiency testing and ongoing monitoring, as needed, throughout the term of the award. Proficiency testing may include testing a small panel of specimens sent by CDC and reporting results back to CDC within a specified timeframe (generally 1 month).
- Describe willingness and capability to share influenza virus-positive specimens with CDC for virologic surveillance and/or special studies. Describe the plan and process to support recurring shipment of aliquots (1ml) from a subset of influenza positive specimens to CDC for antigenic characterization, sequencing, and for other WHO Influenza Collaborating Center surveillance purposes. For planning purposes, it may be assumed that specimen shipments will be required every 2–4 weeks during the influenza season and will require accompaniment of a completed WHO surveillance form (supplied by CDC). Include a description of how respiratory specimens will be stored and whether left over specimen aliquots will be available. Include a description of the laboratory’s ability to ship specimens, including access to dry ice.

e. Describe your plans to verify parent-reported influenza vaccination status with validated records. For children aged 6 months to 17 years, describe the current capability and experience with methods to obtain current season influenza vaccination status (including vaccination date(s), vaccine type, manufacturer, and lot number) and vaccination status from prior seasons (minimum of 5 years) from electronic medical records, electronic vaccine registries or medical abstraction from health care providers, pharmacy chains, schools, and other potential vaccine providers.

f. Describe methods to collect information from enrolled patients about high-risk medical conditions, antiviral use (dates and drugs), clinical outcomes (death, discharge or transfer), discharge diagnoses (ICD9 or 10 codes), measures of illness severity (including ICU admission and dates, mechanical ventilation, hypoxia at admission), and duration of hospitalization using electronic medical records, or other sources.

g. Describe a plan to (a) provide periodic updates (every 2 weeks) on enrollment of influenza-positive cases and influenza-negative controls, laboratory test outcomes, and status of data collection; and (b) provide data to CDC for end-of-season estimates and, possibly mid-season estimates, each with included timelines.

h. Propose methods to estimate the population-based incidence of laboratory confirmed influenza associated with hospitalization using data from all or a subset of enrolled participants.

i. Provide a statement on the ability and willingness to serve as an Emergency Response resource and participate with CDC in pandemic-related studies outside of normal seasonal study activities, should they be needed; additional funding would be made available to support these activities.

4) Perform assessments and evaluations of surveillance network data.

The site must be able to conduct the following assessments and evaluations:

a. Evaluate rotavirus vaccination performance in the United States. For example, evaluations will include
VE, exploring potential waning immunity, explanations for the post-licensure biennial trend in rotavirus incidence and sustained population protection, the performance of rotavirus vaccines in vulnerable populations, and monitoring reassortant and emerging rotavirus strains;
b. Establish the incidence rates of rotavirus among hospitalizations and emergency department visits, and of influenza among hospitalizations;
c. Create baseline surveillance data (including incidence estimates of hospitalization and emergency department visits) for pathogens projected to be potentially vaccine-preventable during the period of performance (e.g., norovirus gastroenteritis and respiratory syncytial virus), and for other AGE and ARI pathogens in order to assess the need for development of vaccines and other interventions;
d. Assess household transmission dynamics, vaccination policies, targeted and vulnerable populations, medical costs, influenza antiviral drug use, antibiotic use, and socioeconomic and microbiological environments potentially relevant to public health interventions.
e. The development and/or application of emerging topics (e.g., pathogen-related advanced molecular detection, possible epidemiological roles of commensal modalities in infection risk, innate susceptibility, etc.) is encouraged.

B. Optional Component

Applicants are not required to, but may elect to, include a competitive Optional Component, described below. The Optional Component portion of the application will be scored separately from the Core Component. The Optional Component must be submitted by the same organization as the Core Component. Only applications selected for funding for the Core Component will be eligible to receive funds for the Optional Component. In addition, both the Core and Optional Components must have an overall priority score between 10 and 50 to be awarded.

The Optional Component is to prospectively follow a birth cohort to the second birthday to incorporate a natural history study of pathogens and immunologic factors related to symptomatic AGE and ARI infections and asymptomatic status in US infants/young children, including but not exclusive to norovirus, rotavirus, RSV and influenza. This component requires full data capture of approximately 200 mothers enrolled during pregnancy and the collection of: a) maternal vaccination and prenatal care histories; b) birth specimens (meconium, cord blood) and maternal blood sample; c) serial blood and stool specimens obtained during infant and well-child visits; d) a maternal breast milk specimen; e) paired maternal/child saliva specimens; f) stool and/or respiratory specimens during symptomatic AGE and ARI illnesses; g) regularly recorded status of infant/child health and epidemiologic factors; h) infant/child vaccination status during the follow-up period; and i) specimen collection/results from household members to indicate transmission and/or asymptomatic carriage. Applicants should specify the extent of laboratory analyses permitted within the budget or other plans and collaborations to do so, including serologic analyses of blood specimens, single nucleotide polymorphisms detected from salivary specimens, bioactive molecules from human milk specimens, and pathogenic and commensal detections from stool and respiratory specimens.

In addition, other optional applied epidemiologic and/or health services research could be proposed as part of the Optional Component. Areas of investigation and activities may include, but are not limited to:

- Determine VE of maternal vaccination to prevent influenza infection among children <6 months of age. Describe methods to obtain current season influenza vaccination status (including vaccination date(s), vaccine type, and manufacturer) using maternal self-report and verification from electronic medical records, real-time electronic vaccine registries or medical abstraction from health care providers, pharmacy chains, and other potential vaccine providers. Determine the specificity and sensitivity of self-reported maternal vaccination status versus medical records.
- Assess changes in infant stool, respiratory and blood specimen results over time, in relation to maternal
• Assess the epidemiological factors between infant infection and transmission to/from other household members.
• Assess factors related to asymptomatic disease and microbiological carriage.
• Assess protective maternal mechanisms against infections during the first two years of life.
• Characterize the effects of maternal-derived RSV-specific antibodies on RSV infection and immunity in infants.
• Collect sera from a subset of enrolled children for testing immunologic status for influenza, RSV, and/or other respiratory viruses.
• Assess relationship between RSV infection and recurrent wheezing/asthma.
• Assess for any association between EV-D68 infection and recurrent wheezing/asthma.
• Characterize antibiotic use among children with viral illnesses and its impact.
• Characterize and compare detection rates and sampling yield (e.g., viral load) by specific respiratory specimen type (e.g., nasal swab, throat swab, nasopharyngeal swab, etc.).
• Assess early clinical markers of illness as predictors for illness outcomes and severity.
• Determine any association between relevant single nucleotide polymorphisms, commensal microorganisms, and pathogen immunity, by matching salivary, fecal, and respiratory sample results.
• Study the impact of incorporating new vaccines or therapeutic agents, such as other immunoprophylaxis (e.g., palivizumab or antiviral drugs), or the impact of new vaccination findings, which may include the following activities:
  • Assess impact of new vaccines or therapeutic agents upon provider policies, practices, and utilization;
  • Collect data from pediatric care providers to document the impact of new vaccines or therapeutic agents recommended for routine use among children;
  • Develop a longitudinal cohort of study subjects upon introduction of a new vaccine or therapeutic agent;
  • Collect health care costs associated with implementing vaccine policy and administration.

Target Population
The target population of this activity is a diverse representation of US children under 18 years of age in the inpatient clinical setting, as well as children <5 years of age in the emergency department clinical setting, with specific targets upon those children seeking medical care for either acute gastroenteritis or acute respiratory illness, and asymptomatic healthy controls <5 years of age enrolled during well-child visits. One site would also target a birth cohort of infants for longitudinal tracking.

An emphasis would be placed on the ability to capture a minimum sample size for both AGE and ARI syndromes, the ability to exhibit geographic and demographic diversity in the captured pediatric population, and, for AGE, to have collected baseline surveillance data during the pre-rotavirus vaccine licensure era to enable trend analyses over the pre-licensure and post-licensure eras.

Collaboration/Partnerships
The ability to synergistically partner with other external resources (e.g., fellowship programs within awarded medical institutions) to enable these advanced projects to be performed efficiently and utilizing the most recent methods and technologies.

Evaluation/Performance Measurement
As part of the application, the PI should include measurable goals and aims based on a five year research project period. The grantee will collaborate with CDC to: (1) establish specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the applicant’s project plan, and (2) develop and implement project performance measures that are based on specific programmatic objectives.

Applications should describe how quality control activities will be conducted and demonstrate the ability to enroll at least 70% of subjects found to be eligible for surveillance during the dates of active surveillance and collect at least 70% of stool and ARI specimens from enrolled subjects.

Also, funded PIs must submit an annual progress report showing their activities and outcomes based on their overall research goals and timeline. For more information on required reporting, please see Section VI of this FOA.

Translation Plan

Applications should include a plan to estimate and report the potential translatability and public health impact of the research.

### Section II. Award Information

**Funding Instrument Type:** Cooperative Agreement
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

**Application Types Allowed:**

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

**Estimated Total Funding:** $38,600,000

- Year 1: $1,000,000 Core Component per award; $1,200,000 Optional Component per award
- Year 2: $1,000,000 Core Component per award; $1,200,000 Optional Component per award
- Year 3: $1,000,000 Core Component per award; $1,200,000 Optional Component per award
- Year 4: $1,000,000 Core Component per award
- Year 5: $1,000,000 Core Component per award

**NOTE:** Only those applications selected for the Core Component awards will be eligible to receive funds for the Optional Component.

Estimated total funding (including direct and indirect costs) available for the first year (12 month budget period) for the Core Component and Optional Component awards is $8,200,000.

Estimated total funding (including direct and indirect costs) available for the entire five year project period for the Core Component awards is $35,000,000.

Estimated total funding (including direct and indirect costs) available for the entire three year project period for the Optional Component award is $3,600,000.

Ceiling for the Core Component for the first 12 month budget period is $1,000,000, including both direct and indirect costs.

Floor for the Core Component for the first 12 month budget period is $800,000, including both direct and indirect costs.
indirect costs.

Ceiling for the Optional Component for the first 12 month budget period is $1,200,000, including direct and indirect costs.

Floor amount for the Optional Component is $1,000,000, including both direct and indirect costs.

Total funding available (including direct and indirect costs) for the Core and Optional Component awards for the entire project period is $38,600,000.

**Anticipated Number of Awards:** 7

Anticipated number of awards: up to 7 Core Component awards for 5 years and 1 Optional Component award for 3 years.

The information below regarding award ceiling and floor is for the Core Component.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

**Award Ceiling:** $1,000,000 Per Project Period

**Award Floor:** $800,000 Per Project Period

**Total Project Period Length:** 5 year(s)

Throughout the project period, CDC’s commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC’s determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement ([http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) will apply to the applications submitted and awards made in response to this FOA.

### Section III. Eligibility Information

#### 1. Eligible Applicants

<table>
<thead>
<tr>
<th>Eligibility Category</th>
<th>State governments</th>
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<td>County governments</td>
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<td>City or township governments</td>
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<td>Special district governments</td>
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<td>Public housing authorities/Indian housing authorities</td>
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<td>Native American tribal organizations (other than Federally recognized tribal governments)</td>
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<td>Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education</td>
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<td>Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education</td>
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<td></td>
<td>Private institutions of higher education</td>
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<td></td>
<td>Others (see text field entitled &quot;Additional Information on Eligibility&quot; for clarification)</td>
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</table>
Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

- Nonprofits (Other than Institutions of Higher Education)

Governments:

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other:

- Native American tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=512f2a5a778311f4274e00454772def21523a&rgn=div8&view=text&node=48:1.0.1.6.34.0.1.18&idno=48](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=512f2a5a778311f4274e00454772def21523a&rgn=div8&view=text&node=48:1.0.1.6.34.0.1.18&idno=48)

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.
For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

### 3. Special Eligibility Requirements

Applications submitted under this funding opportunity announcement must not include activities that overlap with simultaneously-funded research already awarded to applicants under other awards.

Applications that request funds above the ceiling of the award will not move forward to peer review or be eligible for funding.

### 4. Justification for Less than Maximum Competition

N/A

### 5. Responsiveness

Applications that apply only to the Optional Component portion of this FOA will be considered nonresponsive and will not move forward to peer review or be eligible for funding.

### 6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: [https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf](https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf)
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, [https://www.sam.gov/portal/SAM/](https://www.sam.gov/portal/SAM/)
- Grants.gov
- eRA Commons

All applicant organizations must register with [Grants.gov](https://www.grants.gov). Please visit [www.Grants.gov](http://www.Grants.gov) at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.
7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations must obtain a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the System for Award Management (SAM). Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.

If an award is granted, the grantee organization must notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.
2. Content and Form of Application Submission
It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.
In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components.
These forms can be downloaded from the following link: http://grants.nih.gov/grants/forms.htm

3. Letter of Intent
Due Date for Letter of Intent: [Insert 30 days from date of publication]
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.
By the date listed in Part 1. “Overview Information”, prospective applicants are asked to submit a letter of intent that includes the following information:
Name of the Applicant
Descriptive title of proposed research for the core and optional components, if applicable
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity

The letter of intent should be sent to:
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS E-60
Atlanta, GA 30333
4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description). Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
4. **Inclusion Enrollment Report** (Renewal and Revision applications ONLY)
5. **Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

6. **Protection of Human Subjects**
7. **Inclusion of Women and Minorities**
8. **Targeted/Planned Enrollment Table** (for New Application ONLY)
9. **Inclusion of Children**

Other Research Plan Sections

10. **Vertebrate Animals**
11. **Select Agent Research**
12. **Multiple PD/PI Leadership Plan.**
13. **Consortium/Contractual Arrangements**
14. **Letters of Support**
15. **Resource Sharing Plan(s)**
16. **Appendix**

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies. Follow the page limits in the SF 424 unless otherwise specified in the FOA.

All instructions in the SF424 (R&R) Application Guide
Instructions to applicants applying for the Optional Component:

- The project lead for the Optional Component should be identified as a Co-Investigator rather than as the PI unless the project lead is the PI for both the Core and Optional Components.
- Throughout the application, text pertaining to the Optional Component should be titled to begin with the words “Optional Component” to distinguish it from the Core Component and text pertaining to the Core Component should be titled to begin with the words “Core Component”.
- A separate budget for the Optional Component for budget years 1 through 3 must be included in application. It is recommended that this budget be included as a subaward.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Page Limitations


Optional Component: The Research Strategy section of the Research Plan must not exceed 15 pages.

The Page Limitations for supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for the appendices of the Core Component.

The Page Limitations for supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for the appendices of the Optional Component.

The Page Limitations for the Research Strategy section of the Research Plan cited below in Section IV.7. "Page Limitations" are for the Core Component only.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).
9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

**Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.**

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

**Note:** HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

**Unsuccessful Submissions:**

If an application submission was unsuccessful, the applicant must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
   a. If the status states “rejected,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
   a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
   b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **01/15/2016**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

**10. Intergovernmental Review (E.O. 12372)**

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (http://www.archives.gov/federal-register/codification/executive-order/12372.html). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state’s process. Click on the following link to get the current SPOC list: [http://www.whitehouse.gov/omb/grants_spoc/](http://www.whitehouse.gov/omb/grants_spoc/).

**11. Funding Restrictions**

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC. For more information on expanded authority and pre-award costs, go to: [http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf).

Funds related to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

The Paperwork Reduction Act of 1995 (PRA): Applicants should be advised that any activities involving information collection (i.e., posing similar questions or requirements via surveys, questionnaires, telephonic requests, focus groups, etc.) from 10 or more non-Federal entities/persons, including States, are subject to PRA requirements and may require CDC to coordinate an Office of Management and Budget (OMB) Information Collection Request clearance prior to the start of information collection activities. This would also include information sent to or obtained by CDC via forms, applications, reports, information systems, and any other means for requesting information from 10 or more persons; asking or requiring 10 or more entities/persons to keep or retain records; or asking or requiring 10 or more entities/persons to disclose information to a third-party or the general public.

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at [http://www.phe.gov/s3/dualuse](http://www.phe.gov/s3/dualuse), for a comprehensive listing of those requirements.

Non-compliance with this Policy may result in suspension, limitation, or termination of United States Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing
regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

12. Other Submission Requirements and Information

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

**Applicants must complete all required registrations before the application due date.** Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically ([http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144)).

**Important reminders:**
- All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization’s profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters “FWA” before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.


Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission ([http://www.cdc.gov/about/organization/mission.htm](http://www.cdc.gov/about/organization/mission.htm)), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

**Overall Impact**

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).
Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Does the application identify as key personnel at least one senior clinician Principal Investigator (PI) and one clinician co-PI with documented experience leading surveillance projects, and demonstrated success in managing a project team of support staff (i.e., surveillance, data management, data analysis and report production, quality assurance, laboratory, and administrative support staff)? Do the PI and co-PI have documented subject matter expertise and scientific experience to provide leadership in developing research protocols, evaluating data, and critically reviewing reports and manuscripts for publication? Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project?

Does the research team have documented experience in conducting surveillance activities in pediatric populations and demonstrated surveillance data for the pre-licensure and post-licensure vaccine eras?

Does the application include adequate information on the research team’s experience and expertise in conducting AGE, ARI, and influenza surveillance?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Does the application demonstrate an understanding of the development and/or application of emerging topics (e.g., advanced molecular detection, possible epidemiological roles of commensal modalities in infection risk, innate susceptibility, etc.) and a plan for utilizing state-of-the-art methods to explore such emerging topics?

Approach
Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Are methodologies for conducting surveillance for the appropriate disease targets among patients at hospitals and emergency departments within the surveillance area provided in the application? Are these methodologies adequately described? Are these methodologies appropriate for the proposed research?

Is there evidence that the proposed surveillance is population-based?

Does the application provide supporting evidence of the estimated proportion of children in the catchment area who would be captured by the medical institution’s emergency department?

Does the application contain methodologies for vaccine effectiveness assessments? Are the methodologies adequately described? Are the methodologies appropriate?

Does the application contain methodologies for enrollment and data/specimen collection of healthy control subjects, comparable to subject cases?

Does the application include a clear definition of the geographic area and population base in which the surveillance site will operate, including population denominators for calculating disease rates?

Does the application include an adequate description of the demographics of the proposed population base including a description of various special populations as they relate to the proposed activities of the site?

Does the application describe the ability to capture a minimum sample size for rotavirus and influenza vaccine effectiveness evaluations? For AGE and ARI syndromes, the ability to exhibit geographic and demographic diversity in the captured pediatric population? For AGE, to have collected baseline surveillance data during the pre-rotavirus vaccine licensure era to enable trend analyses over the pre-licensure and post-licensure eras?

### Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Does the application document examples of successful collaborations with a research laboratory in managing large volumes of specimens from research study participants?

Does the application demonstrate the team’s ability to develop and maintain strong cooperative relationships broadly with both public and private vaccine providers at the surveillance site, including public health agencies, academic centers, managed care organizations, and community organizations?

Does the application demonstrate that the team has the ability to synergistically partner with other external resources (e.g., fellowship programs within awarded medical institutions) to efficiently utilize the most recent methods and technologies?

Is support from participating agencies, institutions, organizations, laboratories, consultants, etc. indicated in the application’s operational plan?
As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

**Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

As part of the Biohazards assessment, reviewers will evaluate whether the research proposed qualifies as Dual Use Research of Concern. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called “dual use research.” Dual use research of concern is a subset of dual use research defined as: “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.” The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.


### 2. Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

**Protections for Human Subjects**

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements ([http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1)).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

**Inclusion of Women, Minorities, and Children**

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research
Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations
As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

**Resource Sharing Plans**
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: [http://www.cdc.gov/grants/additionalrequirements/index.html](http://www.cdc.gov/grants/additionalrequirements/index.html). Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

**Budget and Period of Support**
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: [http://www.cdc.gov/grants/interestedinapplying/applicationresources.html](http://www.cdc.gov/grants/interestedinapplying/applicationresources.html)

4. Review and Selection Process
Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria. As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.

- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
Availability of funds.
Relevance of the proposed project to program priorities.

Optional Component funding will be limited to those applications recommended for funding of the Core Component. In addition, both the Core and Optional Components must have an overall priority score between 10 and 50 to be awarded.

5. Anticipated Announcement and Award Dates
After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices
Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee’s business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements
Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants
All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf).
Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.
Specific requirements that apply to this FOA are the following:
Generally applicable ARs:

AR-1: Human Subjects Requirements
AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-7: Executive Order 12372 Review
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
The following are additional policy requirements relevant to this FOA:

**Dual Use Research of Concern (DURC)**

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences “Dual Use Research of Concern” (United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. September 24, 2014. Available at: [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf](http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf)) and required this policy to be implemented by September 24, 2015. DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipients in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy. This policy also applies to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Research funded by CDC involving these agents or toxins must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review may be completed by an Institutional Review Entity (IRE) identified by the funded institution. Many institutions task their Institutional Biosafety Committees with this responsibility.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or cooperative agreement plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. For example, CDC may request that the institution periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official.
prior to submitting the manuscript to a journal. CDC’s Institutional Biosecurity Board (IBB) is responsible for approval of all DURC risk mitigation plans. The award recipient is responsible for adhering to the risk mitigation plan, as approved by CDC.

3. Additional Policy Requirements
The following are additional policy requirements relevant to this FOA:

**HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications**
This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: [http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html](http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html)

**Federal Funding Accountability and Transparency Act of 2006**
Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, [www.USASpending.gov](http://www.usaspending.gov). For the full text of the requirements, please review the following website: [https://www.fsrs.gov/](https://www.fsrs.gov/).

**Plain Writing Act**
The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: [http://www.plainlanguage.gov/plLaw/index.cfm](http://www.plainlanguage.gov/plLaw/index.cfm).

**Tobacco and Nutrition Policies**
The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

**Tobacco:**

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

**Nutrition:**

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following
are resources for healthy eating and tobacco free workplaces:

- [http://www.cdc.gov/nutrition/index.html](http://www.cdc.gov/nutrition/index.html)

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

### 4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Planning, directing, and executing the proposed project with CDC staff being substantially involved as a partner.
- Utilizing existing relationships with state and local health departments, and other public and private organizations to facilitate interactions with health care providers and others in addressing study needs and public health issues relating to new vaccines and vaccine polices.
- Shipping samples in a timely way to other laboratories as needed for testing in accordance with surveillance network procedures.
- Conducting auditing, data cleaning and quality assurance checks of the data including quality assurance of laboratory assays in accordance with surveillance network procedures.
- Obtaining and maintaining the appropriate Institutional Review Board approvals for all institutions or individuals participating in the research project.
- Obtaining Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.
- Routinely evaluating progress in achieving the purpose of this program and promptly complying with CDC requests regarding budgetary and programmatic information.
- Analyzing and interpreting data from surveillance network projects, publishing and disseminating findings in collaboration with CDC, as warranted, and being represented at annual investigators’ meetings and on routine conference calls.
- Ensuring the protection of human subjects through ethical review of all protocols involving human subjects at the local institution and at CDC and obtaining the appropriate Institutional Review Board approvals for all institutions or individuals engaged in the conduct of the research project.
• Working with CDC scientists to obtain OMB-PRA approvals, as needed.
• PUBLICATIONS/PRESENTATIONS: Publications, journal articles, presentations, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, for example: “This publication (journal article, etc.) was supported by the Cooperative Agreement Number above from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention”. In addition, the PI/PD must provide to CDC Program abstracts or manuscripts prior to any publication related to this funding. The grantee will not seek to publish or present results or findings from this project without prior clearance and approval from CDC.
• Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf].

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

• CDC investigator(s) will monitor the cooperative agreement as project officers(s);
• Provide consultation, scientific, and technical assistance in designing and conducting surveillance network projects.
• Assist in the development of research protocols for Institutional Review Boards (IRB) review by all cooperating institutions participating in the research projects. For each protocol, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.
• As needed and arranged with investigators, perform laboratory evaluation of specimens or isolates (e.g., molecular epidemiologic studies, evaluation of diagnostic tools obtained in surveillance network projects) and integrate results with data from other surveillance sites.
• Manage, maintain, and update the secure, encrypted CDC Web-based system which may be used by the surveillance network for data entry of surveillance data at the sites, transfer of data from sites to CDC, merging of data from surveillance sites, and creation of data sets and data summaries which are accessible by each site. Merged datasets will be shared among sites for approved analyses that require multisite data.
• Analyze and interpret data from surveillance network projects and publish and disseminate findings with grantees, as warranted.
• Contribute on project activities including research design, methods, data collection, data analysis, the interpretation of results, and obtaining CDC IRB approval of protocols when CDC is engaged in research involving human subjects.
• Preparing the paperwork necessary for submission of research protocols to the CDC Institutional Review Board for review, as needed
• Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
• Complying with the responsibilities for the PI as described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf].

Areas of Joint Responsibilities include:

• Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.

Additionally, a Scientific Program Officer in the NCHHSTP Extramural Research Program Office (ERPO) will be responsible for the normal scientific and programmatic stewardship of the award as described below:

• Named in the Notice of Award as the Program Official to provide overall scientific and programmatic stewardship of the award;
Serve as the primary point of contact on official award-related activities including an annual review of the grantee’s performance as part of the request for continuation application;

- Make recommendations on requests for changes in scope, objectives, and or budgets that deviate from the approved peer-reviewed application;
- Carry out continuous review of all activities to ensure objectives are being met;
- Attend committee meetings and participate in conference calls for the purposes of assessing overall progress, and for program evaluation purposes; and
- Monitor performance against approved project objectives.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report (PHS 2590)](http://www.grants.gov) annually and financial statements as required in the HHS Grants Policy Statement. A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, 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 Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. 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 recipients:

1. **Information on Executive Compensation** when not already reported through the SAM Registration;
2. **Similar information on all sub-awards/subcontracts/consortiums over $25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](http://www.fsrs.gov) on all subawards over $25,000. See the HHS Grants Policy Statement ([http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)) for additional information on this reporting requirement.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report,** (use form PHS 2590, posted on the HHS/CDC website, [www.grants.gov](http://www.grants.gov) and at [http://grants.nih.gov/grants/funding/2590/2590.htm](http://grants.nih.gov/grants/funding/2590/2590.htm), is due 90 to 120 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, 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.

2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends.

3. **A final progress report,** invention statement, equipment/inventory report, and the final FFR are required 90 days after the end of the project period.
B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee’s continuation application/progress report should include:

- **Description of Progress during Annual Budget Period:** Current Budget Period Progress reported on the PHS 2590 ([http://grants1.nih.gov/grants/funding/2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm)): Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- **Research Aims:** list each research aim/project
  
  a) **Research Aim/Project:** purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
  
  b) **Leadership/Partnership:** list project collaborations and describe the role of external partners.

- **Translation of Research (1 page maximum).** When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. **Questions to consider in preparing this section include:**

  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?
  - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
  - How will the findings advance or guide future research efforts or related activities?

- **Public Health Relevance and Impact (1 page maximum).** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. **Questions to consider in preparing this section include:**

  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- **Current Budget Period Financial Progress:** Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- **New Budget Period Proposal:**
  
  - Detailed operational plan for continuing activities in the upcoming budget period, including
updated Measures of Effectiveness for evaluating progress during the upcoming budget period.

- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made.”

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting
The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include 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 in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, the due date for annual FFRs will be **90 days after the end of the calendar quarter in which the budget period ends.** Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at [http://grants.nih.gov/grants/forms.htm](http://grants.nih.gov/grants/forms.htm). For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: [http://www.cdc.gov/grants/interestedinapplying/applicationresources.html](http://www.cdc.gov/grants/interestedinapplying/applicationresources.html)

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era](https://public.era.nih.gov/chl/public/search/commonsRegisteredOrgs.era)). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the “List of Commons Registered...
Organizations” query found at: http://era.nih.gov/commons/. Organizations not yet registered can go to https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http://era.nih.gov/commons/index.cfm.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee’s final report should include:

- **Research Aim/Project Overview**: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings**: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- **Public Health Relevance and Impact**: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- **Publications; Presentations; Media Coverage**: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

### Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

**Application Submission Contacts**

**Grants.gov Customer Support** (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

- Contact Center Phone: 800-518-4726
- Email: support@grants.gov
- Hours: 24 hours a day, 7 days a week; closed on Federal holidays

**eRA Commons Help Desk** (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

- Phone: 301-402-7469 or 866-504-9552 (Toll Free)
- TTY: 301-451-5939
- Email: commons@od.nih.gov
- Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time
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Section VIII. Other Information

Other CDC funding opportunity announcements can be found at [www.grants.gov](http://www.grants.gov).
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.
Public Health Service Act 42 U.S.C. 247b(k)(1).