

Centers for Disease Control and Prevention

National Center for Immunization and Respiratory Diseases Extramural Research Program Office

US Enhanced Surveillance Network to Assess Burden, Natural History, and Effectiveness of Vaccines to Prevent Enteric and Respiratory Viruses in Children

RFA-IP-21-002

Application Due Date: 03/08/2021

US Enhanced Surveillance Network to Assess Burden, Natural History, and Effectiveness of Vaccines to Prevent Enteric and Respiratory Viruses in Children

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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

Notice of Funding Opportunity (NOFO) Title

US Enhanced Surveillance Network to Assess Burden, Natural History, and Effectiveness of Vaccines to Prevent Enteric and Respiratory Viruses in Children

Activity Code

U01 – Research Project - Cooperative Agreement

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-IP-21-002

Assistance Listings (CFDA) Number(s)

93.185

Category of Funding Activity:

Health

NOFO Purpose

Please note red text added in Section IV.2, pages 24-26, to clarify Content and Form of Application Submission.

The goal of this Notice of Funding Opportunity (NOFO) is to support a network of US institutions to develop and implement standard research protocols to conduct prospective active surveillance for: a) acute gastroenteritis (AGE) due to norovirus, rotavirus and other enteric viruses; b) acute respiratory illnesses (ARI) due to respiratory viruses including, but not limited to, influenza, RSV, parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses (including EV-D68), adenoviruses, and coronaviruses (including SARS-CoV-2); and c) acute flaccid myelitis (AFM) syndrome and multisystem inflammatory syndrome in children (MIS-C) among pediatric patients seeking healthcare at medical institutions. The network should also provide accurate estimates of the effectiveness in this population of influenza, rotavirus, COVID-19 and other vaccines against respiratory or enteric virus-associated illnesses projected to become available during the period of performance (e.g., RSV, norovirus). Participating institutions should identify AGE, ARI, AFM and MIS-C illnesses among pediatric patients seeking healthcare or diagnostic testing for acute illness in inpatient, outpatient and emergency departments. Recipients should enroll patients meeting standard symptom criteria, and confirm viral infection using approved molecular assays. Vaccine effectiveness (VE) estimates will be calculated. Estimates of VE, burden of disease, and information on the natural history of disease will be used to: a) inform best practices for diagnosis and treatment protocols; b) inform vaccine recommendations; and c) assess public health impact of vaccination and public health programs to prevent viral illness-related healthcare encounters and medical visits among pediatric populations.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-IP-21-002, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date:	**01/07/2021**
Application Due Date:	**03/08/2021**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time 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:	**04/13/2021**
Secondary Review:	**05/20/2021**
Estimated Start Date:	**09/01/2021**
Expiration Date:	**03/09/2021**
Due Dates for E.O. 12372:	**Due no later than 60 days after the application receipt date.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the

Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) 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.

Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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

In both the **Research Strategy** and **Project Summary/ Abstract (Description)** sections, the application should clearly list each proposed component project by name (i.e., identify the proposed project as Component A, B, or C).

Each application must address both objectives under **Mandatory Core Component A** and may apply for either or both **Optional Components B and C**.

Within the total 25-page limit for the **Research Strategy** of the **Research Plan section** of the application, the page limit for EACH Component project is limited as follows:

- Component A: 15 pages
- Component B: 5 pages
- Component C: 5 pages

Executive Summary

- **Purpose:** The goal of this Notice of Funding Opportunity (NOFO) is to support a network of US institutions to develop and implement standard research protocols to conduct prospective active surveillance for: a) acute gastroenteritis (AGE) due to norovirus, rotavirus and other enteric viruses; b) acute respiratory illnesses (ARI) due to respiratory viruses including, but not limited to, influenza, RSV, parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses (including EV-D68), adenoviruses, and coronaviruses (including SARS-CoV-2); and c) acute flaccid myelitis (AFM) syndrome and multisystem inflammatory syndrome in children (MIS-C) among pediatric patients seeking healthcare at medical institutions. The network should also provide accurate estimates of the effectiveness in this population of influenza, rotavirus, COVID-19 and other vaccines against respiratory or enteric virus-associated illnesses projected to become available during the period of performance (e.g., RSV, norovirus). Participating institutions should identify AGE, ARI, AFM and MIS-C illnesses among pediatric patients seeking healthcare or diagnostic testing for acute illness in inpatient,

outpatient and emergency departments. Recipients should enroll patients meeting standard symptom criteria, and confirm viral infection using approved molecular assays. Vaccine effectiveness (VE) estimates should be calculated. Estimates of VE, burden of disease, and information on the natural history of disease will be used to: a) inform best practices for diagnosis and treatment protocols; b) inform vaccine recommendations; and c) assess public health impact of vaccination and public health programs to prevent viral illness-related healthcare encounters and medical visits among pediatric populations.

- **Mechanism of Support:** U01 – Research Project - Cooperative Agreement.
- **Funds Available and Anticipated Number of Awards:** The estimated total funding available, including direct and indirect costs, for the entire five (5)-year project period is $68,250,000. The estimated number of awards is up to seven (7) for each component. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards, will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period:** The estimated total funding (direct and indirect) for the first year (12-month budget period) is $13,650,000 with individual awards estimated to range from $1,600,000 to $1,950,000 for all components combined. The estimated total funding (direct and indirect) for the entire project period is $68,250,000. The project period is anticipated to run from 09/01/2021 to 08/31/2026.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. “Application and Submission Information” of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III. 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 include multiple PDs/PIs (Co-PIs) and, if so, must include a Leadership Plan that describes the roles, responsibilities and working relationships of the identified PDs/PIs (Co-PIs). However, only one PD/PI may be the primary CDC contact for the award and should be listed first in the application; this contact PD/PI must be at the recipient institution and must be indicated as such in the application.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed.
- **Application Type.** New.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form F is to be used when completing the application package.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

- Public Health Service Act, Section 317 [42 U.S.C. 247b(k)(1)], as amended
- Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Public Law 116-123
- Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136
- Paycheck Protection Program and Health Care Enhancement Act, Public Law 116-139

1. Background and Purpose

This Notice of Funding Opportunity (NOFO) seeks to support a network of US medical institutions to conduct prospective, active surveillance for acute gastroenteritis (AGE) and acute respiratory illnesses (ARI), as well as associated syndromes, including acute flaccid myelitis (AFM) and multisystem inflammatory syndrome in children (MIS-C), in inpatient, emergency department (ED), and outpatient clinical settings, and among asymptomatic healthy controls.

Respiratory viruses are a major cause of morbidity in young children. The burden of pediatric respiratory viral illness and its impact on public health resources make vaccine development and implementation a high priority. In addition to new vaccines, new diagnostic and therapeutic approaches for respiratory viruses are also developing rapidly. Therefore, it is important to establish active surveillance programs to assess the current characteristics of acute respiratory illness epidemiology as well as the impact of future interventions against respiratory viruses in the US.

Population-based surveillance for viral respiratory and enteric illness and associated syndromes, such as AFM and MIS-C, will allow more accurate determination of the rates of disease, natural history and risk factors for infections, and associated complications over time, and provide an infrastructure for evaluation of the impact of existing vaccines (e.g., for influenza, rotavirus) and of new vaccines as they become licensed (e.g., for RSV, norovirus and SARS-CoV-2). Importantly, active surveillance for ARI will provide the necessary platform to estimate influenza vaccine effectiveness in preventing pediatric influenza hospitalizations. In addition, active surveillance for viruses such as RSV and SARS-CoV-2 will provide critical data to better understand and document the disease burden among US infants and children, and to assess the future impact of vaccines under development and/or being assessed in clinical trials. Moreover, active surveillance for acute respiratory illnesses is an important component of prompt detection of outbreaks of emerging pediatric viral pathogens, such as SARS-CoV-2 and EV-D68, and is necessary to assess the need for the development of future interventions against such viral illnesses. Finally, current national surveillance for multisystem inflammatory syndrome in children (MIS-C) relies on reporting from healthcare providers to local, state, and territorial health departments. Determining the burden of MIS-C using active, population-based surveillance will be important to fully define the burden of MIS-C in children.

In addition, rotavirus and norovirus are problems of significant public health importance, causing severe acute gastroenteritis among infants and children. Neither of these viral infections

is nationally notifiable in the United States and testing for these infections is not always performed when a child seeks medical care for AGE. Thus, it is important to conduct active surveillance among infants and children who are hospitalized and are visiting the ED or clinic for symptoms of AGE, followed by laboratory confirmation of the causative pathogen.

In 2006, the Advisory Committee on Immunization Policy (ACIP) recommended universal rotavirus vaccination of US infants with RotaTeq (Merck and Co.), followed in 2008 with the recommendation to add Rotarix (GSK Biologicals) to the US rotavirus immunization schedule. With these rotavirus vaccines now widely used among US infants, active post-licensure surveillance is necessary to: 1) monitor the impact of rotavirus vaccination in reducing the morbidity and mortality from severe rotavirus gastroenteritis; 2) evaluate rotavirus vaccine effectiveness in field use and identify and determine the causes of possible vaccine failure; and 3) monitor the distribution of rotavirus strains.

After rotavirus, the leading cause of severe AGE among US children is norovirus. There is currently no vaccine against norovirus on the US market, but vaccines and prophylaxes are currently under development. Active surveillance for norovirus is necessary to: 1) better understand and document the disease burden attributable to norovirus among US infants and children; and 2) to monitor the distribution of norovirus genogroups and genotypes.

References

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2. Feldstein L, Ogokeh C, Rha B, *et al.,* for the New Vaccine Surveillance Network. Vaccine Effectiveness Against Influenza Hospitalization Among Children in the United States, 2015–2016. J Pediatric Infect Dis Soc, Epub 28 Feb 2020. PMID: 32108879.
3. Hall CB, Weinberg GA, Blumkin AK, *et al.* Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. Pediatrics 2013; 132:e341-8.
4. Kujawski SA, Midgley CM, Rha B, *et al*. Enterovirus D68-Associated Acute Respiratory Illness - New Vaccine Surveillance Network, United States, July-October, 2017 and 2018. MMWR Morb Mortal Wkly Rep. 2019;68(12):277-280.
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6. Rha B, Lively JY, Englund JA, *et al*. SARS-CoV-2 Infections in Children - Multi-Center Surveillance, United States, January-March 2020 [published online ahead of print, 2020 Jun 18]. J Pediatric Infect Dis Soc. 2020;piaa075. doi:10.1093/jpids/piaa075.
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Healthy People 2030 and other National Strategic Priorities

This NOFO is aligned with the HP2030 objectives for:

- Infectious Disease: https://health.gov/healthypeople/objectives-and-data/browse-objectives/infectious-disease and
- Vaccination: https://health.gov/healthypeople/objectives-and-data/browse-objectives/vaccination.

This NOFO 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).

Public Health Impact

The burden of these diseases, their impact on public health resources, and the lack of alternative measures to control these diseases, make vaccines a high priority. Therefore, it is important to establish active surveillance programs in order to assess the current characteristics of acute viral illness epidemiology as well as to inform future surveillance programs that may monitor the impact of future interventions against viral infections causing ARI or AGE in the US. Funded activities will provide an active US pediatric disease surveillance system to assess a wide spectrum of AGE and ARI pathogens and conduct evaluations related to existing and potential

public health interventions, including:

- Vaccine effectiveness for licensed vaccines including rotavirus and influenza and vaccine effectiveness for vaccines licensed in the future (such as for SARS-CoV-2);
- Burden and natural history of disease for pathogens and 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.

Results from research conducted under this notice of funding opportunity should yield high impact public health findings and/or strategies that should contribute to a reduction in overall burden to healthcare and improve the health of the US population.

Relevant Work

1. RFA-IP16-004: Enhanced Surveillance for New Vaccine Preventable Diseases (http://www.grants.gov/web/grants/search-grants.html, Keyword: RFA-IP16-004; Opportunity Status: Archived).
2. Katz EM, Gautam R, Bowen MD. 2017.Evaluation of an alternative recombinant thermostable *Thermus thermophilus* (rTth)-based real-time reverse transcription-PCR kit for detection of rotavirus A. J Clin Microbiol 55:1585–1587. https://doi.org/10.1128/JCM.00126-17.
3. Guidance for Clinicians on the Use of RT-PCR and Other Molecular Assays for Diagnosis of Influenza Virus Infection at http://www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm
4. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2019–2020 MMWR Recommendations and Reports / August 23, 2019 / 68(3);1–21. https://www.cdc.gov/mmwr/volumes/68/rr/rr6803a1.htm
5. Nix WA, Oberste MS, Pallansch MA. Sensitive, semi-nested PCR amplification of VP1 sequences for direct identification of all enterovirus serotypes from original clinical specimens. J Clin Microbiol 2006;44:2698–704.

2. Approach

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

Each application MUST address both objectives under **Mandatory Core Component A** and may also address either or both **Optional Components B and C**. Each component and its accompanying budget and budget justification must be clearly identified in the application using clear headings/identifiers (please see Section IV.2 of this NOFO for more detailed information regarding application format).

Objectives/Outcomes

A. <u>Mandatory Core Component A</u> for Years 1 through 5, up to $1,100,000 per year (direct and indirect costs) per award for both Mandatory Objectives 1 and 2. Both Objectives must be addressed as part of the Mandatory Core Component A.

<u>Mandatory Objective 1</u>: Population-based active surveillance for respiratory and enteric viral pathogens in pediatric inpatient and emergency department settings and asymptomatic controls.

Establish and operate a surveillance platform for pediatric viral pathogens in order to achieve the following objectives:

1. Perform prospective, active surveillance to determine the etiology and burden of inpatient and emergency department (ED) acute viral respiratory and enteric diseases among the pediatric population.
2. Characterize the clinical and epidemiologic factors of pediatric infections (including in asymptomatic children) through active surveillance.
3. Evaluate vaccine effectiveness and impact of vaccines and other interventions (e.g., immunoprophylaxis with antiviral agents or other therapeutics) available or projected to become available during the period of performance.

The application should address all of the stated objectives and include, at a minimum, the following information in the submission:

1. Describe the setting of the proposed surveillance site with a defined pediatric catchment population in a geographically defined area to conduct year-round surveillance activities. Applications should include, at a minimum, details of study activities that address the following:

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.).

i. Letters of support from participating agencies, institutions, organizations, laboratories, and consultants as indicated in the application's operational plan are encouraged.

b. Describe the geographic area and population base in which the surveillance site will operate, including population denominators for calculating disease rates. (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.)

i. Describe the demographics of the proposed population base, including a description of various special populations as they relate to the proposed activities of the site.

c. Describe the estimated proportion of children in the catchment area who would be

captured by the medical institution's hospital, ED, and outpatient settings (for asymptomatic controls) where surveillance would take place.

d. Describe investigators' experience in conducting surveillance activities in pediatric populations.

e. Provide a timeline and explanation to describe how surveillance activities will begin no later than November 1, 2021.

2. Describe how active, prospective surveillance activities among children with acute gastroenteritis (AGE) and acute respiratory illness (ARI) will be conducted in surveillance hospitals, emergency departments (EDs), as well as in asymptomatic "healthy control" (HC) children at outpatient well-child visits (see Table 1) consistent with previously used methods (applicants may refer to listed publications and previous surveillance network at the following website: https://www.cdc.gov/surveillance/nvsn/index.html.)

Table 1. Summary of surveillance enrollment activities

Subject group (by illness)	Targeted Pathogen	Enrollment period	Age group (years)	Clinical setting
AGE	AGE pathogens (1)	Year-round	<18	Inpatient and ED
ARI	ARI pathogens (2)	Year-round	<18	Inpatient and ED
Healthy controls	AGE and ARI pathogens (1,2)	Year-round	<18	Well child clinics

(1) AGE pathogens include: norovirus, rotavirus.

(2) ARI pathogens include: influenza, RSV, parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses (including EV-D68), adenoviruses, and coronaviruses (including SARS-CoV-2).

The application should include, at a minimum, details of study activities to:

a. Describe procedures to systematically screen patients for eligibility and enroll consenting subjects in the following settings:

i. In the inpatient settings, screen admissions and systematically enroll children with ARI and/or AGE in the inpatient setting at least 5 days per week during the enrollment period.

1. For ARI cases, goal enrollment is at least ~60% of inpatient subjects found to be eligible for surveillance during the year. In addition; goal enrollment during influenza season is approximately 400 inpatient enrollees aged 6 months to 17 years with ARI; sites able to enroll more than 400 patients should specify this in the application. (Refer to section on estimating influenza VE in hospitalized children below.)

2. For AGE cases, goal enrollment for inpatient and ED patients combined should be a minimum of 75% of eligible cases during the year.

ii. In the ED, screen ED patients and systematically enroll children evaluated in the ED with AGE and/or ARI at least 4 days per week during the enrollment period.

1. For ARI cases, goal enrollment is at least ~50% of ED patients found to be eligible for surveillance during the year.

2. For AGE cases goal enrollment for inpatient and ED patients combined should be a minimum of 75% of eligible cases during the year.

iii. Screen outpatient clinic settings and systematically enroll asymptomatic "healthy controls" at least 1 day per week during the period of active surveillance to meet target enrollments established with technical assistance from CDC to determine optimal ratio of cases to controls.

iv. Conduct quality control activities and 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.

b. Describe procedures to collect epidemiological and clinical information from enrolled subjects through parent/guardian interviews and medical record reviews. These should include, but are not limited to:

i. Admission and discharge diagnoses (ICD-10 codes)
ii. Symptoms
iii. Onset of illness
iv. Clinical outcomes (e.g., death, discharge or transfer)
v. Risk factors (e.g., underlying medical conditions, high-risk conditions/behaviors, exposure history)
vi. Vaccination history
vii. Markers for the course and severity of disease (e.g., duration of hospitalization, ICU admission and dates, mechanical ventilation, hypoxia);
viii. Treatments received such as use of antiviral or immune modulatory drugs (with dates)
ix. Clinical radiographic and laboratory results including virologic testing
x. Medical costs.

c. Additional information should be collected to assess household transmission dynamics (i.e., number or household occupants, rooms, etc.), vaccination policies (school, local), targeted and vulnerable populations, and socioeconomic factors (household income, etc.) relevant to public health interventions.

d. Describe procedures to collect study specimens from enrolled children (with goal from at least 70% of enrolled), including stool specimens from children enrolled in AGE surveillance, respiratory (i.e., nasal and throat swabs) specimens from children enrolled in ARI surveillance, and both stool and respiratory specimens from healthy control subjects.

i. Describe approaches to collect any salvaged clinical specimens (e.g., whole blood, sera, plasma, cerebrospinal fluid, and/or other types) that have 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.

e. Describe procedures to process, test, store, and ship study specimens.

i. For stool specimens, describe procedures to process, aliquot, store, extract, and test specimens by approved real-time RT-PCR assays for norovirus and rotavirus and ship duplicate aliquots of specimens for further characterization. Participate in CDC-sponsored proficiency testing.

ii. For respiratory specimens, describe the procedures to process, aliquot, and store locally, including multiple aliquots of specimens (original, lysis buffer, extracted sample) with a system for tracking inventory of aliquots; ship duplicate aliquots of specimens in a timely way to laboratories as needed for further characterization. Describe procedures to perform following activities:

1. Perform approved, timely, sensitive nucleic acid-based diagnostics for respiratory pathogens including, but not limited to. influenza, RSV, parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses (including EV-D68), adenoviruses, and coronaviruses (including SARS-CoV-2).

a. For influenza, describe the 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.

i. 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.

ii. Describe information on experience and competency with these methods (e.g., number of assays run/year; comparisons to other assays or results from validation studies, other measures of proficiency; letters of support; and publications).

b. For SARS-CoV-2, describe approved, standardized, validated molecular assays used to detect SARS-CoV-2 and provide evidence of competency in the use of the approved molecular assay.

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

3. Describe the plan and process to support recurring shipment of aliquots (1 ml) from a subset of positive specimens to other laboratories for further characterization, sequencing and for other surveillance purposes.

iii. For salvaged clinical specimens, describe procedures to store and ship to other laboratories as needed for further characterization.

3. Describe approaches to evaluate performance and impact of vaccines and other interventions (e.g., immunoprophylaxis with antiviral agents or other therapeutics) projected to become available during the period of performance. Describe methodology for collecting vaccination data (for rotavirus, influenza, and other pathogens for which vaccines may be developed, such as SARS-CoV-2) with accuracy and completeness (e.g., dose, type, dates of administration, vaccine manufacturer) for enrolled subjects that will enable accurate evaluations of vaccine

effectiveness, coverage, and impact in the population.

a. Evaluate rotavirus vaccination performance in the United States. For example, evaluations should include vaccine effectiveness (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. Assess influenza vaccine effectiveness (VE) in preventing laboratory-confirmed influenza infections among hospitalized children with ARI less than 18 years of age (i.e., information on underlying conditions, medical outcomes, antiviral use, and vaccination; collected specimen testing for influenza A subtypes and B lineages). Aggregated data from the participating sites should 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. Applications should include, at a minimum, details addressing all the following in the application.
    i. Describe procedures to achieve the goal study sample size enrollment each influenza season (approximately 400 enrollees aged 6 months to 17 years with ARI during the influenza season; sites able to enroll more than 400 patients should specify this in the application). 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]).
    ii. For children aged 6 months to 17 years, describe plans to verify parent-reported influenza vaccination status with validated records (e.g., electronic medical records, electronic vaccine registries or medical abstraction from health care providers, pharmacy chains, schools, and other potential vaccine providers) to obtain current season influenza vaccination status (including vaccination date(s), vaccine type, manufacturer, and lot number) and vaccination status from prior seasons.
    iii. Describe methods to determine VE of maternal vaccination to prevent influenza infection among children less than 6 months of age, including 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.
    iv. 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).
c. Methods for determining COVID-19 vaccination (once vaccines become available), vaccine type, date of vaccination and number of doses will depend upon documentation of COVID-19 vaccination in electronic medical records, real-time electronic vaccine registries or medical abstraction from health care providers, non-traditional providers, public health departments, schools, and other potential vaccine providers.

4. Perform other assessments and evaluations of surveillance network data with technical

assistance from CDC. In addition to assessments of vaccine performance, the site should conduct the following assessments and evaluations:

a. Generate baseline surveillance data (including incidence rate estimates of hospitalizations, and emergency department visits, and clinical and epidemiologic characterizations of illness) for vaccine-preventable pathogens (e.g., influenza, rotavirus), pathogens projected to be potentially vaccine-preventable during the period of performance (e.g. norovirus, respiratory syncytial virus, EV-D68, and SARS-CoV-2), and for other AGE and ARI pathogens (such as; parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses adenoviruses, and coronaviruses) in order to assess the need for development of vaccines and other interventions.

5. Describe procedures to perform timely, uniform, consistent, secure, and accurate data collection and transmission with technical assistance from CDC.

a. Provide timely reporting (e.g., within 1–2 weeks) of case counts with key demographic and clinical information and testing results.
b. Conduct routine data cleaning activities with technical assistance from CDC to ensure data quality for short-term (e.g., within 1–2 weeks for key data variables) and longer-term (e.g., routinely during the course of surveillance year for all data variables) goals (e.g., data for early/interim VE estimates).
c. Manage standardized data dictionaries and Application Programming Interface (API) tokens with technical assistance from CDC.

Mandatory Objective 2: Surveillance and epidemiologic characterization of acute flaccid myelitis (AFM) syndrome in children.

Conduct surveillance activities for acute flaccid myelitis (AFM), to include the following:

1. Define baseline rates of AFM in pediatric sites through active case finding using the following case definition: patients meeting the clinical criterion for AFM (acute onset of flaccid limb weakness) and a spinal MRI showing at least some gray matter involvement (https://www.cdc.gov/acute-flaccid-myelitis/hcp/case-definitions.html)

    a. Conduct active surveillance for AFM on inpatient pediatric and neurology services in hospitals within the defined catchment area.
    b. Establish incident rates of AFM among hospitalizations and in the defined catchment area.

2. Compare rates of AFM to rates of circulating respiratory and gastrointestinal infections at each site.

3. Characterize the clinical spectrum of pediatric AFM and describe differences between other similar neurologic conditions. 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).

B. <u>Optional Component B</u> for Years 1 through 5, $350,000 per year (direct and indirect costs) per award.

Population-based active surveillance for respiratory and enteric viral pathogens in outpatient settings.

Establish and operate surveillance for pediatric viral pathogens among children presenting to outpatient care with acute respiratory illness (ARI) and acute gastroenteritis (AGE).

The application should address all of the stated objectives and include, at a minimum, the following information in the submission:

1. Describe how active, prospective surveillance activities among children with ARI and AGE presenting to surveillance site outpatient care (e.g., clinics, clinic associated facilities) will be conducted consistent with methods described for inpatient/ED patient surveillance detailed in core component above (see Mandatory Component A above).
    a. In outpatient care settings, systematically enroll children evaluated for AGE and/or ARI at least 3 days per week during the year.
        i. For ARI cases, goal enrollment is at least ~50% of outpatient patients found to be eligible for surveillance during the periods of active surveillance.
        ii. For AGE cases, goal enrollment is at least ~50% of outpatient patients with a stool sample found to be eligible for surveillance during the year.
    b. Describe procedures to collect epidemiological and clinical information from enrolled subjects through parent/guardian interviews and medical record reviews.
    c. Describe procedures to collect study specimens from enrolled children, including stool specimens from children enrolled in AGE surveillance, respiratory (i.e., nasal and throat swabs) specimens from children enrolled in ARI surveillance.
    d. Describe procedures to process, test, store, and ship study specimens, consistent with methods described for inpatient/ED patient surveillance detailed in core component above (see Mandatory Component A). This includes performing approved, timely, sensitive nucleic acid-based diagnostics for respiratory pathogens including, but not limited to, influenza, RSV, parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses (including EV-D68), adenoviruses, and coronaviruses (including SARS-CoV-2).
    e. For stool specimens, describe procedures to process, aliquot, store, extract, and test specimens by approved real-time RT-PCR assays for norovirus and rotavirus and ship duplicate aliquots of specimens to other laboratories for further characterization. Participate in CDC-sponsored proficiency testing.
2. Perform evaluations of surveillance network data with technical assistance from CDC, including:
    a. Generate baseline surveillance data (including incidence rate estimates of outpatient visits, and clinical and epidemiologic characterizations of outpatient illness) for vaccine-preventable pathogens (e.g., influenza, rotavirus), pathogens projected to be potentially vaccine-preventable during the period of performance

(e.g., norovirus, respiratory syncytial virus, EV-D68, and SARS-CoV-2), and for other ARI and AGE pathogens (such as; parainfluenza viruses, human metapneumovirus, rhinoviruses, enteroviruses adenoviruses, and coronaviruses) in order to assess the need for development of vaccines and other interventions.

3. Describe procedures to perform timely, uniform, consistent, secure, and accurate data collection and transmission with technical assistance from CDC, consistent with methods described for inpatient/ED patient surveillance detailed in core component above (see Mandatory Component A).

C. Optional Component C for Years 1 through 5, $500,000 per year (direct and indirect costs) per award

Determine incidence, spectrum of disease and risk factors associated with multisystem inflammatory syndrome in children (MIS-C).

The objective of this surveillance component will be to identify and characterize children meeting the case definition for MIS-C during the project period, including risk factor evaluation and description of long-term sequelae. The current CDC case definition for MIS-C is as follows (https://www.cdc.gov/mis-c/hcp/) but may be refined over time:

- An individual aged less than 21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (greater than two) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms.

*Fever greater than 38.0°C for 24 or more hours, or report of subjective fever lasting 24 or more hours.

**Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin.

Applications should include descriptions of the following activities:

1. Define incidence rates of MIS-C in pediatric sites through active case finding.

a. Conduct active surveillance for MIS-C on inpatient pediatric hospital wards and intensive care units in hospitals within the catchment area using the current CDC case definition (https://www.cdc.gov/mis-c/hcp/). Applications should describe active case finding procedures that can include (but are not limited to):

i. Use of prospective surveillance activities performed under Components A and/or B.

ii. Review of documented positive laboratory results for current or recent SARS-CoV-

2 infection by RT-PCR (or other molecular assay), serology, or antigen test.

iii. Identification of patients who have received treatment such as intravenous immunoglobulin (IVIG).

iv. Case finding through consultation with critical care, infectious disease, and rheumatology specialists.

b. Establish incidence rates of MIS-C among hospitalizations and in the defined catchment area.

c. If the CDC case definition is expanded to include milder disease during the project period, expand surveillance to define incidence of MIS-C among children evaluated in emergency departments and outpatient settings in the defined catchment area.

2. Describe the spectrum of clinical characteristics and phenotype of MIS-C, including phenotypes and diagnostic criteria that differentiate between MIS-C and acute COVID-19.

a. 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).

3. Conduct studies to elucidate risk factors for MIS-C, including identifying host risk factors (age, sex, race/ethnicity, underlying conditions, host genomics, microbiome, severity of acute infection/quantitative and qualitative immune response), environmental risk factors (increased likelihood of infection/exposure, medications), population-level risk factors (density, socioeconomic status, occupational patterns, household characteristics), and viral risk factors (genetic characterization, viral load).

4. Describe the administration of therapeutics for MIS-C, including investigational and off-label medications, including treatment strategies by MIS-C phenotype, initiation relative to days from hospital presentation, and outcomes.

5. Characterize the extent and time to recovery, and describe long-term outcomes and clinical sequelae (e.g., cardiac and other organ systems) by medical record review and parent interview(s) and/or electronic survey(s) at pre-determined intervals.

Target Population

The target population for all components is a diverse representation of US children under 18 years of age in the inpatient, ED, and outpatient clinical setting; specifically, those children seeking medical care for either acute gastroenteritis, acute respiratory illness, and associated syndromes including acute flaccid myelitis (AFM) and multisystem inflammatory syndrome in children (MIS-C), and asymptomatic healthy controls.

Collaboration/Partnerships

The goal of this notice of funding opportunity is to support a network of US institutions that will implement a standard research protocol to conduct prospective active surveillance for AGE, ARI and AFM and MIS-C syndromes among pediatric patients seeking healthcare at medical

institutions. Awardees will work collaboratively to perform surveillance activities to achieve study goals and objectives. Investigators from each site will participate on a steering committee with technical assistance from CDC; this steering committee is not advisory to CDC.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a five (5)-year research project period. The application should include specific, measurable, achievable, realistic and time-phased (SMART) project objectives for each activity described in the application's project plan and describe the development and implementation of project performance measures based on specific programmatic objectives.

PIs of funded applications must submit an annual progress report showing project activities and outcomes based on the overall research goals and timeline. For more information on required Reporting, please see Section VI. of this NOFO.

For each component, the application should include an evaluation/performance measurement plan. Progress should be identified by achievement of relevant milestones which may include, but are not limited to:

- The type of evaluations (i.e., process, outcome or both) to be conducted.
- Key evaluation questions.
- Other information (e.g., performance measures to be developed by the applicant).
- Potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
- Conducting quality control activities and demonstrating the ability to enroll at least ~60% of subjects found to be eligible for surveillance during the dates of active surveillance and collecting at least 70% of stool and ARI specimens from enrolled subjects.

Translation Plan

For each component, the application should describe how the findings of this work will further the understanding of the clinical and epidemiologic characteristics of viral infections (and associated syndromes), as well as inform and evaluate policy and recommendations for existing vaccines/interventions and those that may become available during the funded period. 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 translation plan should describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

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: $68,250,000

Estimated Total Funds Available (Mandatory Core Component A plus two Optional Components B and C), including direct and indirect costs (Years 1 through 5): $68,250,000

Estimated Total Funds Available (Mandatory Core Component A plus two Optional Components B and C), including direct and indirect costs, for the first 12-month budget period: $13,650,000

Estimated Number of Awards for each component: Up to seven (7).

Estimated Total Funds Available for Component A (Years 1 thorough 5): $38,500,000

Estimated Total Funds Available for Component B (Years 1 through 5): $12,250,000

Estimated Total Funds Available for Component C (Years 1 through 5): $17,500,000

Ceiling for Component A per award for first 12-month budget period: $1,100,000

Floor for Component A per award for first 12-month budget period: $900,000

Ceiling for Component B per award for first 12-month budget period: $350,000

Floor for Component B per award for first 12-month budget period: $300,000

Ceiling for Component C per award for first 12-month budget period: $500,000

Floor for Component C per award for first 12-month budget period: $400,000

Anticipated Number of Awards: 7

Award ceiling: $1,950,000 per award for first 12-month budget period for all components combined.

Award floor: $1,600,000 per award for first 12-month budget period for all components combined.

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

Award ceiling and floor are for the first 12-month budget period only.

Award Ceiling:	$1,950,000 Per Budget Period
Award Floor:	$1,600,000 Per Budget Period
Total Period of Performance Length:	5 year(s)

Throughout the Period of Performance, 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/ sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	State governments County governments City or township governments Special district governments Independent school districts Public and State controlled institutions of higher education Native American tribal governments (Federally recognized) Public housing authorities/Indian housing authorities Native American tribal organizations (other than Federally recognized tribal governments) Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education Others (see text field entitled "Additional Information on Eligibility" for clarification)

Additional Eligibility Category:

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:

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."

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. Additional Information on Eligibility

- Public and private non-profit institutions of higher education
- The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Nonprofit 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

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

If an applicant requests a funding amount greater than the ceiling of $1,100,000 for Component A in the first budget period, $350,000 for Component B in the first budget period or $500,000 for Component C in the first budget period as indicated in Section II. of this NOFO, HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

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://cage.dla.mil/
- 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/index.html .
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit 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 Principal Investigator (PD/PI) 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 eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission

process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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 recipient 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 recipient 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity 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 NOFO 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.

Applications may include multiple PDs/PIs (Co-PIs) and, if so, must include a Leadership Plan that describes the roles, responsibilities and working relationships of the identified PDs/PIs (Co-PIs). However, only one PD/PI may be the primary CDC contact for the award and should be listed first in the application; this contact PD/PI must be at the recipient institution and must be indicated as such in the application.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via: http://grants.nih.gov/support/index.html .

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf, except where instructed in this Notice of Funding Opportunity 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 package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

*****IMPORTANT NOTE*****

- The applicant only needs to submit one SF424R&R application for all three (3) **Components (A through C)**; however, the budget and the budget justification needs to be listed separately for each **Component (A through C)** (i.e., up to three budgets and

three budget justifications in one SF424R&R application). Please see below for additional requirements.

- In both the **Research Strategy** and **Project Summary/ Abstract (Description)** sections, the application should clearly list each proposed component project by name (i.e., identify the proposed project as Component A, B, or C).
- Each application must address both objectives under **Mandatory Core Component A** and may apply for either or both **Optional Components B and C**.
- Within the total 25-page limit for the **Research Strategy** of the **Research Plan section** of the application, the page limit for EACH Component project is limited as follows:

    - Component A: 15 pages
    - Component B: 5 pages
    - Component C: 5 pages

- The **Research Strategy** of the **Research Plan** for applicants applying for only the **Mandatory Core Component A**, and no **Optional Components**, must still remain at 15 pages; likewise, the **Research Strategy** of the **Research Plan** for applicants applying for the **Mandatory Core Component A** and only one **Optional Component** must be limited to 15 pages for the **Mandatory Core Component A** and 5 pages for the **Optional Component** (either B or C).
- Supporting materials for the **Research Plan** narrative included as appendices may not exceed 10 PDF files (for all components combined) with a maximum of 50 pages for all appendices (for all components combined).
- Throughout the **Research Strategy** and other application sections, text pertaining to a given component should be titled to begin with the words **"Component A"** or **"Component B"** or **"Component C"** to distinguish components from one another.

• For each Component applied for, applicants must submit a separate PHS398 Research Plan (which includes the Research Strategy that is limited to 15 pages for Component A and to 5 pages each for Components B and C), Senior/Key Person Profiles and Budget pages (Sections A-K) using the SF424 (R&R) forms. Guidance for completing the SF424 (R&R) and PHS398 forms can be found at: http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf

• The Research Plan, Senior/Key Person Profiles and the Budget pages for Components B and C, if applied for, will need to be submitted as attachments under Item #12 [Other Attachments] using the SF424(R&R) "Research and Related Other Project Information Form" within the Component A SF424 (R&R) application. The project lead for Components B and C should be identified as a Co-Investigator rather than as the PI unless the project lead is the PI for Component A. Components B and C must be titled to begin with the words "Component B" and "Component C", respectively, to distinguish them from "Component A" and from each other. In addition, the combined total direct costs for Components B and C must be listed in the SF424 (R&R) budget as item #8 under "Other Direct Costs" in Section F of the Component A budget for budget periods 1 through 5. A detailed budget justification for Components B and C must be included in the application for budget years 1 through 5 and should be included in Section K after the Component A budget justification for each respective budget period. Start a new page for each

Component budget narrative.

• Applications applying for Components B and/or C that do not have the Research Plan, Senior/Key Person Profiles and the Budget pages as separate attachments for Components B and/or C, respectively, may not be forwarded for review or funded. Sections of the application must be titled accurately for Components A, B and C so that they may be differentiated. Budgets for Components B and C, if applied for, must be included in the Component A budget for each respective budget period or Components B and C may not be forwarded for review or funded.

As part of the initial scientific merit review, **Components A through C** will each receive an overall impact score and will be rank ordered separately by this score. Only applications receiving a **Component A** award will be eligible to receive a **Component B or C** award. Please see Section V.4 of this NOFO for additional review information.

Letters of Support from partners or other organizations should be placed in the PHS 398 Research Plan "Other Research Plan Section" of the application under "9. Letters of Support".

Please include all of the eight (8) mandatory forms listed below in the application package:

Mandatory

1. SF424(R&R)[V2.0];
2. PHS 398 Cover Page Supplement [V4.0];
3. Research and Related Other Project Information [V1.4];
4. Project/Performance Site Location(s) [V2.0];
5. Research and Related Senior/Key Person Profile (Expanded) [V2.0];
6. Research and Related Budget [V1.4];
7. PHS 398 Research Plan [V4.0];
8. PHS Human Subjects and Clinical Trials Information [V1.0].

If multiple collaborating institutions will be involved, please include in this section of the application your single IRB (sIRB) Plan:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified engaged institutions or participating sites will agree to rely on the proposed sIRB and that any institutions or sites added after award will rely on the sIRB.
- Briefly describe how communication between institutions and the sIRB will be handled.
- Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study

at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.

Please include the one (1) optional form listed below, if applicable, in the application package:

Optional

1. R&R Subaward Budget Attachment(s) Form 5 YR 30 ATT.

3. Letter of Intent

Due Date for Letter of Intent: **01/07/2021**

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 CIO 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 institution

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this notice of funding opportunity

The letter of intent should be sent to:

Gregory Anderson, MPH, MS

Extramural Research Program Office

Office of the Associate Director of 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

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4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

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 components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf and http://grants.nih.gov/grants/how-to-apply-application-guide.htm for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, 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 NOFO.
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 time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf and here: http://grants.nih.gov/grants/how-to-apply-application-guide.htm must be followed along with any additional instructions

provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• A description of the data to be collected or generated in the proposed project;
• Standards to be used for the collected or generated data;
• Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of
provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights -
this section should address access to identifiable and de-identified data);
• Statement of the use of data standards that ensure all released data have appropriate documentation that
describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation
and access are not justified (this section should address archiving and preservation of identifiable and deidentified
data).
Examples of DMPs may be found here: USGS, http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans

or University of California https://dmp.cdlib.org/

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.

*****PLEASE NOTE: If applications go beyond the page limit designated for a given section or component, excess pages will be removed from the application prior to peer review and may negatively affect the scoring.*****

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, 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 50 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.
Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.
Applicants are able to access, view, and track the status of their applications in the eRA Commons.
Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.
Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time 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).
Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.
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. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/08/2021**

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 (https://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:
https://www.whitehouse.gov/wp-content/uploads/2020/04/SPOC-4-13-20.pdf.

11. Funding Restrictions

Expanded Authority:

For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.
All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 75, terms and conditions, 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.

Protecting Life in Global Health Assistance:
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additional-requirements/ar-35.html).

Public Health Data:
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

> **Data Management Plan:**
> Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
> Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html for revised AR-25.

Human Subjects:
Funds relating 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.
If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to

conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.
Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

Additional Funding Restrictions:

1) Awards made under this NOFO should have no scientific or budgetary overlap with other funded awards.

2) Funds relating 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.

If the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included in this NOFO. Please see Section IV.2 of this NOFO, "Content and Form of Application Submission" for guidance on sIRB Plan content.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

3) Funds relating to the conduct of research involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.

4) 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, for a comprehensive listing of those requirements.

Non-compliance with this Policy may result in suspension, limitation, or termination of US 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.

5) Please note the requirement for inclusion of a Data Management Plan (DMP) in applications described above under "Funding Restrictions" and also in AR-25 in the Additional Requirements section of this NOFO (https://www.cdc.gov/grants/additionalrequirements/ar-25.html). Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

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

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

Please note the new requirement for a **Risk Assessment Questionnaire** (described above) that should be uploaded as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application.

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 (https://grants.nih.gov/grants/how-to-apply-application-guide.html).

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.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or non-responsive 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 (https://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 a PI or investigator team 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)?
- Does the PI or investigator team 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 investigators?
- 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?
- Does the investigator team have experience and expertise in conducting AGE and ARI 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?

- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to public health?

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?

- Does the application adequately describe methodologies for conducting surveillance for the appropriate disease targets among patients in all settings: inpatient, outpatient and emergency department settings within the surveillance area proposed in the application?
- 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 inpatient, outpatient and emergency departments?
- Does the application contain appropriate and adequately described methodologies for vaccine effectiveness assessments?
- Does the application contain methodologies for enrollment and data/specimen collection of asymptomatic 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 collecting data on the racial/ethnic diversity of populations proposed for study?
- Does the application include geographically diverse target populations to increase generalizability of results?

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 provide evidence of successful past collaborations with a research laboratory in processing and managing large volumes of specimens from research study participants or the potential to create such collaborations?
- Does the application describe the capacity 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 describe the capacity to synergistically partner with other external resources (e.g., fellowship programs within awarded medical institutions) to efficiently utilize the most recent methods and technologies?
- Does the application demonstrate support from participating agencies, institutions, organizations, laboratories, consultants, etc. in the operational plan?

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 (https://www.cdc.gov/grants/additionalrequirements/ar-1.html).

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 (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four 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) 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 4) 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 (https://olaw.nih.gov/guidance/vertebrate-animal-section.htm).

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.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

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.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter with the application.

Resource Sharing Plan(s)
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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility,

storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

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

The budget can include both direct costs and indirect costs as allowed.

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

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

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

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 NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- 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.

As part of the initial scientific merit review, each **Component (A through C)** will receive a separate overall impact score representing the scientific merit of the component; components will be rank ordered separately by this score.

It is estimated that up to seven (7) **Core Component A** awards will be made in rank order by overall impact score. An applicant must be awarded **Component A** in order to be eligible to be awarded **Component B or C** projects. Thus, one application will receive up to three (3) independent overall impact scores for the projects proposed (one each for **Components A, B, and C**).

Component A will be rank ordered by overall impact score and the acceptable funding range for this component will be determined using these scores. Once the fundable range has been determined for **Component A** applications, from among the fundable applications, the best scoring **Component B** project followed by the best scoring **Component C** project, in that order, will be awarded, in rank order by overall impact score; this process will continue for the next best scoring **Component B** project followed by the next best scoring **Component C** project and so forth, as available funds allow, for perpetuity.

Review of risk posed by applicants.

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

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

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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

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 NOFO 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 (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/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.

Recipient 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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: https://www.archives.gov/federal-register/cfr.

Specific requirements that apply to this NOFO are the following:

CDC Administrative Requirements:

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-8: Public Health System Reporting Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-15: Proof of Non-profit Status

AR-16: Security Clearance Requirement

AR-20: Conference Support

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-23: Compliance with 45 C.F.R. Part 87

AR-25: Policy on Public Health Research and Non-research Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-27: Conference Disclaimer and Use of Logos

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR 31 - Distinguishing Public Health Research and Public Health Nonresearch

AR 32 – FY 2012 Enacted General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

AR-36: Certificates of Confidentiality

AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

Lobbying Note:

See "Additional Requirement (AR)-12" link above for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.

A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123) agrees to:

1. Comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19;
2. In consultation and coordination with HHS, provide, commensurate with the condition

of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and
3. Assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

To view brief descriptions of relevant CDC requirements visit: http:// www.cdc.gov/ od/OGS /funding/ grants/additional_ req.shtm

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:
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 applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274, 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.

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

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic

version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, 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 must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

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, cooperative agreement or contract 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. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of 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.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additional-requirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additional-requirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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 Part 75, 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 Officers are 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:

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access.
- 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).
- 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.

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

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access.
- 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.
- Assisting the PI, as needed, in complying with the PI responsibilities 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

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

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) 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 recipients 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; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over

$25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

- **Please note:** FFR reporting is now via the Payment Management System (PMS): https://pms.psc.gov/
- **The Recipient Organization** no longer needs to provide HHS/CDC with an original, plus one hard copy of the reports listed below (only electronic submissions as indicated below).

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**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. 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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through the Payment Management System (PMS) **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 to be submitted **120 days after the end of the period of performance**.

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.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 contribute 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. Report listed by Research Aim/Project.
- 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.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

- Special reporting requirements for any COVID-19 activities may be added to the Notice of Grant Award.

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) 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.
The due date for final FFRs is 120 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients 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 recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://era.nih.gov/ 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: https://era.nih.gov/docs/Commons_UserGuide.pdf.

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, health care 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 period of performance. 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.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long-term preservation of the data.

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 Notices of Funding Opportunities can be found at 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, Section 317 [42 U.S.C. 247b(k)(1)], as amended.
- Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Public Law 116-123.
- Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136.
- Paycheck Protection Program and Health Care Enhancement Act, Public Law 116-139.