Centers for Disease Control and Prevention

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES

Network of Community Cohorts for Monitoring Changes in Respiratory Virus Epidemiology (Pandemic Preparedness Cohorts)

RFA-IP-24-045

02/20/2024

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

National Center for Immunization and Respiratory Diseases

Notice of Funding Opportunity (NOFO) Title

Network of Community Cohorts for Monitoring Changes in Respiratory Virus Epidemiology (Pandemic Preparedness Cohorts)

Activity Code

U01 – Research Project - Cooperative Agreements

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-IP-24-045

Assistance Listings Number(s)

93.083

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to establish: 1) a multi-site community-based cohort study that would allow close monitoring of the burden of acute respiratory illness in the community, contributions of various respiratory viruses to this burden, and the impact of vaccination and other interventions on risk of infection and/or severe outcomes, and 2) a case-ascertained household transmission study (or multi-site study) that would support ongoing assessment of transmission dynamics of respiratory viruses of interest

and factors (i.e., demographic, clinical, or household-level factors) that may impact transmission.

While hospital-based platforms are key to assessing frequency and risk factors for severe disease, community-based platforms are essential for understanding age-specific incidences of infection, risk factors for infection, socioeconomic burden of infections (such as days of work/school lost), and the clinical spectrum of illness. They are important for characterizing the immune response to infection or reinfection and long-term outcomes, and they are key to understanding the impact of individual- and household-level mitigation factors (including but not limited to vaccination) on all of these measures. This type of network may be especially useful for detecting changes in any of these factors when a new virus or viral variant begins circulating.

Case-ascertained household transmission studies are well-positioned to quickly and efficiently enable us to understand transmission dynamics of respiratory viruses (or sublineages/types of existing viruses that undergo frequent mutation, such as SARS-CoV-2 and influenza) and assess potential mitigation factors. These studies can also be valuable for characterizing viral shedding dynamics and infectiousness. These studies were key during the COVID-19 pandemic to understanding if changes in hospitalization rates were due to changes in transmissibility/infection rates versus changes in severity of illness. They are also great resources for assessing how history of vaccination or prior history of infection effect transmission to close contacts.

This NOFO would build on the lessons learned during the COVID-19 pandemic and establish a consolidated network of community cohorts to monitor a range of respiratory viruses among community members who develop symptoms of acute respiratory illness. Incorporation of multi-pathogen testing will allow us to better understand the relative contribution of various viruses to the overall community burden of respiratory disease now in the post-pandemic setting, and how the clinical spectrum of these illnesses compare, in a setting in which multiple new preventive products are becoming available. This would also support the establishment of a case-ascertained transmission study (or multi-site study) that would be able to assess SARS-CoV-2, Respiratory Syncytial Virus (RSV), and other prioritized respiratory viruses on an ongoing basis.

The combination of these studies will generate much greater visibility on risk factors for infection and the effectiveness of various interventions in reducing infections and viral transmission, factors that are relevant to reducing overall morbidity and mortality related to respiratory viruses. Should a new variant or virus arrive, this platform would be well positioned to further expand testing to better understand potential concerns like proportion symptomatic, timing of transmission, likelihood of asymptomatic transmission and other related questions. Such questions may be key to developing public health guidance should additional mitigation measures become necessary.

Key Dates

Publication Date:

To receive notification of any changes to RFA-IP-24-045, 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:
01/19/2024
01/19/2024

Application Due Date:
02/20/2024
02/20/2024

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 11:59 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on 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.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

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:
04/25/2024

Secondary Review:
05/22/2024

Estimated Start Date:
08/01/2024

Expiration Date:
02/21/2024

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - 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 40 pages.

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

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

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

NOTE: This NOFO includes four components: Component A1, A2, B and C. There are no limits to which components an applicant may apply. An applicant may apply for one, or all, or any combination of these components, with one exception: Component A2 applicants must also apply for Component A1, whereas Component A1 applicants are not required to apply for Component A2. Component A2 awards can only be made to the award recipients of Component A1.

The Research Strategy component of the Research Plan is limited to 40 pages maximum, including 12 pages each for Component A1, B and C, and no more than 4 pages for Component A2.

Executive Summary

- **Purpose:** The purpose of this NOFO would be to: 1) establish a network of community-based cohorts, including diverse age groups (e.g., 0-5 years old, 5-17 years old, 18-64 years old, and 65+ years old, etc.), demographic characteristics (e.g., race/ethnicity, gender, etc.), and regions in the US to support ongoing monitoring of changes in respiratory virus epidemiology in the years following the COVID-19 pandemic with the potential of also including in-depth immunologic studies in a limited number of sites; and 2) establish a case-ascertained household transmission study (or multi-site study) to monitor transmissibility of respiratory viruses and the impact of vaccination and other mitigation measures on transmission to close contacts. The combination of these networks will enhance preparedness to quickly obtain data on infection risk, transmission, and effectiveness of preventive measures in response to a novel virus or variant. **Note:** this is a multi-component NOFO, which includes four (4) components: A1, A2, B and C. There are no limits to which components an applicant may apply. An applicant may apply for one, or all, or any combination of these components, with one exception: Component A2 applicants must also apply for Component A1, whereas Component A1 applicants are not required to apply for Component A2. Component A2 awards can only be made to Component A1 award recipients.
- **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 **$95,250,000**. The number of awards will be no more than **nine (9),** including: **five (5)** Component A1, **two (2)** Component A2 (**included** in the five (5) of Component A1)**, three (3)** Component B, and **one (1)** Component C**.** 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) will be **$19,050,000** with each individual awards as: $2,400,000 for Component A1, $500,000 for Component A2, $1,600,000 for Component B, and $1,250,000 for Component C. The estimated total funding (direct and indirect) for the entire project period will be **$95,250,000**. The project period is anticipated to run from **08/01/2024 to 07/31/2029**.
- **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. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply. **NOTE:** CDC does not make awards to individuals directly.
- **Number of PDs/PIs.** There will only be one PD/PI for each application.
- **Number of Applications.** Only one application per institution (normally identified by having a unique entity identifier [UEI] number) is allowed.
- **Application Type.** New
- **Application Materials.** See Section IV.1 for application materials. Please note that SF424 (R&R) Form H is to be used when completing the application package. Please see https://grants.nih.gov/grants/how-to-apply-application-guide.html

Section I. Funding Opportunity Description

Statutory Authority

Public Health Service Act, Section 317; 42 U.S.C. 247b(k)(1) and 42 U.S.C. 247b(k)(2)

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.

American Rescue Plan Act of 2021, Public Law 117-2.

1. Background and Purpose

Analyses of data from the Global Burden of Disease study indicate that there were over 17 billion reported cases of upper respiratory infection globally (representing over 40% of all illness episodes captured in that study) and an additional 489 million reported cases and 2.5 million deaths due to lower respiratory tract infection in 2019.

Since emerging as a novel respiratory virus, SARS-CoV-2 alone is reported to have caused over 750 million diagnosed infections and nearly 7 million deaths globally. Over the past three years,

over 75% of the US population are estimated to have been infected with SARS-CoV-2, many people more than once, and over 95% of US adults now have antibodies against COVID-19 either from infection, vaccination, or both. Underlying immunity and the widespread availability of treatment has drastically changed the COVID-19 pandemic landscape when compared to 2020; however, COVID-19 remained the 4th most common cause of death and leading infectious cause in the US in 2022. Close monitoring of this virus is still required, as it continues to evolve and acquire mutations that increase its ability to evade the immune response, sustaining the risk for further increases in cases, hospitalizations, and deaths.

RSV is another respiratory virus for which the immune landscape may be changing drastically over the next few years. RSV is estimated to cause over 2 million outpatient visits, over 200,000 hospitalizations, and over 10,000 deaths, each year in the US, with children younger than 5 years old making up the majority of cases and adults older than 65 years old accounting for the majority of deaths. In the fall of 2023, CDC recommended new RSV vaccines for certain adults older than 60 years old and pregnant persons, and long-lasting monoclonal antibodies to reduce the risk of severe RSV in infants. These new preventive products have the potential to drastically change the burden of disease for this virus which is currently the most common cause of hospitalization in infants in the US.

At the start of the COVID-19 pandemic, infrastructure for understanding the epidemiology of a rapidly evolving virus in real-time was limited. Given the long lead time required for the US Government to start new projects, CDC harnessed a variety of studies and platforms designed for other purposes to begin collecting the specimen and survey data it needed to understand COVID-19 risk, burden, severity, immunity, and long-term sequelae. Because these projects were funded through emergency response funds, they were often time limited.

Currently, for SARS-CoV-2, RSV, and most other respiratory viruses, the majority of the platforms used to monitor the burden of illness and the effectiveness of preventive measures are hospital- and laboratory-based surveillance networks. These networks provide CDC with geography-specific estimates of hospitalizations and deaths, or for the laboratories, numbers of patients tested for particular respiratory viruses and the percentage that test positive. Changes in the percent positivity is considered a marker for increased transmission, although testing for respiratory viruses at health centers is generally not standardized or routine. As a result, the markers we currently have generally lag behind the actual increases in infections and cases. In addition, changes in hospitalization and deaths may occur due to a combination of transmissibility and severity; the relative contribution of each of these sources can be difficult to disentangle without additional data on the overall burden of disease.

It is likely that these studies only show us the tip of the iceberg when it comes to the overall burden and impact of these respiratory viruses, and they are not well-equipped to capture populations that do not readily access healthcare. Understanding the burden of disease, including loss of school/work, long-term morbidity, and equity challenges that results in differential healthcare access require community- or population-based epidemiologic studies.

The purpose of this NOFO is to: 1) establish and sustain a network of community-based cohorts, including diverse age groups, demographic characteristics, and regions in the US to support ongoing monitoring of changes in respiratory virus epidemiology in the years following the COVID-19 pandemic with the potential of also including in-depth immunologic studies in a limited number of sites; and 2) establish and sustain a case-ascertained household transmission

study (or multi-site study) to monitor transmissibility of prioritized respiratory viruses and the impact of vaccination and other mitigation measures on transmission to close contacts. The combination of these networks will enhance CDC preparedness to quickly obtain data on infection risk, transmission, and effectiveness of preventive measures in response to a novel virus or variant.

Health Equity:

CDC supports efforts to improve the health of populations disproportionately affected by infectious diseases by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity.

A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in infectious diseases are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (https://www.cdc.gov/socialdeterminants/index.htm). These include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic challenges. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after health disparities are eliminated

Applicants should use data, including social determinants' data, to identify communities within their jurisdictions that are disproportionately affected by infectious diseases and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, applicants should consider social determinants of health in the development, implementation, and evaluation of specific efforts and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

Healthy People 2030 and other National Strategic Priorities

This NOFO will enable CDC to track the annual (or when relevant more frequent) incidence of acute respiratory illness among a community-based cohort, incidence of symptomatic infection for a wide range of respiratory viruses, and transmissibility of multiple respiratory viruses in a household setting. As such, this NOFO supports the following Health and Human Service (HHS) Strategic Plan topic areas:

Strategic Goal 2: Safeguard and Improve National and Global Health Conditions and Outcomes

Strategic Objective 2.1: Improve capabilities to predict, prevent, prepare for, respond to, and recover from disasters, public health and medical emergencies, and threats across the nation and globe.

Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All

Strategic Objective 4.1: Improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion.

Strategic Objective 4.2: Invest in the research enterprise and the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs.

Strategic Objective 4.3: Strengthen surveillance, epidemiology, and laboratory capacity to understand and equitably address diseases and conditions.

Strategic Objective 4.4: Improve data collection, use, and evaluation, to increase evidence-based knowledge that leads to better health outcomes, reduced health disparities, and improved social well-being, equity, and economic resilience.

Public Health Impact

The approach described in this NOFO will allow for community-based surveillance of respiratory virus infections and allow close monitoring for changes in respiratory virus epidemiology that may signal a change in transmission, severity, or effectiveness of preventive efforts requiring additional public health or broader intervention. This has been designed to capture the type of data that was needed to make public health decisions during the COVID-19 pandemic, but also to capture this data across a range of respiratory viruses, age groups, and geographies.

These activities support multiple strategic priorities within CDC, including:

Coronavirus and other Respiratory Viruses Division (CORVD) Strategic Priority (Coronavirus and Other Respiratory Viruses Division (CORVD) | NCIRD | CDC)

- *Track and study respiratory viruses through surveillance, lab tests, and epidemiologic studies on infection, outcomes, and the efficacy of treatment and prevention*

National Center for Immunization and Respiratory Disease (NCIRD) Strategic Priority (Office of the Director (OD) | NCIRD | CDC):

- *Improve prevention, detection, and control of respiratory disease threats, including COVID-19*

CDC's 2022-2027 Strategic Plan: Advancing Science and Health Equity (Core Capabilities (cdc.gov))

- *Develop and deploy world-class data and analytics*
- *Build on the current foundation for strong global health capacity and domestic preparedness.*

Relevant Work

Over the last few years, CDC has funded multiple limited-term contracts, that are either ended or to be ended before this NOFO starts, with SARS-CoV-2 specific objectives shared with many of

the primary objectives in this NOFO. Some of the publications from the contracts or from projects of similar study designs as the one(s) described here are below.

Component A1: CDC-funded Longitudinal Community Cohort Studies

Sample protocols/study designs:

- Post-COVID Conditions: CDC Science | CDC (See list of prospective cohort studies)
- Arizona Healthcare, Emergency Response, and Other Essential Workers Surveillance (Az Heroes) Study (cdc.gov)
- JMIR Research Protocols - Research on the Epidemiology of SARS-CoV-2 in Essential Response Personnel (RECOVER): Protocol for a Multisite Longitudinal Cohort Study
- Study protocol for the Innovative Support for Patients with SARS-COV-2 Infections Registry (INSPIRE): A longitudinal study of the medium and long-term sequelae of SARS-CoV-2 infection | PLOS ONE
- CASCADIA: a prospective community-based study protocol for assessing SARS-CoV-2 vaccine effectiveness in children and adults using a remote nasal swab collection and web-based survey design | BMJ Open

Sample publications/outputs:

1. Clinical and virologic characteristics of the first 12 patients with coronavirus disease 2019 (COVID-19) in the United States | Nature Medicine
2. Infectious viral shedding of SARS-CoV-2 Delta following vaccination: A longitudinal cohort study - PubMed (nih.gov)
3. Association of Initial SARS-CoV-2 Test Positivity With Patient-Reported Well-being 3 Months After a Symptomatic Illness | Public Health | JAMA Network Open | JAMA Network
4. Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021 | MMWR (cdc.gov)
5. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021 | MMWR (cdc.gov)
6. Risk Factors for Reinfection with SARS-CoV-2 Omicron Variant among Previously Infected Frontline Workers - Volume 29, Number 3—March 2023 - Emerging Infectious Diseases journal - CDC

Component A2: Recent CDC-funded Respiratory Virus Immunology Studies

Sample protocols/study designs:

- Post-COVID Conditions: CDC Science | CDC (See list of prospective cohort studies)
- Arizona Healthcare, Emergency Response, and Other Essential Workers Surveillance (Az Heroes) Study (cdc.gov)
- JMIR Research Protocols - Research on the Epidemiology of SARS-CoV-2 in Essential Response Personnel (RECOVER): Protocol for a Multisite Longitudinal Cohort Study

- CASCADIA: a prospective community-based study protocol for assessing SARS-CoV-2 vaccine effectiveness in children and adults using a remote nasal swab collection and web-based survey design | BMJ Open

Sample publication/outputs:

1. Shedding of Culturable Virus, Seroconversion, and 6-Month Follow-up Antibody Responses in the First 14 Confirmed Cases of Coronavirus Disease 2019 in the United States | The Journal of Infectious Diseases | Oxford Academic (oup.com)
2. Twelve-Month Follow-up of Early COVID-19 Cases in the United States: Cellular and Humoral Immune Longevity | Open Forum Infectious Diseases | Oxford Academic (oup.com)
3. Severe Acute Respiratory Syndrome Coronavirus 2 Infection History and Antibody Response to 3 Coronavirus Disease 2019 Messenger RNA Vaccine Doses | Clinical Infectious Diseases | Oxford Academic (oup.com)
4. Neutralizing Antibody Response to Pseudotype Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Differs Between mRNA-1273 and BNT162b2 Coronavirus Disease 2019 (COVID-19) Vaccines and by History of SARS-CoV-2 Infection | Clinical Infectious Diseases | Oxford Academic (oup.com)]

Component B: CDC-funded Respiratory Virus Transmission Studies

Sample protocols/study design

- Respiratory Virus Transmission Network (RVTN) | CDC

Sample publications/outputs:

1. Patterns of Virus Exposure and Presumed Household Transmission among Persons with Coronavirus Disease, United States, January–April 2020 - Volume 27, Number 9—September 2021 - Emerging Infectious Diseases journal - CDC
2. Transmission of SARS-COV-2 Infections in Households — Tennessee and Wisconsin, April–September 2020 | MMWR (cdc.gov)
3. Household Transmission of SARS-CoV-2 from Children and Adolescents | NEJM
4. Behaviors Associated With Household Transmission of SARS-CoV-2 in California and Colorado, January 2021–April 2021 - PMC (nih.gov)
5. Magnitude and Determinants of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Household Transmission: A Longitudinal Cohort Study | Clinical Infectious Diseases | Oxford Academic (oup.com)
6. Association of Culturable-Virus Detection and Household Transmission of SARS-CoV-2, California and Tennessee, 2020–2022 | The Journal of Infectious Diseases | Oxford Academic (oup.com)
7. SARS-CoV-2 B.1.1.529 (Omicron) Variant Transmission Within Households — Four U.S. Jurisdictions, November 2021–February 2022 | MMWR (cdc.gov)
8. Scientific Brief: SARS-CoV-2 Transmission | CDC

Additional Background:

1. Global burden of upper respiratory infections in 204 countries and territories, from 1990 to 2019 (thelancet.com)

2. Trends in the global burden of lower respiratory infections: the knowns and the unknowns (thelancet.com)
3. WHO Coronavirus (COVID-19) Dashboard | WHO Coronavirus (COVID-19) Dashboard with Vaccination Data
4. Provisional Mortality Data — United States, 2022 | MMWR (cdc.gov)
5. COVID-19 Data Review: Update on COVID-19–Related Mortality | CDC
6. RSV Surveillance and Research | CDC

2. Approach

This NOFO includes four components: Component A1, A2, B and C. There are no limits to which components an applicant may apply. An applicant may apply for: 1) one; 2) all, or 3) any combination of Component A, B and C. However, applicants applying for Component A2 must also apply for Component A1, whereas Component A1 applicants are not required to apply for Component A2. Component A2 awards can only be made to the award recipients of Component A1.

Applicants should indicate clearly in the application the geographical location and catchment areas in HHS regions for each Component applying for.

Component A1: Longitudinal cohort with weekly symptom screening and symptomatic swabbing ($2,400,000 each for 5 awards annually)

Focus:

The focus of this component is to establish and sustain a community-based cohort to:

- Monitor the incidence and burden of respiratory illness
- Assess for changes in respiratory virus epidemiology and clinical outcomes
- Assess participant knowledge, attitudes, and practices with regard to preventative measures
- Assess the effectiveness of interventions such as non-pharmaceuticals, pharmaceuticals, and vaccines in preventing disease

Outcomes:

Primary outcomes will include annual/seasonal incidence of SARS-Cov-2, RSV, and other key respiratory viruses (e.g., adenovirus, human metapneumovirus, human seasonal coronaviruses, influenza, parainfluenza viruses, rhinovirus/enterovirus) and effectiveness of vaccines in preventing symptomatic infection.

Each awardee will be expected to recruit a minimum of 2000 individuals per site, ideally in households; included household and individuals should be demographically diverse. Applications should aim to recruit participants across the age-spectrum, with a roughly equal split of ages younger than 5 years old, 5-17 years old, 18-64 years old, and 65+ years old, in order to facilitate age-specific sub-analysis across the full network.

Activities:

Activities for this component should include the following:

- Weekly screening for symptoms of respiratory illness

- Self-collection of nasal swabs for symptomatic participants
- Multi-pathogen testing of all swabs including common respiratory viruses (e.g., SARS-CoV-2, RSV-A/B, adenovirus, human metapneumovirus, human seasonal coronaviruses, influenza, parainfluenza viruses, rhinovirus/enterovirus, including enterovirus D68) in real-time
- Genomic sequencing of a subset of samples
- Retention/banking of all specimens for a defined amount of time for possible supplemental testing
- Post-illness surveys to assess healthcare use, use of therapeutics, school absence/loss of work, symptoms, duration of symptoms and incidence of post-acute sequelae
- Baseline and periodic updating of receipt of vaccines and other prophylactic measures from the immunization information systems, electronic medical records (when available), and self-report

Applicants may propose additional activities:

- Asymptomatic swabbing; this may, for example, occur during particular seasons, for particular viruses of interest, or triggered by apparent changes in viral transmission
- Assessment or use of different specimen types (e.g., saliva)
- More extensive genomic testing and analysis

Sample size:

Applicants are strongly encouraged to provide a sample size justification that demonstrates that their sampling plan has adequate power (over 80%) to measure their site-specific annual/seasonal incidence of infection, across a range of respiratory viruses to within ±2 percentage points with a 95% confidence interval, if the true incidence falls between 2%-20%. Additional sample size information should include power to estimate incidence for potentially smaller subgroups (e.g., children younger than 5 years old or adults older than 65 years old).

Component A2: In-depth immunologic assessments ($500,000 each for 2 awards that are awarded with Component A1 annually)

Applicants applying for Component A1 may apply for Component A2 to be awarded with additional funds to support more in-depth immunologic testing among participants.

Focus:

The purpose of this testing will include: to monitor existing immunity to respiratory viruses, allow for analyses of how well respiratory virus antibody assays (beyond COVID-19) correlate with protection, and support greater analysis of how immunity to respiratory viruses wanes with time after infection, vaccination, or both. Neutralization studies, such as for SARS-CoV-2 (including variants), and RSV subtypes, or enterovirus D68 (EV-D68), may also be included to monitor how well participants are able to neutralize particular viral strains, new viral variants, or following use of new preventative products (vaccines, monoclonal antibodies).

Activities:

Activities implemented in this component will include:

- Collection of specimens for performance of serologic assessments. Time points will likely include a baseline/enrollment, and then at least twice a year (e.g., before and after the typical respiratory virus season). Additional targeted testing may include post-infection, and post-vaccination testing to measure immunologic response to both;
- Testing of specimens including the use of quantitative, semi-quantitative binding antibody tests, and potentially neutralization studies to monitor the immune response;
- Storage of specimens, with the potential for sending additional specimens to CDC for further analysis as needed.

Component B: Case-ascertained Household Transmission ($1,600,000 each for 3 awards annually)

Focus:

This component aims to better understand the transmission dynamics of SARS-CoV-2, RSV, and other prioritized respiratory viruses in CDC's mission. Through prior collaborations and research efforts, it seems that the most efficient way to study transmission of respiratory viruses is through case-ascertained household transmission studies. In this design, individuals with recent laboratory-confirmed infections are enrolled, and their household members are followed to detect respiratory virus infection. In this way, case-ascertained household transmission studies are resource-efficient, as they identify a highly exposed population that can be followed prospectively to describe many epidemiologic factors associated with infection. However, they are challenging to implement and conduct, as they are resource-intensive.

Activities:

Applicants who apply for this component should describe the source of their household index cases (and how these will be identified in a timely manner) and their manner of recruiting household contacts to participate in this study. This may or may not include index cases identified through Component A1. Applicants should further describe requirements for proportion of required household contacts who will participate, sampling frequency and specimen types, power to assess differences in secondary transmission, risk factors for infection and transmission, and fraction of cases that are asymptomatic, with their proposed approach.

Applicants should describe how they will enroll and assess a minimum of 100 households per year during the project period. Different respiratory viruses may be prioritized for case-ascertained household transmission during different years of funding (e.g., year 1 may prioritize SARS-CoV-2 or RSV, and subsequent years may prioritize other viruses). Applications should include a plan for how to do the following:

- Identify and recruit individuals with infections across the spectrum of illness from asymptomatic (if possible) to those seeking outpatient care for an illness.
- Enroll and evaluate (test) other household members immediately after someone is infected. Methods should be creative to circumvent likely challenges but also be able to enroll sufficient numbers of households over annual or seasonal periods of virus circulation.
- Enroll sufficient sample size to meet research objectives; this may be accomplished through Component A participation, traditional recruitment strategies using those seeking

outpatient care for an illness, or novel approaches to identify symptomatic and asymptomatic individuals who are infected.
- Collect serial symptom surveys and respiratory specimens for viral PCR testing to describe all household members and identify all infections within a given time frame (e.g., two weeks from time of exposure/first household infection but may vary depending on which virus is being targeted).
- Provide access to data and lab results to CDC in a timely way in order to provide the situational awareness that is now commonly requested of CDC.

Applicants may propose additional activities, such as:

- Additional specimen collection and/or testing to evaluate comparative performance of specimens or tests;
- Viral culture, genomic sequencing, or additional laboratory testing and analysis;
- Conducting environmental swabbing, wastewater, or aerosol specimen testing to better understand respiratory virus shedding and transmission within households.

Component C: Data Hub/Analytic Support ($1,250,000 for 1 award annually)

Focus:

Applicants may apply to serve as a data hub for communicating and managing data across the partners and support analytics in order to ensure the timely sharing and release of data. The awardee will serve as a central coordinating partner across all components and partners in collaboration with CDC.

Activities:

Applicants should demonstrate how to conduct the activities for this component as below:

- Support harmonized protocol development across sites in collaboration with CDC.
- Develop data entry and data management tools.
- Serve as a warehouse of data across all partner sites.
- Merge data files, clean data, and develop analytic datasets.
- Lead and support projects under this NOFO in completing key analytic products to accomplish primary objectives.
- Develop internal dashboards to track study progress.
- Develop outward facing dashboards displaying incidence and other key measures in real time, ideally updated weekly.
- Set up and coordinate cohort study meetings with CDC and other component award recipients, takes meeting minute notes, and develop and maintain a tracking system for all study activities.

Objectives/Outcomes

Component A1: Longitudinal cohort with weekly symptom screening and symptomatic swabbing ($2,400,000 each for 5 awards annually)

- Estimate the annual/seasonal incidence of symptomatic respiratory virus infection by pathogen across the age spectrum using a multi-site network of community-based cohorts. Outputs to include:

    - Age-stratified annual incidence of symptomatic respiratory virus illness – by respiratory pathogen; and proportion of symptomatic infection attributed to each (e.g., SARS-CoV-2, respiratory syncytial virus, adenovirus, human metapneumovirus, human seasonal coronaviruses, influenza, parainfluenza, rhinovirus/enterovirus)
    - Estimated burden of respiratory virus illnesses including acute morbidity, short term loss of school/work, long-term morbidity and, long term loss school/work – by respiratory pathogen

- Estimate effectiveness of respiratory virus vaccines and preventive measures and assess benefits of treatment for respiratory virus infection. Outputs to include:
    - Real-world effectiveness of key preventive measures against symptomatic infection, including respiratory virus vaccines (COVID-19 and RSV)
    - Assessment of treatment uptake and comparison of outcomes (severity, long-term morbidity) among persons with treated and untreated respiratory virus infections

- Monitor changes in perceptions and receptiveness to respiratory virus interventions over time, including:
    - Assessment of uptake of key interventions (vaccines, therapeutics, non-pharmaceutical interventions), and predictors of uptake
    - Assess knowledge, attitudes, perceptions, and behaviors regarding these interventions

- Develop platform that can be used to perform in-depth investigations of newly emerging or evolving respiratory pathogens, through monitoring clinical course and describing/assessing:
    - Clusters of new symptom presentation
    - Changes in healthcare seeking and/or hospitalization
    - Reports of long-term sequelae following infection
    - Link above factors to sequencing data as appropriate

Component A2: In-depth Serologic Assessments ($500,000 for 2 awards that have applied for and awarded with Component A1 annually)

- Monitor immune response and characterize duration of immunity to SARS-CoV-2, RSV, and other viruses as feasible through assessing longitudinal virus-specific antibodies across one or more respiratory virus seasons.
- Assess post-infection (and post-reinfection) and post-vaccination immune responses, especially in regard to ability to neutralize new variants/sub-variants when they arise.
- Assess serologic correlates of protection against subsequent virus-specific symptomatic illness episodes.
- Use serologic responses after the typical respiratory season to capture infections missed by symptomatic surveillance and testing (e.g., asymptomatic infections)
- Among young children, assess age of seroconversion against respiratory viruses to gain a better understanding of timing of initial infections and acquisition of infection-induced immunity.

Component B: Case-ascertained Household Transmission ($1,600,000 each for 3 awards annually)

- Evaluate epidemiologic and clinical risk factors for respiratory virus infection and transmission.
- Compare household secondary attack rates for specific respiratory virus/viruses of interest.
- Characterize the spectrum and duration of symptoms associated with respiratory virus infection, including stratified by patient characteristics.
- Estimate the frequency of symptomatic and asymptomatic respiratory virus infections among index case-patients and household contacts.
- Determine the timing and relationship of viral shedding relative to symptoms within infected individuals.
- Describe viral shedding over the time course of infections.
- If possible, assess environmental contamination of respiratory viruses within households.
- If possible (or if needed), validate new diagnostic tests and/or specimen types for various respiratory viruses. This may include relative comparison of antigen tests to PCR tests, performance of various types of specimens collected for testing, or comparing performance of test types and specimen types based on individual-level characteristics (e.g., age or symptom status).

Component C: Data Hub/Analytic Support ($1,250,000 for 1 award annually)

- Ensure and promote harmonization of approach for each component across participating sites.
- Ensure and promote data quality.
- Ensure and promote rapid analysis of data for dissemination to the public or use by policymakers.
- Support real-time monitoring and when possible, information sharing through dashboards and similar tools.

Target Population

For Component A1, applicants should demonstrate that they can recruit a minimum of 2000 participants per site and then sustain a cohort of this size throughout the evaluation period, with replacement as needed should there be withdrawals. Participants should be enrolled as households whenever possible. Awardees should aim to recruit participants across the age-spectrum, with a roughly equal split between four age categories: 1) younger than 5 years old, 2) 5-17 years old, 3) 18-64 years old, and 4) 65+ years old, in order to facilitate age-specific sub-analysis across the full network.

For Component B, applicants should demonstrate that they will be able to enroll at least 100-150 households per year, and they should describe how index patients will be identified in order to assess transmission of a variety of respiratory pathogens. Applicants should further describe requirements for proportion of required household contacts who must participate, sampling frequency and specimen types, power to assess differences in secondary transmission, risk factors for infection and transmission, and fraction of cases that are asymptomatic, with their proposed approach.

For both Components A and B, applicants should aim to enroll diverse populations and should include in their application a description of the demographic diversity (e.g., race, ethnicity, gender, languages spoken, distribution of urban/rural, social vulnerability index or other markers of socioeconomic diversity, etc.) of their catchment area and describe how they will ensure that participants are, at a minimum, representative of the underlying population in their community. Over-sampling of more marginalized populations is encouraged.

Collaboration/Partnerships

Component A (A1 and A2) applicants are expected to partner closely with their local health system and health departments. Because patients will be surveyed about their healthcare seeking behavior and clinical outcomes of infection, with additional data on health outcomes from electronic health record (EHR) data, applicants should highlight collaborations that would support access to EHR systems. Similarly, because patients will be surveyed about their uptake of respiratory virus vaccination, other preventive products (e.g., monoclonal antibodies), and treatments, applicants should have systems in place to verify vaccination status with their statewide vaccine registries in addition to verifying other preventive and therapeutic projects via EHR.

Evaluation/Performance Measurement

The application should include measurable goals and aims based on a **five (5)** year research project period. The application should describe 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.

For each component, the application should include an evaluation/performance measurement plan. Progress should be identified by achievement of relevant milestones which may include:

- Type of evaluations (e.g., process, outcome, or both) to be conducted
- Key evaluation questions
- Other information (e.g., performance measures to be developed by the applicant)

Translation Plan

The applicant should submit a plan describing how the findings and outcomes will be translated for 1) sharing with the public, 2) informing policy, and 3) informing the medical and scientific communities.

This information should be understandable to a variety of audiences, including policymakers, practitioners/clinicians, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential end users.

3. Funding Strategy

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) and/or the American Rescue Plan of

2021 [P.L. 117-2] agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

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

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

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

Section II. Award Information

Funding Instrument Type:
CA (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:
$95,250,000
Estimated total funding available for the first year (first 12 months), including direct and indirect costs: $19,050,000

Estimated total funding available for the entire project period, including direct and indirect costs: $95,250,000

Estimated Total Annual Budget Period Funding for the NOFO:

Year 1: $19,050,000

Year 2: $19,050,000

Year 3: $19,050,000

Year 4: $19,050,000

Year 5: $19,050,000

Estimate Annual Budget Period Funding per Award by Component:

Component A1: $2,400,000 each for 5 awards

Component A2: $500,000 each for 2 awards, awarded only to Component A1 award recipients

Component B: $1,600,000 each for 3 awards

Component C: $1,250,000 for 1 award

Ceiling by Component – per Award Amount in the first year:

Component A1 – $2,400,000

Component A2 – $500,000, awarded only to Component A1 award recipients

Component B – $1,600,000

Component C – $1,250,000

The **Total Ceiling for an award** is $5,750,000 when one recipient receives all four components.

Floor by Component – per Award Amount in the first year:

Component A1 – $1,800,000

Component A2 – $375,000, awarded only to Component A1 award recipients

Component B – $1,200,000

Component C – $937,500

The **Floor for an award** is $937,500 when one recipient only receives the lowest component amount.

Anticipated Number of Awards:
9
The award numbers below are all anticipated:

Component A1: 5

Component A2: 2 (included in the 5 award recipients of Component A1)

Component B: 3

Component C: 1

Approximately, the maximum number of awards will be 9, when 5 Component A1 (overlapping with the 2 Component A2), 3 Component B and 1 Component C award recipients are distinctly different applicants (aka, when no recipients receive more than one component award of A1, B and C).

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

Award Ceiling:
$5,750,000
Per Budget Period

Award Floor:
$937,500
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 (https://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.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

Additional Eligibility Category:

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

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Governments:

U.S. Territory or Possession

Other:

Faith-based or Community-based Organizations

Regional Organizations

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR.

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

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

It is the applicant's responsibility to ensure that the application meets all responsiveness criteria listed in this section. Applications that do not meet all of the following Responsiveness criteria will be considered nonresponsive and will not be forwarded for peer review. The following criteria are required for responsiveness:

• Clearly state the component(s) the application is applying for

Applications must clearly indicate which component(s) they apply for on the Specific Aim page. Applications without such info will be considered as non-responsive and not move forward for review processing. CDC will notify the applicant that the application did not meet the submission requirement.

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 Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- 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 Senior/Key Personnel (including 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 Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 SAM.gov and the SAM.gov Knowledge Base.

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 UEI 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 NOFO 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 entity identifier [UEI] number) is allowed.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov 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.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide 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 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.

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

Mandatory

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

Please note: Follow the instructions in this NOFO for including a Data Management Plan in the Resource Sharing Plan section of the PHS 398 Research Plan Component of your application.

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.

If applying for more than one component, please follow the instruction as below:

- The **Specific Aim** page should clearly specify the components the application applies for.
- **Research Strategy** for Component A1, B or C is limited to 12 pages each; Component A2 is limited to 4 pages.
- Content of each component should be clearly indicated.
- Geographical locations and catchment areas in HHS region should be specified for Component A1, A2, B and C in either the Specific Aim page if space allowed or in the Research Strategy section at the beginning of each component.
- In addition to a summary of the total budget, applicants should provide a separate budget and justification for each component that they are applying for and include budget and justification for any sub-awardees/contractors.

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.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 01/19/2024

01/19/2024
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. "Overview Information", prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the applicant organization
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

If possible, please also indicate which component(s) the application will include. Component applications are not locked in by the LOI should there any change after sending the LOI.

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

Telephone: 404-718-8833
Email: GAnderson@cdc.gov

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 at How to Apply - Application Guide 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 at How to Apply - Application Guide 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).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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, excess pages will be removed from the application prior to peer review and may negatively affect the application's 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 40 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices. 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 at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages for due date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications 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 must be 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 02/20/2024

02/20/2024
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. 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.

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

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) Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously funded research under other awards (no scientific, budgetary or percent effort overlap allowed).

2) **Please note:** Certain grants or recipients are not eligible for expanded authorities. In addition, one or more expanded authority may be overridden by a special term or condition of the award. The Notice of Award (NoA) will indicate the applicability of expanded authorities by reference to the HHS Grants Policy Statement or through specific terms and conditions of the award. Therefore, recipients must review the NoA to determine whether and to what extent they are, or are not, permitted to use expanded authorities.

3) 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. Please see Section IV.2 of this NOFO, "Content and Form of Application Submission" for guidance on single IRB (sIRB) Plan content.

4) 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.

5) Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

6) 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 USG funding, or loss of future US Government (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.

7) 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.

11. 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. 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 UEI.

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. Documents uploaded for the Risk Questionnaire are not counted towards the page limit in Appendices.

Please also note: 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.

Application Submission

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

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

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

Important reminders:
All Senior/Key Personnel (including any Program Directors/Principal Investigators (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.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the UEI 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 nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (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?

For all Components:

- Does the application indicate the geographical location and catchment areas in HHS regions for each applying component?

Component A1: Longitudinal community-based cohort

- Does the application demonstrate the public health benefit of community-based monitoring of respiratory viruses, and how the study results might impact public health guidance or public uptake of key interventions?

Component A2: In-depth serologic assessment

- Does the application demonstrate a strong understanding of the types of public health questions that can be explored through this serologic sub-study?

For Component B: Case-ascertained household transmission

- Does the application describe the public health benefit of case-ascertained household transmission studies, and what types of public health questions this project will inform?

For Component C: Data hub/Analytical support

- Does the application describe the public health benefit of timely data analysis and dissemination?
- Does the application describe the importance of harmonization across multiple sites to increase diversity and improve power to achieve primary study aims across each of the components?

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?

Component A1: Longitudinal community-based cohort

- Does the investigator team have the capacity and experience recruiting, enrolling, and sustaining participants in a longitudinal cohort study over multiple years?
- Does the investigator team have experience with respiratory virus epidemiology, including estimating the incidence of symptomatic respiratory virus infections for multiple respiratory viruses?
- Do the investigators have experience estimating the effectiveness of respiratory virus vaccines and prevention measures?
- Do the investigators have experience collecting data to monitor changes in perceptions and receptiveness to respiratory virus interventions over time?
- Does the investigator team have experience developing a platform that can be used to perform investigations of newly emerging or evolving respiratory pathogens?

Component A2: In-depth serologic assessment

- Does the investigator team include personnel with expertise in respiratory virus immunology, specifically serologic studies?
- Has the investigator team previously published studies that address topics such as correlation of antibody titers with protection from infection, magnitude or duration of immune response, or ability to neutralize new variants following vaccination infection?

Component B: Case-ascertained household transmission

- Does the investigator team have previous experience implementing a case-ascertained household transmission study and calculating transmission metrics for respiratory viruses?
- Does the investigator team have experience and subject matter expertise related to SARS-CoV-2 and RSV?

Component C: Data hub/Analytical support

- Does the applicant have the capacity and experience serving as a data-hub or cleaning, managing, and analyzing data for a multi-site project?
- Does the applicant have experience creating dashboards or other systems to allow real-time monitoring of study progress and results?
- Does the applicant have experience analyzing and publishing data on respiratory viruses including seasonal/annual incidence and vaccine effectiveness?

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?

For all Components:

- Is the proposed research innovative and offering reasonable potential for concrete applications of interest and value to the scientific field?

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?

Component A1: Longitudinal community-based cohort

- Does the application demonstrate how the applicants will establish and sustain a community-based cohort to monitor the incidence and burden of respiratory illness?
- Does the application demonstrate how the team will establish and sustain a cohort of 2000 or more individuals, predominantly household members, over multiple years of follow-up?
- Does the applicant describe how they will achieve approximate equal distribution between the following four age categories: 1) younger than 5 years old, 2) 5-17 years old, 3) 18-64 years old, and 4) 65+ years old?
- Does the application describe the demographic make-up of their catchment community and provide details as to how they will recruit diverse populations to participate in this study?
- Does the proposed target population represent the diversity of their catchment population or provide for enhanced recruitment or more marginalized populations?
- Does the application include weekly symptom screening, plans for participants to submit nasal swabs if symptomatic, and testing of those nasal swabs to include multiple respiratory viruses (e.g., SARS-CoV-2, RSV, influenza, adenovirus, human coronaviruses, human metapneumovirus, parainfluenza viruses, rhinovirus/enteroviruses)?
- Does the application demonstrate how their site will contribute to an ongoing assessment of changes in respiratory virus epidemiology and clinical outcomes?

Component A2: In-depth serologic assessment

- Does the application demonstrate how they will support serologic testing among enrolled participants, including what laboratory assays they propose to use, where laboratory testing will be done, and how samples will be shared with CDC for further collaboration?
- Does the application demonstrate how they will follow participants through longitudinal assessment at enrollment and at least twice per year?

Component B: Case-ascertained household transmission

- Does the application demonstrate how to identify individuals with recent laboratory confirmed respiratory viral infection and offer timely enrollment (less than 5 days from symptom onset or first positive test) to both this individual and a sufficient proportion of household members to detect respiratory viral infection and transmission?
- Does the application demonstrate how all demographic, household, and clinical information will be collected from all participants?
- Does the application demonstrate how to follow the enrolled household population to collect information and describe the epidemiologic factors associated with the infection?
- Does the application demonstrate a suitable approach to estimate secondary transmission from within households (application should demonstrate ability to identify the person with the first illness in the household, i.e., the primary household case)?
- Does the application demonstrate how the applicant will identify and enroll a minimum of 100 households per season? Methods should be creative to circumvent likely challenges but also be able to enroll sufficient numbers of households over annual or seasonal periods of virus circulation.

- Does the application demonstrate how the applicant will collect serial symptom surveys and respiratory specimens for viral PCR testing to describe all household members and identify all infections within a given time frame, regardless of symptoms, (e.g., two weeks from time of exposure/first household infection but may vary depending on which virus is being targeted)?
- Does the application clearly describe the frequency and duration of testing that will be implemented?
- Does the application demonstrate how the applicant will provide access to data and laboratory results to CDC in a timely way in order to provide the situational awareness that is now commonly requested of CDC?

Component C: Data hub/Analytical support

- Does the application demonstrate how they will harmonize protocol development across sites and with CDC?
- Does the application demonstrate how the applicant will successfully develop data management tools, coordinate data collection and cleaning, and support analysis of the key objectives?
- Does the application demonstrate how the applicant will develop dashboards to track study progress and routinely display data findings (ideally weekly)?
- Does the applicant describe analytic approaches they will use to achieve the primary objectives listed for Components A and B?

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?

For all Components:

- Does the application demonstrate that the applicant (including subcontractors) has capacity to conduct all components of the project, including recruitment and sustaining cohort participants, conducting client surveys, maintaining specimen storage and testing, executing data collection, storage, and analysis, and reporting and disseminating project findings?
- Does the application include letters of support from all proposed collaborators and/or subcontractors?

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/additional-requirements/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/women/research/index.htm) 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://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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.

Applications from Foreign Organizations

N/A

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/additional-requirements/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.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

Other examples of DMPs may be found here USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

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 budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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.

Additional Considerations for Funding Recommendations:

This NOFO intends to detect changes in respiratory virus epidemiology in the United States. Applications for each component may be funded out of rank or score order to allow for maximum geographic reach of surveillance. The geographical location of the applicants and/or the proposed catchment area of the HHS regions for each component stated in the applications may be taken into consideration for each of the four components to ensure populations from multiple HHS regions, in order to enhance geographic diversity and the ability to more quickly detect changes that may start in a particular part of the country before spreading to the rest.

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 UEI, 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).

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to

this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

CDC Administrative Requirements:

Generally applicable ARs:

AR-1: Human Subjects Requirements

AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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: Research Definition

AR-32: Appropriations Act, General Provisions

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

AR-36: Certificates of Confidentiality

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

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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

To view brief descriptions of relevant CDC requirements visit: https://www.cdc.gov/grants/additional-requirements/index.html

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: https://www.plainlanguage.gov/.

Employee Whistleblower Rights and Protections Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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:

- Collaborating with CDC and other award recipients of the same Component to develop a shared protocol to be implemented across sites and ensuring harmonization of the overall approach.
- Developing a proposal for any laboratory studies to be used in the project, and ultimately agreeing on the final laboratory assessments with CDC.
- Identifying a laboratory to run all tests, and storing specimens for future testing, based on an agreed upon plan established prior to the start of the project.
- Participating in meetings with CDC to provide updates on protocol development, study progress, and findings. Meetings will occur a minimum of monthly but are expected to occur weekly to biweekly during more intensive phases such as the program design, and data analysis periods. Progress updates should be shared in written format as well (ideally prior to scheduled meetings).
- Participating in quarterly meetings inclusive of CDC, other Component award recipients, and the Component C award recipient to harmonize efforts, share progress, challenges, and solutions. These meetings are expected to occur more frequently during the study design/protocol development, and data analysis/manuscript development phases.
- Participating in a PI work group for each Component that will consist of the Component award recipients, Component C award recipient, and CDC technical staff.
- Collaborating with CDC and other members of the PI work group to develop a product dissemination plan, inclusive of all manuscripts, presentations, dashboards and other outputs that this cooperative agreement will generate.
- Ensuring that all publication/presentations developed by their team and/or subcontractors are discussed and agreed on by the PI work group before they are developed.
- Sharing an updated de-identified dataset with CDC and/or the Component C award recipient on a monthly basis.
- Ensuring timely data collection and cleaning. Descriptive data should be made available on a dashboard or public-facing web-page (ideally updated weekly) in addition to any planned otherwise planned/proposed dissemination methods.
- Managing any subcontracts and ensuring that all parties are performing as expected in order to achieve the technical objectives of this cooperative agreement.

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html
- 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 recipient 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 https://www.cdc.gov/grants/additionalrequirements/ar-25.html
- 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
- Coordinating PI work-group that for each Component will consist of Component awardees, Component C awardee, and CDC technical staff.
- Collaborating with other members of the PI work-group on the development of a product dissemination plan, inclusive of all manuscripts, presentations, dashboards and other outputs that this cooperative agreement will generate.
- Monitoring study progress and providing timely feedback to support study investigators in achieving study objectives, and ensure study products are of high scientific quality.

Areas of Joint Responsibility include:

- Collaborating in the development of human subject research protocols and additional documents for IRB review by all cooperating institutions participating in the project and for OMB review, if needed.
- For applications that are successfully funded under this NOFO, the recipient agrees that upon award, the application and the summary of reviewers' comments for the application may be shared with the CDC staff who will provide technical assistance, as described above. The recipient organization will retain custody of and have primary rights to the information, data, and software developed under this award, subject to U.S. Government rights of access and consistent with current HHS/CDC grant regulations and policies.

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 for official pre-award activities and for all 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.
- Monitor progresses 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).

A. Submission of Reports

The Recipient Organization must submit:

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 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the 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:

N/A

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 budget period. 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.

Additional resources on the Payment Management System (PMS) can be found at

https://pms.psc.gov.

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 period of performance. 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).

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://commons.era.nih.gov/commons/ 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, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the 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.

6. Termination

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

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

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

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

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

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

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

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

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

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal

year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

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

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

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

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

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

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

Agency Contacts:

Scientific/Research Contact
Jamal Z. Bankhead, DrPH
Extramural Research Program Office (ERPO)
Office of the Associate Director of Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Telephone: 404-630-5091
Email: Jbankhead@cdc.gov

Peer Review Contact
Gregory Anderson, MPH
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
Telephone: 404-718-8833
Email: GAnderson@cdc.gov

Financial/Grants Management Contact
Angie Willard
Office of Grants Services
Office of Financial Resources
Office of the Chief Operating Officer
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Telephone: 770-488-2863
Email: AWillard@cdc.gov

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 of Federal Regulations.

Public Health Service Act, Section 317; 42 U.S.C. 247b(k)(1) and 42 U.S.C. 247b(k)(2)

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.

American Rescue Plan Act of 2021, Public Law 117-2.