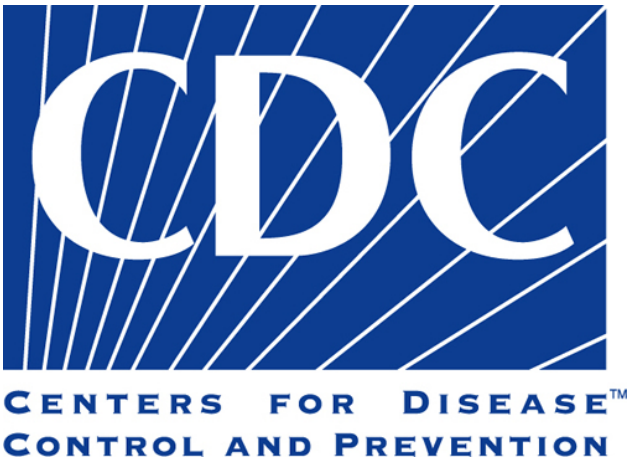

Centers for Disease Control and Prevention

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Pregnant People-Infant Linked Longitudinal Surveillance

CDC-RFA-DD-23-0003

04/10/2023

Table of Contents

Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-DD-23-0003. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Notice of Funding Opportunity (NOFO) Title:

Pregnant People-Infant Linked Longitudinal Surveillance

C. Announcement Type: New - Type 1:

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

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DD-23-0003

E. Assistance Listings Number:

93.073

F. Dates:

1. Due Date for Letter of Intent (LOI):
03/07/2023
Recommended but not Required
The purpose of an LOI is to allow CDC program staff to estimate the number of applications and plan for the review of submitted applications.
LOI must be sent via email by 03/07/2023 to:
Christina Winfield
Email address: preg_infant_surv@cdc.gov

2. Due Date for Applications:
04/10/2023
11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call
The CDC program will hold an Informational Conference Call for potential applicants to ask questions on February 22, 2023 from 2:00-3:00 PM Eastern Standard Time. The PowerPoint, script, and all questions and answers will be posted on the website after the call. Applicants can access the latest information related to the call at https://www.cdc.gov/pregnancy/nofo/DD-23-0003.html.

F. Executive Summary:

Summary Paragraph
A priority of the Division of Birth Defects and Infant Disorders is to conduct pregnant people-infant linked longitudinal surveillance on exposures and outcomes of public health interest through both a clinical and population-based approach. These approaches collect health information from various sources, resulting in robust data across multiple years from pregnancy into childhood. The purpose of this Notice of Funding Opportunity (NOFO) is to sustain, improve, and expand surveillance efforts from entities that have data systems to identify pregnant people-infant linked longitudinal data to ensure timely reporting of key exposures and outcomes that impact pregnant people and infants, to improve data quality and share evolving outcome data, to innovate clinical strategies, and to build a strong collaborative network. Priority exposures and outcomes of public health interest may include, but are not limited to, medication for opioid use disorder, cytomegalovirus, neonatal abstinence syndrome, stillbirths, and other conditions that may have serious public health impacts on pregnant people and infants. CDC will also fund entities with informatics expertise to advance interoperability, evaluate data quality, and disseminate data through visualizations. Furthermore, this network could be leveraged for emerging, reemerging, and persistent public health threats to pregnant people and infants.

a. Eligible Applicants:
Open Competition

b. NOFO Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
22
Component A: Up to 10

Component B: Up to 10

Component C: Up to 2

d. Total Period of Performance Funding:
$20,000,000

e. Average One Year Award Amount:
$770,000
Components A-C – estimated funding ranges and approximate average award per budget year

- A: $300,000 - $500,000 = **$400,000**
- B: $320,000 - $800,000 = **$560,000**
- C: $700,000 - $2,000,000 = **$1,350,000**

f. Total Period of Performance Length:
4 year(s)

g. Estimated Award Date:
August 31, 2023

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

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview
Pregnant people-infant linked longitudinal surveillance importantly assesses the impact of key exposures and outcomes that may negatively affect these populations. Infectious and non-infectious conditions impact these populations, and data related to long-term consequences are limited. Through pregnant people-infant linked longitudinal surveillance, CDC has captured clinical and health department information, including comorbidities during pregnancy, adverse pregnancy outcomes, risk to neonates, and adverse infant and childhood outcomes. These efforts have informed clinical recommendations and public health policies and improved the quality of surveillance efforts. Collaboration and coordination are key components of our surveillance framework across federal, clinical, & public health partners providing integral input into data structure and implementation.
To build a comprehensive approach for pregnant people-infant linked longitudinal surveillance, the National Center on Birth Defects and Developmental Disabilities, Division of Birth Defects and Infant Disorders is announcing an opportunity to fund multiple surveillance programs under a single mechanism. This NOFO will sustain, improve, and expand our existing pregnant people-infant linked longitudinal surveillance efforts by

- Strengthening informatics infrastructure & supporting data-to-action pipeline
- Capturing exposures or outcomes, including those that are not nationally notifiable

- Understanding how data are shared between clinical & health department sites with CDC to improve data quality and sharing
- Assessing the state of the science, disseminating data, and updating messages through innovative up-to-date approaches

This NOFO has three components and each applicant should apply to only one. Component A will fund entities that directly maintain and enter information into the electronic health records, are able to demonstrate existing linkages between pregnant person and infant records, and are able to provide data for children through six years of age. Component B will fund entities that have access to population-based state or jurisdiction-wide established public health data systems to identify pregnant people and pregnancy outcomes and conduct longitudinal follow-up. Component C will fund entities that have informatics and health data science expertise. Priority exposures and outcomes of public health interest must include one of the following, but are not limited to, medication for opioid use disorder, cytomegalovirus, neonatal abstinence syndrome, stillbirths, or other conditions (e.g. mpox, polysubstance abuse) that may have serious public health impacts on pregnant people and infants and to which CDC can provide technical assistance. This surveillance network could be leveraged for emerging, reemerging, and persistent public health threats to pregnant people and infants.
Each recipient will conduct some or all activities specific to the components and the exposure and/or outcome(s) of interest. All recipients are expected to work together across NOFO recipients as part of a multidisciplinary collaborative. Also, Component A and B recipients will need to share data consistent with the goals of this NOFO. This funding opportunity builds on and is expected to coordinate with and leverage, but not duplicate, the workforce, laboratory system, and data-related progress made via Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC; CDC-RFA-CK19-1904) and other funding opportunities and investments.

b. Statutory Authorities

This program is authorized under Sections 301 and 317C of the Public Health Service Act [42 U.S.C. 241 and 247b-4], as amended.

c. Healthy People 2030

This NOFO is related to the overarching goal to "Eliminate health disparities, achieve health equity, and attain health literacy to improve the health and well-being of all" & topic areas of Pregnancy and Childbirth (Pregnancy and Childbirth - Healthy People 2030 | health.gov), including the following objectives:

- MICH-D02: Reduce the proportion of women who use illicit opioids during pregnancy
- MICH-01: Reduce the rate of fetal deaths at 20+ weeks gestation
- MICH-02: Reduce the rate of infant deaths
- MICH-05: Reduce severe maternal complications identified during delivery hospitalizations
- MICH-10: Increase the proportion of pregnant women who receive early & adequate prenatal & pediatric care

d. Other National Public Health Priorities and Strategies

HHS Strategic Goal 2, 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

HHS Strategic Goal 2, Objective 2.3: Reduce the impact of mental and substance use disorders through prevention, early intervention, treatment, and recovery support – "Encourage healthcare providers' use of screening and brief intervention approaches for alcohol, opioid, and other substance use disorders to reduce…effects of harmful substance use in pregnancy"
HHS Strategic Goal 3, Objective 3.2: Safeguard the public against preventable injuries and violence or their results – "Protect women from harmful exposures before, during, and after pregnancy, such as from…alcohol, opioid, and other harmful substance use, and improve outcomes for newborns and pregnant women"

HHS Strategic Goal 4, Objective 4.3: Strengthen surveillance, epidemiology, and laboratory capacity to understand and equitably address diseases and conditions

e. Relevant Work
This NOFO builds on activities conducted under previous and current NOFOs, including

- CDC-RFA-CK19-1904: Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)
- CDC-RFA-OT18-1802: Preventive Health and Health Services - Strengthening Public Health Systems and Services through National Partnerships to Improve and Protect the Nation's Health - financed in part by Prevention and Public Health Funds (PPHF)
    - Task Force for Global Health: MAT-LINK and MAT-LINK2
    - Council of State and Territorial Epidemiologists: Neonatal Abstinence Syndrome Surveillance

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Component A: Entities that directly maintain and enter information into the electronic health records, including clinical and laboratory data, are able to demonstrate existing linkages between pregnant person and infant records, and are able to provide data for children through six years of age.

Component B: Entities that have access to population-based state-or jurisdiction wide established public health data systems to identify pregnant people and pregnancy outcomes and conduct longitudinal follow-up.
Component C: Entities that have informatics and health data science expertise.

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-term Outcomes

All Components A, B, and C: Coordinate with CDC and recipients of other components to identify opportunities for collaboration, improve data quality, and disseminate findings Engage in data modernization initiatives Establish collaborations with internal and external program partners to strengthen data collection and translation of data Routinely monitor and evaluate data for completeness, accuracy, and timeliness Use data for prevention activities	**Improved surveillance data collection between clinical and public health partners** **Increased access and availability of EHR and public health data** **Improved timely reporting of key exposures and outcomes that impact pregnant people and their infants** **Improved surveillance system data that can be leveraged for emerging threats during pregnancy to pregnant people and their infants** **Increased awareness by CDC of the data and how data are shared and processed between clinics and health departments for public health reporting**	**Expanded and strengthened collaborative network to address important public health issues that have an impact during pregnancy and to infants** **Improved data structure and increased interoperability** Improved data quality and data flow between clinics and health departments to CDC to support surveillance Increased data availability to internal and external partners	Availability of timely, high-quality, modern and efficient surveillance data related to reporting of key exposures and outcomes that impact pregnant people, infants, and children Improved public health strategies, innovate clinical recommendations, and identify novel findings for key exposures and outcomes related to pregnant person-infant dyads
Component A Only Access, extract, and abstract			

electronic health record (EHR) data from pregnant person-infant dyads from pregnancy through six years of age for surveillance and submit data to CDC	**Increased implementation of prevention activities and dissemination of finding**		
Component B Only Conduct surveillance for pregnant person-infant dyads using standardized surveillance case definitions or surveillance guidance and submit data to CDC (Optional) Improve monitoring of infants and children to assess long-term outcomes			
Component C Only Advance interoperability and data infrastructure, develop and revise data schemas, and prepare datasets			

for analysis and reporting Post-processing of data from components A and B and provide technical assistance to those recipients Evaluate data flow from clinical and health department sites in general to CDC to provide recommendations for improvement			

i. Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to sustain, improve, and expand surveillance efforts from clinical sites and health departments related to pregnant people-infant linked longitudinal data to ensure availability of timely, high-quality, modern, and efficient surveillance data related to reporting of key exposures and outcomes that impact pregnant people, infants, and children. These efforts can be used to improve public health strategies, innovate clinical recommendations, and identify novel findings.

ii. Outcomes

The NOFO recipients are expected to demonstrate measurable progress toward addressing short-term and intermediate outcomes depicted in the logic model. The outcomes for Components A, B, and C include the following:

- Improved surveillance data collection between clinical and public health partners.
- Increased access and availability of electronic health record and public health data.
- Improved timely reporting of key exposures and outcomes that impact pregnant people and their infants.
- Improved surveillance system data that can be leveraged for emerging threats during pregnancy to pregnant people and their infants.
- Increased awareness by CDC of the data and how the data are shared and processed between clinics and health departments for public health reporting.
- Increased implementation of prevention activities and dissemination of findings.
- Expanded and strengthened collaborative network to address important public health issues that have an impact during pregnancy and to infants.
- Improved data structure and increased interoperability.

iii. Strategies and Activities

The strategies and activities of this NOFO include those that are listed in the Strategies and Activities column in the logic model above and are restated here with additional detail. Each recipient will conduct some or all activities within their component and is expected to collaborate and coordinate across NOFO recipients as part of a multidisciplinary collaborative. The purpose of Component C is to provide support to Components A and B.

Priority exposures and outcomes of public health interest may include, but are not limited to, medication for opioid use disorder (MOUD), cytomegalovirus, neonatal abstinence syndrome (NAS), stillbirths, and other conditions (e.g. mpox, polysubstance use) that may have serious impacts on pregnant people and infants and to which CDC can provide technical assistance. The parenthesis below indicates to which exposure or outcome the activity is related. Those related to any of the outcomes are indicated as "ALL". Applicants should indicate the exposure and/or outcome(s) of interest they are applying for and should indicate at least one of the priority exposures or outcomes. Additionally, they may indicate interest in more than one priority exposure or outcome. In addition to the priority outcomes, applicants should indicate if they are open to providing data for "other" emerging exposures and/or conditions that may have serious impacts on pregnant people and infants as needed or as becomes available based on CDC's input and availability of funds. Applicants may indicate "other-unspecified" for future emerging exposures and/or outcome and/or propose a specific (e.g. mpox, polysubstance use, etc.) exposure or outcome of interest. While it is recognized that any activities related to infants will not be applicable for stillbirth surveillance, stillbirth is considered for activities identified as relevant to "ALL" exposures and/or outcomes. Please note that activities for exposures or outcomes proposed for this NOFO should not currently be funded through other mechanisms (e.g., ELC Project W mechanism or CSTLTS partnership NOFO).

Component A: Entities that directly maintain and enter information into the electronic health records, including clinical and laboratory data, are able to demonstrate existing linkages between pregnant person and infant records, and are able to provide data for children through six years of age.

Component B: Entities that have access to population-based state-or jurisdiction wide established public health data systems to identify pregnant people and pregnancy outcomes and conduct longitudinal follow-up.

Component C: Entities that have informatics and health data science expertise.

All Components A, B, and C

Coordinate with CDC and recipients of other components to identify opportunities for collaboration, improve data quality, and disseminate findings

- (ALL) Participate in regular individual and group meetings as specified by CDC
- (ALL) Collaborate with CDC in the analysis and dissemination of surveillance data, including prevalence, epidemiology, surveillance methodologies, and data quality based on appropriate co-authorship and data analysis agreements
- (ALL) Develop, implement, and summarize a plan for identifying best practices and measuring effectiveness of strategies to assess impact of efforts based on evaluation plan

- (ALL) Conduct or attend virtual or in-person events (as appropriate) to disseminate findings

Engage in data modernization initiatives

- (ALL) Assess and report the current capacity, gaps, and opportunities to modernize the public health data infrastructure and workforce.
- (ALL) Participate in discussions related to data standardization, exchange, dissemination, use, shared services and infrastructure, and data infrastructure design, planning and implementation.
- (ALL) Engage in open sharing of code and software developed for this project with CDC and the surveillance network.

Establish collaborations with internal and external program partners to strengthen data collection and translation of data

- (ALL)Establish partnerships with federal, state, local, clinical, and/or community organizations that refer individuals to services or are service providers accepting referrals for infants and their families. This can include, but is not limited to Title V/ Children and Youth with Special Health Care Needs (CYSHCN) programs, MOUD clinics, harm reduction programs, early intervention programs, etc.
- (ALL) Participate in meetings, share updates and perspectives, and identify priorities for identifying exposures/outcomes
- (ALL) Disseminate results and lessons learned to agency, memberships, and constituents

Routinely monitor and evaluate data for completeness, accuracy, and timeliness

- (ALL) Implement strategies to improve data completeness, accuracy, and timeliness of reporting of surveillance data to health departments and CDC
- (ALL) Resolve data validation and quality issues with each submission as specified by CDC
- (ALL) Provide appropriate meta-data information with each submission, informing CDC of data issues and resubmissions
- (ALL) Review and provide feedback on data quality reports (e.g., missingness, discrepancies, etc.)

Use data for prevention activities (Components A and B)

- (ALL) Identify services and/or resources to support pregnant persons, postpartum persons, infants, their caregiver(s), and/or families
- (ALL) Develop plan to use surveillance data to support referrals for families for public health and healthcare services. This can include but is not limited to direct outreach to families for referral, provision of case information to partner organizations that are authorized to conduct family outreach and referral to services, integration of evidence-

based strategies such as peer navigators and wraparound services, and/or provision of aggregate data to referring programs to support resource allocation.

Component A Only

Access, extract, and abstract electronic health record (EHR) data from pregnant person-infant dyads from pregnancy through 6 years of age for surveillance and submit data to CDC

- (ALL) Demonstrate ability to access data directly from electronic health records including administrative, medication, laboratory, ultrasound, emergency room, delivery hospitalization, referrals, well-visits, postpartum, and other health data from pregnant person and infants through 6 years of age
- (ALL) Establish data sharing legal documentation
- (MOUD) Demonstrate appropriate licensure or certification (e.g., treatment program)
- (ALL) Construct a case list of pregnant person-infant dyads data based on case definition and eligibility criteria for exposure or outcome for all pregnancy outcomes, including a dyad ID generated by the recipient, year of data available, and other factors discussed with recipient and CDC
- (ALL) Review, provide feedback, and revise list of variables for exposure or outcome of interest to include for extraction/abstraction
- (ALL) Extract and abstract electronic health record data based on specific criteria, including use of Health Level International (HL7), Fast Healthcare Interoperability Resources (FHIR), Application Programming Interface (API), Extensible Markup Language (XML) schemas, RxNorm, SNOMED, LOINC, and Research Electronic Data Capture (REDCap)
- (ALL) Participate in abstraction and extraction tools trainings and test functionality
- (ALL) Import CDC REDCap XML template into recipient's REDCap instance
- (ALL) Submit maternal date of birth (month/day/year) and pregnancy outcome files separately as CSV files through Secure Data Exchange (SDX) for all dyads listed in the case list to CDC
- (ALL) Share individual-level data consistent with CDC standards to CDC and as outlined in this NOFO at a minimum bi-annually with the possibility of monthly to quarterly depending on exposure and/or outcome

Component B Only

Conduct surveillance for pregnant person-infant dyads using standardized surveillance case definitions or surveillance guidance and submit data to CDC

- (ALL) Conduct surveillance for priority exposures or outcomes based on CDC surveillance protocols using standardized surveillance case definitions based on multiple existing data sources. This could include, but is not limited to case surveillance, hospital

discharge, administrative data, laboratory data, vital records, birth defects registry, medical records (birth hospitalization and well-child visits), etc. Documentation of case ascertainment processes and linkage details should be submitted to CDC on a regular basis.

- (ALL) Prepare datasets using the minimum data structure and definition provided by CDC
- (ALL) For medical record abstractions that require sampling (note: some exposures/outcomes will require medical review for all cases), submit documentation on sampling approach and line list with selected cases to conduct weighting of the data
- (ALL) Share individual-level data consistent with CDC standards to CDC and as outlined in this NOFO at a minimum bi-annually with the possibility of monthly to quarterly depending on exposure and/or outcome
- (NAS) Implement the Tier 1 component of the CSTE NAS standardized surveillance case definition using multiple data sources. This could include, but is not limited to hospital discharge data, administrative data, laboratory data, vital records, hepatitis C surveillance data, birth defects surveillance data, etc. Conduct medical record review of all NAS cases to ensure complete capture of case information.
- (NAS) Access administrative data to implement the Tier 2 component of the CSTE NAS standardized surveillance case definition to conduct NAS surveillance in the jurisdiction
- (NAS) Link Tier 1 and Tier 2 surveillance data sources to identify cases identified in both data sources. For cases identified through Tier 2 but not Tier 1 surveillance, review and abstract information from the medical record to determine if the case meets the CSTE Tier 1 case definition
- (Stillbirth) Use the National Center for Health Statistics (NCHS) recommended case definition for stillbirth as defined in the MODEL Law. Specifically, include fetal deaths at 20 or more weeks of gestation; if no gestational age is available, include fetuses weighing 350 grams or more. Data sources could include, but are not limited to discharge data from hospitals and prenatal diagnostic clinics, labor and delivery logs, administrative data, vital records, birth defects surveillance data, etc. Conduct medical record review of all stillbirth cases to ensure complete capture of case information, to include information on fetal autopsy and placental histopathology reports.
- (Stillbirth) Link medical record data to fetal death certificates to identify stillbirth cases in both data sources. For cases identified through fetal death certificates but not medical record abstraction, review and abstract information from the medical record to determine if the case meets the stillbirth case definition.

(Optional) Improve monitoring of infants and children to assess long-term outcomes

- (ALL) Identify data sources that contain information about healthcare access, health, developmental, educational, and quality of life outcomes among infants born with the exposure/outcome of interest in your jurisdiction through 6 years of age. These can include but are not limited to medical records, vital records, hospital discharge data,

administrative data, Medicaid data, educational data, early intervention program data, family surveys, etc.

- (ALL) Collaborate with partners to address operational and policy requirements to access external data sources to augment surveillance data and/or external or internal requirements to link external data sources with surveillance data.
- (ALL) Assess feasibility and/or conduct longitudinal surveillance for health, developmental, educational, and/or quality of life outcomes among children born with the exposure/outcomes of interest through direct data collection, data linkage, or related methodologies based on surveillance protocol for exposure and/or outcome of interest. Of note, CDC may request that exposures and outcomes that have known or potential impact on neurodevelopment to be followed for specified time periods but not greater than 6 years.
- (ALL) Prepare datasets using the minimum data structure and definition provided by CDC
- (ALL) Share individual-level data consistent with CDC standards to CDC and as outlined in this NOFO at a minimum bi-annually with the possibility of monthly to quarterly depending on exposure and/or outcome

Component C Only

Advance interoperability and data infrastructure, develop and revise data schemas, and prepare datasets for analysis and reporting

- Review existing data structures and provide recommendations, identify opportunities to standardize variables, infrastructure, or datasets across systems within the Division of Birth Defects and Infant Disorders
- Review existing schemas to identify improvements and to integrate appropriate data standards
- Based on exposures and outcomes of interest identified in Component A, map existing and new variables to schemas for data extraction
- Provide technical assistance to Component A and B recipients to integrate appropriate schemas and extract data from electronic health records

Post-process data from components A and B and provide technical assistance to those recipients

- Develop approaches for calculating sampling weights (if applicable) and applying to analyses or dashboards for reporting
- Review and implement data quality processes, workflow, and timeliness across systems and provide recommendations for streamlining
- Provide data quality and completeness reports to recipients after each data submission
- Track data received, reviewed, sent back, and finalized between recipients and CDC

- Create data visualizations and dashboards

Evaluate data flow from clinical and health department sites in general to CDC to provide recommendations for improvement

- Collect information on how data are provided and captured between clinics and health departments for public health reporting
- Pilot interoperable applications to improve efficiency and accuracy of abstracted data from electronic health records for reporting to health departments and CDC
- Identify and recommend appropriate next steps and recommendations for improvements in a final report

1. Collaborations

a. With other CDC programs and CDC-funded organizations:
Applicants are to only apply to Component A, Component B, or to Component C of this Notice of Funding Opportunity, and not more than one. Each recipient will conduct all required activities indicated for their respective component and is expected to collaborate and coordinate across NOFO recipients, as well as with CDC programs and centers, institutes, and offices (CIOs) as part of a multidisciplinary collaborative.

b. With organizations not funded by CDC:
Recipients may need to consult and communicate with affiliated institutions, referring health care providers or entities, and/or treatment or service providers (e.g., substance use clinics, general pediatric providers, behavioral specialists, social service providers, health departments) to collect relevant information. Applicants are encouraged to provide letters of support from these organizations or providers, as appropriate. Letters of support should be saved as a PDF file and named “Letters of Support.” They should then be uploaded to www.grants.gov under the "Other Attachments Form."

Applicants should also describe specific agencies and organizations, including state, local, and/or community-based organizations, with whom the applicant currently or previously collaborated on related to the exposure or outcome of interest and identify other organizations expected to join in the network to accomplish the proposed activities. Recipients should establish, build, and/or maintain collaborative relationships that will support the implementation of the proposed strategies and activities to maximize public health impact and contribute to long-term goals.

2. Target Populations
The target populations for this NOFO include, but are not limited to, those individuals affected by the priority exposures and outcomes of interest: medication for opioid use disorder, cytomegalovirus, neonatal abstinence syndrome, stillbirths, and other conditions (e.g. mpox, polysubstance use) that may have serious impacts on pregnant people and infants and to which CDC can provide technical assistance. More specifically, the populations to be served by this NOFO will vary across recipients.

Applicants for Component A must target populations based on exposure and/or outcome of interest. All Component A applicants must be able to provide the following:

The applicants must provide data on a minimum of 75 pregnant person-infant dyads and demonstrate ability to provide data that includes a time period no earlier than deliveries in

2014. The applicant will need to demonstrate ability to link and provide electronic health record (EHR) data for children through six years of age. EHR data must include well-child visit records, laboratory, medication, referrals, and any developmental screeners and diagnoses conducted. The first surveillance year will include pregnant person-infant dyads with a pregnancy outcome between January 2014 (or earliest available after this date) through August 31, 2021. The second surveillance year will include a minimum of pregnant person-infant dyads with a pregnancy outcome through 2024 with appropriate updates in subsequent years based on exposure and/or outcome.

Applicants for Component B must target populations based on exposure and/or outcome of interest. The following criteria should be considered for each priority exposure under Component B:

The population-based stillbirth surveillance activities should include all stillbirths to pregnant people who are residents of a defined geographic area during January 1, 2020 to December 31, 2026. Applicants should define and describe the geographic area and population covered under this NOFO with specific focus on populations with the highest stillbirth burden as informed through health disparities data and account for sociodemographic characteristics. The geographic area must include a minimum of 200 estimated stillbirth cases per year. Surveillance activities are likely to have broader impacts on people of childbearing potential, families contemplating pregnancy, public health professionals, health care providers, and pregnant people. The goal is to include a source population across the jurisdictions that is diverse with regard to geography, urbanicity, racial/ethnic composition, and socioeconomic status.

The population-based NAS surveillance activities should include all infants with an NAS diagnosis born to pregnant people who are residents of a defined geographic area during Janurary 1, 2023 through December 31, 2026. Applicants should define and describe the geographic area and population covered under this NOFO with specific focus on jurisdictions with the highest NAS burden. The geographic area must include a minimum of 200 estimated NAS cases per year.

The population for all other exposures should include 1) all pregnant people who meet standardized surveillance case definitions for specific exposures and their infants, 2) all infants and children who meet standardized surveillance case definition for exposure or congenital infection and their mothers. Applicants may decide to include the entire jurisdiction or focus on geographic populations in the jurisdictions with the highest burden. If the entire jurisdiction is not selected, medical record abstraction for the selected geographic area should include all cases that meet inclusion criteria; depending on capacity, CDC can provide technical assistance (e.g., sampling) if the selected area exceeds medical record abstraction of more than 200 estimated cases per year. Surveillance period will be dependent on exposure being recommended but should be no earlier than January 2018 and would go forward to the most current birth cohort year available.

Applicants for Component C will serve those that use clinical and public health data sources through Components A and B. The work under this NOFO will target increased surveillance across clinic and health department sites to improve data quality, timeliness, and efficiency related to reporting of key exposures and outcomes that impact pregnant people, their infants, and children.

a. Health Disparities

CDC defines health equity as a state in which every person has the opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities. Social and health inequities related to maternal and child health are longstanding and exacerbated with certain exposures.

The activities will focus on all pregnant person-infant dyads who meet the target population criteria. All applicants should provide information on how they will ensure that activities include diverse representation to serve populations of interest. Applicants should describe the characteristics of their patient/resident population (e.g., total number of pregnant person-infant dyads overall and by exposure/outcome, ethnicity, race, gender, socioeconomic status) and geographic location in their application (i.e., rural, urban), with special attention to those populations that may have experienced long-standing social and health inequities and have a high burden of exposures or outcomes. Applicants with access to or serving diverse populations are encouraged to apply.

Information collected will be analyzed by race/ethnicity and socioeconomic factors to identify and describe health disparities among pregnant person person-infant dyads based on exposure and outcome of interest.

This cross-cutting approach may also include modernization efforts to improve the collection, linkage, and use of equity-related data. (Source: CDC DMI and Health Equity)

iv. Funding Strategy

Applicants can only apply for one component.

Component A: We anticipate up to 10 awards will be funded to entities that directly maintain and enter information into the electronic health records and clinical and laboratory data, are able to demonstrate existing linkages of pregnant person and infant records, and are able to provide data for children through six years of age. Component A recipients are expected to address all the strategies listed in the logic model and in the Strategies and Activities section of the NOFO 1) in the section marked for Components A, B, and C and 2) in the section marked for Component A only. Component A recipients will be funded up to $500,000 per award for Year 1. Funding award ceilings for Years 2, 3, and 4 are not set.

Component B: We anticipate up to 10 awards will be funded to entities that have access to population-based state-or jurisdiction wide established public health data systems to identify pregnant people, outcomes, and conduct longitudinal follow-up if applicable for children for specified time periods but not greater than 6 years. Component B recipients are expected to address all the strategies listed in the logic model and in the Strategies and Activities section of the NOFO 1) in the section marked for Components A, B, and C and 2) in the section marked for Component B only. Component B recipients will be funded up to $800,000 per award for Year 1. Funding award ceilings for Years 2, 3, and 4 are not set.

Component C: We anticipate up to two awards will be funded to entities that have informatics and data health science expertise. Component C recipients are expected to address all the strategies listed in the logic model and in the Strategies and Activities section of the NOFO 1) in the section marked for Components A, B, and C and 2) in the section marked for Component C

only. Component C recipients will be funded up to $2,000,000 per award for Year 1. Funding award ceilings for Years 2, 3, and 4 are not set.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Strategy

The evaluation and performance measurement strategy will be used to assess the performance of the overall project. Measures and outputs are subject to change. Evaluation and performance measures must be tracked by recipients and reported to CDC as requested. Measures and outputs are meant to be collective across sites unless otherwise indicated. Applicants must include an evaluation plan that aligns with the strategies and activities in the logic model, includes the key questions (as appropriate) and performance measures, describes personnel assigned to evaluation activities, includes a timeline, describes anticipated outcomes, and describes use of evaluation results for program improvement.

CDC and recipients will use findings from these measures to: 1) ensure program implementation and continuous system improvement, 2) demonstrate achievement of program outputs and short-term outcomes, 3) provide an evidence base for potential future changes to the surveillance methodology, and 4) assess the usefulness, scalability, and effectiveness of dissemination strategies. Information will lead to improvements in implementation of current and future pregnant people-infant linked longitudinal surveillance activities and demonstrate progress toward reaching program goals. Findings should be disseminated to sites and partners through scientific publications at conferences or in publications to improve upon or report on the performance in achieving strategic and scientific objectives.

Key evaluation questions that may be answered include, but are not limited to the following:

- To what extent can surveillance capacity be improved including the impact of jurisdictional surveillance methods on case identification?
- To what extent can data quality be improved including methods to improve the timeliness of surveillance data and impact of medical records review on data completeness and accuracy?
- To what extent can prevention activities be improved, including operational and policy barriers to supporting referrals, number of families referred, number of families receiving services and timeliness of referrals, effectiveness of screening and recommendations, tracking children, and access to and linkage of data sources?

Process evaluation measures:

CDC has provided example process measures that can be used by recipients to describe how they will monitor and report performance measurement data annually. Please include these measures at a minimum.

<u>Component A and B</u>

- Define the exposure and/or outcome of interest
    - Does proposed exposure and/or outcome of interest align with priorities listed?

- Establish agreements for access to data sources
    - Number of data sources with data use agreement in place
- Staff training and data quality assurance
    - Number of trained staff in place within six months of notification of award
- Data management and reporting
    - Did site submit datasets to CDC by established deadlines?
    - Percentage of data validations and quality issues resolved
    - Percentage of meta-data information complete with each data submission
    - Number of data completeness/quality (e.g., missingness, discrepancies, etc.) reports reviewed
    - Number of analyses (routine or other) conducted using surveillance data
- Workplan for listed activities
    - Workplan submitted to CDC within six months of notification of award
- Performance monitoring and evaluation
    - Evaluation plan developed and submitted to CDC within six months of notification of award
    - Number of conference presentations and manuscripts published related to evaluation activities

Component C

- Data management and reporting
    - Number of schemas developed, and shared with recipients
    - Percentage of data validations and quality issues resolved
    - Number of data completeness/quality (e.g., missingness, discrepancies, etc.) reports reviewed
- Workplan for listed activities
    - Site workplan submitted to CDC within six months of notification of award
- Performance monitoring and evaluation
    - Site evaluation plan developed and submitted to CDC within six months of notification of award

Outcome evaluation measures:

Recipients should track and report on these measures at the end of the surveillance year. Please include these measures at a minimum. These measures correspond to outcomes in the logic model.

Improved surveillance data collection between clinical and public health partners.

- Number of variables with 0% missing values
- Number of variables collected for the surveillance system
- (Component A) Documentation of the number of queries required to consider data complete or final
- Documentation of best practices and measuring effectiveness of strategies to assess impact of efforts

Increased access and availability of electronic health record and public health data.

- Data reported to CDC according to the required data submission schedule
- Percentage of complete data available for analysis and public access when applicable based on final list of variables and data dictionary

Improved timely reporting of key exposures and outcomes that impact pregnant people and their infants.

- Description and number of activities that improved timely reporting

Improved surveillance system data that can be leveraged for emerging threats during pregnancy to pregnant people and their infants.

- Documentation of current capacity, gaps, and opportunities to modernize the public health data infrastructure and workforce
- Extent of demonstrated utilization of data systems

Increased awareness by CDC of how data are shared and processed between clinics and health departments.

- Documentation of how data are being shared between clinics and health departments

Increased implementation of prevention activities and dissemination of findings.

- Number of services and/or resources identified to support pregnant persons and infants and their caregivers/families post-hospital discharge.
- Documentation of plans for using surveillance data to support referrals for families for public health and healthcare services
- Number of presentations based on analysis of data to internal and external partners
- Number of manuscripts published in peer-review journals
- Number of partnerships or collaborations established

Expanded and strengthened collaborative network to address important public health issues that have an impact during pregnancy and to infants.

- Documentation of memorandum of agreements with relevant clinic system or health department programs provided
- Number of partnerships with federal, state, local, clinical, and/or community organizations that refer individuals to services or are service providers accepting referrals for infants and their families established.
- Documentation of lessons learned, best practices, and priorities for identifying exposures/outcomes
- Number of times results and lessons learned were disseminated to agency, memberships, and constituents

Improved data structure and increased interoperability (Component C)

- Documentation of recommendations for standardizing variables, infrastructure, or datasets
- Number of existing schemas identified for improvements and integrated appropriate data standards
- Based on exposures and outcomes of interest identified in Component A, percentage of existing and new variables mapped for data extraction
- Percentage of time providing technical assistance to recipients to integrate appropriate schemas and extract data from electronic health records

Data Management Plan (DMP)

All sites funded under this cooperative agreement will collect data for surveillance activities. Component A will use a CDC-provided data collection structure and CDC will provide technical support for using this structure and data quality checks. Once the data are received by CDC, it is subject to applicable federal law for data sharing. CDC will append data from all sites into a pooled dataset by exposure and/or outcome. Data provided for medication for opioid use disorder or emerging threats during or around the time of pregnancy are covered under an Assurance of Confidentiality. Data at CDC will be monitored, stored, and managed consistent with applicable federal law. Applicants must include a draft data management plan that includes, but is not limited to, the type of data that will be collected, procedures for collecting the data, how data will be stored, procedures for providing access to the data, and provisions for maintaining data.

The DMP may be submitted as a checklist, paragraph, or other format that addresses:

- A description of the data to be collected or generated in the proposed project;
- The standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to the data, including a description for the provisions for the protection of privacy, confidentiality, security, and intellectual property, or other rights;

- Statement of the use of data standards that ensure all documentation that describes the method of collection, what the data represent, and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified; and,
- Other additional requirements based on the program.
- CDC does not have a standard format for DMP. During the period of performance, program will provide guidance and technical assistance to recipients for updating or revising DMP, as needed.

ii. Applicant Evaluation and Performance Measurement Plan

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

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additional-requirements/ar-25.html.

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

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

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

c. Organizational Capacity of Recipients to Implement the Approach

All applicants must demonstrate their existing or potential capacity to successfully execute all proposed strategies and activities to meet the project requirements of each funding component to which they are applying. Applicants should indicate their understanding and capacity to share data with CDC as described in the NOFO. Applicants should address infrastructure (the applicant organization's physical space, equipment, and capacity to work remotely), partnership development, evaluation and performance monitoring, financial reporting, budget management and administration, personnel management (including developing staffing plans, and developing and training workforce), and expertise and experience related to all component-specific project focus areas. Applicants must provide (as attachments) CVs/resumes for proposed NOFO-funded personnel, position descriptions for positions that are currently vacant, and an overall organizational chart for their organization and other relevant organizations involved in the project. Applicants must name the attachments "CVs/Resumes" and "Organizational Charts" and upload them as PDF files under "Other Attachment Forms" at www.grants.gov.

Key capacity considerations to address in the application for Components A and B:

- Applicants must describe their experience related to surveillance of priority exposure and/or outcome of interest and any other pregnant person-infant linked longitudinal surveillance and describe the current operational capacity to conduct pregnant person-infant linked longitudinal surveillance.
- Applicants must have public health authority, legislative mandate, or otherwise provide evidence (e.g., MOU/MOA or letter of support) from the state government or governing body (e.g. substance use clinic, university, etc.) that they would have access to health records including individual level Personally Identifiable Information (PII) and can share individual-level data, including date of birth (i.e., month/day/year) with CDC. This evidence should include the priority exposures or outcomes that the applicant proposes to monitor. This document should be labeled as "Legal Authority".
- Applicant may also provide evidence (e.g., MOU/MOA or letter of support) from the state government or governing body outlining access to other data sources including but not limited to early intervention, education, and/or Medicaid data. Applicants must name the attachments "Health_1", "Health_2", etc., "Education_1", "Education_2", etc., "Early Intervention_1", "Early Intervention_2", etc., "Medicaid_1", "Medicaid_2", etc., and upload them as PDF files under "Other Attachment Forms" at www.grants.gov.
- (Component B) Applicants for Component B may include state governments (including District of Columbia), special district governments and local governments (includes county, city, and townships) or their bona fide agents serving a County population of 2,000,000 or more or a City population of 400,000 or more, U.S. territories and freely associated-state governments. Populations for county and city jurisdictions are based on the 2020 U.S. Census resources. Component B applicants must submit documentation providing accurate population size served by the public health authority based on the 2020 U.S. Census. Documentation includes a signed letter from any public health agency leadership or their designee on organizational letterhead stating the population size served. Applicant must name this file "Organizational Capacity_Component B" and upload it as a PDF to www.grants.gov.
- Applicants must provide a project management structure sufficient to meet the outcomes of the project and that clearly defines staff roles.

- Applicants must describe their resources and staffing levels for this project. The exact personnel and percentage of time allotted may vary by site. However, there are basic project staff requirements, including having actively involved Principal Investigator(s), a Project Coordinator (at least 75% effort on project), an Epidemiologist (at least 20%), Record Abstractors (at least one full-time equivalent), and at least 20% data management/programmer/informatics support.
- Applicants must have adequate technical and facility resources to meet the project's goals and previous experience submitting quality and timely individual-level data successfully. Applicants should have the ability to:
    - Describe previous efforts providing quality and timely individual-level data, this can include inclusion of key data in analyses, meeting data submission deadlines on time, and a description of the final data
    - Configure, manage, and provide raw data from health sources including formatting data into CDC-specified formats for data submissions
    - (Component A) Include informational technology (IT) infrastructure to utilize and maintain a Research Electronic Data Capture (REDCap) database, use of HL7, FHIR, and XML schemas
    - (Component A) Ability to electronically share linked maternal-infant health information including RxNorm, SNOMED, LOINC, vaccination, procedure and diagnostic codes

Key capacity considerations to address in the application for Component C:

- Applicants must describe their experience and expertise in providing relevant technical assistance specific to informatics and data science.
- Applicants must describe a successful history of collaboration with governmental public health agencies across the US, of varying sizes and geographic regions, including (but not limited to) the technical assistance areas in which they propose to work under this cooperative agreement.
- Applicants must describe the capacity to quickly engage Components A and B recipients soon after award and have the relevant staffing, established contact list, administrative systems, and partnerships in place to do so. It is acceptable for this broad reach and capacity to be obtained through sub-awards or consortia of organizations working together, under a prime recipient.
- Acceptable documentation must include signed letters by any public health government agency leaders or their designees on organizational letterhead describing experience with receiving technical assistance from Component C applicants on key public health workforce strategies, foundational capabilities, and/or data modernization initiatives; organizational charts; and resumes or CVs for key personnel positions that are currently filled (include position descriptions for vacant positions). Applicant must name this file "Organizational Capacity_Component C" and upload it as a PDF to www.grants.gov.

d. Work Plan

Applicants are required to provide a detailed work plan for Year 1 of the project and a high-level work plan for subsequent years. No specific work plan format is required as long as the work plan crosswalks to the strategies and activities, outcomes, and performance measures presented in the logic model and narrative sections of this NOFO. A sample work plan format is presented below. Applicants should complete the table for each period of performance outcome. If a particular activity leads to multiple outcomes, it should be described under each outcome measure.

Period of Performance Outcome: [from Outcomes section and/or logic model]		**Outcome Measure:** [from Evaluation and Performance Measurement section]	
Strategies and Activities	**Process Measure** [from Evaluation and Performance Measurement section]	**Responsible Position / Party**	**Completion Date**
1.			
2.			
3.			
4.			
5.			
6.			

e. CDC Monitoring and Accountability Approach

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

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

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

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.

- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

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

CDC will provide an optional example of a standardized performance measurement template for recipients to complete. Emphasis will be placed on process measures for yearly reporting and on outcome measures for reporting at the end of the surveillance year activities. CDC will provide feedback on process measures and on aggregated outcome measures during regular calls and through yearly summary reports.

f. CDC Program Support to Recipients

CDC staff will be substantially involved beyond site visits and regular performance and financial monitoring during the period of performance of this cooperative agreement. Substantial involvement means that the recipient can expect federal programmatic partnerships in carrying out the efforts under the award. The CDC program will work in partnership with the recipient to ensure the success of the cooperative agreement by:

i. Technical Assistance

CDC provides the following technical assistance to:

- Assist recipients with surveillance activities including surveillance protocols, the operationalization of case definitions, and providing data dictionaries and other resources
- Provide technical consultation regarding surveillance methods including data collection and abstraction, quality assurance, evaluation, analyses, and reporting
- Share with recipients the data collection specifications and structure used by CDC team for tracking, abstraction, and data management of pregnant people-infant linked longitudinal dyads
- Provide initial training and provide ongoing technical support in surveillance procedures for extraction, abstraction and data management
- Provide tools and guidelines for extracting and abstracting clean record-level de-identified data
- Provide updated information on relevant CDC, US Department of Health and Human Services (HHS), and other policies and regulations that affect the programs
- Conduct priority analyses and priority publications (e.g., MMWR prevalence reports) consistent with applicable federal requirements

ii. Informational Sharing Among Recipients

CDC provides the following technical assistance to:

- Facilitate the development of Data Sharing and/or Publication Guidelines and make relevant updates as needed
- Develop procedures and documentation for data abstraction and data management
- (Component A) Manage a data sharing proposal system, and schedule proposal updates from authors consistent with applicable federal requirements. This system fosters collaboration and information sharing among sites
- (Component A) Compile datasets and distribute to investigators

B. Award Information

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

2. Award Mechanism:
U01

3. Fiscal Year:
2023
Estimated Total Funding:
$5,000,000

4. Approximate Total Fiscal Year Funding:
$5,000,000
This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding:
$20,000,000
Amount represents estimated total funding for the performance period.

6. Total Period of Performance Length:
4 year(s)

7. Expected Number of Awards:
22
Component A: Up to 10

Component B: Up to 10

Component C: Up to 2

8. Approximate Average Award:

$770,000
Per Budget Period

Components A-C – estimated funding ranges and approximate average award per budget year

- A: $300,000 - $500,000 = **$400,000**
- B: $320,000 - $800,000 = **$560,000**
- C: $700,000 - $2,000,000 = **$1,350,000**

9. Award Ceiling:
$0
Per Budget Period

The Award Ceiling is None. Please refer to the Approximate Total Fiscal Year Funding, Average One Year Award Amount, and Approximate Average Award for the anticipated total funding amount for Year 1. This amount is approximate and is subject to the availability of funding.

10. Award Floor:
$0
Per Budget Period

11. Estimated Award Date:
August 31, 2023
Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

12. Budget Period Length:
12 month(s)

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

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

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
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)

23 (Small businesses)

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

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

Additional Eligibility Category:

Government Organizations:

State (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

State controlled institutions of higher education

American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

American Indian or Alaska native tribally designated organizations

Other:

Private colleges and universities

Community-based organizations

Faith-based organizations

2. Additional Information on Eligibility

Eligible applicants must have the public health authority, legislative mandate or otherwise show legal access to the requisite data to conduct clinic or population-based surveillance. This authority allows unique and specific access to datasets from multiple data sources that are required to implement the activities outlined in this NOFO. This may be an MOU, letter of support, or other legal documentation to demonstrate public health authority, legislative mandate, or legal access to the data. Eligible applicants must document this authority in "Other Attachment Forms" with attachment name "Legal Authority" as a PDF uploaded to www.grants.gov. CDC will consider any application that does not include this required documentation as non-responsive, and it will receive no further review.

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a Bona Fide Agent of a state government, a letter from the state government as documentation of the status is required and should be submitted under "Other Attachment Forms" with attachment name "Bona Fide Agent." If the Bona Fide Agent attachment does not specify legal authority, the applicant must include an attachment named "Legal Authority" in "Other Attachment Forms".

The NOFO has three components: A, B, and C. Eligible applicants may only apply for Component A, Component B, or Component C. If an applicant submits multiple applications, all applications will be deemed non-responsive, and none will receive further review. In the "Descriptive Title of Applicant's Project" on the SF-424 form, applicants must identify the component to which they are applying.

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

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

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Required Registrations

1. Required Registrations

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

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). 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. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number by registering in SAM.gov prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned to the registering organization.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their UEI numbers before accepting any funds.

b. System for Award Management (SAM):

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

c. Grants.gov: The first step in submitting an application online is registering your organization atwww.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option atwww.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more

than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	System for Award Management (SAM)	1. Go to SAM.gov and designate an E-Biz POC (You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an individual account in Grants.gov using organization's new UEI	It takes one day (after you enter the EBiz POC name and EBiz POC email in SAM) to	Register early! Applicants can

		number to become an Authorized Organization Representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	register within minutes.

2. Request Application Package

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

3. Application Package

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

4. Submission Dates and Times

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

a. Letter of Intent Deadline (must be emailed)

03/07/2023
The purpose of an LOI is to allow CDC program staff to estimate the number of applications and plan for the review of submitted applications.
LOI must be sent via email by 03/07/2023 to:
Christina Winfield
Email address: preg_infant_surv@cdc.gov

b. Application Deadline

Number Of Days from Publication 60

04/10/2023
11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

Due Date for Informational Conference Call

The CDC program will hold an Informational Conference Call for potential applicants to ask questions on February 22, 2023 from 2:00-3:00 PM Eastern Standard Time. The PowerPoint, script, and all questions and answers will be posted on the website after the call. Applicants can access the latest information related to the call at https://www.cdc.gov/pregnancy/nofo/DD-23-0003.html.

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

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

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

6. Content and Form of Application Submission

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

7. Letter of Intent

Is a LOI:
Recommended but not Required
A Letter of Intent (LOI) is requested but optional. The purpose of an LOI is to allow CDC program staff to estimate the number of applications and plan for their review. Please include the following information in the LOI:

Number and title of this NOFO;

Descriptive title of the proposed project (including for which component you are applying)

Description of the exposure(s) and/or outcome(s) you are proposing to include as part of surveillance

Name, address, telephone number, and email address of the Principal Investigator or Project Director;

Name, address, telephone number, and email address of the primary contact for writing and submitting the application.

The LOI must be sent via email by 03/07/2023 to:

Christina Winfield

CDC/NCBDDD/DBDID

Email: preg_infant_surv@cdc.gov

8. Table of Contents

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

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

9. Project Abstract Summary

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

10. Project Narrative

Multi-component NOFOs may have a maximum of 15 pages for the “base” (subsections of the Project Description that the components share with each other, which may include target population, inclusion, collaboration, etc.); and up to 4 additional pages per component for

Project Narrative subsections that are specific to each component.

Text should be single spaced, 12 point font, 1-inch margins, and number all pages. Page limits include work plan; content beyond specified limits may not be reviewed.

Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity Announcement. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

Any content beyond the 4 additional pages may not be reviewed.

a. Background

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

b. Approach

i. Purpose

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

ii. Outcomes

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

iii. Strategies and Activities

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

1. Collaborations

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

2. Target Populations and Health Disparities

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

c. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

- Describe other information (e.g., measures, data sources).

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

d. Organizational Capacity of Applicants to Implement the Approach

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

11. Work Plan

(Included in the Project Narrative's page limit)

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

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative,

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

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

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

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

If applicable and consistent with the cited statutory authority for this announcement, applicant

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

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

Applicants must name this file "Budget Narrative" and upload it as a PDF file

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

13. Pilot Program for Enhancement of Employee Whistleblowers Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations

(CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

13a. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be

required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.

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

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

13b. Copyright Interests Provisions

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

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

13c. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to

preserve and to make the data accessible in a timely manner. See web link for additional information: https://www.cdc.gov/grants/additional-requirements/ar-25.html.

14. Funding Restrictions

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

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

15. Other Submission Requirements

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

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

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a

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

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.
https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=GetStarted%2FGetStarted.htm

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

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call thewww.grants.gov Contact Center at 1-800-518-4726 or e-mail them

at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application.

Such requests are handled on a case-by-case basis.

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

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

E. Review and Selection Process

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

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by the Office of Grants Services. Complete applications will be reviewed for responsiveness by Grants

Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

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

i. Approach

ii. Evaluation and Performance Measurement

iii. Applicant's Organizational Capacity to Implement the Approach

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

i. Approach **Maximum Points:** 40

Components A and B

Overall Strategy (20 points)

- To what extent does the applicant describe an approach to meet the overall strategy and activities of this NOFO? (5 points)
- To what extent does the applicant describe an approach that would efficiently and effectively propose their priority exposure(s) and/or outcome(s) of interest, including appropriate target population(s) and a description of proposed surveillance area, ability to serve a population with a specified public health burden, and ability to conduct longitudinal follow-up of children and/or collect and analyze relevant data as designated by activities in this NOFO (5 points)
- Description of case ascertainment methods, established data linkage, proposed data sources and existing ability to access data for this surveillance including ability to link to data on social determinants of health and behavioral health (e.g., counseling, psychosocial, nonpharmacological services, WIC, social services, child welfare, education, vital records, correction systems, etc.) (5 points)
- Clearly addresses all the of the strategies identified within the appropriate component and the activities to be completed (5 points)

Work Plan (20 points)

- To what extent does the applicant present a work plan that aligns with the strategies, activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC? (10 points)
- To what extent does the applicant include measurable timelines, clear monitoring and evaluation procedures, and specific activities for meeting the proposed outcomes? (10 points)

Component C

Overall Strategy (30 points)

- To what extent does the applicant describe an approach to meet the overall strategy and activities of this NOFO? (5 points)
- Description of their ability to review and provide recommendations related to appropriate data structures, interoperability, and data standards (5 points)
- Experience with data modernization, working with CDC, health departments, and entities that have access to electronic health records (8 points)
- Experience with data processing and using various data management, analysis, and sharing platforms (e.g., SQL, R, Python, SAS, PowerBI, REDCap) (8 points)
- Clearly addresses all the of the strategies identified within the appropriate component and the activities to be completed (4 points)

Work Plan (10 points)

- To what extent does the applicant present a work plan that aligns with the strategies, activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC? (5 points)
- To what extent does the applicant include measurable timelines, clear monitoring and evaluation procedures, and specific activities for meeting the proposed outcomes? (5 points)

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

Components A, B, and C

Evaluation and Performance Measurement Plan (EPMP) (25 points)

- To what extent does the applicant's EPMP appropriately describe:
- Monitoring and evaluation procedures and the ability to collect data on the process and outcome measures specified? (10 points)
- The ability to report on process and outcome measures, generate appropriate outputs, and demonstrate the outcomes of the NOFO? (10 points)
- How evaluation and performance measures will be used to monitor progress and for continuous improvement of the NOFO activities? (5 points)

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

Components A and B

- To what extent does the applicant describe organizational capacity sufficient to conduct surveillance for priority exposure and/or outcome of interest? (7 points)

- To what extent does the applicant provide a staffing plan and project management structure sufficient to meet the outcomes of the project and clearly defines staff roles? (8 points)
- To what extent does the applicant provide evidence from the state government or governing body that they would have access to individual-level personally identifiable information from health and education records, if funded? (8 points)
- To what extent does the applicant demonstrate that they have adequate technical and facility resources to meet the project's goals and previous experience submitting quality and timely individual-level data successfully? (8 points)
- To what extent does the applicant demonstrate ability to synergize efforts with existing or previous CDC surveillance efforts related to pregnant person-infant linked longitudinal surveillance? (4 points)

Component C

- To what extend does applicant demonstrate experience and expertise in providing relevant technical assistance specific to informatics and data science? (9 points)
- To what extent does applicant demonstrate a successful track record of collaborating successfully with governmental public health agencies across the US, of varying sizes and geographic regions, including (but not limited to) the technical assistance areas in which they propose to work under this cooperative agreement? (9 points)
- To what extent does applicant demonstrate the capacity to quickly engage Components A and B recipients soon after award and have the relevant staffing, established contact list, administrative systems, and partnerships in place to do so? (8 points)
- To what extent does applicant demonstrate informatics experience with electronic health records and public health reporting with health departments? (9 points)

Budget **Maximum Points:** 0

The budget is not scored. The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds.

c. Phase III Review

Applications will be scored through an Objective Review process and ranked. Applicants may be funded out of rank order to ensure broad reach and to promote diversity across recipients in the following areas:

- Demonstrated ability to add emerging, reemerging, or persistent exposures and/or outcomes beyond the selected exposures and/or outcomes that meet CDC criteria (e.g., adverse impact on pregnancy, fetal, infant or child outcomes) and for which CDC can provide technical assistance
- Ability to reach underserved or underrepresented populations by exposure or outcome to ensure inclusiveness, diversity, and representativeness

- Equal distribution across geographic location, including rural vs urban and HHS regions, including the opportunity for potential overlap with Components A and B to advance collaborative efforts to ensure capacity by exposure and outcomes is distributed across the U.S. and not clustered in a single region

Component C:

- Applicants that seek to cover more of the strategies included in Component C may be funded over those with fewer strategies, but have total higher scores. Maximizing coordination and streamlining across the component recipients is in the best interest of the NOFO and the Component A and B recipients they are intended to serve.

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

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

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

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

(1) Financial stability;

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

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

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

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

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

2. Announcement and Anticipated Award Dates

Estimated award announcement date: 08/01/2023

Estimated award date: 08/31/2023 via Notice of Award

Budget/project period start date: 09/30/2023

F. Award Administration Information

1. Award Notices

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

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

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

2. Administrative and National Policy Requirements

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

Brief descriptions of relevant provisions are available at https://www.cdc.gov/grants/additional-requirements/index.html.

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

Generally applicable ARs:

- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2030

- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act Requirements
- AR-25: Data Management and Access
- AR-26: National Historic Preservation Act of 1966
- 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-37: Prohibition on certain telecommunications and video 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 CFR 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

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider- obligations/index.html and https://www.hhs.gov/civil-rights/for- individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

3. Reporting

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

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

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

Report	**When?**	**Required?**
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	*6 months into award*	*Yes*
Annual Performance Report (APR)	*No later than 120 days before end of budget period. Serves as yearly continuation application.*	*Yes*
Data on Performance Measures	N/A	No
Federal Financial Reporting Forms	*90 days after the end of the budget period.*	*Yes*

Final Performance and Financial Report	*90 days after end of project period.*	*Yes*

a. Recipient Evaluation and Performance Measurement Plan (required)
With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

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

Performance Measurement

• Performance measures and targets

• The frequency that performance data are to be collected.

• How performance data will be reported.

• How quality of performance data will be assured.

• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).

• Dissemination channels and audiences.

• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).

• The frequency that evaluations will be conducted.

• How evaluation reports will be published on a publicly available website.

• How evaluation findings will be used to ensure continuous quality and program improvement.

• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).

• Dissemination channels and audiences.

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

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

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

The recipient must submit the Annual Performance Report via https://www.grantsolutions.gov 120 days prior to the end of the budget period.

Recipients can submit an updated evaluation plan in the appendix of their annual continuation

applications and should note where changes have been made to the plan since the first submission in budget year 1.

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

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

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

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

No additional final performance and financial report requirements.

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

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1)

information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.

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

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

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

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

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

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

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

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

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative

agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

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

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

6. Termination

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

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

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

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

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

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

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For programmatic technical assistance, contact:

First Name:
Christina

Last Name:
Winfield
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

Address:

Telephone:

Email:
preg_infant_surv@cdc.gov

Grants Management Office Information

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

First Name:
Petricia

Last Name:
Sailor
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:
2939 Flowers Rd

Atlanta GA 30341

Telephone:
770-488-1520

Email:
tre9@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

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

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

H. Other Information

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

- Project Abstract
- Project Narrative

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

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

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

Position descriptions

Letters of Support

Organization Charts

Non-profit organization IRS status forms, if applicable

Indirect Cost Rate, if applicable

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Bona Fide Agent status documentation, if applicable

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

- (Component A and B) Legal Authority documentation (e.g. MOU or letter of support)
- (Component B) Organizational Capacity_Component B"
- (Component C) Organizational Capacity_Component C"

Other data sources (also described in the Organizational Capacity section): Applicants must name the attachments "Health_1", "Health_2", etc., "Education_1", "Education_2", etc., "Early Intervention_1", "Early Intervention_2", etc., "Medicaid_1", "Medicaid_2", etc.

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov. The Project Narrative must include all of the following headings (including sub-headings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities

to be conducted over the entire period of performance as identified in the CDC Project Description section.

I. Glossary

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

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

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

Assistance Listings: A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

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

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

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

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

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

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

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

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

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

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

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

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

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

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

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

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

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

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

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.
Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

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

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

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

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

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

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

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount. Memorandum of Understanding (MOU) or Memorandum of Agreement**(MOA):** Document that describes a bilateral or multilateral agreement between parties expressing a

convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

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

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

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

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

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

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

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

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs. **Program Strategies:** Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

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

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

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

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

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

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

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

UEI: The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is free. If an organization does not know its UEI number or needs to register for one, visit www.sam.gov.

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