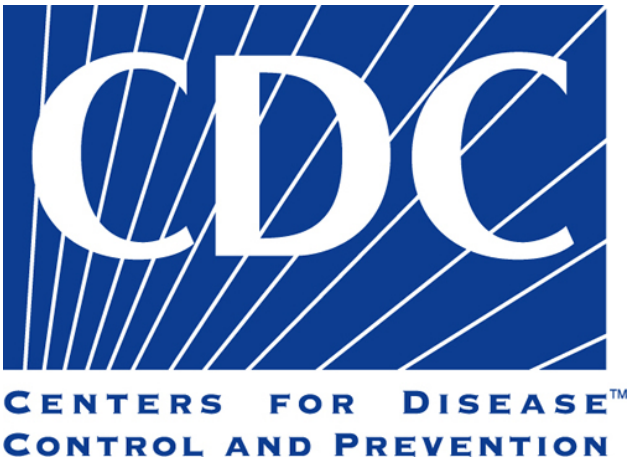


Centers for Disease Control and Prevention

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Population-based Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents with Congenital Heart Defects

CDC-RFA-DD22-2203

05/28/2022

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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-DD22-2203. 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) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

Population-based Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents with Congenital Heart Defects

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)).

New - Type 1

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DD22-2203

E. Assistance Listings Number:

93.073

F. Dates:

1. Due Date for Letter of Intent (LOI):

04/22/2022

2. Due Date for Applications:
05/28/2022
11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call:
4/26/2022; 1:00
EDT; Zoom https://cdc.zoomgov.com/j/1618323691?pwd=WTkxUTdJYXZuV0RvZXhhaUt4TUh5QT09
Meeting ID: 161 832 3691; Passcode: $Ba0JKDv
Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
Meeting ID: 161 832 3691; Passcode: 49531055

G. Executive Summary:

1. Summary Paragraph
NOFO #CDC-RFA- DD22-2203 solicits non-research, cooperative agreement applications to identify a population-based sample of children and adolescents born between 2006 and 2021 (cases 2-17 years of age at survey completion) with congenital heart defects (CHD) from U.S. birth defects surveillance systems with active case-ascertainment and to survey their parents or caregivers to collect information regarding the children's outcomes, including cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care from childhood to adulthood, and mortality, as well as needs and experiences of their caregivers. Improved understanding of the longer-term outcomes and healthcare needs among children and adolescents with CHD and their caregivers may inform development of strategies directed at decreasing mortality and improving the health and well-being of children and adolescents with CHD and their families. Measurable outcomes of the program will be in alignment with the following performance goal for the National Center on Birth Defects and Developmental Disabilities (NCBDDD): 1) Enhance the quality and utility of birth defects surveillance systems.

a. Eligible Applicants:
Open Competition

b. Funding Instrument Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
3
Range: 2-4 awards

d. Total Period of Performance Funding:
$4,000,000

e. Average One Year Award Amount:
$350,000

f. Total Period of Performance Length:
4

g. Estimated Award Date:
August 31, 2022

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
Congenital heart defects (CHD) are the most common type of structural birth defects in the United States, affecting approximately 1 in 110 live-born children, and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs. Due to advances in survival, there are approximately 1 million children and adolescents with CHD in the U. S. With vast declines in mortality from pediatric heart disease over the past 30 years, it is vital to evaluate health, social, educational, and quality of life outcomes beyond infancy and early childhood. However, current population-based research on these longer-term outcomes among children with CHD rely on national survey data (e.g. National Survey of Children's Health) or administrative healthcare data, which lack detailed information on type of CHD, presence of other birth defects, details at birth (e.g. preterm birth), or non-medical outcomes (e.g. educational needs).

Existing birth defects surveillance systems identify babies born with birth defects, but do not track identified cases through later childhood and adolescence. Data is limited to their birth defect diagnoses and characteristics at birth. Therefore, for this surveillance project, we intend to use data from U.S. birth defect surveillance systems with active case-ascertainment to identify a population-based sample of children and adolescents with CHD born between 2006 and 2021 (i.e. 2 to 17 years of age at survey completion). Surveys will be completed by caregivers and linked to vital record and birth defect surveillance system data to assess the children's longer-term outcomes including cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care planning from childhood to adulthood, and mortality as well as needs and experiences of their caregivers. Collected data will offer new opportunities to assess health equity among those with CHD.

The federal Patient Protection and Affordable Care Act (PL 111-148, Section 10411) authorized CDC to "enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into a nationally-representative, population-based surveillance system" for the purpose of facilitating "further research into the types of health services patients use and to identify possible areas for educational outreach and prevention."

In FY15, via a cooperative agreement with March of Dimes, CDC funded the Congenital Heart Survey To Recognize Outcomes, Needs, and well-beinG (CH-STRONG), a project that surveyed 19- to 38-year-olds with CHD identified from three U.S. birth defects surveillance systems with

active case-ascertainment to collect information on their longer-term outcomes. This NOFO will use similar case identification, tracking and tracing, and recruitment methodology as CH-STRONG to collect information on longer-term outcomes of children and adolescents with CHD and their families.

b. Statutory Authorities
This program is authorized under Section 301 of the Public Health Service Act [42 U.S.C. 241], as amended.

c. Healthy People 2030
'NCBDDD is committed to achieving the health promotion objectives of " Healthy People 2030 "This NOFO addresses the following priority areas:

- Reduce the rate of deaths in children and adolescents aged 1-19 years
- Increase the proportion of children and adolescents who
    - Receive a developmental screening
    - Are developmentally ready for school
    - Receive care in a medical home
    - Get support for their transition to adult health care
- Increase the proportion of children with
    - developmental delays who get intervention services by age 4 years
    - special health care needs who have a system of care
    - mental health problems who get treatment

d. Other National Public Health Priorities and Strategies
CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. One of the strategies that CDC employs to accomplish this goal includes monitoring health through surveillance. Disease specific surveillance systems are critical for the accomplishment of this and other objectives that support CDC's mission.

This program is aligned with CDC's mission of saving lives and protecting people from health threats (http://www.cdc.gov/about/organization/mission.htm) and with CDC's role of conducting critical science, providing health information that protects our nation against expensive and dangerous health threats, and responding when these arise.

e. Relevant Work
This NOFO expands the National Center on Birth Defects and Developmental Disabilities' programs conducting birth defects surveillance across the lifespan. In FY15, via a cooperative agreement with March of Dimes, CDC funded the Congenital Heart Survey To Recognize Outcomes, Needs, and well-beinG (CH-STRONG), a project that surveyed 19 to 38-year-olds with CHD identified from three U.S. birth defects surveillance systems with active case-ascertainment to collect information on their longer-term outcomes. Refer to https://www.cdc.gov/ncbddd/heartdefects/research.html.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Bold indicates period of performance outcome.

CDC-RFA-DD22-2203 Logic Model: Population-based Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents with Congenital Heart Defects

Bold indicates period of performance outcome

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
<u>Program Planning</u> · Engage partners; prioritize program goals · Implement management and staffing plans <u>Tracking and Tracing and Recruitment</u> · Identify eligible cases with CHD; track and trace their parents/ caregivers · Recruit parents/ caregivers to participate in survey project <u>Data Management and Reporting</u> · Link birth defect surveillance system, vital status, tracking & tracing, recruitment, and census data; create standardized dataset · Submit all standardized de-identified individual-level data to CDC for linkage to survey data · Assess quality and completeness of data · Describe outcomes of children and adolescents with CHD; describe needs	**· Improved understanding of healthcare barriers, utilization, and other outcomes** **· Improved understanding of needs and experiences of caregivers of individuals with CHD** **· Improved understanding of racial/ethnic and socioeconomic patterns in experiences and outcomes** **· Improved understanding of the strengths and limitations of population-based surveillance among children and adolescents with CHD** **· Improved information to stakeholders on outcomes of children with CHD and needs/experiences of caregivers**	· Improved ability of policymakers to make data-informed decisions · Improved ability to develop effective secondary prevention strategies to reduce the public health impact of CHD **· Increased awareness among stakeholders of issues and disparities among U.S. children with CHD and their caregivers** **· Improved ability to develop surveillance programs to understand the outcomes of individuals with CHD**	· Improved health among children and adolescents with CHD · Improved quality of life of children and adolescents with CHD and their caregivers · Improved continuity of care of individuals with CHD

and experiences of caregivers <u>Dissemination</u> · Share information with stakeholders, communicate results			

i. Purpose

This NOFO supports population-based surveillance of children with CHD to examine childhood and adolescent outcomes as well as needs and experiences of their caregivers. High-quality data will improve understanding of the epidemiology and public health significance of CHD. Surveillance data will also allow monitoring of special sub-populations with CHD (e.g., racial/ethnic, sociodemographic diversity), and potentially identify factors to inform development of effective secondary prevention strategies.

ii. Outcomes

As identified in the logic model, the following are the outcomes the recipient is expected to achieve during the period of performance:

<u>Short-term outcomes:</u>

- Improved understanding of healthcare barriers, utilization, and other outcomes
- Improved understanding of needs and experiences of caregivers of individuals with CHD
- Improved understanding of racial/ethnic and socioeconomic patterns in experiences and outcomes
- Improved understanding of the strengths and limitations of population-based surveillance among children and adolescents with CHD
- Improved information to stakeholders on outcomes of children with CHD and needs/experiences of caregivers

<u>Intermediate outcomes:</u>

- Increased awareness among stakeholders of issues among U.S. children with CHD and their caregivers
- Improved ability to develop surveillance programs to understand the outcomes of individuals with CHD

iii. Strategies and Activities

The logic model presents the strategies and component activities to be undertaken to achieve the period of performance outcomes.

<u>Program Planning</u>

- Identify and engage partners: Demonstrate effective relationships and cooperation with appropriate partners (e.g., birth defects surveillance program, state health department).
- Identify and prioritize program goals: Identify goals, measurable objectives, performance measures, responsible parties, and timeline to achieve the desired outcomes of the project.

- Develop a management and staffing plan for implementation of this program.
- Applicant must identify and describe any database or data transmission restrictions and whether and how these restrictions may limit descriptive analyses and reporting of results required by this NOFO.
- Describe how information about this project will be disseminated to stakeholders (meetings, leadership briefings, newsletters, website, etc.)
- Participate on all cooperative agreement calls and on-site meetings. All sites will have at least one representative on all group calls and will lead projects on a shared basis.
- Join the CDC shared project folder where all NOFO # DD22-2203 documents (e.g., meeting minutes, project protocols) will be stored. All recipients are expected to post relevant documents to this folder during the period of performance.
- Update CDC and other recipients monthly on project status and outputs. Maintain recipient-specific documentation on data sources, collection methods, linkage, data quality assessment.

Tracking and Tracing and Recruitment

- Access, link, and use data from birth defects surveillance systems with active case-ascertainment to identify eligible cases with CHDs. Applicants should demonstrate, through memorandums of understanding/ agreement (MOUs/MOAs) and/or letters of support from the owners of the data and/or any revelant authorities. the ability to access and share the data per the NOFO guidelines. Applicants must file the MOUs or MOAs, as appropiate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov .
    - Applicants must confirm that from CYs 2006-2021, a minimum of **30,000** births per year occurred within the catchment area of their proposed birth defect surveillance system.
- Eligible cases
    - Born between 2006-2021
    - Identified in a birth defect surveillance registry with active case ascertainment and eligible ICD-9-CM/BPA (or equivalent ICD-9-CM/ICD-10-CM) CHD codes
        - All cases with CHD codes in Appendix A must be included, at a minimum.
        - Recipients are encouraged to expand upon the included list of CHDs (i.e. identify and include children with CHDs outside of the list in Appendix A). Applicants should list the additional CHD codes captured by their birth defect surveillance system that they would like to propose for inclusion, if funded. A final list of eligible CHD cases will be discussed and agreed upon with CDC.
- Establish vital status of cases: Link identified cases to death certificate data to establish vital status. Recipients should link to in-state death certificates, at minimum. If possible, recipients should further attempt to link birth defects surveillance data to out-of-state death certificates or the National Death Index.

- Leverage online databases and search engines to track and trace current contact information of parents/caregivers of eligible cases with CHD, including those who have moved out-of-state
    - Tracking and tracing must be performed at the individual level. The more limited quality and completeness of data produced from batch tracing will not be sufficient for this project.
    - Applicant must describe in detail all databases for tracking and tracing that they currently have the ability to link to and all databases they have future plans to link to (e.g. Accurint, Whitepages, and other databases that may include current contact information such as Women, Infants, and Children [WIC] or Department of Motor Vehicles [DMV]). Applicants should further specify the owners of each database and which databases will identify current contact information for parents/caregivers who currently reside out-of-state.
    - At a minimum, the recipient should plan to abstract the following information from the respective birth defects surveillance systems and vital records data to use in tracking and tracing:
        - Birth date
        - Race and/or ethnicity
        - Last name of infant with CHD
        - Mother's maiden name and/or married name
        - City and county of birth and zip code of residence
- Provide input on formatting of survey material and standardized recruitment procedures
- Using address information from tracking and tracing, mail surveys and other recruitment materials to parents/ caregivers of eligible cases with CHD to participate in survey project

<u>Data Management and Reporting</u>

- Collect/store standardized data from birth defect surveillance system, vital records, and from operational processes including tracking & tracing and recruitment
    - Applicants must provide letters of support or a memorandum of agreement / understanding / engagement, or other documentation from the agency authorized to grant access to each required data source that may be used for tracking and tracing (e.g., vital records, WIC, DMV, etc), linked to additional data sources, submitted to CDC, and distributed to other recipients as a multi-site dataset for analyses. The letters of support or agreement must specify all the years for which data are available and state that data access is granted (or will be granted, if the applicant is awarded, along with a reasonable timeline for obtaining access), as well as any limitations regarding data use. If applicable, a copy of these documents should accompany each application.
    - Recipients will use a standardized REDCap database to organize and manage their tracking and tracing and recruitment processes. All recipients will be responsible for using and maintaining the database to facilitate and evaluate the progress of both locating and recruiting participants. This database will be site-specific; sites will use this information to monitor their progress and inform CDC

of the number and status of eligible adults tracked and traced and, if unsuccessful, the reason why.
    - All completed survey data will be collected and managed by CDC - Return envelopes for completed surveys will include CDC's address. CDC will inform project staff from funded sites upon receipt of surveys completed by individuals recruited by their site so that recipients can update their database.

- Geocode address at birth and, for survey responders, address at time of survey, and link to census tract-level indicators of socioeconomic status (e.g. percent of families in the census tract living below the federal poverty level). Link birth defects surveillance, vital status information, tracking and tracing status, recruitment status, and census tract level indicators to create a standardized dataset for submission to CDC.
- Following an established and agreed-upon timeline, submit standardized de-identified individual-level data to CDC, including standardized data elements using a common database in a secure manner. CDC will link site-transmitted data to survey data to create a complete project analytic dataset. CDC has a secure network that will be used for this project and recipients will need to obtain and maintain access
    - Under applicable grant regulations in 45 CFR 75.322, CDC is authorized to collect data first produced under a funded award. All data submitted to CDC becomes subject to applicable federal law, including but not limited to the Freedom of Information Act and Federal Records Act.
- Before and after submission to CDC, assess site-specific and pooled datasets for data quality and completeness; collaborate with other recipients and CDC on data formatting and cleaning decisions
- Compare and assess differences between survey respondents and non-respondents
- Describe population of individuals born between 2006-2021 with CHD and their caregivers, including
    - cardiac and other healthcare utilization,
    - barriers to health care, quality of life,
    - social and educational outcomes,
    - transition of care from childhood to adulthood,
    - mortality
    - needs and experiences of the caregivers
- Decide upon priority analyses using pooled data from all recipients with CDC and other recipients.
- Conduct analyses of multi-site data from all recipients.

<u>Dissemination</u>

- Use the multi-site data to communicate project information and results to healthcare providers, patients, families, stakeholders, the public, and other target audiences via publications, presentations, and other methods, together with CDC and other recipients.
- Participate in collaborative projects/manuscripts using multi-site data whenever possible, with CDC and other recipients.

1. Collaborations

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

Collaborate with CDC and other NOFO #DD22-2203 recipients and provide input on standardized processes, methods, standardization of data collection and analysis, dissemination, and other project activities.

b. With organizations not funded by CDC:

- Demonstrate effective relationships and cooperation with appropriate partners (e.g., birth defects surveillance program, state or local officials, cross-department personnel, including informatics personnel, community-based organizations, medical centers specializing in congenital heart defects). Applicants must provide letters of support or a memorandums of understanding/agreement (MOUs/MOAs), or other documentation from the agency authorized to grant access to each required data source: 1) birth defects surveillance data; 2) data that may be used for tracking and tracing (e.g., vital records, DMV, etc.). The letters of support or agreement must specify all the years for which data are available and state that data access is granted (or will be granted, if the applicant is awarded, along with a reasonable timeline for obtaining access), de-identified data linked to survey data and census data can be shared with CDC and other NOFO recipients, as well as any limitations regarding data use. If applicable, a copy of these documents should accompany each application. Applicants must file the MOUs or MOAs, as appropriate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov.
  Grant regulations found at 45 CFR Part 75 apply to this NOFO, which govern the CDC's access to data being collected or developed under a grant/cooperative agreement, thereby negating the need for a Data Use Agreement (DUA) with CDC on this project.

2. Target Populations

Applicants should describe the population of individuals born between 2006-2021 who have been diagnosed with the CHDs identified by diagnosis codes in Appendix A at a minimum, as evidenced by inclusion in a population-based birth defects surveillance system with active case-ascertainment, including demographics such as race/ethnicity, socioeconomic status, and rural/urban distribution. Recipients are encouraged to expand upon the included list of CHDs (i.e., identify and include children with CHDs outside of the list in Appendix A). Therefore, applicants should list the additional CHD codes captured by their birth defect surveillance system that they would like to propose for inclusion, if funded.

a. Health Disparities

Surveillance data should be population-based, and not limited to children and adolescents receiving healthcare, receiving cardiology care, or based on type of health insurance (e.g., Medicaid). The applicant's defined geographic area and population covered should include all children with the CHDs listed in Appendix A at a minimum. To address health disparities, data reported to CDC will include, but are not limited to ethnicity, race, gender, geography (e.g., rural, urban), and language spoken at home.

iv. Funding Strategy

Not Applicable

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and progress reports:
Prepare a written assessment of the accomplishments, challenges, and opportunities of the CHD surveillance project including, but not limited to problems encountered, lessons learned, and potential improvements. CDC will work with recipients to finalize measures within the first six months of the period of performance.

Strategies and Activities:

- Program planning activities: identify/engage partners, prioritize program goals. Indicators for success:
    - Partners are identified and letters of support are included in application.
    - Updates are provided to CDC on routine partner meetings and calls.
    - Program goals are identified and prioritized.

- Project management activities: develop a management and staffing plan; develop and implement a communication plan. Indicators for success:
    - Comprehensive management and staffing plan provided in application.
    - Communication plan developed and implemented.

- Case identification activities: use population-based birth defects surveillance systems with active case-ascertainment to identify eligible cases with CHDs. Cases must be included for each of the birth years between 2006-2021 and have at a minimum, but not limited to, the CHD diagnoses listed in Appendix A. Indicators for success:
    - Identified all individuals born between 2006-2021 with CHD, including, but not limited to the CHD diagnoses in Appendix A, from a population-based birth surveillance program with active case-ascertainment.
    - Recipients are encouraged to expand upon the included list of CHDs (i.e., identify and include children with CHDs outside of the required list in Appendix A). Applicants should list the additional CHD codes captured by their birth defect surveillance system that they would like to propose for inclusion, if funded.

- Tracking and tracing activities: link identified cases to state vital records data, at minimum, and National Death Index data if available, to establish vital status and cause(s) of death. Leverage online databases and search engines to track and trace current contact information of parents/caregivers of cases with CHD. Indicators for success:
    - Vital status and if applicable, cause of death, have been established for cases
    - Most recent addresses have been identified for parents/caregivers of cases

- Recruitment activities: Recruit parents/caregivers of eligible cases with CHD to participate in survey project, distribute survey materials. Indicators for success:
    - Surveys and related materials have been finalized
    - Parents/caregivers of eligible cases have been contacted and survey materials have been distributed

- Data management and reporting activities: Standardize birth defect surveillance system, tracking & tracing, and recruitment data; geocode address at birth and, for survey responders, address at time of survey and link to census tract socioeconomic indicators; link birth defects surveillance data, vital status information, tracking & tracing status,

recruitment status, and census tract-level socioeconomic indicators for each individual; create standardized dataset. Indicators for success:

- Standardized tracking and recruitment database has been developed and maintained
- Birth defects surveillance data, vital status, census tract-level indicators, and indicators of tracking/tracing and recruitment success have been developed and standardized
- All de-identified individual level data on all respondents and non-respondents has been submitted to CDC within agreed benchmarks and timeframes.
    - Under applicable grant regulations in 45 CFR 75.3222, CDC is authorized to collect data first produed unfer a funded award. All data submitted to CDC becomes subject to applicable federal law, including but not limited to the Freedom of Information Act and Federal Records Act.

- Data assessment activities: Jointly with CDC and other funded recipients and using multi-site data, assess quality of data, compare respondents to non-respondents, describe outcomes of children and adolescents with CHD, describe needs and experiences of caregivers. Indicators for success:
    - Prior to submission to CDC, site-specific data has been assessed and cleaned
    - Data cleaning plan for multi-site data has been developed; multi-site analytic dataset distributed by CDC has been assessed to confirm no further cleaning is needed.
    - Information on respondents and non-respondents has been compared and documented.
    - Multi-site data analysis plan developed, and descriptive statistics generated on child/adolescent population with CHDs
    - Outcomes including cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care from childhood to adulthood, and mortality for children and adolescents with CHD have been assessed.
    - Needs and experiences of the caregivers of children and adolescents with CHD have been assessed.
    - Racial/ethnic, socioeconomic, or rural/urban differences in outcomes and caregiver needs have been assessed.

- Dissemination activities: share project information results. Indicators for success:
    - Communication plan is developed with input and assistance from CDC and implemented.
    - Information shared regularly with CDC and other recipients.
    - Multi-site project information and results communicated to target audiences via publications, presentations, and other methods.

Outputs:

- Population-based cohort of children and adolescents born between 2006-2021 with CHDs

    - Indicator for success: population-based cohort of children and adolescents with CHDs has been developed, submitted to CDC, included in multi-site database, analyzed, and findings disseminated.

- Information on outcomes including cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care from childhood to adulthood, and mortality
    - Indicator for success: multi-site report(s) on outcomes of children and adolescents with CHDs has/have been drafted and disseminated.

- Information of needs and experiences of the caregivers of children and adolescents with CHD
    - Indicator for success: multi-site report(s) on needs and experiences of the caregivers of children and adolescents with CHDs has/have been drafted and disseminated

Outcomes:

- Improved understanding of age-specific mortality
    - Indicator for success: dissemination of multi-site publication(s) and conference presentations/webinars for stakeholders that describe the age-specific mortality of children and adolescents with CHDs

- Improved understanding of healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care, and mortality
    - Indicator for success: dissemination of multi-site publication(s) and conference presentations/webinars for stakeholders that describe the outcomes of children and adolescents with CHDs, including healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care, and mortality

- Improved understanding of racial/ethnic and socioeconomic disparities in healthcare use and longer-term outcomes
    - Indicator for success: dissemination of multi-site publication(s) and conference presentations/webinars for stakeholders that describe the racial/ethnic and socioeconomic disparities in healthcare use and longer-term outcomes among children and adolescents with CHDs

- Improved understanding of needs and experiences of caregivers of individuals with CHD
    - Indicator for success: dissemination of multi-site publication(s) and conference presentations/webinars for stakeholders that describe the needs and experiences of caregivers of individuals with CHD

- Increased awareness among people living with CHD, families affected by CHD, healthcare and social service providers, and public of nationwide CHD issues
    - Indicator for success: dissemination of multi-site publication(s) and their key messages through various media, and conference presentations/webinars for stakeholders that increase awareness of nationwide CHD issues.

Data Management Plan (DMP)

Applicants should submit a DMP in their application as part of their Evaluation and Performance Management Plan. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds. The DMP may be outlined in a narrative format or as a checklist, but, at a minimum, should include:

- Description of the data to be produced in the proposed project
- How access will be provided to the data (including provision for protection of privacy, confidentiality, security, intellectual property, or other right)
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
- Plans for archival and long-term preservation of the data or explaining why long-term preservation and access cannot be justified

Examples of DMPs include: the USGS site: https://www.usgs.gov/products/data-and-tools/data-management/data-management-plans.

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

Strong applicants must describe the level of organizational capacity necessary to implement the NOFO successfully.

In their description of organizational capacity, applicants should elaborate on:

- Staff with skill sets to implement the awards such as: program and performance management, CHDs clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development including publication of original manuscripts, evaluation, performance monitoring, informatics, and financial reporting.
    - CVs of existing staff should be included. If there are any vacant positions, the applicant should include a job description (including applicant qualifications) and address both the recruiting strategies and estimated timeline for filling the position.
- Collaborations with birth defects surveillance programs and state health departments
    - Applicants should identify the geographic region and characteristics of eligible cases captured in the birth defect surveillances system
- Their ability to begin immediate implementation of the NOFO activities
- Any previous experience successfully recruiting participants, administering surveys, managing data, and disseminating findings in a timely manner as the lead author/lead organization
- Their capacity to lead and publish original manuscripts in a timely manner, as evidenced by citations of recent first- or senior-author publications
- Describe the availability of facilities and equipment necessary to carry out this project.

Furthermore, applicants must have the public health authority, legislative mandate, or otherwise show legal access to the requisite surveillance data from 2006-2021 and ability to share de-identified individual-level data with CDC. Under applicable grant regulations in 45 CFR 75.3222, CDC is authorized to collect data first produed unfer a funded award. All data submitted to CDC becomes subject to applicable federal law, including but not limited to the Freedom of Information Act and Federal Records Act. Applicants should demonstrate, through MOUs/MOAs and/or letters of support from data owners or relevant authorities, the ability to access and share the data per the NOFO guidelines. Applicants must file the MOUs or MOAs, as appropriate, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov. Applicants must address HIPAA and IRB requirements and must provide letters of support from agencies that house source data authorizing its use for case-finding, access, and sharing required data.

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.

- In this format, the table would be completed for each period of performance outcome. If a particular activity leads to multiple outcomes, it should be described under each outcomes 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.			

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.

Within 6 months after the period of performance start date, CDC and the funded recipients will finalize the work plan and performance measures.

f. CDC Program Support to Recipients

Functioning as an additional surveillance site, CDC will identify eligible CHD cases using data derived from the Metropolitan Atlanta Congenital Defects Program and will perform tracking and tracing, recruitment, and data linkage for these cases. All survey data from survey participants across all sites will be collected and entered by CDC. Additionally, CDC will provide the following support to recipients:

- Provide advisory technical assistance on key design and methodological issues.
- Facilitate the communication/coordination among recipients regarding standardization of procedures and tools to improve the efficiency of activities.
- Collaborate with recipients on developing timelines for data transmission and other key activities.
- Develop survey instruments and submit for Office of Management and Budget approval; collaborate with recipients on minor modifications to the survey, formatting of survey material, and standardized recruitment procedures
- Assist in the development of a standardized database used by recipients to organize and manage tracking and tracing and recruitment processes.
- Convene recipients regularly by conference call and in-person to support collaboration and shared learning.
- If needed, provide on-line webinars and in-person training.
- In collaboration with recipients, develop and provide a template for the central reporting of de-identified, individual-level data sets.
- Assist in performing data analysis and/or quality assurance verification.
- Develop and maintain the centralized database used by recipients for the transmission of de-identified, de-duplicated individual level data. Compile data across sites and perform quality reviews of data.
- Work with recipients to develop priority reports and publications.
- Analyze data and author/coauthor reports and publications.
- Assist with evaluation of the project.

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:

U50
Special Cooperative Investigations/Assessment of Control/Prevention Methods

3. Fiscal Year:
2022

4. Approximate Total Fiscal Year Funding:
$1,000,000

5. Total Period of Performance Funding:
$4,000,000
This amount is subject to the availability of funds.

Estimated Total Funding:
$4,000,000

6. Total Period of Performance Length:
4

year(s)

7. Expected Number of Awards:
3
Range: 2-4 awards

8. Approximate Average Award:

$350,000
Per Budget Period

9. Award Ceiling:
$400,000
Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor:
$150,000
Per Budget Period

11. Estimated Award Date:
August 31, 2022

12. Budget Period Length:
12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown

in the “Notice of Award.” This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

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

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

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
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")

2. Additional Information on Eligibility

Only one application per organization as determined by the organization’s Dun & Bradstreet number will be accepted.

Eligible applicants must have the public health authority, legislative mandate or otherwise show legal access to the requisite data to conduct population-based birth defects 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. Eligible applicants must document this authority in "Other Attachment Forms" with attachment name "Legal Authority". 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 or local government as eligible to submit an application in lieu of a state or local government application. If applying as a Bona Fide agent of a state or local government, a letter from the state or local 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 award ceiling for this NOFO is $400,000. CDC will consider any application requesting an award higher than the ceiling amount as non-responsive and it will receive no further review.

3. Justification for Less than Maximum Competition

Not Applicable

4. Cost Sharing or Matching

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

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

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

PLEASE NOTE: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission (SF-424, field 8c). In preparation for the federal government's April 4, 2022 transition to the Unique Entity Identifier (UEI) from the Data Universal Numbering System (DUNS), applicants must obtain a UEI. 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. Entities registering in SAM.gov prior to April 4, 2022 must still obtain a DUNS number before registering in SAM.gov registration. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number to register in SAM.gov prior to April 4, 2022. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B).

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number will be provided at no charge.

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

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number 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 at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.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	Data Universal Number System (DUNS) (Required	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit #	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/

	until April 4, 2022)	4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number		webform) or call 1-866-705-5711
2	System for Award Management (SAM)	1. Retrieve organizations DUNS number (required until April 4, 2022) 2. 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
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS 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	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

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 notice of 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)

04/22/2022

b. Application Deadline

05/28/2022
11:59 pm U.S. Eastern Standard 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 Information Conference Call
4/26/2022; 1:00
EDT; Zoom https://cdc.zoomgov.com/j/1618323691?pwd=WTkxUTdJYXZuV0RvZXhhaUt4TUh5QT09
Meeting ID: 161 832 3691; Passcode: $Ba0JKDv
Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
Meeting ID: 161 832 3691; Passcode: 49531055

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 DUNS.

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

Duplication of Efforts

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

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

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

7. Letter of Intent

A 1–2-page LOI is requested, but not required. The purpose of a LOI is to provide CDC program staff the estimated number of applications and plan the review of the submitted applications.

LOIs may be sent via e-mail to:

Kandi Givner
CDC, NCBDDD

Telephone number: 404.498.2694
Fax number: 770.488.3263 / 3266
Email address: xla7@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

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov. The Project Narrative must include **all** of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

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

b. Approach

i. Purpose

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

ii. Outcomes

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

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing 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 project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

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

2. Target Populations and Health Disparities

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

c. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

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

d. Organizational Capacity of Applicants to Implement the Approach

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

11. Work Plan

(Included in the Project Narrative's page limit)

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

12. Budget Narrative

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

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

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

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

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national

standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and 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.

Applicants should include travel costs for 3 days/2 nights to CDC (Atlanta, GA) for 1 recipient meeting for a minimum of 2 project staff per year. Applicants should also include costs to reimburse eligible participants, in the form of a gift card, for survey completion.
The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address:
http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective

oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

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

14. Pilot Program for Enhancement of Employee Whistleblower Protections

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

15. Copyright Interests Provisions

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

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

16. Funding Restrictions

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

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

Recipients may not use funds for the same activities that are being or were funded from another source.

17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:
https://www.cdc.gov/grants/additional-requirements/ar-25.html.

18. Other Submission Requirements

a. Electronic Submission:

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

b. Tracking Number: Applications submitted through 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 when www.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 by www.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= Get_Started%2FGet_Started. htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.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 that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.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 CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the 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

Background and Understanding of the Public Health Burden and Impact (5 of 40 Points)

- To what extent does the applicant demonstrate a clear, concise understanding of the requirements, objectives, and purpose of this NOFO that are aligned with the activities, outputs, and outcomes in the CDC Project Description?
- To what extent does the applicant describe the composition of and data available from the surveillance birth population, including a description of: the population-based birth defect surveillance system and its active case-finding methods (i.e. surveillance program staff regularly contact health care providers to ascertain new cases) which will be used to identify all eligible CHD cases in the catchment area; the number of births per year in catchment area by race/ethnicity; the number and prevalence of CHDs captured annually between 2006 and 2021; and the expected size of the case population for tracking and tracing? If the applicant will be using data for a subset of the state (e.g., selected counties), this must be clearly described. The number of total

births in the catchment area must meet the minimum 30,000 births per year for 2006-2021.

Work Plan (15 of 40 Points)

- To what extent do the activities describe the proposed intent to conduct comprehensive population-based surveillance among children and adolescents born between 2006-2021 with CHDs? Are the outcome measures clear and measurable to address the need and the main activities of this NOFO?
- To what extent is the plan to carry out the proposed objectives? Does the project plan include a comprehensive plan for the first budget period? Does the plan include quantitative process and outcome measures?
- To what extent does the applicant include a realistic, accurate, and achievable timeline to complete the activities in the specified period of performance?
- To what extent does the applicant describe their planned collaboration and demonstrate relationships with appropriate partners both internal and external to the state health department?

Methods (20 of 40 Points)

- To what extent are the proposed methods for case identification, tracking and tracing, recruitment, data linkage, data collection, and data reporting feasible? Do they clearly describe the processes to be used to accomplish the work plan within the project timeframe?
- Does the applicant plan to identify and include children with CHDs outside of the minimally required list of CHDs in Appendix A? If so, to what extent does that applicant describe the CHDs they plan to include (e.g. the specific diagnoses codes, the severity of the defects, the number/prevalence of cases) and how these plans will improve generalizability of project outputs?
- To what extent does the applicant describe methods and data sources that will be used to determine vital status of cases? To what extent will these data sources identify both in- and out-of-state deaths?
- To what extent has the applicant identified appropriate staff to conduct tracking and tracing and an appropriate timeline given the number of proposed cases?
- To what extent does the applicant describe methods and data sources that will be used to determine current contact information of the caregivers during tracking and tracing? To what extent will these data sources identify current contact information of caregivers of cases who reside both in and out of state?
- To what extent does the applicant describe plans to maintain a database to track, facilitate, and evaluate the progress of both locating and recruiting participants?
- To what extent does the applicant describe any restrictions to transmitting individual level, de-identified, de-duplicated data from the birth defect surveillance system or other data sources and how they might address these issues to ensure required de-identified data is submitted to CDC and accessible to all recipients for data analysis?
- To what extent does the applicant describe how they will share individual level, de-identified, de-duplicated data with CDC?

- To what extent does the applicant describe intended collaboration with CDC and other NOFO recipients on the development of recruitment materials and standardized recruitment procedures, standardization of databases and data elements, assessment of data quality, data analyses, and dissemination of multi-site findings as well as participation on group calls?

ii. Evaluation and Performance Measurement **Maximum Points:** 30

- To what extent does the applicant's Evaluation and Performance Measurement Plan include and adequately describe quantitative and qualitative process and outcome measures and a Data Management Plan?
- To what extent does the applicant describe how they will achieve these measures and alternative actions if not met?
- To what extent does the applicant describe the evaluation of the key components of the project, such as identifying cases with eligible CHD codes from birth defects surveillance system data, conducting data linkages to other relevant datasets including vital records and census data, tracking and tracing caregivers of eligible cases for current residence, recruiting parent/caregivers to participate in the survey, data collection, reporting, assessment, and communicating findings to stakeholders?

iii. Applicant's Organizational Capacity to Implement the Approach **Maximum Points:** 30

- To what extent has the applicant identified appropriate staff for program and performance management, CHD clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development, evaluation, performance monitoring, and financial reporting? To what extent do the identified staff members have relevant experience and expertise in their respective areas? Are CVs provided for staff?
- To what extent does the applicant describe their collaborations with birth defects surveillance programs and state health departments?
- If additional staff or consultants are needed, to what extent has the applicant demonstrated the ability to identify and hire needed staff and consultants in a timely manner? Are short position descriptions and hiring timeline provided for vacant positions? Has the applicant demonstrated the ability to identify and hire sub-recipients?
- To what extent does the applicant describe their ability to begin immediate implementation of the NOFO activities?
- To what extent does the applicant provide evidence of legal authority (via letters of support or other documents) to access the relevant data sources and to share de-identified, de-duplicated individual-level data with CDC and other NOFO #DD22-2203 recipients, including addressing any HIPAA and IRB requirements? Examples of past access and transmission should be described. Applicants must provide letters of support from agencies that house source data authorizing its use for case-finding, access, and sharing of required data.

- To what extent does the applicant show evidence of previous experience successfully recruiting participants, administering surveys, managing data, and disseminating findings in a timely manner as the lead author/lead organization?
- To what extent does the applicant demonstrate capacity to lead and publish original manuscripts in a timely manner, as evidenced by citations of recent first- or senior-author publications?

Budget **Maximum Points:** 0

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.

To what extent does the applicant describe and indicate the availability of facilities and equipment necessary to carry out this project.

To what extent did the applicant agree to use cooperative agreement funds for travel by project staff to participate in CDC-sponsored workshops and regional annual meetings.

If the applicant requests indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. The indirect cost rate agreement should be uploaded as a PDF file with "Other Attachment Forms" when submitting via Grants.gov.

c. Phase III Review

CDC may fund applications out of rank order in consideration of the following factors:

- Number of cases to be included, tracked and traced. Applicants proposing a larger number of cases may be prioritized.
- Diversity of identified CHD cases in terms of race/ethnicity and socioeconomic status. Applicants demonstrating greater diversity of identified CHD cases may be prioritized.
- Geographic location and diversity of the multi-site data (i.e. statewide or select counties, urban/rural diversity, region). Applicants offering data from different geographic regions and/or with more geographic diversity than other applicants may be prioritized.
- Availability of funds and program priorities.

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

Awards are anticipated to be announced in August 2022 with a 9/30/2022 start date.

F. Award Administration Information

1. Award Notices

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

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

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

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

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

AR-1: Human Subjects Requirements
AR-8: Public Health System Reporting Requirements
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2020
AR-12: Lobbying Restrictions
AR-14: Accounting System Requirements
AR-15: Proof of Non-profit Status
AR-21: Small, Minority, And Women-owned Business
AR 23: Compliance with 45 C.F.R. Part 87
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Data Management and Access
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR-31: Research Definition
AR-32: Appropriations Act, General Provisions
AR-34: Language Access for Persons with Limited English Proficiency

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 must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. 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.

• Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. 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 taking appropriate steps 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	6 months into award	Yes

Plan, including Data Management Plan (DMP)		
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 period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

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

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

Performance Measurement

• Performance measures and targets
• The frequency that performance data are to be collected.
• How performance data will be reported.
• How quality of performance data will be assured.
• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
• Dissemination channels and audiences.
• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).
• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publically available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on

improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

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

b. Annual Performance Report (APR) (required)
The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

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

- SF-424A Budget Information-Non-Construction Programs.
- Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

The recipients must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

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

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

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

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

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

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

Program Office Contact

For programmatic technical assistance, contact:

First Name:
Kandi

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

Address:
Mailstop S106-3, 4770 Buford Highway, Atlanta, GA 30341-3717

Telephone:
404-498-2694

Email:
xla7@cdc.gov

Grants Staff Contact

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

First Name:
Rhonda

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

Address:
2939 Flowers Rd.
Atlanta, GA 30341

Telephone:
404-498-4104

Email:
RMelancon@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

Bona Fide Agent status documentation, if applicable

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 compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

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

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

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

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

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).

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

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

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

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

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

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

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

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

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

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

NOFO-specific Glossary and Acronyms

AMENDMENT #1: ***Amended Part I Section F.3 and Part II Section D.4.b to include date and login for the 4/26/2022 NOFO informational Zoom meeting.***

Appendix A - Minimum list of congenital heart defects to be ascertained by NOFO recipients

ICD-9-BPA	Description
745000	Truncus arteriosus
745100	Dextro-transposition of great arteries with intact ventricular septum
745110	Dextro-transposition of great arteries with ventricular septal defect (VSD)
745200	Tetralogy of Fallot
745200 plus 746020	Tetralogy of Fallot plus absent pulmonary valve
745200 plus 745510	Pentalogy of Fallot
746000	Pulmonary valve atresia/intact ventricular septum
746030	Pulmonary valve atresia with VSD
746100	Tricuspid atresia
746700	Hypoplastic left heart syndrome
747100	Coarctation of the aorta, preductal (proximal)
747110	Coarctation of the aorta, postductal (distal)
747120	Coarctation of the aorta, juxtaductal
747190	Coarctation of the aorta, NOS
747310	Pulmonary atresia with VSD (tetralogy of Fallot variant)
747420	Total anomalous pulmonary venous return/connection/drainage

ICD-9-CM	Description
745.0	Truncus arteriosus
745.10	Dextro-transposition of the great arteries
745.19	Dextro-transposition of the great vessels
745.2	Tetralogy of Fallot
746.01	Pulmonary valve atresia
746.1	Tricuspid atresia
(747.3 or 746.01) plus 745.4	Pulmonary atresia with VSD
(747.31 or 746.01) plus 745.4	Pulmonary atresia with VSD
746.7	Hypoplastic left heart syndrome
747.10	Coarctation of the aorta
747.41	Total anomalous pulmonary venous return

ICD-10-CM	Description
Q20.0	Common arterial trunk
Q20.3	Discordant ventriculoarterial connection
Q20.5	Discordant atrioventricular connection
Q20.8	Other congenital malformations of cardiac chambers and connections
Q20.9	Congenital malformations of cardiac chambers and connections, unspe
Q21.3	Tetralogy of Fallot

Q22.0	Pulmonary valve atresia
Q22.0 plus Q21.0	Pulmonary valve atresia with VSD
Q22.3 plus Q21.0	Other congenital malformations of pulmonary valve with VSD
Q22.4	Congenital tricuspid stenosis
Q22.6	Hypoplastic right heart syndrome
Q23.4	Hypoplastic left heart syndrome
Q25.1	Coarctation of aorta
Q25.2 (includes Q25.21 and Q25.29)	Atresia of aorta
Q25.5 plus Q21.0	Atresia of pulmonary artery with VSD
Q26.2	Total anomalous pulmonary venous connection
Q26.4	Anomalous pulmonary venous connection, unspecified