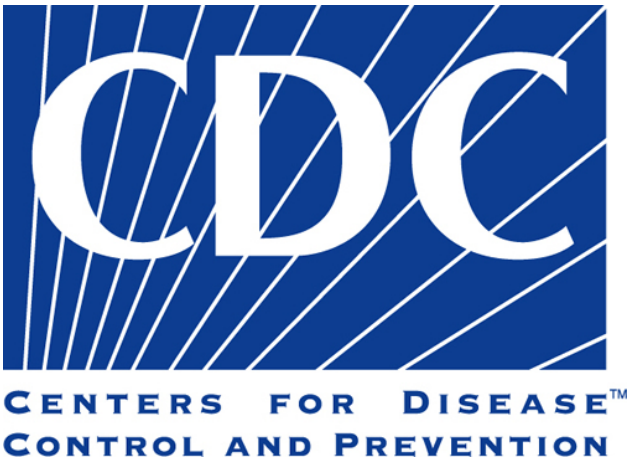


Centers for Disease Control and Prevention

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Surveillance of Congenital Heart Defects Among Children, Adolescents, and Adults

CDC-RFA-DD-24-0051

05/14/2024

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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-DD-24-0051. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Notice of Funding Opportunity (NOFO) Title:

Surveillance of Congenital Heart Defects Among Children, Adolescents, and Adults

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 purposes of this NOFO, research is defined as set forth in 45 CFR 75.2 and, for further clarity, as set forth in 42 CFR 52.2 (see eCFR :: 45 CFR 75.2 -- Definitions and *https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf*. In addition, for purposes of research involving human subjects and available exceptions for public health activities, please see 45 CFR 46.102(l) (*https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102#p-46.102(l)*).

New- Type 1

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DD-24-0051

E. Assistance Listings Number:

93.073

F. Dates:

1. Due Date for Letter of Intent (LOI):
03/18/2024
Recommended but not Required
March 18, 2024

2. Due Date for Applications:
05/14/2024
11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call
Topic: DD24-0051 CHD STAR 2 NOFO - Informational Call

Time: Mar 27, 2024 11:00 AM Eastern Time (US and Canada)

Join ZoomGov Meeting

https://cdc.zoomgov.com/j/1610383146?pwd=d0R6bXgrSk9sdW9YWEpJVHBWWGZ6UT09

Meeting ID: 161 038 3146

Passcode: 8.^thV?E

One tap mobile

+16692545252,,1610383146#,,,,*57472469# US (San Jose)

+16468287666,,1610383146#,,,,*57472469# US (New York)

Dial by your location

• +1 669 254 5252 US (San Jose)

• +1 646 828 7666 US (New York)

• +1 646 964 1167 US (US Spanish Line)

• +1 415 449 4000 US (US Spanish Line)

• +1 551 285 1373 US (New Jersey)

• +1 669 216 1590 US (San Jose)

Meeting ID: 161 038 3146

Passcode: 57472469

Find your local number: https://cdc.zoomgov.com/u/adbU2aKUYw

Join by SIP

• 1610383146@sip.zoomgov.com

Join by H.323

• 161.199.138.10 (US West)

• 161.199.136.10 (US East)

Meeting ID: 161 038 3146

Passcode: 57472469

G. Executive Summary:

Summary Paragraph

NOFO # DD24-0051 solicits non-research, cooperative agreement applications to conduct population-based surveillance of congenital heart defects (CHD) to describe health outcomes including health equity, with the goal of identifying opportunities to improve the health of all people living with CHD. This project will involve a required component (A) and an optional component (B). The population included in this surveillance activity can be an entire state or a region within a state. Individuals with CHD should be identified through existing data sources including the jurisdiction birth defects surveillance system, electronic health records, administrative data (e.g., Medicaid/Medicare, hospital discharge), or other sources available to funding recipients.

a. NOFO Type:

CA (Cooperative Agreement)

b. Approximate Number of Awards

8

Component A: 3-7 awards

Component B: 1 award

c. Total Period of Performance Funding:

$15,500,000

d. Average One Year Award Amount:

$450,000

Component A: Up to $400,000

Component B: Up to $50,000 for Year 1 budget period, up to $300,000/year Years 2-5

e. Total Period of Performance Length:
5 year(s)

f. Estimated Award Date:
September 01, 2024

g. Cost Sharing and / or Matching Requirements:
No

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview
Congenital heart defects (CHD) affect about 1% of all births in the United States and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs. Improvements in early detection and treatment of CHD and consequently in survival have resulted in many people, including those affected by a severe CHD, living into adolescence and adulthood. An estimated two million persons in the U.S. are living with a CHD, including over one million adults; about 12% of these affected adults have a severe CHD. Most current efforts to conduct population-based surveillance of CHD have focused on monitoring newborns. However, limited data exist on the descriptive epidemiology of CHD beyond early childhood in the U.S. Despite the public health burden, the lack of population-based surveillance precludes reliable data on people with CHD, their survival, healthcare utilization, and characteristics associated with long-term outcomes.

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 FY12, CDC funded three recipients to pilot innovative methods of conducting population-based surveillance of adolescents and adults living with CHD, finding that surveillance is feasible, though linkage/deduplication is labor-intensive. In FY15, CDC funded five recipients to develop or expand surveillance of CHD and share individual level, de-duplicated, de-identified data with CDC. For both prior NOFOs, cases were identified through healthcare encounters with CHD diagnosis codes from various data sources. Through these projects we found that CHD diagnosis codes have limitations in identifying CHD cases accurately. Therefore, in FY19, CDC modified surveillance methods to more accurately identify CHD cases, funding seven recipients to conduct surveillance of children, adolescents, and adults with CHD ages 0-55 years over a ten-year surveillance period. These seven recipients were funded to develop new methods to increase

true case identification and assess longer-term outcomes among individuals with CHD. In FY20, CDC funded one recipient to validate billing codes for congenital heart defects in healthcare claims data and determine best ways to use healthcare claims for CHD surveillance across the lifespan, using machine learning and natural language processing.

Through NOFO #DD24-0051, recipients will translate lessons learned from prior NOFOs to conduct population-based surveillance of CHD to describe health outcomes including health equity, with the goal of identifying opportunities to improve the health of all people living with CHD. Component A recipients will identify CHD cases through various data sources, including birth defects surveillance, clinical data, hospital discharge data, and healthcare claims data. Component B will develop and refine a machine learning model that improves accuracy of CHD case identification and will apply the model to data collected through Component A, thereby improving generalizability of results obtained from large administrative datasets and enhancing public health surveillance efforts.

b. Statutory Authorities
This program is authorized under Section 399V-2 of the Public Health Service Act [also cited as 42 U.S.C. 280g-13].

More specifically, CDC acting through the Secretary is authorized to study and track the epidemiology of congenital heart disease to understand health outcomes for individuals with congenital heart diseases across all ages.

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 infant deaths
- Reduce the rate of deaths in children and adolescents aged 1-19 years
- Increase the proportion of children and adolescents who
    - Receive care in a medical home
    - Get support for their transition to adult health care
- Improve cardiovascular health in adults
- Improve cardiovascular health and reduce deaths from heart disease and stroke

Reduce maternal deaths

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 many 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). This program is also aligned 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 (http://www.cdc.gov/ncbddd/heartdefects/research.html).

In FY12 under NOFO #DD12-1207, CDC funded three recipients to pilot innovative methods of conducting population-based surveillance of adolescents and adults living with CHD identified through healthcare encounters from 2008-2010.

In FY15 under NOFO #DD15-1506, CDC funded five recipients to develop or expand their surveillance of CHD and share individual level, de-duplicated, de-identified data with CDC. For both prior NOFOs, cases were identified through healthcare encounters with CHD codes from various data sources in 2011-2013.

In FY19, under NOFO #DD19-1902, Component A, CDC funded seven recipients to conduct surveillance of children, adolescents, and adults with CHD ages 0-55 years over a ten-year surveillance period, 2010-2019. Recipients were funded to develop new methods to increase true case identification and assess longer-term outcomes among individuals with CHD.

In FY20, under NOFO #DD19-1902, Component B, CDC funded one recipient to validate billing codes for congenital heart defects in healthcare claims data and determine best ways to use healthcare claims for CHD surveillance across the lifespan, using machine learning and natural language processing.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Components A & B Program Planning • Identify/engage partners, establish partnership collaborations; prioritize program goals, define source population,	**Component A** • Improved knowledge about the characteristics of individuals identified from multiple data sources • **Improved understanding of:** ○ **age-specific mortality in individuals with CHD**	**Components A & B:** • Improved ability to develop surveillance programs • Improved use of surveillance data to understand the outcomes	**Component A & B:** • Improved health among individuals of all ages with CHD • Improved quality of life of individuals of all

identify data sources Project Management • Develop management and staffing plan • Obtain or demonstrate legal authority to access data Data Reporting • Collect/store standardized data, submit individual-level data to CDC Dissemination • Share information, communicate results • Inform stakeholders on healthcare utilization, comorbidities, and outcomes of individuals with CHD **Component A** Case Identification • Use all available data sources (birth defects registry data, clinical and administrative	○ **healthcare use, comorbidities and outcomes of individuals with CHD** ○ **health equity among individuals with CHD** ○ **racial, ethnic, and socioeconomic patterns in healthcare use and long-term outcomes in individuals with CHD** ○ **Respiratory viruses (including COVID-19, influenza A, influenza B, and RSV) among individuals with CHD with and without current respiratory immunizations** ○ **healthcare use during the COVID-19 pandemic among individuals with CHD** ○ **the potential impact of state and**	of individuals with CHDs • Improved ability of policy-makers to make data-informed decisions • Improved ability to develop effective secondary prevention strategies to reduce the public health impact of CHD Component B: • Improved accuracy of surveillance of CHD	ages with CHD • Improved continuity of care of individuals of all ages with CHD

data) to identify eligible cases with CHD Data collection • Establish vital status of identified cases, link identified cases to other data sources • Geocode address, link healthcare and census data, create standardized dataset Data Assessment • Describe population with CHD • Validate 200-300 randomly selected cases per site (if funded for DD19-1902) • Assess quality and accuracy of data Dissemination • Work with local/state partners to use site-specific CHD data **Component B** Data Assessment	**national healthcare policies on individuals with CHD** • **Increased awareness among stakeholders of nationwide CHD issues** Component B: • Improved understanding of how machine learning algorithms and models can be applied to surveillance data to identify individuals with CHD		

• Develop and refine a machine learning model for the surveillance data collected through Component A • Apply this machine learning model to data collected from all recipients funded through Component A <u>Data Reporting</u> • Document the process from raw data (from Component A) to final classification for complete reproducibility • Submit pre-processed dataset and model via standardized format, model code and documentation, and results (i.e., model's classification for each individual person) to CDC <u>Dissemination</u>			

• Share information, communicate results			

i. Purpose

This NOFO supports population-based surveillance of CHD to describe health outcomes and health equity, with the goal of identifying opportunities to improve the health of all individuals living with CHD.

ii. Outcomes

Short-term outcomes:

Component A:

- Improved knowledge about the characteristics of individuals identified from multiple data sources
- Improved understanding of:
  - age-specific mortality in individuals with CHD
  - healthcare use, comorbidities, and outcomes of individuals with CHD
  - health equity among individuals with CHD
  - racial, ethnic, and socioeconomic patterns in healthcare use and long-term outcomes in individuals with CHD
  - Respiratory viruses (including COVID-19, influenza, and RSV) and immunizations among individuals with CHD
  - healthcare use during the COVID-19 pandemic among individuals with CHD
  - the potential impact of state and national healthcare policies on individuals with CHD
- Increased awareness among stakeholders of nationwide CHD issues

Component B:

- Improved understanding of how machine learning algorithms and models can be applied to surveillance data to identify individuals with CHD

Intermediate outcomes:

Component A:

- Inform stakeholders on healthcare utilization, comorbidities, and outcomes of individuals with CHD

Component B:

- Improved accuracy of surveillance of CHD

iii. Strategies and Activities

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

Program Planning

- Identify and engage partners, establish partnership collaborations: Demonstrate effective relationships and cooperation with appropriate partners (e.g., state officials/state health departments; cross-department personnel, including informatics personnel within state health department; birth defects surveillance programs; medical centers; academic medical centers specializing in CHD; community-based organizations; patient/parent CHD support groups within catchment area/region).
- Identify and prioritize program goals: Identify goals, measurable objectives, and performance measures, responsible parties, and timeline to achieve the desired outcomes of the project.
- Define and describe the source population: Provide a clear definition of the source population (a minimum total population size of the defined geographic region should equal 1 million per year as evidenced by census data). For planning, the three-year time period of 2021-2023 (calendar years) should be used.
- Identify data sources: Name and describe each data source that will be used to identify individuals with CHD. Indicate sources that can be accessed immediately and those that will need additional approvals. Describe any new datasets that might be used, and how access to those will be obtained, and estimated length of time to obtain data. Data should be population-based, or information should be provided on how the data will provide estimates that approximate population-based estimates with respect to racial/ethnic and socioeconomic diversity. Utilization of population-based birth defects surveillance program data is strongly encouraged.

Project Management

- Develop a management and staffing plan for implementation of this program.
- Document legal authority to access data: Provide evidence of legal authority to access each of the proposed data sources and to share de-identified, de-duplicated individual-level data with CDC and other recipients of this cooperative agreement, including addressing any HIPAA and IRB requirements. Examples of past access and data

transmission should be described. It is strongly recommended that applicants provide letters of support (or other documents) from each agency that houses source data authorizing access and sharing of required data. Data elements are included in the Appendix.

- 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 workgroups and will lead projects on a shared basis.
- Update CDC and other recipients regularly (at a minimum, monthly) on project status and outputs. Maintain recipient-specific documentation on data sources, collection methods, linkage, data reconciliation (e.g., how recipient determined race/ethnicity of case when information differed in multiple data sources).

Case Identification

- Use all available data sources (birth defects registry data, clinical and administrative data sources) to identify eligible cases with congenital heart defects (CHD). Applicants should demonstrate, through memorandums of understanding (MOUs) and/or letters of support, the ability to access and share the data per the NOFO parameters. Demonstrate capacity to access, link, and use data from healthcare database(s) to identify individuals with one or more healthcare encounters during 2021-2023.

Eligible cases:

o Will be ages 0-64 years at any time between 2021-2023

o Reside in the source population geographic area at any time during 2021-2023

o Have one or more of the following ICD-10-CM (or equivalent ICD-9-CM or BPA) CHD codes in a case finding data source (birth defects registry data, clinical and administrative data):

Severity	**ICD-10-CM codes**
Severe	Q23.4, Q22.4, Q22.6, Q20.4, Q22.0, Q20.0, Q20.1, Q20.2, Q21.3, Q20.3, Q20.5, Q21.2, Q25.21, Q26.2
Shunt	Q21.0, Q21.1, Q21.8, Q21.9, Q25.0, Q21.4, Q26.3, Q26.4
Valve	Q22.3, Q22.1, Q22.2, Q22.5, Q22.8, Q22.9, Q23.0, Q23.1, Q23.8, Q23.9, Q23.2, Q23.3, Q24.4, Q24.3, Q25.1, Q25.3, Q25.42, Q25.29, Q25.41, Q25.5, Q25.71, Q25.79
Other	Q24.2, Q24.5

Other Vascular	Q25.45, Q25.47, Q25.48

Data collection

- Access and link existing data sources that will be used to assess outcomes of identified cases: demonstrate capacity to access, link (to identified cases), and analyze data from clinics, health providers, vital records, birth defect registries, immunization systems, hospital discharge, payers, and other sources.
- Describe in detail all databases the applicant can currently link to and has future plans to link to, including owner of database, number and demographic characteristics of individuals in database, and representativeness of individuals in database to source population.
- Identify and describe any database/data use agreement or IRB data transmission restrictions and whether and how these restrictions may limit descriptive analyses and reporting of results.
- Describe the proposed linkage process including how the data will be de-duplicated both within and across each data set.
- Establish vital status of identified cases: Link identified cases to National Death Index (NDI) data to establish vital status; recipients may choose to link first to state death records and then link those who did not link to state death records, to NDI.
- Determine most recent address in data, geocode address, and link healthcare encounter data to census data to collect census tract-level demographic and socioeconomic status indicators agreed upon by CDC and all program recipients (e.g. % below federal poverty level; % Hispanic ethnicity; rurality).
- Create standardized diagnostic, morbidity, and healthcare resource utilization groupings as agreed upon by CDC and all program recipients.

Data Reporting

- Collect/store standardized data: Collect and store data from all data sources (case-finding, healthcare encounters, NDI, vital records, census data, etc.) in a standardized manner with common data elements
    - Refer to Appendix or www.cdc.gov/ncbddd for a copy of the required data elements to be used for this project.
    - Submit to CDC de-identified, de-duplicated individual level data, including standardized data elements using a common database in a secure manner in a timeline established by CDC. Component A recipients will have final dataset submitted to CDC by end of project Year 3 (September 2027). CDC has a secure network that will be used for this project and recipients will need to obtain and maintain access.

Data Assessment

- Improve knowledge of characteristics of individuals with CHD, including age-specific mortality, healthcare utilization, comorbidities, and other outcomes, and improve understanding of racial/ethnic, socioeconomic, or rural/urban patterns in healthcare use or long-term outcomes.
- Describe population of individuals with CHD including:
- Examine state and national healthcare policies that have an impact on people with CHD
- Assess quality of data sources for completeness of data (e.g., percent missing demographic data, provider type).
- ***If applicant was previously funded for NOFO #DD19-1902:*** In Year 1 of the current NOFO (#DD24-0051), validate 200-300 randomly selected cases through abstraction of detailed medical records to complement work of Component B of this program.
- Healthcare utilization
- Distribution of CHD severity, cardiac/non-cardiac comorbidities, long-term outcomes
- Racial/ethnic, socioeconomic, or rural/urban differences in healthcare use and long-term outcomes
- Examine respiratory viruses and immunization among individuals with CHD, including changes in healthcare utilization in individuals with CHD over the course of the COVID-19 pandemic

Dissemination

- Work collaboratively with all recipients and CDC using the multi-site data to communicate project information and results to healthcare providers, patients, families, stakeholders, the general public and other target audiences via publications, presentations, and other methods.
- Work with local/state partners to use site-specific CHD data and understanding of the epidemiology of CHD, to identify potential areas for systems-based improvements.
- Participate in collaborative projects/manuscripts using multi-site data whenever possible.
- Lead one or more collaborative manuscripts using multi-site data and submit to CDC clearance within 12 months of data finalization.

Component B

Program Planning

- Identify and engage partners as needed, establish collaborations: The collaborative team of staff and partners should include machine learning experts, data scientists, data engineers, epidemiologists, birth defects surveillance experts, and CHD subject matter experts.

- Identify and prioritize program goals: Identify goals, measurable objectives, performance measures, responsible parties, and timeline to achieve the desired outcomes of the project.

Project Management

- Develop a management and staffing plan for implementation of this program: Identified staff must include staff members or collaborating partners who have experience training machine learning models for healthcare data with administrative diagnosis codes (e.g., ICD-10-CM), and have the appropriate expertise to understand existing machine learning models, implement transfer learning of pre-trained models to new data, and adjust parameters and thresholds of the machine learning pipeline or otherwise refine pre-trained models as needed for proper application to new data.

Data Assessment

- Develop and refine a machine learning model for the surveillance data collected through Component A: The recipient should refer to materials and references provided by CDC upon funding for descriptions of existing machine learning models (pre-trained on similar data) to be used as the base for this component of the current NOFO. The recipient must evaluate the annotated dataset of the 200-300 validated cases per Component A recipient (among those previously funded for NOFO #DD19-1902), including calculating the positive predictive value, negative predictive value, and other relevant metrics. The recipient must then use the annotated data to further develop and refine the pre-trained models provided by CDC via transfer learning, such that they can be confidently applied to data on all cases identified in Component A. Recipients must apply the refined machine learning models to data collected from all recipients funded through Component A.

Data Reporting

- Document the end-to-end process from raw data (from Component A) to final classification with transparency for complete reproducibility and accurate use. Submit all datasets (including raw and preprocessed datasets), all source code to train the model, the final trained model (via a standardized format), documentation, and results (i.e., model's classification for each individual person) to CDC in a secure manner. CDC has a secure network that will be used for this project and recipients will need to obtain and maintain access.

Dissemination

- Add the source code(s), trained model(s), and corresponding documentation on a publicly available platform (e.g., GitHub)

- Work collaboratively with all recipients and CDC using the multi-site data to communicate project information and results to healthcare providers, patients, families, stakeholders, the general public and other target audiences via publications, presentations, and other methods. The multi-site data should include the model's classification for each individual person.

Participate in collaborative projects/manuscripts using multi-site data whenever possible.

1. Collaborations
Components A & B

1. Collaborate with CDC and NOFO #DD24-0051 recipients to provide input on standardized processes, methods, standardization of data collection, and other project activities (required).

a. With other CDC programs and CDC-funded organizations:
Components A & B

1. Collaborate with CDC and NOFO #DD24-0051 recipients to provide input on standardized processes, methods, standardization of data collection, and other project activities (required).

b. With organizations not funded by CDC:
Component A

· Collaborate and coordinate across state agencies and clinical settings for data collection. Demonstrate effective relationships and cooperation with appropriate partners with access to clinical databases, administrative databases, immunization records, birth defects surveillance data. Past collaborations with each of these partners should be described.

· Letters of support are strongly encouraged from all agencies that will contribute data to the project. For all source data that the applicant does not "own", a letter of support from the holder of the data must be included, that addresses timeline for access to the data and an understanding that individual level, de-duplicated, de-identified data will be shared with CDC and the other NOFO #DD24-0051 recipients.

· All applicants are strongly encouraged to partner with a birth defects surveillance program and provide a letter of support describing the collaboration. If the applicant is not a state health department, then the applicant is strongly encouraged to include a letter of support from the state health department.

· Involve appropriate within-region partners, such as health care providers, community-based organizations, academic medical centers and/or outpatient centers specializing in CHD care, and other organizations to assist with project activities.

· The collaborative team should comprise personnel with expertise in birth defects surveillance, clinical care of patients with CHD, informatics, data scientists, epidemiology, project management/coordination.

· Work with CDC and other recipients to agree on standardized processes, methods, standardization of data collection, and other project activities.

· Provide evidence of legal authority to access individual-level, identifiable data from the relevant data sources for identification of sources.

· Provide evidence of legal authority to share individual-level, de-duplicated, de-identified data from the relevant data sources.

Component B

· The collaborative team should comprise personnel with machine learning, data science, and data engineering, epidemiology, expertise in birth defects surveillance, and clinical care of patients with CHD.

· Work with CDC and other recipient(s) to agree on standardized processes, methods, standardization of data collection, and other project activities.

2. Population(s) of Focus

Component A: Describe the population of individuals aged 0-64 with CHD including demographics, such as race/ethnicity, or socioeconomic status, or rural/urban distribution and reside in the defined geographic area of the source population.

Component B: N/A

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

a. Health Disparities

The goal of health equity is for everyone to have a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Broadly defined, social determinants of health are non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. See content below and in other sections (e.g., Approach, Collaborations, Populations of Focus) for information on how this specific NOFO affects social determinants of health.

A health disparity is a preventable difference in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged. Health disparities are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these diseases and conditions.

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A health disparity is a preventable difference in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged. Health disparities are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these diseases and conditions.

Surveillance data should be population-based, and not limited to individuals aged 0-64 years 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 individuals aged 0-64 years with the CHD ICD-10-CM codes listed on page 8 (Strategies & Activities, Case Identification section). To address health disparities, data reported to CDC should include but not limit to ethnicity, race, gender, geography (e.g., rural, urban), and language spoken at home.

iv. Funding Strategy

Component A: 3-7 awards for 5 year period of performance; up to $400,000 average award per budget period

Component B: Up to $50,000 for Year 1, up to $300,000/year for Years 2-5

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Strategy

Component A:

<u>Evaluation and progress reports:</u>

- Prepare a written assessment of the accomplishments, challenges, and opportunities of the CHD surveillance project including a description of the problems encountered, lessons learned, potential improvements, etc.
- CDC will work with recipients to finalize measures within the first six months of the period of performance.

Strategies/Activities:

- <u>Program Planning activities</u>: Identify/engage partners, establish partnership collaborations; prioritize program goals, define source population, identify data sources.

Indicators for success:

- Partners are identified and letters of support from all agencies that will contribute data to the project are included in application.
- If the applicant is not a state health department, a letter of support from the state health department is included in the application.
- Updates are provided to CDC on routine partner meetings and calls.
- Program goals are identified and prioritized.
- Source population is defined, data sources are identified.

- Project Management activities: Develop management and staffing plan; obtain legal authority to access data.

Indicators for success:

- Comprehensive management and staffing plan provided in application.
- Progress on implementation of staffing plan provided to CDC.
- Evidence of legal authority, or detailed steps/timeline needed to obtain legal authority is provided in application.
- Dissemination plan is described

- Case Identification activities: Use all available data sources (birth defects registry data, clinical and administrative data) sources to identify eligible cases with congenital heart defects (CHD)

Indicators for success:

- Individuals with one or more ICD code for CHD identified in case finding data sources.

- Data Collection activities: Establish vital status of identified cases, link identified cases to other data sources; geocode address, link healthcare and census data, create standardized dataset.

Indicators for success:

- Vital status of identified cases have been established.
- Data sources have been accessed and linked; linkage success rates for vital records, immunization records, and healthcare data have been calculated.
- Addresses have been geocoded.
- Data elements have been collected in standardized manner at each site.

- Data Reporting activities: collect/store standardized data, submit de-identified, de-duplicated individual level encounter and summary level data to CDC.

  Indicators for success:

- Data standardization and storage processes are documented and sent to CDC.
- De-identified, de-duplicated individual level data has been submitted to CDC within agreed upon benchmarks and timeframes.
- Feasibility of having final linked, deduplicated, de-identified dataset to CDC by the end of Year 3 is described in application.

- Data Assessment activities: Describe population with CHDs; validate 200-300 randomly selected cases per site (if funded for DD19-1902); assess quality and accuracy of data.

  Indicators for success:

- Data analysis plan developed and descriptive statistics generated on population with CHD, including healthcare utilization, CHD severity, cardiac/non-cardiac comorbidities, and other long-term outcomes.
- Racial/ethnic, socioeconomic, or rural/urban differences in healthcare use and long-term outcomes have been assessed.
- Respiratory viruses and related immunizations (e.g., COVID-19, influenza, RSV) among individuals with CHD has been assessed.
- If funded for NOFO #DD19-1902, 200-300 randomly selected cases have been validated.

- Dissemination activities: Share information, communicate results.

  Indicators for success:

- Communication plan is developed (including metrics on estimating audience reach, indicators of engagement: e.g., clicks, opens, comments, re-tweets, references/citations, altmetric scores), submitted to CDC, and implemented.
- CDC is notified each time project-related reports (publications, presentations, newsletters, etc.) have been disseminated.
- Information shared regularly with CDC and other recipients.
- Project information and results communicated.
- Site-specific CHD data has been shared with local/state partners.

Outputs:

- **Population-based cohort of individuals aged 0-64 years with CHDs**

  Indicator for success: population-based cohort of individuals aged 0-64 years with CHD has been developed, submitted to CDC, met quality standards, analyzed, and findings disseminated. Dissemination of publication(s) and conference presentations/webinars (measure/report number of conference/webinar participants) that describe population-based cohort of individuals with CHD, by CHD severity and age.

- **CHD cases validated**

  Indicator for success: If applicant was previously funded for NOFO #DD19-1902, in Year 1 of NOFO #DD24-0051, 200-300 randomly selected cases are validated through medical record abstraction

Descriptive epidemiology and mortality

Indicator for success: standardized data have been contributed to support multi-state analyses of descriptive epidemiology of individuals aged 0-64 years with CHD; report(s) on descriptive epidemiology and mortality of individuals aged 0-64 years with CHD has/have been drafted, submitted to CDC clearance within 12 months of data finalization, and disseminated. Dissemination of publication(s) and conference presentations/webinars (measure/report number of conference/webinar participants) that describe epidemiology and mortality for persons with CHD, by CHD severity and age.

Outcomes:

- **Improved understanding of age-specific mortality of individuals with CHD.**

  Indicator for success: Describe estimated reach of disseminated publications (e.g, altmetric scores) and number of participants participating in conference and webinar presentations that describe age-specific mortality of individuals with CHD.

- **Improved understanding of health equity among individuals with CHD.**

Indicator for success: Describe estimated reach of disseminated publications (e.g., altmetric scores) and number of participants participating in conference and webinar presentations that describe health equity among individuals with CHD. **Improved understanding of racial/ethnic or socioeconomic patterns in healthcare use or long-term outcomes in study population**

Indicator for success: Describe estimated reach of disseminated publications (e.g., altmetric scores) and number of participants participating in conference and webinar presentations that describe racial/ethnic or socioeconomic patterns in healthcare use or long-term outcomes in study population.

- **Improved understanding of respiratory viruses (including COVID-19 and influenza) and related immunizations among individuals with CHD**

Indicator for success: Describe estimated reach of disseminated publications (e.g., altmetric scores) and number of participants participating in conference and webinar presentations that describe respiratory viruses and related immunizations among individuals with CHD.

- **Increased awareness among health service providers, patients, parents and public of nationwide CHD issues**

Indicator for success: dissemination of publication(s) (describe estimated reach, e.g, altmetric scores) and their key messages through various media, and conference presentations/webinars (measure/report number of conference/webinar participants) for partners that increase awareness of nationwide CHD issues.

Component B:

Evaluation and progress reports:

- Prepare a written assessment of the accomplishments, challenges, and opportunities of the CHD surveillance project including a description of the problems encountered, lessons learned, potential improvements, etc.
- CDC will work with recipients to finalize measures within the first six months of the period of performance.

Strategies/Activities:

- Program Planning activities: Identify/engage partners, establish partnership collaborations; prioritize program goals, define source population, identify data sources
    - Partners are identified (machine learning experts, data scientists, data engineers, epidemiologists, birth defect surveillance experts, CHD subject matter experts) and letters of support are included in application.

Indicators for success:

- Updates are provided to CDC on routine partner meetings and calls.
- Program goals are identified and prioritized.

- Project Management activities: Develop management and staffing plan
    - Comprehensive management and staffing plan with appropriate machine learning expertise provided in application.

Indicators for success:

- Progress on implementation of staffing plan provided to CDC.

- Data Assessment activities: develop and refine an existing machine learning model (pre-trained on similar data) for the surveillance data collected through Component A; apply this refined machine learning model to data collected from all recipients funded through Component A
    - Pre-trained machine learning model modified by transfer learning using the annotated dataset of the 200-300 validated cases per Component A recipient (among those previously funded for NOFO #DD19-1902), and evaluated, including calculating the positive predictive value, negative predictive value, and other relevant metrics.

Indicators for success:

- Machine learning model developed and applied to data collected from all recipients through Component A.
- Data reporting activities: document the end-to-end process from raw data (from Component A) to final classification for complete reproducibility; submit all datasets (including raw and preprocessed), all source code to train the model, the final trained model (via standardized format), documentation, and results (i.e., model's classification for each individual person) to CDC

Indicators for success:

- End-to-end process from raw data (from Component A) to final classification documented
- Datasets, source code to train the model, the final trained model (in standardized format), documentation, and results submitted to CDC

- Dissemination activities: Share information, communicate results

  Indicators for success:

- Communication plan is developed, submitted to CDC, and implemented.
- Information shared regularly with CDC and other recipients.
- Project information and results communicated
- Source codes, models, and corresponding documentation are publicly available
- Site-specific CHD data has been shared with local/state partners

Outputs

- **Machine learning model trained and applied to data collected through Component A**

  Indicator for success: models trained, tested, applied to Component A data; datasets, source code to train the model, the final trained model (in standardized format), documentation, and results submitted to CDC and released on a publicly available platform (e.g. GitHub).

- **Labeled dataset for population-based cohort of individuals aged 0-64 years with CHD**

  Indicator for success: Multi-site dataset of all individuals with administrative CHD codes in the population-based cohort from Component A includes model's classification for each individual; this labeled dataset has been submitted to CDC, met quality standards, analyzed, and findings disseminated.

Outcomes

- **Improved understanding of how machine learning algorithms and models can be applied to surveillance data to identify individuals with CHD**

  Indicator for success: dissemination of publication(s) (describe estimated reach, e.g., altmetric scores) and conference presentations/webinars (measure/report number of conference/webinar participants) describing how machine learning model was developed and applied to administrative data for surveillance of individuals with CHD and relevant metrics of the data before and after application.

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 applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement, including, as applicable to the award, how findings will contribute to reducing or eliminating health disparities and inequities.
- 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).
- How evaluation findings will be disseminated to communities and populations of interest in a manner that is suitable to their needs.
- 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.

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.

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

c. Organizational Capacity of Recipients to Implement the Approach

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

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

Component A:

- Their capacity to either create a new or enhance an existing surveillance system, ensuring that individuals aged 0-64 years with CHD are included.
- Staff with skill sets to implement the awards such as: program and performance management, CHD 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.
- Their capacity to include a geographically representative source population (a minimum total population size of the defined geographic region should equal 1 million individuals per year as evidenced by census data).
    - Applications should identify the proposed defined geographic region and population characteristics.
- Their ability to begin immediate implementation of the NOFO activities.

- Their legal authority to access and share with CDC and other recipients multiple, linked existing individual level, de-duplicated, de-identified data from the relevant data sources inclusive of individuals aged 0-64 years with CHD.
    - Applicants should demonstrate, through MOUs and/or letters of support, the ability to access and share the data per the NOFO guidelines.
    - A Data Use Agreement (DUA) is generally not needed between a NOFO recipient and CDC, because the NOFO itself serves that function. If a DUA is needed with CDC and/or other NOFO recipients, the recipient must document that within the proposal and collaborate with CDC to develop and sign DUAs within the first 6 months of the award. Applicants must describe required data use agreements (DUAs) to access and share data with CDC and other DD #24-0051 recipients.
    - Applicants must indicate any restrictions (e.g., IRB, HIPAA) to provide all required data elements as indicated in Appendix A.

- Their capacity to lead and publish original manuscripts in a timely manner, as evidenced by citations of recent first- or senior-author publications.

Component B:

- Staff or collaborating partners with skill sets to implement this component such as: program and performance management, machine learning expertise using healthcare data sets, data science and engineering expertise, CHD clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development, evaluation, performance monitoring, and financial reporting.
    - CVs of key staff or collaborating partners should be included and a brief position description of existing staff or collaborating partners. If there are any vacant positions, the applicant should include a proposed job description including qualifications for successful applicants (e.g., education, experience) and address both the recruiting strategies and estimated timeline for filling the position. Applicants should demonstrate, through MOUs and/or letters of support, the ability to access and share the data per the NOFO guidelines.

- Their experience and expertise in:
    - using machine learning to improve the validity of case identification using administrative healthcare data.
    - performing transfer learning to apply existing machine learning models (pre-trained on similar data) to new data.
    - publishing original manuscripts on machine learning efforts to improve the validity of healthcare data in a timely manner, as evidenced by citations of recent publications.
    - posting source code(s), trained model(s), and corresponding documentation on a publicly available platform in a timely manner, as evidenced by hyperlinks to previous releases of machine learning models and documentation.

- Their ability to begin immediate implementation of the NOFO activities.

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

Component A:

· 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.

· Develop timelines for ongoing data transmission and other key activities.

· 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.

· Assist with submission of data from each recipient to a central repository (maintained at CDC in a secure manner) at least on a quarterly basis.

· Develop and maintain the centralized database used by recipients for the transmission of de-identified, de-duplicated individual level data. Compile data across sites, perform quality reviews of data, and disseminate data.

Component B:

· Work with recipients to develop priority reports and publications. Analyze data and author/coauthor reports and publications. Assist with evaluation of the project.

· 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.

· Develop timelines for data access, linkage, medical record review and other key activities.

· 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.

· Assist in performing data analysis and/or quality assurance verification.

· Work with recipients to develop priority reports and publications.

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:
2024
Estimated Total Funding:
$3,100,000
4. Approximate Total Fiscal Year Funding:
$3,100,000
This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding:
$15,500,000
6. Total Period of Performance Length:
5 year(s)

7. Expected Number of Awards:
8
Component A: 3-7 awards

Component B: 1 award

8. Approximate Average Award:

$400,000
Per Budget Period

Component A: Up to $400,000

Component B: Up to $50,000 for Year 1 budget period, up to $300,000/year Years 2-5

9. Award Ceiling:
$500,000
Per Budget Period

Component A: $500,000 per budget period

Component B: $300,000 per budget period

10. Award Floor:
$50,000
Per Budget Period

11. Estimated Award Date:
September 01, 2024

12. Budget Period Length:
12 month(s)

Throughout the period of performance, 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 (period of performance) 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).

DA is not available for this NOFO

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)

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

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

Additional Eligibility Category:

Government Organizations:

State (includes the District of Columbia)

Local governments or their bona fide agents

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

State controlled institutions of higher education

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

American Indian or Alaska native tribally designated organizations

Other:

Private colleges and universities

Community-based organizations

Faith-based organizations

2. Additional Information on Eligibility

Organizations will determine eligibility per Section 399V-2 of the Public Health Service Act (42 U.S.C. 280g-13)

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No

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: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number associated with your organization's physical location prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned through SAM.gov registration. Some organizations may have multiple UEI numbers. Use the UEI number associated with the location of the organization receiving the federal funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). All information relevant to the SAM number must be current at

all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

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

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

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

Step	System	Requirements	Duration	Follow Up
1	System for Award Management (SAM)	1. Go to SAM.gov and create an Electronic Business Point of Contact (EBiz 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.	7-10 Business Days but may take longer and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an account in Grants.gov, then add a profile by adding the organization's new UEI number. 2. The EBiz POC can designate user roles, including Authorized Organization Representative (AOR). 3. AOR is authorized to submit applications on behalf of the organization in their workspace.	Allow at least one business day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	Register early! Applicants can register within minutes.

2. Request Application Package

Applicants may access the application package at www.grants.gov. Additional information about applying for CDC grants and cooperative agreements can be found here: https://www.cdc.gov/grants/applying/pre-award.html

3. Application Package

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

4. Submission Dates and Times

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

a. Letter of Intent Deadline (must be emailed)

Due Date for Letter Of Intent 03/18/2024

03/18/2024
March 18, 2024

b. Application Deadline

Due Date for Applications 05/14/2024

05/14/2024
11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

Due Date for Informational Conference Call
Topic: DD24-0051 CHD STAR 2 NOFO - Informational Call

Time: Mar 27, 2024 11:00 AM Eastern Time (US and Canada)

Join ZoomGov Meeting

https://cdc.zoomgov.com/j/1610383146?pwd=d0R6bXgrSk9sdW9YWEpJVHBWWGZ6UT09

Meeting ID: 161 038 3146

Passcode: 8.^thV?E

One tap mobile

+16692545252,,1610383146#,,,,*57472469# US (San Jose)

+16468287666,,1610383146#,,,,*57472469# US (New York)

Dial by your location

• +1 669 254 5252 US (San Jose)

• +1 646 828 7666 US (New York)

• +1 646 964 1167 US (US Spanish Line)

• +1 415 449 4000 US (US Spanish Line)

• +1 551 285 1373 US (New Jersey)

• +1 669 216 1590 US (San Jose)

Meeting ID: 161 038 3146

Passcode: 57472469

Find your local number: https://cdc.zoomgov.com/u/adbU2aKUYw

Join by SIP

• 1610383146@sip.zoomgov.com

Join by H.323

• 161.199.138.10 (US West)

• 161.199.136.10 (US East)

Meeting ID: 161 038 3146

Passcode: 57472469

5. Pre-Award Assessments

Duplication of Efforts

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

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

6. Content and Form of Application Submission

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

7. Letter of Intent

Is a LOI:
Recommended but not Required
A 1–2-page LOI is requested and optional. The purpose of a LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications. The LOI should identify whether the applicant is applying for Component A or B (or both) and a short description of applicant's planned activities must be e-mailed to:

Eileen McGowan

CDC, NCBDDD, Birth Defects Monitoring and Research Branch

Telephone number: 404.498.1014

Fax number: 770.488.3263 / 3266

E-mail: osk0@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, Word, or Excel file format under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

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

10. Project Narrative

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

Project Narrative subsections that are specific to each component.

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

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

a. Background

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

b. Approach

i. Purpose

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

ii. Outcomes

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

iii. Strategies and Activities

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

1. Collaborations

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

2. Population(s) of Focus and Health Disparities

Applicants must describe the specific population(s) of focus in their jurisdiction and explain how to 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 Population(s) of Focus and Health Disparities requirements as described in the CDC Project Description, including (as applicable to this award) how to address health disparities in the design and implementation of the proposed program activities.

c. Applicant Evaluation and Performance Measurement Plan

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

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see https://www.cdc.gov/os/integrity/reducepublicburden/index.htm.
- 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 or reaccreditation 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. These goals may include supporting vital records offices participating in the Vital Records and Health Statistics Accreditation Program, certifying vital records offices to meet industry standards. 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; provide financial assistance to support accreditation related fees and/or support staff time to coordinate accreditation activities; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and can upload it as a PDF, Word or Excel file format 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.

Each applicant applying for Component A should include travel costs for 3 days/2 nights to CDC (Atlanta, Georgia) for one recipient meeting for a minimum of 2-3 project staff per year.

Applicants should include a detailed budget justification by budget category for Year 1 for Component A only or Component B only (as appropriate) and estimated total amounts by budget category for Years 2-5 (Component A) and Years 2-5 (Component B).

13. Employee Whistleblower Rights and Protections

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

13a. Funds Tracking

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

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

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

13b. Copyright Interests Provisions

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

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

13c. Data Management Plan
As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information: https://www.cdc.gov/grants/additional-requirements/ar-25.html.

14. Funding Restrictions

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

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

NOT APPLICABLE

15. Intergovernmental Review

You will need to submit application information for intergovernmental review under Executive Order 12372. Under this order, states may design their own processes for obtaining, reviewing, and commenting on some applications. Some states have this process and others don't.

To find out your state's approach, see the list of state single points of contact. If you find a contact on the list for your state, contact them as soon as you can to learn their process. If you do not find a contact for your state, you don't need to do anything further. This requirement never

applies to American Indian and Alaska Native tribes or tribal organizations.

16. Other Submission Requirements

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

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

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

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or review the Applicants section on www.grants.gov.

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

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

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

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

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

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

E. Review and Selection Process

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

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by the Office of Grants Services. Complete applications will be reviewed for responsiveness by Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

NOFO reviewers will follow CDC's merit review process by evaluating eligible and responsive applications in accordance with the criteria below. Reviewers may be external to the federal government (non-federal personnel), federal personnel, or a mix of federal and non-federal personnel.

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

Component A:

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

- 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 source population for their surveillance effort? To what extent does the applicant have a sufficient population size with

diversity, e.g., with respect to factors including but not limited to race/ethnicity and socioeconomic status, included in the surveillance population? The minimum total population size of the defined geographic region should equal 1 million per year as evidenced by census data.

- To what extent does the applicant adequately describe how their system will include calendar year 2021-2023? What data sources will be included for surveillance?
- To what extent does the applicant describe the estimated number of individuals aged 0-64 years with CHD which will be ascertained during the 2021-2023 period?

Work Plan (15 of 40)

- To what extent do the activities describe the proposed intent to conduct comprehensive population-based surveillance among individuals aged 0-64 years with CHD? Are the outcome measures clear and measurable to address the need and the main activities of the NOFO?
- To what extent will the plan achieve the proposed objectives? Does the project plan include a comprehensive plan for the first budget period? Does the plan include quantitative processes and outcome measures?
- To what extent does the applicant include a reasonable and achievable timeline to complete the activities in the specified period of performance?
- To what extent does the applicant describe the feasibility to have the final linked, deduplicated, de-identified dataset to CDC by the end of Year 3?
- To what extent does the applicant describe their planned collaborations and demonstrate relationships with appropriate partners both internal and external to the state health department? To what extent does the applicant provide letters of support from all agencies that will provide data to the project? If the applicant is not a state health department, is a letter of support from the state health department provided?

Methods (20 of 40)

- To what extent are the proposed methods for case identification, date collection, and data linkage clearly described?
- To what extent are the proposed methods for case identification, date collection, and data linkage feasible within the project timeline?
- To what extent will the methods accomplish the program goals?
- To what extent does the applicant describe proposed data sources and detailed timeline for access of data sources?
- To what extent does the applicant describe how the data is population-based or, if not population-based, to what extent does the applicant provide information on how the data will approximate population-based estimates with respect to racial/ethnic and socioeconomic diversity?
- For previously funded DD#19-1902 recipients only: To what extent does the applicant describe the ability to validate 200-300 cases by end of Year 1?

- To what extent does the applicant describe proposed linkage and de-duplication process, including surveillance years 2021-2023?
- To what extent do the proposed methods address the procedures for generation of the standardized data elements (included in Appendix), process for submitting de-identified, deduplicated data to CDC, analysis, and dissemination of findings?

Component B

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

- 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?

Work Plan (15 of 40)

- To what extent do the activities describe the proposed intent to develop, refine, and apply an existing machine learning model (pre-trained on similar data) on the surveillance data collected through Component A? Are the outcome measures clear and measurable to address the need and the main activities of the NOFO?
- To what extent will the plan achieve 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 reasonable and achievable timeline to complete the activities in the specified period of performance?
- To what extent does the applicant describe a collaborative team of machine learning experts, data scientists, data engineers, epidemiologists, birth defect surveillance experts, and CHD subject matter exerts? If the applicant plans to collaborate with partners for this component, to what extent does the applicant describe their planned collaborations and demonstrate relationships with appropriate partners and provide letters of support?

Methods (20 of 40)

- Are the proposed methods for development and refinement of a pre-trained machine learning model for application to Component A data feasible and do they clearly describe the processes to be used to accomplish the work plan within the project timeline?
- To what extent will the proposed methods accomplish the program goals?
- To what extent does the applicant describe the plans for submitting all datasets (including raw and preprocessed datasets), all source code to train the model, the final trained model (via a standardized format), transparent documentation for complete

reproducibility and accurate use, and results (i.e., model's classification for each individual person) to CDC?

To what extent does the applicant describe making source code(s), trained model(s), and corresponding documentation transparent, publicly available, and in a timely manner?

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

Component A:

- To what extent does the applicant's Evaluation and Performance Measurement plan include and adequately describe the performance measures and 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 and accessing data sources, conducting data linkage of identified cases to other data sources, establishing vital status, data collection, validation of 200-300 cases (if previously funded for DD#19-1902 only) reporting, assessment, and communicating findings to partners?

Component B:

- To what extent does the applicant's Evaluation and Performance Measurement plan include and adequately describe the performance measures and 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 development, refinement, and application of a pre-trained machine learning model for the surveillance data collected through Component A?

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

Component A:

- 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 including recent first- or senior-author original publications, evaluation, performance monitoring, and financial reporting? 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 partnerships and collaborations with appropriate partners (e.g., state officials/state health departments; cross-department personnel, including informatics personnel within state health department; birth defects

surveillance programs; medical centers; academic medical centers specializing in CHD; community-based organizations; patient/parent CHD support groups within catchment area/region)?

- If the applicant is not a state health department, is a letter of support from the state health department provided?
- If additional staff or consultants are needed, has the applicant demonstrated the ability to identify and hire needed staff and consultants in a timely manner? Are short position descriptions and a 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 describe their legal authority to access proposed data sources and to share de-identified, de-duplicated, individual-level data with CDC and other NOFO #DD24-0051 recipients, including any HIPAA, IRB and DUA requirements? Examples of past access and successful transmission to CDC should be described. Applicants are strongly encouraged to provide letters of support from all agencies that will provide data, authorizing its use for access and sharing of required data elements (Appendix).

Component B:

- To what extent has the applicant identified appropriate staff or collaborating partners for program and performance management, machine learning expertise, data science, data engineering, epidemiology, birth defect surveillance, CHD subject matter expertise, communication/material development, evaluation, performance monitoring, and financial reporting? To what extent do the identified staff members or collaborating partners have relevant experience and expertise in their respective areas? Are CVs provided?
- 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 positions 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 expertise and experience with:
    - using machine learning to improve the validity of case identification using administrative healthcare data?
    - performing transfer learning to apply existing machine learning models (pre-trained on similar data) to new data?
    - publishing on machine learning efforts to improve the validity of healthcare data, as evidence by citations of recent publications?
    - posting source code(s), trained model(s), and corresponding documentation on a publicly available platform in a timely manner, as evidenced by hyperlinks to previous releases of machine learning models and documentation?

- To what extent does the applicant describe their ability to begin immediate implementation of the NOFO activities?

Budget **Maximum Points:** 30

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. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project. Award recipients agree to use cooperative agreement funds for travel by project staff agreed-upon by CDC to participate in CDC-sponsored workshops, or other called meetings such as regional or 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.

The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/documents/Budget-Preparation-Guide.pdf.

c. Phase III Review

CDC may fund applications out of the rank order determined by the review panel. The following factors may affect the funding decision:

1. Diversity of population, e.g., with respect to factors including but not limited to race/ethnicity and socioeconomic status, included in the surveillance population. Applicants demonstrating greater diversity of identified CHD cases may be prioritized.
2. Size of the population under surveillance and the ability to obtain data that is population-based. Applicants proposing a larger number of cases may be prioritized.
3. Geographic location and diversity (i.e. not clustered in one region, urban, rural). Applicants offering data from different geographic regions and/or with more geographic diversity than other applicants may be prioritized.
4. 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 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 review of risk may impact reward eligibility.

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.

Additionally, we may ask for additional information prior to the award based on the results of the CDC's risk review.

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 2024 with a 9/30/2024 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 annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

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

2. Administrative and National Policy Requirements

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

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

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

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

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the period of performance. 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.

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.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes

Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	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	No

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 specific populations or achieving expected outcomes).

• Dissemination channels and audiences.

• Other information requested as determined by the CDC program.

Evaluation

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

• The frequency that evaluations will be conducted.

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

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

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

• Dissemination channels and audiences.

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

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

This report must include the following:

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

- Indirect Cost Rate Agreement.

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

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.

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 120 days after the end of the period of performance. The Final FFR is due 120 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

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

- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

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.

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 $30,000.

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

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

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

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

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

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign

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

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

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

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

5) Contents of Reports: The reports must contain:

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

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

6. Termination

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

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

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

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

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

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

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For programmatic technical assistance, contact:

First Name:
Justin

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

Address:
4770 Buford Hwy NE,

Atlanta, GA 30341

Telephone:
404.488.4096

Email:
jgi7@cdc.gov

Grants Management Office Information

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

First Name:
Kasheena

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

Address:
4770 Buford Highway MS-S102-1 Atlanta GA 30341.

Telephone:
(404) 498-0773

Email:
dfb7@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** that can be uploaded as a PDF, Word, or Excel file format 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:
Indirect Cost Rate, 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 collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

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

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

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

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

Community engagement: The process of working collaboratively with and through groups of people to improve the health of the community and its members. Community engagement often involves partnerships and coalitions that help mobilize resources and influence systems, improve relationships among partners, and serve as catalysts for changing policies, programs, and practices.

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.

Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment (from Executive Order 13985).

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: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.

Health Equity: The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Health Inequities: Particular types of health disparities that stem from unfair and unjust systems, policies, and practices and limit access to the opportunities and resources needed to live the healthiest life possible.

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: The act of creating environments in which any individual or group can be and feel welcomed, respected, supported, and valued to fully participate. An inclusive and welcoming climate embraces differences and offers respect in words and actions for all people.

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 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.

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).

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: The non-medical factors that influence health outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. https://www.cdc.gov/about/sdoh/index.html

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

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

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

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

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

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