Centers for Disease Control

National Center on Birth Defects and Developmental Disabilities

Surveillance of Congenital Heart Defects Among Children, Adolescents, and Adults
CDC-RFA-DD19-1902
Application Due Date: 04/17/2019
Surveillance of Congenital Heart Defects Among Children, Adolescents, and Adults
CDC-RFA-DD19-1902
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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-DD19-1902. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:
Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:
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 this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1/sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:
CDC-RFA-DD19-1902

E. Assistance Listings (CFDA) Number:
93.073

F. Dates:
1. Due Date for Letter of Intent (LOI): 03/18/2019

3. Date for Informational Conference Call:
Not applicable.

G. Executive Summary:
1. Summary Paragraph:
Notice of Funding Opportunity (NOFO) #CDC-RFA-DD19-1902 solicits non-research, cooperative agreement applications to develop accurate and complete, population-based surveillance of congenital heart defects (CHDs) among children, adolescents, and adults. In FY19, CDC plans to fund 4-10 recipients for a five-year period of performance to develop surveillance of individuals aged 1-45 years with CHDs in order to examine descriptive epidemiology, survival, healthcare utilization, comorbidities, and other outcomes over time (Component A). CDC also plans to fund 1-3 recipients for a three-year project to validate billing codes (e.g. ICD-9-CM, ICD-10) for CHDs in healthcare claims data, and determine best ways to use healthcare claims data for surveillance of CHDs across the lifespan (Component B). Improved understanding of the public health significance of CHDs may inform development of strategies directed at decreasing mortality and improving the health of children, adolescents, and
adults with CHDs. Measurable outcomes of the program will be in alignment with the following performance goal for the National Center on Birth Defects and Developmental Disabilities (NCBDDD): 1) Enhance the quality and utility of birth defects surveillance systems.

**a. Eligible Applicants:** Open Competition

**b. NOFO Type:** Cooperative Agreement

**c. Approximate Number of Awards:** 6

Component A: 4-10 awards

Component B: 1-3 awards

**d. Total Period of Performance Funding:** $11,500,000

Component A: 9/1/2019 - 8/31/2024; 5 years

Component B: 9/1/2019 - 8/31/2022; 3 years

**e. Average One Year Award Amount:** $400,000

Component A: $400,000 average award per budget period

Component B: $200,000 average award per budget period

**f. Total Period of Performance Length:** 5

**g. Estimated Award Date:** 08/01/2019

**h. Cost Sharing and / or Matching Requirements:** N

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

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**Part II. Full Text**

**A. Funding Opportunity Description**

**Part II. Full Text**

**1. Background**

**a. Overview**

Congenital heart defects (CHDs) are one of the most prevalent birth defects in the United States, affecting about 1% of all births, and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs. Improvements in treatment of CHDs and consequently in survival have resulted in many individuals, even those affected by a severe CHD, living into adolescence and adulthood. An estimated 2 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 CHDs have focused on monitoring newborns. However, little data exist on the descriptive epidemiology of CHDs beyond early childhood in the U.S. Despite the public health burden, the lack of population-based surveillance precludes reliable data on individuals with CHDs, their survival, healthcare
utilization, comorbidities, and 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.”

Through NOFO #DD19-1902, CDC plans to build upon prior projects by funding 4-10 recipients for a five year period of performance to develop surveillance of individuals aged 1-45 years with CHDs in order to examine descriptive epidemiology, survival, healthcare utilization, comorbidities, and other outcomes over time (Component A). CDC also plans to fund 1-3 recipients for a three-year project to validate billing codes (e.g. ICD-9-CM, ICD-10) for CHDs in healthcare claims data and determine best ways to use healthcare claims data for surveillance of CHDs across the lifespan (Component B). Improved understanding of the public health significance of CHDs may inform development of strategies directed at decreasing mortality and improving the health of persons with CHDs. Applicants can apply for Component A only, Component B only, or both components. However, only one application per organization as determined by the organization’s Dun & Bradstreet number will be accepted for each Component. Therefore, any organization applying for both Component A and Component B will submit a separate application for each component and it will be evaluated separately.

In the two prior NOFOs, cases were identified through healthcare encounters with CHD codes from various data sources. This NOFO will further refine surveillance methodology, assess survival, and identify healthcare encounters and, if possible, non-healthcare information over a longer time period than previous projects. Compared to previous projects, NOFO #DD19-1902 project guidelines modify the case definition and case-finding criteria with the aim of increasing validity of CHD cases captured through the surveillance systems. All funded recipients (including those previously funded under NOFO #DD12-1207 and/or NOFO #DD15-1506) must comply with all case identification and eligibility, data collection, reporting, and other aspects of NOFO #DD19-1902.

b. Statutory Authorities

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

c. Healthy People 2020

This NOFO addresses “Healthy People 2020” priority area of Maternal, Infant, and Child Health, and specifically MICH-1.7, reduce the rate of infant deaths related to birth defects (congenital heart defects) (http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives). This NOFO will conduct surveillance among children, adolescents, and adults living with CHDs, and will assess healthcare utilization, comorbidities and outcomes over time, specifically from 2008 - 2017.
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](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.

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 CHDs identified through healthcare encounters. ([http://www.cdc.gov/ncbdd/heartdefects/research.html](http://www.cdc.gov/ncbdd/heartdefects/research.html)).

In FY15 under NOFO #DD15-1506, CDC funded five recipients to develop or expand their surveillance of CHDs 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.

2. CDC Project Description

a. Approach

**Bold** indicates period of performance outcome.

<table>
<thead>
<tr>
<th>Strategies and Activities</th>
<th>Short-Term Outcomes</th>
<th>Intermediate Outcomes</th>
<th>Long-Term Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components A &amp; B</td>
<td>Component A</td>
<td>Components A &amp; B</td>
<td>Component A &amp; B</td>
</tr>
<tr>
<td>Program Planning</td>
<td>· Diverse partnership collaborations are established</td>
<td>· Improved ability to develop surveillance programs to understand the outcomes of individuals with CHDs</td>
<td>· Improved health among individuals of all ages with CHDs</td>
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<tr>
<td>· Identify/engage partners, prioritize program goals, define source population, identify data sources</td>
<td>· Improved knowledge about the characteristics of individuals identified from multiple data sources</td>
<td>· Improved quality of life of individuals of all ages with CHDs</td>
<td>· Improved quality of life of individuals of all ages with CHDs</td>
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<tr>
<td>Project management</td>
<td>· Improved understanding of</td>
<td></td>
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<tr>
<td>· Obtain management and staffing plan</td>
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<tr>
<td>Data Reporting</td>
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<tr>
<td>· Collect/store standardized data, submit individual-level</td>
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<tr>
<td>Component A</td>
<td>Component B</td>
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<tr>
<td><strong>Case Identification</strong></td>
<td><strong>Case Identification</strong></td>
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<tr>
<td>- Identify cases with CHDs</td>
<td>- Use healthcare claims data to identify individuals with a CHD billing code between 2008-2017</td>
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<tr>
<td><strong>Data collection</strong></td>
<td><strong>Data collection</strong></td>
<td></td>
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<tr>
<td>- Establish vital status of cases, link cases to other data sources</td>
<td>- Collect healthcare claims data on identified cases, link cases to clinical records, review clinical records for CHD status</td>
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<td></td>
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<tr>
<td>- Geocode address, link healthcare and census data, create standardized dataset</td>
<td>- Calculate positive predictive value (PPV) of healthcare claims data, develop/test algorithms to maximize PPV and sensitivity</td>
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<tr>
<td><strong>Data Assessment</strong></td>
<td><strong>Data Assessment</strong></td>
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<tr>
<td>- Describe population with CHDs, assess quality/accuracy of data</td>
<td>- Calculate positive predictive value (PPV) of healthcare claims data, develop/test algorithms to maximize PPV and sensitivity</td>
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</tr>
</tbody>
</table>

### Component A
- Improved understanding of healthcare utilization, comorbidities and outcomes
- Improved understanding of racial/ethnic and socioeconomic patterns in healthcare use and long-term outcomes
- Increased awareness among stakeholders of nationwide CHD issues

### Component B
- Improved understanding of validity and utility of healthcare claims data for surveillance of individuals of all ages with CHDs
- Improved accuracy of surveillance of CHDs

### Improved understanding
- Improved understanding of healthcare utilization, comorbidities and outcomes
- Improved understanding of racial/ethnic and socioeconomic patterns in healthcare use and long-term outcomes
- Improved awareness among stakeholders of nationwide CHD issues

### Improved accuracy
- Improved accuracy of surveillance of CHDs
- Improved ability to develop effective secondary prevention strategies to reduce the public health impact of CHDs

### Improved information
- Improved information to stakeholders on healthcare utilization, comorbidities and outcomes
i. Purpose
This NOFO supports population-based surveillance of children, adolescents, and adults with CHDs to examine descriptive epidemiology, survival, healthcare utilization, comorbidities and other outcomes over time. High-quality data will improve understanding of the epidemiology and public health significance of CHDs. Surveillance data will also allow monitoring of special sub-populations with CHDs (e.g., racial/ethnic, sociodemographic diversity), and potentially identify factors to inform development of effective secondary prevention strategies.

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

Component A: (individuals aged 1-45 years with CHDs)

Short-term outcomes:

- Diverse partnership collaborations are established which will result in comprehensive identification of cases and healthcare encounters to fulfill program goals
- Improved knowledge on the characteristics of individuals identified from multiple high-quality data sources
- Improved understanding of age-specific mortality
- Improved understanding of healthcare utilization, comorbidities and other outcomes
- Improved understanding of racial/ethnic and socioeconomic patterns in healthcare use and long-term outcomes
- Improved understanding of the strengths and limitations of data sources for providing information about individuals with CHDs
- Increased awareness among health service providers, patients, parents and public of national CHD issues

Intermediate outcomes:

- Improved information to the public, patients, families, and policy makers on healthcare utilization, comorbidities and outcomes of individuals

Component B: (individuals of all ages with CHDs)

Short-term outcomes:

- Improved understanding of the validity and utility of healthcare claims data for CHD surveillance including differences by individual or healthcare characteristics

Intermediate outcomes:

- Improved accuracy of identification and surveillance of CHDs using healthcare claims data
iii. Strategies and Activities

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

**Component A:**

**Project Management:**

- Develop a management and staffing plan for implementation of this program.
- 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.
- Join the CDC shared project folder where all NOFO #DD19-1902 multi-site documents (e.g. meeting minutes, project protocols) will be stored. All recipients are expected to post relevant documents to this folder during the period of performance.
- Update CDC and other recipients monthly on project status and outputs. Maintain recipient-specific documentation on data sources, collection methods, linkage, data reconciliation (e.g. how recipient determined race/ethnicity of case when information differed in multiple data sources).

**Program Planning:**

- Identify and engage partners: Demonstrate effective relationships and cooperation with appropriate partners (e.g., birth defects surveillance program, clinical cardiology organizations with access to congenital cardiac clinical databases, state health department, community-based organizations, medical centers).
- Identify and prioritize program goals: Identify goals, measurable objectives, and performance measures 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 during 2008-2017.
- Identify data sources for current and future case-finding: Name and describe each data source that will be used for case-finding. Population-based birth defects surveillance program and/or a local or national congenital cardiac clinical databases must be used to identify all cases with CHDs who are aged 1-45 years at any time during 2008-2017.

**Using both types of data sources is strongly encouraged and preferred.**

- Identify currently available and possible future data sources for healthcare encounters: Name and describe additional data sources (e.g., administrative billing records) that will be used to find healthcare encounters of all types (not limited to cardiac care) occurring between 2008-2017 for the identified cases.
- Identify possible data sources for non-health information (e.g., education or employment data) that may be used to supplement healthcare encounter information.
- Indicate sources that can be accessed immediately, those that will need additional approvals, and how access will be obtained, and a timeline for access. 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.

Case Identification:

- Demonstrate capacity to access, link, and use data from birth defects surveillance programs and/or congenital cardiac clinical databases to identify eligible cases with CHDs. Applicants should demonstrate, through memorandums of understanding (MOUs) and/or letters of support, the ability to access and share the data per the NOFO guidelines.
  - Applicants must identify a minimum total of 2,000 individuals with CHDs from all the case-finding database(s); cases may be identified in the database(s) from any period of time, but must be ages 1-45 years during 2008-2017
  - Of identified cases, at least 300 must be aged <18 years during the years 2008-2017 and at least 300 cases must be aged 35-45 years during 2008-2017
- Eligible cases:
  - Will be ages 1-45 years at any time between 2008-2017
  - Reside in the source population geographic area at any time during 2008-2017
  - Have one or more of the following ICD-9-CM (or equivalent ICD-10-CM) CHD codes in birth defect surveillance program data and/or in a local or national clinical cardiac database:
    - Severe: 745.0, 745.1, 745.10, 745.11, 745.12, 745.19, 745.2, 745.3, 745.6, 745.60, 745.69, 746.01, 746.1, 746.7, 747.11, 747.41
    - Shunt: 745.4, 745.5, 745.61, 745.8, 745.9, 747.0, 747.42
    - Valve: 746.0, 746.00, 746.02, 746.09, 746.2, 746.3, 746.4, 746.5, 746.6, 746.81, 746.83, 747.1, 747.10, 747.22, 747.3, 747.31, 747.39
    - Other: 745.7, 746.8, 746.82, 746.84, 746.85, 746.87, 746.89, 746.9, 747.2, 747.20, 747.21, 747.29, 747.4, 747.40, 747.49, 747.9, 648.5x, V13.65

Data Collection:

For individuals aged 1-45 years with CHDs identified through case-finding, a consolidated dataset will be developed by linking cases to vital records and 2008-2017 healthcare encounter and, if possible, non-healthcare data from multiple sources.

- Demonstrate capacity to access, link, and use data from state vital records and National Death Index (NDI), healthcare claims database(s), clinics, health providers, hospital discharge, payers, and other sources.
- Link identified cases to 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.
- Link identified cases to birth certificate, as needed, to obtain full information on case (e.g. name) to facilitate linkage to healthcare encounter data.
- Link identified cases to additional existing data sources to collect standardized data elements documented between 1/1/2008-12/31/2017 (e.g. all healthcare claims occurring between 2008 and 2017).
o Applicant must describe in detail all databases they currently can link and 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.

o Applicant must identify and describe any database or IRB data transmission restrictions and whether and how these restrictions may limit descriptive analyses and reporting of results.

o Applicant must describe the proposed linkage process including how the data will be de-duplicated both within and across each data set.

o Refer to www.cdc.gov/ncbddd for a copy of the data elements to be used for this study.

- Explore methods to understand in- and out-migration in catchment area of identified CHD cases during surveillance period (1/1/2008-12/31/2017).
- Determine most recent address in data, geocode address, and link healthcare encounter data to census data to assess census tract-level demographic and socioeconomic status (e.g. % below federal poverty level; % Hispanic ethnicity; rurality).
- Create standardized diagnostic, morbidity, and healthcare resource utilization groupings.

Data Reporting:

- Collect/store standardized data from all data sources (case-finding, healthcare encounters, NDI, Vital records, census data, and non-healthcare data, if possible).
- At least quarterly, submit to CDC de-identified, de-duplicated individual level data, including standardized data elements using a common database 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.

Data Assessment:

Improve knowledge on characteristics of individuals aged 1-45 years with CHDs, 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

- Calculate age-specific mortality, major causes of death, and healthcare utilization before death for persons aged 1-45 with CHDs, overall and by CHD severity (as defined Section A.2.a(iii) - Strategies and Activities).
- Describe population of individuals aged 1-45 with CHDs seeking healthcare during 2008-2017, including:
  o Healthcare utilization patterns over time
  o Distribution of CHD severity, incidence of cardiac and non-cardiac comorbidities, and long-term outcomes
  o Racial/ethnic, socioeconomic, or rural/urban differences in healthcare use and long-term outcomes
  o Non-healthcare outcomes, if possible (e.g. employment, education)
- Examine outcomes overall and by CHD severity, age, year(s) (2007-2018), and other characteristics of interest
- With CDC and other recipients, decide upon priority analyses using pooled data from all
recipients.
- Conduct analyses of site-specific data and participate in analyses using pooled data from all recipients.

Improve understanding of strengths and limitations of integrated surveillance for CHDs among public health practitioners
- Assess quality of data sources for completeness of healthcare and non-healthcare data (e.g., percent missing demographic data, provider type).
- Use case-finding data source(s) to compare information on CHD type and severity to other data sources, including whether and how frequently the CHD was documented. Calculate concordance of CHD type and severity across data sources and PPV of healthcare claims data, using case-finding data sources as the gold standard.

Dissemination:
- Work collaboratively together and with 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.
- Participate in collaborative projects/manuscripts using multi-site data whenever possible.

**Component B:**

**Project Management:**
- Develop a management and staffing plan for medical record review.
- Join the CDC shared project folder where all NOFO #DD19-1902 multi-site documents (e.g. meeting minutes, project protocols) will be stored. All recipients are expected to post relevant documents to this folder during the period of performance.
- 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.
- Describe how information about this project will be disseminated to stakeholders (meetings, leadership briefings, newsletters, website, etc).

**Program Planning:**
- Identify and engage partners: Demonstrate effective relationships and cooperation with appropriate partners (e.g., administrative healthcare claims database(s) owners, hospitals and clinics with congenital cardiac specialists).
- Identify and prioritize program goals: Identify goals, measurable objectives, and performance measures to achieve the desired outcomes of the project.
- Identify data sources for healthcare encounters: Name and describe healthcare claims
data that will be used to identify individuals with one or more CHD code(s) documented in billing records during 2008-2017.

- Identify data sources for medical record review; these should not be limited only to cardiology or other specialty clinic records, but should be representative of all individuals with CHDs seeking healthcare in the healthcare system.

Case Identification:

- Demonstrate capacity to access, link, and use data from healthcare claims database(s) to identify individuals with one or more healthcare encounters during 2008-2017 with one or more of the following ICD-9-CM (or equivalent ICD-10-CM) CHD codes documented.
  - Severe: 745.0, 745.1, 745.10, 745.11, 745.12, 745.19, 745.2, 745.3, 745.6, 745.60, 745.69, 746.01, 746.1, 746.7, 747.11, 747.41
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  - Other: 745.7, 746.8, 746.82, 746.84, 746.85, 746.87, 746.89, 746.9, 747.2, 747.20, 747.21, 747.29, 747.4, 747.40, 747.49, 747.9, 648.5x, V13.65

Data Collection:

- Collect data from the healthcare claims database(s) on all CHD code(s), cardiac-related procedures, healthcare encounter type when CHD documented (i.e. inpatient, outpatient, emergency), pregnancies, demographic characteristics, and timing of diagnoses relative to each other, the individual’s birth, and pregnancy among a woman with CHDs, and any additional information that may help in determining a true CHD case.
- Demonstrate capacity to access, link, and abstract data from clinical medical records.
- Link identified cases to clinical charts and medical records on a minimum of 1,500 individuals (at least 300 in each CHD severity group, based on most severe CHD code documented for individual) with one or more healthcare claims with a CHD code.
  - Applicant must describe the proposed linkage process, including how the data will be de-duplicated both within and across each data set
  - Linked data should be representative of individuals seeking healthcare in the healthcare system (i.e. not limited to cardiology or other specialty clinic records)
- Develop a process of medical record abstraction by clinicians supervised by a clinician trained in congenital cardiology, possibly supplemented with technology such as natural language processing, using agreed-upon standard CHD definitions and project-specific CHD severity groups to:
  - Determine whether the individual with a CHD code in healthcare claims data has a CHD, the CHD severity, CHD type, and other relevant information (e.g. cardiac-related procedures, pregnancy)
  - Determine final case status for cases with incomplete or uncertain diagnoses in medical record

Data Reporting:
• Collect and store standardized data from healthcare claims and medical records.
• Submit de-identified, de-duplicated individual level data including standardized data elements using a common database in a secure manner to CDC at least quarterly and meet deadlines specified by CDC. CDC has a secure network that will be used for this project.

**Data Assessment:**

Improve understanding of the validity of healthcare claims data to examine comorbidities and other outcomes among individuals with CHDs

• Using medical record as the gold standard, calculate PPV of healthcare claims data for individuals with one or more CHD codes in healthcare claims data.
  o Determine PPV overall, by age, CHD severity, CHD type, pregnancy status, International Classification of Diseases (e.g. ICD-9-CM, ICD-10) and any other relevant characteristics found in healthcare claims data
• Develop and test algorithms to identify individuals with CHDs in healthcare claims data (e.g. by machine learning or other methods using number and timing of healthcare visits with a CHD code, type of healthcare encounter, procedure type, etc.) that improve PPV and maximize area under the receiver operating characteristic (ROC) curve.
  o Determine how each algorithm affects sensitivity, prevalence estimates, and generalizability of findings on specific cardiac and non-cardiac outcomes of interest (e.g. renal disease, hypertension, heart failure)
  o Determine how each algorithm performs by age group, CHD severity, CHD type, and other relevant individual or healthcare characteristics
• Compare and contrast the algorithms in other existing datasets such as MarketScan or Medicaid data, in collaboration with CDC.

**Dissemination:**

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

1. Collaborations

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

Components A & B

• Work with CDC and NOFO #DD19-1902 recipients to agree on standardized processes, methods, standardization of data collection, and other project activities (required).

b. With organizations not funded by CDC:
Component A

- Demonstrate effective relationships and cooperation with appropriate partners such as the birth defects surveillance program and clinical cardiology organizations (e.g. Adult Congenital Heart Disease clinics) with access to congenital cardiac clinical databases, state health department, community based organizations, medical centers. Past collaborations with these partners should be described. Letters of support from a minimum of three partners are required.
- All applicants are strongly encouraged to partner with a birth defects surveillance program and a clinical cardiology organization and provide letters of support from all.
  - If the applicant is a birth defects surveillance program, they are strongly encouraged to partner with clinical cardiology organizations and provide a letter of support.
  - If the applicant is a clinical cardiology organization with access to congenital cardiac clinical database(s), they are strongly encouraged to partner with a birth defects surveillance program and provide a letter of support.
  - If the applicant is not a state health department, then the applicant is required 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 be comprised of personnel with expertise in birth defects surveillance, clinical care of patients with CHDs, informatics, epidemiology, project management/coordination.
- Collaborate and coordinate across state agencies and clinical settings for data collection. 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 access to the data and an understanding that individual level, de-duplicated, de-identified data from the relevant data sources will be shared with CDC and the other NOFO #DD19-1902 recipients. For case-finding data source(s), the letter of support should state the data can be used for case-finding.
- 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.
- Provide evidence of legal authority to share individual-level, de-duplicated, de-identified data from the relevant data sources.

Component B

- Involve appropriate within-region partners, such as health care providers, academic medical centers and/or outpatient centers specializing in CHD care, and other organizations to assist with project activities. Past collaborations with these partners should be described. Letters of support from a minimum of two partners are required.
- The collaborative team should be comprised of personnel with expertise in birth defects
surveillance, clinical care of patients with CHDs, informatics, epidemiology, project management/coordination.

- Collaborate and coordinate across appropriate agencies and clinical settings for data collection. 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 the required access to the data, including a timeline to obtain data, and an understanding that individual level, de-duplicated, de-identified data from the relevant data sources will be shared with CDC and the other Component B recipient(s).
- Work with CDC and other recipient(s) 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.
- Provide evidence of legal authority to share individual-level, de-duplicated, de-identified data from the relevant data sources.

2. Target Populations

**Component A**: Describe the population of individuals aged 1-45 who have been diagnosed with a CHD, as evidenced by inclusion in a population-based birth defects surveillance programs and/or clinical cardiology database, 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**: The focus of validation activities should be on individuals of all ages with CHDs who had a healthcare encounter 1/1/2008-12/31/2017 with a billing code for a CHD and how this population is representative of individuals with CHDs seeking healthcare in the source population.

**a. Health Disparities**

Not applicable.

**iv. Funding Strategy**

Component A: 4-6 awards for 5 year period of performance; $400,000 average award per budget period

Component B: 1-3 awards for 3 year period of performance; $200,000 average award per budget period

**b. Evaluation and Performance Measurement**

**i. CDC Evaluation and Performance Measurement Strategy**

**Component A**:  

**Evaluation and progress reports:**

- Prepare a written assessment of the accomplishments, challenges, and opportunities of the
CHDs 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, identify/prioritize program goals, define source population, identify data sources. **Indicators for success:**
  - Partners are identified and letters of support are included in application.
  - Updates are provided to CDC on routine partner meetings and calls.
  - Program goals are identified and prioritized.
  - Source population is defined, data sources are identified.

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

- **Case Identification activities:** use population-based birth defects surveillance programs and/or congenital cardiac clinical databases to identify eligible cases with CHDs. Cases must be aged 1-45 years and reside in the specified geographic catchment area at any time during 2008-2017. It is strongly encouraged and preferred that applicants use both types of data sources for case-finding. **Indicators for success:**
  - Identified a minimum of 2,000 individuals with CHDs in the case-finding database(s); at least 300 individuals <18 years of age and at least 300 individuals 35-45 years of age.

- **Data Collection activities:** link identified cases to state vital records and National Death Index data to establish vital status and cause(s) of death, link identified cases to additional existing data sources to collect key data elements on healthcare encounters and, if possible, non-healthcare information. **Indicators for success:**
  - For identified cases, other data sources have been accessed and linked for all years from 2008 to 2017.
  - Data elements have been collected in standardized manner at each site.
  - Standardized diagnostic, morbidity, and healthcare resource utilization groupings have been created.
  - Most recent addresses have been geocoded for identified cases.

- **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 Assessment activities: calculating age-specific mortality, describing population with CHDs with healthcare and, if possible, non-healthcare information, from 2008-2017, assess quality of data sources for completeness of healthcare and, if possible, non-healthcare data (e.g., % missing demographic data, provider type), compare information in case-finding to other data sources. **Indicators for success:**

  o Data analysis plan developed and descriptive statistics generated on population with CHDs, including healthcare utilization, severity of CHD (as defined in Section A.2.a (iii) - Strategies and Activities), comorbidities, and other long-term outcomes.
  o Racial/ethnic, socioeconomic, or rural/urban differences in healthcare use and long-term outcomes have been assessed.
  o Age-specific mortality, major causes of death, and healthcare utilization before death have been assessed.
  o Quality of data sources has been assessed, documented, and shared with CDC.
  o Comparison of information between data sources has been completed, documented, and shared with CDC.

• Dissemination activities: share project information and results. **Indicators for success:**

  o Communication plan is developed, submitted to CDC, and implemented.
  o Information shared regularly with CDC and other recipients.
  o Project information and results communicated to target audiences via publications, presentations, and other methods.

**Outputs:**

• **Population-based cohort of individuals aged 1-45 years with CHDs**

  o **Indicator for success:** population-based cohort of individuals aged 1-45 years with CHDs has been developed, submitted to CDC, analyzed, and findings disseminated.

• **Descriptive epidemiology and mortality**

  o **Indicator for success:** report(s) on descriptive epidemiology of individuals aged 1-45 years with CHDs has/have been drafted and disseminated.

• **Additional information on health & if possible, non-health outcomes (e.g., educational)**

  o **Indicator for success:** report(s) on health & non-health outcomes of individuals aged 1-45 years with CHDs has/have been drafted and disseminated.
Outcomes:

- **Improved understanding of strengths & limitations of integrated surveillance for CHDs among public health practitioners**
  - **Indicator for success:** dissemination of publication(s) and conference presentations/webinars describing the strengths and limitations of integrated surveillance for CHDs.

- **Improved understanding of health outcomes of study population with CHDs**
  - **Indicator for success:** dissemination of publication(s) and conference presentations/webinars for stakeholders that describe the health outcomes of the population with CHDs.

- **Improved understanding of racial/ethnic or socioeconomic patterns in healthcare use or long-term outcomes in study population**
  - **Indicator for success:** dissemination of publication(s) and conference presentations/webinars for stakeholders that describe racial/ethnic or socioeconomic patterns in healthcare use or long-term outcomes of the population with CHDs.

- **Increased awareness among health service providers, patients, parents and public of nationwide CHD issues**
  - **Indicator for success:** dissemination of publication(s) and their key messages through various media, and conference presentations/webinars for stakeholders that increase awareness of nationwide CHD issues.

- **Improved ability to calculate age-specific mortality for persons with CHDs**
  - **Indicator for success:** dissemination of publication(s) and conference presentations/webinars that calculate the age-specific mortality for persons with CHDs, by CHD severity and type.

Component B:

**Evaluation and progress reports:**

- Prepare a written assessment of the accomplishments, challenges, and opportunities of the CHDs surveillance project including a description of the problems encountered, lessons learned, potential improvements, etc.
- Draft evaluation measures are below. 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, identify/prioritize program goals, define source population, identify data sources. **Indicators for success:**
  
  o Partners are identified and letters of support are included in application.
  o Updates are provided to CDC on routine partner meetings and calls.
  o Program goals are identified and prioritized.
  o Source population is defined, data sources are identified.

• **Project Management activities:** develop a management and staffing plan; develop and implement communication plan. **Indicators for success:**
  
  o Comprehensive management and staffing plan provided in application.
  o Communication plan is developed and implemented.

• **Case Identification activities:** use data from healthcare claims database(s) to identify eligible individuals with CHDs who had one or more healthcare encounters between 2008-2017. **Indicators for success:**
  
  o Individuals with CHD codes are identified.

• **Data Collection activities:** collect key data elements from healthcare claims data, link identified cases to medical records, and develop process of medical record review. **Indicators for success:**
  
  o Key data elements have been collected from healthcare claims database(s) in a standardized manner.
  o Identified a minimum of 1,500 cases linked to medical records; at least 300 individuals in each CHD severity group (as defined Section A.2.a (iii) - Strategies and Activities).
  o Process for medical records review using agreed-upon standard and project-specific definitions and protocols developed, documented, and submitted to CDC.
  o Medical records have been reviewed according to developed protocol.

• **Data Reporting activities:** collect/store standardized data, submit de-identified, de-duplicated individual level encounter and summary level data to CDC. **Indicators for success:**
  
  o Data standardization and storage processes are documented and sent to CDC.
  o De-identified, de-duplicated individual level data and results of medical record review have been submitted to CDC at least quarterly within agreed upon benchmarks and timeframes.

• **Data Assessment activities:** calculate PPV of healthcare claims data for individuals with one or more CHD-coded healthcare claims; Develop and test algorithms to identify individuals with CHDs in healthcare claims data (e.g. by machine learning or other methods using number and timing of healthcare visits with a CHD code, type of healthcare encounter, etc.) that improve PPV and maximize area under the ROC curve;
compare and contrast the algorithms in other existing datasets.  **Indicators for success:**

- Data analysis plan has been developed.
- PPV and other statistics of healthcare claims data have been calculated.
- Algorithms developed and tested in healthcare claims data to improve PPV and maximize area under the ROC curve.
- Algorithms compared and contrasted in other data sources.
- Findings documented and shared with CDC.

**Dissemination activities:** sharing project information and results. **Indicators for success:**

- Communication plan is developed, submitted to CDC for review, and implemented.
- Information shared regularly with CDC and other Component B recipient(s).
- Project information and results communicated to target audiences via publications, presentations, and other methods.

**Outputs:**

- **Cohort of individuals with CHD codes in healthcare claims database(s) had CHDs validated with medical record information**
  
  - **Indicator for success:** cases identified in healthcare claims database(s) had CHD coding validated against medical record information; report(s) on PPV of healthcare claims data for surveillance of individuals with CHDs created and disseminated.

- **Algorithm developed and tested to use healthcare claims data for surveillance of individuals with CHDs**
  
  - **Indicator for success:** algorithms developed, tested, submitted results to CDC; report(s) on algorithm created and disseminated.

**Outcomes:**

- **Improved understanding of validity and utility of healthcare claims data for surveillance of individuals of all ages with CHDs, overall and by individual or healthcare characteristics**
  
  - **Indicator for success:** dissemination of publication(s) and conference presentations/webinars describing the validity and utility of healthcare claims data for surveillance of individuals with CHDs.

- **Improved accuracy of surveillance of CHDs using healthcare claims data**
  
  - **Indicator for success:** Reports written that compare and contrast algorithms in other data sources, in collaboration with CDC.
Data Management Plan (DMP)

Applicants must 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:

- Descriptions of the data to be produced in the proposed project
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- 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


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.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP), if applicable, for accuracy throughout the lifecycle of the project. 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/additionalrequirements/ar-25.html](https://www.cdc.gov/grants/additionalrequirements/ar-25.html).

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 a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

c. Organizational Capacity of Recipients to Implement the Approach

Component A:

Applicants should possess the capacity to either create a new or enhance an existing surveillance system, ensuring that individuals aged 1-45 years with CHDs are included. Successful applicants must describe the level of organizational capacity necessary to implement the NOFO successfully. Organizational capacity includes skill sets to implement the awards such as: program and performance management, CHDs clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development, 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.

The eligible organizations should have the 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 during 2008-2017) and have 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 1-45 years with CHDs. Applicants should demonstrate, through MOUs and/or letters of support, the ability to access and share the data per the NOFO guidelines. Applicants will identify the proposed defined geographic region and population characteristics.

Component B:

Applicants should possess the capacity to access and link healthcare claims data on at least 1,500 individuals to clinical records. Successful applicants must describe the level of organizational capacity necessary to implement the NOFO successfully. Organizational capacity includes skill sets to implement the awards such as: program and performance management, CHDs clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development, evaluation, performance monitoring, and financial reporting. CVs of key staff should be included and a brief position description of existing staff. 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. Eligible applicants will have the capacity to access, link, and use data from healthcare claims database(s) to identify a minimum of 1,500 individuals (at least 300 in each defined CHD severity group (as defined in Section A.2.a (iii) - Strategies and Activities). Applicants should demonstrate, through MOUs
and/or letters of support, the ability to access and share the data per the NOFO guidelines.

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.

<table>
<thead>
<tr>
<th>Period of Performance Outcome:</th>
<th>Outcome Measure:</th>
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</thead>
<tbody>
<tr>
<td>[from Outcomes section and/or logic model]</td>
<td>[from Evaluation and Performance Measurement section]</td>
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</table>

<table>
<thead>
<tr>
<th>Strategies and Activities</th>
<th>Process Measure [from Evaluation and Performance Measurement section]</th>
<th>Responsible Position / Party</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>1.</td>
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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.

f. CDC Program Support to Recipients (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff is substantially involved in the program activities above and beyond routine grant monitoring.

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

Component B:

- 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.
• Analyze data and author/coauthor reports and publications.
• Assist with evaluation of the project.

B. Award Information

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

2. Award Mechanism:
   U50
   U50 - Special Cooperative Investigations/Assessment of Control/Prevention Methods

3. Fiscal Year: 2019

4. Approximate Total Fiscal Year Funding: $2,300,000

5. Approximate Period of Performance Funding: $11,500,000
   This amount is subject to the availability of funds.

Component A: 9/1/2019 - 8/31/2024; 5 years
Component B: 9/1/2019 - 8/31/2022; 3 years

Estimated Total Funding: $11,500,000

6. Approximate Period of Performance Length: 5 year(s)

7. Expected Number of Awards: 6
   Component A: 4-10 awards
   Component B: 1-3 awards

8. Approximate Average Award: $400,000 Per Budget Period
   Component A: $400,000 average award per budget period
   Component B: $200,000 average award per budget period

9. Award Ceiling: $500,000 Per Budget Period
   This amount is subject to the availability of funds.
   Component A: $500,000 per budget period
   Component B: $300,000 per budget period

10. Award Floor: $100,000 Per Budget Period
    Component A: $300,000 per budget period
    Component B: $100,000 per budget period

11. Estimated Award Date: 08/01/2019
12. Budget Period Length: 12 month(s)

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

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

C. Eligibility Information

1. Eligible Applicants

<table>
<thead>
<tr>
<th>Eligibility Category</th>
<th>Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled &quot;Additional Information on Eligibility&quot;</th>
</tr>
</thead>
</table>

Additional Eligibility Category:

2. Additional Information on Eligibility

Only one application per organization as determined by the organization’s Dun & Bradstreet number will be accepted for each Component. Therefore, any organization applying for both Component A and Component B will submit a separate application for each component and it will be evaluated separately.

A Bona Fide Agent is an agency/organization identified by the state or local government as eligible to submit an application in lieu of a state or local government application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Attach this documentation behind the first page of your application form or for electronic applications, use a PDF file and attach as "Other Documents" and label as appropriate.

The award ceiling for Component A is $500,000 and $300,000 for Component B. CDC will consider any application requesting an award higher than the respective Component amount as non-responsive and it will receive no further review.

3. Justification for Less than Maximum Competition

Not applicable.

4. Cost Sharing or Matching

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

5. Maintenance of Effort
Maintenance of effort if 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.

a. Data Universal Numbering System:
All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.
The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http://fedgov.dnb.com/webform/displayHomePage.do. The DUNS number will be provided at no charge.
If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):
The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. 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 www.SAM.gov.

c. Grants.gov:
The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.
All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

<table>
<thead>
<tr>
<th>Step</th>
<th>System</th>
<th>Requirements</th>
<th>Duration</th>
<th>Follow Up</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Data Universal Number</td>
<td>1. Click on <a href="http://fedgov.dnb.com/webform">http://fedgov.dnb.com/webform</a></td>
<td>1-2 Business Days</td>
<td>To confirm that you have been issued a new</td>
</tr>
<tr>
<td></td>
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<td>2. Select Begin DUNS</td>
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</tbody>
</table>
### System (DUNS) search/request process

3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit #
4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number

| System for Award Management (SAM) formerly Central Contractor Registration (CCR) | 1. Retrieve organizations DUNS number  
2. Go to [www.sam.gov](http://www.sam.gov) and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)  
3-5 Business Days but up to 2 weeks and must be renewed once a year | For SAM Customer Service Contact [https://fsd.gov/fsd-gov/home.do](https://fsd.gov/fsd-gov/home.do) Calls: 866-606-8220 |
|---|---|---|
| 2 | 1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR)  
2. Once the account is set up the E-BIZ POC will be notified via email  
3. Log into grants.gov using the password the E-BIZ POC received and create new password  
4. This authorizes the AOR to submit applications on behalf of the organization | Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov) | Register early! Log into grants.gov and check AOR status until it shows you have been approved |

### Request Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at [www.grants.gov](http://www.grants.gov). If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC OGS staff at 770-488-
2700 or e-mail OGS ogstims@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

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 or postmarked by)
Due Date for Letter of Intent: 03/18/2019

b. Application Deadline
Due Date for Applications: 04/17/2019, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Information Conference Call
Not applicable.

5. CDC Assurances and Certifications
All applicants are required to sign and submit “Assurances and Certifications” documents indicated at http://www.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljijmaa))/Homepage.aspx.
Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file “Assurances and Certifications” and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://www.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljijmaa))/Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

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

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

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

**Duplication of Efforts**

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to more than one 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.”

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<th>6. Content and Form of Application Submission</th>
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<td>Applicants are required to include all of the following documents with their application package</td>
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7. Letter of Intent
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:

Bill Paradies
CDC, NCBDDD, Birth Defects Branch
Telephone number: 404.498.3919
Fax number: 770.488.3263 / 3266
E-mail: wep2@cdc.gov

8. Table of Contents
(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the “Table of Contents” for the entire submission package.
Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary
(Maximum 1 page)
A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative
(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)
Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include all of the following headings (including subheadings): Background, Approach,
Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

### a. Background

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

### b. Approach

#### i. Purpose

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

#### ii. Outcomes

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

#### iii. Strategies and Activities

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

### 1. Collaborations

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

### 2. Target Populations and Health Disparities

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

c. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

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

d. Organizational Capacity of Applicants to Implement the Approach

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

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

12. Budget Narrative

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

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

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

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the
intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed. Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction’s vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

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

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 2-3 (Component B).

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

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

Executive Order 12372 does not apply to this program.

15. Pilot Program for Enhancement of Employee Whistleblower Protections

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


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.

17. 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:
  o 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
  o the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
• See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
• The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
• In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

Recipients may not use this NOFO cooperative agreement funds for the same activities that are being or were funded from another federal funding source.

18. Data Management Plan
As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant’s assurance of the quality of the public health data through the data’s lifecycle and plans to deposit 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/additionalrequirements/ar-25.html

19. Other Submission Requirements
a. Electronic Submission:
Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option. If Internet access is not available or if the forms cannot be accessed online, applicants may contact the OGS TIMS staff at 770-488-2700 or by e-mail at ogstims@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to OGS TIMS staff for processing from www.grants.gov on the deadline date.

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

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

If you do not receive a “validation” e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

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

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical
difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis. An applicant’s request for permission to submit a paper application must:

1. Include the [www.grants.gov](http://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](http://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 (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

### E. Review and Selection Process

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

**a. Phase 1 Review**

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

**b. Phase II Review**

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

i. Approach

ii. Evaluation and Performance Measurement

iii. Applicant’s Organizational Capacity to Implement the Approach

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

**i. Approach**

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<th>Component A:</th>
<th>Maximum Points: 40</th>
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**Background and Understanding of the Public Health Burden and Impact (5 of 40 Points)**

- To what extent does the applicant demonstrate a clear, concise understanding of the requirements, objectives, and purpose of this NOFO that are aligned with the activities, outputs, and outcomes in the CDC Project Description?
To what extent does the applicant describe the source population for their surveillance effort? Does the applicant have a sufficient population size with diversity in both race/ethnicity and socioeconomic status included in the surveillance population?

To what extent does the applicant describe the case-finding data sources, including population-based birth defects surveillance systems and/or congenital cardiac clinical data as stipulated in the NOFO?

To what extent does applicant describe the data sources available for healthcare encounter and, if possible, non-healthcare information, and how their system will include calendar years 2008-2017?

Does the applicant provide a description of the estimated number of individuals aged 1-45 years with CHDs from case-finding data source(s) overall, for analyses on mortality, and percent of those that may be residing in the catchment area during 2008-2017, for analyses on healthcare utilization and outcomes?

**Work Plan (15 of 40 Points)**

- Do the activities describe the proposed intent to conduct comprehensive surveillance among individuals aged 1-45 years with CHDs? Do the activities include the ascertainment of long-term health and non-health outcomes? Are the outcome measures clear and measurable to address the need and the main activities of this NOFO?
- To what extent does the applicant's plan carry out the proposed objectives? Does the project plan include a comprehensive plan for the first budget period? Does the plan include quantitative process and outcome measures?
- To what extent does the applicant include a reasonable and achievable timeline to complete the activities in the specified period of performance?
- Does the applicant document a minimum of 2,000 total individuals with CHDs in case-finding database(s) and at least 300 individuals <18 years of age and at least 300 individuals 35-45 years of age?
- To what extent does the applicant define a total source population size of at least 1 million individuals per year during 2008-2017 and the accuracy and reasonableness of how that estimate was obtained?
- Does the applicant describe their planned collaboration with appropriate partners both internal and external to the state health department? Does the applicant demonstrate relationships and cooperation with appropriate partners and provide at least three letters of support from partners (e.g., birth defects surveillance program, clinical cardiology organizations with access to congenital cardiac clinical databases, state health department, community based organizations, medical centers) and a letter of support from the health department if the applicant is not the state health department?

**Methods (20 of 40 Points)**

- Are the proposed methods for case identification and collection of data for identified cases feasible and do they clearly describe the processes to be used to accomplish the work plan within the project timeframe?
- To what extent will the methods accomplish the program goals?
To what extent does the applicant describe case-finding data source(s)? Does the applicant use both birth defects surveillance program data and clinical cardiac database(s) for case-finding?
To what extent does the applicant describe other data sources that will link to case-finding data sources?
To what extent does the applicant describe how the data is population-based, or does the applicant provide information on how the data will approximate population-based estimates with respect to racial/ethnic and socioeconomic diversity?
Does the applicant propose and describe their planned methods to explore in- and out-migration of cases from the catchment area during the surveillance years?
To what extent does the applicant describe the proposed linkage and de-duplication process, including surveillance activities for 2008-2017?
To what extent do the proposed methods address the procedures for generation of the standardized data elements, process for submitting de-identified, de-duplicated data to CDC (including both encounter and summary record data), analysis and dissemination of findings, and plan for communicating findings to stakeholders?
To what extent does the applicant describe any restrictions to transmitting the required data elements and how they might address these issues?
To what extent does the applicant describe how they will share individual level, de-identified, de-duplicated data with CDC and the other recipients?
Does the applicant describe a plan to use case-finding data source(s) to compare information on CHD type and severity to other data sources, including whether and how frequently a CHD was documented?

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

To what extent does the applicant demonstrate a clear, concise understanding of the requirements, objectives, and purpose of this NOFO that are aligned with the activities, outputs, and outcomes in the CDC Project Description?
To what extent does the applicant describe the healthcare claims data source(s) that will be used for case-finding and the medical records that will be used for validation of CHDs?
To what extent does the applicant describe the availability of at least 1,500 individuals with CHDs (at least 300 in each CHD severity group) identified from healthcare claims data that can be linked to medical records for review?
To what extent does the applicant identify and describe other medical records from throughout the healthcare system (not only cardiology clinics or other specialty care clinics) that will be reviewed?

Work Plan (15 of 40 Points)

Do the activities describe the proposed intent to validate billing codes for CHDs in healthcare claims data? Are the outcome measures clear and measurable to address the
Methods

- Are the proposed methods for data access, linkage and medical record review feasible and do they clearly describe the processes to be used to accomplish the work plan within the project timeframe?
- To what extent will the methods accomplish the program goals?
- To what extent does the applicant describe all data sources (healthcare encounter and clinic data)?
- To what extent does the applicant describe medical record review by clinicians?
- To what extent does the applicant describe a plan for determining PPV overall, by age, CHD severity, CHD type, pregnancy status, International Classification of Diseases code, and by any other relevant characteristics found in healthcare claims data?
- To what extent does the applicant describe a plan to develop and test algorithms to identify individuals with CHDs in healthcare claims data (e.g. by machine learning or other methods and using information such as number and timing of healthcare visits with a CHD code, type of healthcare encounter, etc.) that improve PPV and maximize area under the receiver operating characteristic (ROC) curve?
- To what extent does the applicant describe a plan to determine how each algorithm affects sensitivity, prevalence estimates, and generalizability of findings on specific cardiac and non-cardiac outcomes of interest? Does the applicant describe a plan to determine how each algorithm performs by age group, CHD severity, CHD type, and other relevant individual or healthcare characteristics?
- To what extent does the applicant describe a plan to compare and contrast the algorithms in other existing healthcare claims datasets, such as MarketScan or Medicaid data?

ii. Evaluation and Performance Measurement

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 for case identification and other data sources for healthcare encounter and, if possible, non-healthcare information, conducting data linkages of identified cases to other data sources, establishing vital status, data collection, reporting, assessment, and communicating findings to stakeholders?

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 identifying and accessing data sources, identifying cases with CHD codes and linking to clinical records, conducting medical record review, calculating PPV, and developing and testing algorithms that improve PPV and maximize area under the ROC curve for identifying individuals with CHDs in healthcare claims data?

iii. Applicant's Organizational Capacity to Implement the Approach

Component A:

• Has the applicant identified appropriate staff for program and performance management, CHDs clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development, 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 collaborations between birth defects surveillance programs and clinical cardiology organizations?
• 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 hiring timeline provided for vacant positions? Has the applicant demonstrated the ability to identify and hire sub-recipients?
• To what extent does the applicant describe their ability to begin immediate implementation of the NOFO activities?
• To what extent does the applicant provide evidence of legal authority (via letters of support or other documents) to access the relevant data sources and to share de-identified, de-duplicated individual-level data with CDC and other NOFO #DD19-1902 recipients, including addressing any HIPAA and IRB requirements? Examples of past access and transmission should be described. Applicants must provide letters of support from agencies that house source data authorizing its use for case-finding, access, and sharing of required data.
• To what extent did the applicant describe past or current experience with linking the identified data sources, or linking other data sets of similar size and complexity?
• To what extent does the applicant 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? Does the applicant provide letters of support from a minimum of three partners. If the applicant is a birth defects surveillance program, they are strongly encouraged to partner with clinical cardiology organizations and provide a letter of support. If the applicant is a clinical cardiology organizations with access to congenital cardiac clinical databases, they are strongly encouraged to partner with a birth defects surveillance program and provide a letter of support. If the applicant is not a state health department, then the applicant is required to include a letter of support/bona fide agent letter from the state health department.
• Does the applicant provide a letter of support from the holder of the data they wish to access that addresses access to the data and an understanding that individual level, de-duplicated, de-identified data from the relevant data sources will be shared with CDC and the other recipients? For case-finding data source(s), the letter of support should state the data can be used for case-finding.
• Does the applicant provide recent letters from each organization that owns the data sources granting legal authority to access the individual-level, identifiable data, use birth defect registry and/or clinical databases for case-finding, link to other data sources, and share de-identified data with the CDC and other recipients during the project period?
• Does the applicant describe their legal authority to access individual-level, identifiable data from birth defects surveillance systems and/or clinical cardiology databases and to use these data sources for case-finding?
• Does the applicant describe their legal authority to share individual-level, de-identified data with CDC and other recipients?
• Does the applicant describe their legal authority to access and share healthcare encounter and, if possible, other non-healthcare information from 2008-2017?

Component B:

• To what extent has the applicant identified appropriate staff for program and performance management, CHDs clinical expertise, data analysis, data linkage, epidemiologic and surveillance expertise, communication/material development, 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?
• 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 hiring timeline provided for vacant positions? Has the applicant described their ability to identify and hire sub-recipients?
• To what extent does the applicant demonstrate their ability to begin immediate implementation of the NOFO activities?
• To what extent does the applicant provide evidence of legal authority (via letters of
support or other documents) to access the relevant data sources and to share de-identified, de-duplicated individual-level data with CDC and other NOFO #DD19-1902 recipients, including addressing any HIPAA and IRB requirements? Examples of past access and transmission should be described. Applicants must provide letters of support from agencies that house source data authorizing its use for case-finding, access, and sharing of required data.

- To what extent does the applicant 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?
- Does the applicant provide a letter of support from the holder of the data they wish to access that addresses access to the data and use of data for linkage and medical record review? Additionally it should address an understanding that individual level, de-duplicated, de-identified data from the relevant data sources will be shared with CDC and the other recipients.
- Does the applicant provide recent letters from each organization that owns the data sources granting legal authority to access the individual-level, identifiable data, link to other data sources, and perform medical record review to validate the identified cases?
- Does the applicant describe their legal authority to access data and/or datasets of individual-level, identifiable data for calendar years 2008-2017, including access to case-finding data source(s), and clinical data sources that can be linked for medical record review?
- Does the applicant describe their legal authority to share individual-level de-identified data with CDC and other recipients?

**Budget**

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](http://www.cdc.gov/grants/documents/Budget-Preparation-Guide.pdf)

c. Phase III Review
Applications will be funded in order by score and rank determined by the review panel. The following factors may affect the funding decision:

1. Diversity of population in terms of race/ethnicity, age, and socioeconomic status.
2. Number of cases to be included.
3. Size of the population under surveillance and the ability to obtain data that is population-based.
4. Geographic location and diversity (i.e. not clustered in one region, urban, rural).
5. Availability of funds and program priorities.

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

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

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

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

1. Financial stability;
2. Quality of management systems and ability to meet the management standards prescribed in this part;
3. History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
4. Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
5. The applicant's ability to effectively implement statutory, regulatory, or other requirements.
imposed on non-Federal entities. CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

### 2. Announcement and Anticipated Award Dates

Awards are anticipated to be announced in August 2019 with a 9/1/2019 start date.

### F. Award Administration Information

#### 1. Award Notices

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

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

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

#### 2. Administrative and National Policy 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

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

3. Reporting

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

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

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

<table>
<thead>
<tr>
<th>Report</th>
<th>When?</th>
<th>Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient Evaluation and Performance Measure</td>
<td>6 months into award</td>
<td>Yes</td>
</tr>
<tr>
<td>-----------------------------------------</td>
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<tr>
<td></td>
<td>No later than 120 days before end of budget period. Serves as yearly continuation application.</td>
<td>Annually in APR and also 30 days after the end of the budget period.</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
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**a. Recipient Evaluation and Performance Measurement Plan (required)**

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

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

**Performance Measurement**

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

**Evaluation**

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publically available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

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

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed. This report must include the following:

• **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
• **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
• **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
• **Successes**
  o Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
  o Recipients must describe any additional successes (e.g., identified through evaluation results or lessons learned) achieved in the past year.
  o Recipients must describe success stories.
• **Challenges**
  o 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.
  o 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**
  o 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)
  o SF-424A Budget Information-Non-Construction Programs.
For Year 2 and beyond, award recipients may request in their APR up to 75% of their estimated unobligated funds be carried over into the next budget period.

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

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

Annually in APR and also 30 days after budget period end.

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. 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)
This report is due 90 days after the end of the period of performance. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory
4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov. Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000. For the full text of the requirements under the FFATA and HHS guidelines, go to:


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.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Bill Paradies, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Mailstop S106-3

4770 Buford Highway
Atlanta, GA  30341-3717

Telephone: (404) 498-3919
Email: wep2@cdc.gov

Grants Staff Contact
For **financial, awards management, or budget assistance**, contact:

LaKasa Wyatt, Grants Management Specialist  
Department of Health and Human Services  
Office of Grants Services  
Mailstop TS-2  
4770 Buford Highway  
Atlanta, GA 30341-3717  
Telephone: (770) 488-2728  
Email: lgw5@cdc.gov

For assistance with **submission difficulties related to** [www.grants.gov](http://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.

For all other **submission** questions, contact:  
Technical Information Management Section  
Department of Health and Human Services  
CDC Office of Financial Resources  
Office of Grants Services  
2920 Brandywine Road, MS E-14  
Atlanta, GA 30341  
Telephone: 770-488-2700  
Email: ogstims@cdc.gov

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

**H. Other Information**

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at [www.grants.gov](http://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  
- CDC Assurances and Certifications  
- Report on Programmatic, Budgetary and Commitment Overlap  
- Table of Contents for Entire Submission

For international NOFOs:
Optional attachments, as determined by CDC programs:

- Resumes / CVs
- Position descriptions
- Letters of Support
- Organization Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate, if applicable
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

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 [http://www.cdc.gov/grants/additional_requirements/index.html](http://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 (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

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

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.
**Budget Period or Budget Year**: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

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

**CDC Assurances and Certifications**: Standard government-wide grant application forms.

**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. [http://www.cdc.gov/grants/additionalrequirements/index.html](http://www.cdc.gov/grants/additionalrequirements/index.html).

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

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

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

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

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

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

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

**Health Equity:** Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

**Health Inequities:** Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

**Healthy People 2020:** National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

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

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

**Intergovernmental Review**: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State’s process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental-Review-SPOC_01_2018_OFFM.pdf.

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

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

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

**Maintenance of Effort**: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

**Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA)**: Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

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

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

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

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

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

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

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

**Plain Writing Act of 2010:** The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

**Program Strategies:** Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

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

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

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

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

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

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

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

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

NOFO-specific Glossary and Acronyms