

Centers for Disease Control and Prevention

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

I-FASD: Understanding Clinical Data and Pathways to Inform Surveillance of Children with Fetal Alcohol Spectrum Disorders

CDC-RFA-DD22-2202

Application Due Date: May 2, 2022

Table of Contents

A. Funding Opportunity Description 3
B. Award Information 16
C. Eligibility Information 18
D. Application and Submission Information 19
E. Review and Selection Process 31
F. Award Administration Information 34
G. Agency Contacts 41
H. Other Information 42
I. Glossary 43

Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-DD22-2202. 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:

I-FASD: Understanding Clinical Data and Pathways to Inform Surveillance of Children with Fetal Alcohol Spectrum Disorders

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-DD22-2202

E. Assistance Listings Number:

93.073

F. Dates:

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

April 1, 2022

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

3. Due Date for Informational Conference Call:
March 14, 2022 - The CDC program will hold an Informational Conference Call for potential applicants to ask questions. Applicants can access the latest information related to the call at https://www.cdc.gov/ncbddd/fasd/nofo.html

G. Executive Summary:

1. Summary Paragraph
There are no existing data sources that provide ongoing, systematic estimates of the number of children with Fetal Alcohol Spectrum Disorders (FASDs). Multi-institutional healthcare data are a potential source of public health surveillance information that have yet to be explored. CDC plans to fund entities for a feasibility project to enhance understanding of existing healthcare data and explore opportunities to leverage these data for public health surveillance of children with FASDs. For this feasibility project, CDC will work with entities to identify data sources (e.g., medical records) and data elements that contain relevant information about children referred, evaluated, diagnosed, or receiving care for an FASD. Information will be analyzed for a sample of children to characterize the availability and quality of prenatal exposure, diagnosis-related, and other relevant information related to FASDs and to describe the referral, evaluation, diagnosis, and care pathways and processes for children suspected of or diagnosed with FASDs. Information from key informants will also be collected to provide insight about opportunities to use healthcare data for surveillance purposes, and to provide insight about FASD diagnosis and care pathways and processes. This project will contribute to increased knowledge of current data sources and practices as well as benefits and challenges associated with healthcare data to inform future public health surveillance of children with FASDs.

a. Eligible Applicants:
Open Competition

b. Funding Instrument Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
3

d. Total Period of Performance Funding:
$4,050,000

e. Average One Year Award Amount:
$450,000

f. Total Period of Performance Length:
3

g. Estimated Award Date:
August 01, 2022

h. Cost Sharing and / or Matching Requirements:
No

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

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Fetal Alcohol Spectrum Disorders (FASDs) are a group of overlapping conditions that can occur in a person who was exposed to alcohol before birth. These lifelong conditions include both neurodevelopmental and physical problems. Recent point-in-time studies found the prevalence of first grade children with FASDs across the US ranged from 11.3 to 71.4 per 1,000. However, systematic, ongoing estimates of children living with an FASD in the general US population are unavailable. Public health surveillance of children with FASDs has been a challenge for several reasons, including lack of information or documentation on prenatal alcohol exposure (PAE), which is required to diagnose most FASD conditions; lack of consistency in how and where exposure information is documented in healthcare records; lack of agreed upon diagnostic criteria; and high rates of missed diagnosis or misdiagnosis. Further, prenatal exposure to other substances and limited information about these exposures, other co-morbid conditions, and stigma presents additional challenges to diagnosis and public health surveillance of children with FASDs.

Information from existing healthcare data is a potential source of surveillance data, but there is a need to better understand the availability and quality of information as well as the processes and pathways by which children suspected of or diagnosed with an FASD are referred, evaluated, diagnosed, and/or receive care. Therefore, the purpose of this project is to enhance understanding about the feasibility of using existing healthcare records for public health surveillance of children with FASDs. CDC plans to fund entities with experience and expertise providing health care services to children suspected of or living with FASDs. CDC will work with recipients to identify data sources (e.g., medical records, administrative claims data, educational records, as available) and data elements that contain relevant information about children referred, evaluated, diagnosed, and/or receiving care for an FASD. Relevant information from healthcare records will be analyzed for a sample of children to characterize the availability and quality of information related to FASDs as well as to describe the referral, evaluation, diagnosis, and treatment pathways and processes for children suspected of or diagnosed with FASDs. Information from clinical experts and other key informants will also be used to provide insight about the strengths, challenges, and quality of existing healthcare data, as well as to provide insight about the care pathways for children suspected of or diagnosed with FASDs.

Findings will inform development of future public health surveillance projects by identifying key variables from healthcare data that might be used to identify children with FASDs; identifying variables prone to missing information and that might hinder identification of children with an FASD; and understanding how children with an FASD diagnosis might differ from those who might otherwise be diagnosed, but lack sufficient PAE documentation or other relevant information. Furthermore, findings will contribute to understanding the diagnostic pathways for children suspected of or diagnosed with FASDs, including potential disparities along these

pathways, and may provide insight about the impact of other substance exposures on FASD diagnosis and receipt of care. Findings from this project will also support CDC's data modernization initiative, aimed to improve real-time data reporting of public health information.

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

c. Healthy People 2030
This NOFO relates to the Healthy People 2030 topic areas of Pregnancy and Childbirth, Drugs and Alcohol, and Women. This NOFO specifically relates to objective MICH-09: "Increase abstinence from alcohol among pregnant women" (https://health.gov/healthypeople/objectives-and-data/browse-objectives/pregnancy-and-childbirth/increase-abstinence-alcohol-among-pregnant-women-mich-09) as it will inform future public health surveillance of children with FASDs.

d. Other National Public Health Priorities and Strategies
The authorizing legislation for Title V Maternal and Child Health Services Block Grant in the Social Security Act mandates the annual state-level reporting of "the proportion of infants born with fetal alcohol syndrome" (Sec. 506(a)(2)(B) of the Social Security Act [42 U.S.C. 706 (a)(2)(B)] https://www.ssa.gov/OP_Home/ssact/title05/0506.htm

e. Relevant Work
CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) is congressionally authorized to conduct fetal alcohol syndrome (FAS)-related activities. NCBDDD's Division of Birth Defects and Infant Disorders' scientific agenda includes an objective to conduct and improve surveillance related to prenatal substance exposures and child outcomes. CDC monitors the prevalence of alcohol use among women of reproductive age and pregnant persons and previously supported projects to conduct surveillance of children with FAS. This NOFO extends prior work and aligns with the Division's agenda by understanding how healthcare data may be leveraged for surveillance of children with FASDs.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

CDC-RFA- DD22-2202 Logic Model: **I-FASD: Understanding Clinical Data and Pathways through Care to Inform Surveillance of Children with FASDs**

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
1. **Identify data sources and data elements (e.g., electronic medical records, diagnostic codes, procedure**	**Increase knowledge of current practices and data sources for identification, evaluation,**	Improve surveillance methods that address challenges and needs to inform	Enhance surveillance of children with FASDs to determine prevalence and information related to alcohol and other

codes, vital records, school records, as available) to inform future surveillance of children with FASDs 2. **Characterize the availability of information related to FASDs and the quality of this information in health care record systems (e.g., diagnostic and procedure codes and other clinical and administrative data)** 3. **Describe the process for identifying, referring, evaluating, diagnosing, and treating children suspected of or diagnosed with FASDs**	**diagnosis, referral for care and treatment of children with FASDs** **Increase knowledge of challenges and benefits of using clinical and other administrative data for surveillance of children with FASDs**	future design of FASD surveillance Improve ability to estimate the proportion, characteristics, disparities, comorbidities, and healthcare experiences for children with FASDs	substances Improve recognition and documentation of FASDs as a neurodevelopmental condition Adapt surveillance practices and measures to identify disparities surrounding FASD-related referrals, diagnoses, and treatments

i. Purpose

Existing healthcare data is an information source for public health surveillance of children with FASDs, but there is a need to better understand these data. This feasibility project will characterize information accessible within health-related data systems for children suspected or diagnosed with an FASD, as well as describe the referral, evaluation, and diagnosis processes. Findings will inform development of surveillance activities by identifying and characterizing the quality of data elements and will also contribute to understanding about pathways through care for children with FASDs.

ii. Outcomes

The funded recipients are expected to achieve two short-term outcomes: 1) increase knowledge of current practices and data sources available for assessing the public health impact of children with FASD, including identification, evaluation, diagnosis, referral for care and treatment; and 2)

increase knowledge of challenges and benefits of using clinical and other administrative data for surveillance of children with FASDs.

iii. Strategies and Activities

Strategy 1: Identify data sources and data elements (e.g., electronic medical records, diagnostic codes, procedure codes, vital records, school records, as available) to inform current and future surveillance of children with FASDs

- Activity 1a. Identify and describe data that contain relevant sociodemographic, clinical encounter, diagnostic, and other health-related information about children referred, evaluated, diagnosed, or receiving care for an FASD.
    - Identify and describe available data sources, that might include medical records, referral information, claims databases, vital records, early intervention records, school records, or other administrative databases.
    - Identify and describe available data elements, which might include sociodemographic characteristics (e.g., sex, race/ethnicity), diagnostic information (e.g., dysmorphology information, prenatal exposure to alcohol or other substances, growth), and other clinical information (e.g., neurodevelopmental status, co-occurring medical conditions).
    - Identify and describe common procedure, diagnostic, or billing codes used to document health or health-related encounters for children referred, evaluated, or diagnosed with FASDs.

- Activity 1b. Based on data sources and data elements identified, collaborate with other funded recipients and CDC to develop a plan to collect quantitative information to address Strategy 2 and Strategy 3:
    - Define subpopulations of interest for data abstraction (e.g., children referred for an FASD evaluation, but not evaluated or diagnosed with an FASD; children referred, for an FASD evaluation, evaluated for an FASD, but not diagnosed with FASD; children diagnosed with an FASD) and relevant timeframes (e.g., diagnosed and/or receiving relevant clinical services within prior 5 years).
    - Draft and review a data collection tool and protocol to abstract and link standardized sociodemographic, clinical encounter, diagnostic, and other health-related information, as available, among de-identified, de-duplicated samples from each funded recipient for subpopulations of interest.
    - Pilot the quantitative data collection tool and protocol among an agreed upon sample of records (e.g., 3-5 records). The data collection tool should be revised and edited until the beta/pilot testing of the form results in successfully capturing all required data elements.
    - Abstract a minimum of 50 deduplicated records among subpopulation of children referred for an FASD evaluation.

- Activity 1c. Collaborate with other funded recipients and CDC to develop a plan to collect qualitative information to address Strategy 2 and Strategy 3. For each strategy:
    - Develop a list of key informants (e.g., clinical experts, support staff, information specialists, families or caregivers) within each funded recipient's organization and affiliated institutions.

- Identify an appropriate qualitative method(s) (e.g., focus groups, key informant interviews) for each recipient to collect information.
- Develop question lists, interview guides, and data collection protocols for qualitative data collection.

Strategy 2: Characterize the availability of information related to FASDs and the quality of this information in health care record systems (e.g., diagnostic and procedure codes and other clinical and administrative data)

- Activity 2a. Using the quantitative data collection tool, abstract linked, standardized data and develop de-identified, non-duplicated, individual-level dataset(s) for populations of interest. Recipients will use the quantitative data collection tool to collect information for children within each subpopulation of interest mentioned above.
- Activity 2b. Using the qualitative data collection tool for Strategy 2, collect information from key informants about the strengths, challenges, and quality of clinical and administrative data.
- Activity 2c. Collaborate with CDC and other funded recipients to analyze and/or interpret quantitative and qualitative data (pooled and/or site-specific), as available, to:
    - Describe the quality of data sources and data elements. Data sources and elements might include clinical information (e.g., diagnosis related information, clinical notes/verbatim text) as well as sociodemographic information (e.g., race/ethnicity). Quality assessments might include describing the rates of missing information, consistency between data sources, etc.
    - Describe impact of missing or poor-quality data sources/elements on ability to evaluate, diagnose, or provide care for children suspected of or diagnosed with FASDs.
    - Describe correlates and potential contributors to missing or poor-quality data.
    - Describe opportunities, strengths, and challenges related to using clinical and administrative data to advance future surveillance activities for individuals with FASDs (e.g., data sources with incomplete information or that are not captured in health record systems; opportunities to link healthcare data to extant data sources).
- Activity 2d. Collaborate with CDC and other funded recipients to communicate project information and results, as appropriate, to healthcare providers, researchers, and other partners (e.g., individuals with FASDs and their families or caregivers) via reports, publications, presentations, and other methods.

Strategy 3: Describe the process for identifying, referring, evaluating, diagnosing, and caring for children suspected of or diagnosed with FASDs

- Activity 3a. Using the qualitative data collection tool for Strategy 3, collect information from key informants about the identification, referral, evaluation, diagnosis, and care process for children suspected of or diagnosed with an FASD.
- Activity 3b. Collaborate with CDC and other funded recipients to analyze and/or interpret quantitative and qualitative data (pooled and/or site-specific), as available, to:

- Identify and describe the sequence of health-related encounters for children suspected of or diagnosed with an FASD who are referred, evaluated, diagnosed, or receive care.
- Identify and describe clinical services, treatments, and health-related or other social services that are provided or referred to children after diagnosis with an FASD.
- Identify and describe exchange of health-related information between healthcare providers who refer, evaluate, diagnose, or provide care for children with FASDs.
- Identify and describe diagnostic and treatment delays (i.e., the time between when a neurodevelopmental concern is identified/ raised by a caregiver or clinician, when an FASD or differential diagnosis is made, and when children are referred to or begin receiving services) to identify factors that may contribute to delays in appropriate diagnosis.

- Activity 3c. Collaborate with CDC and other funded recipients to communicate project information and results, as appropriate, to healthcare providers, researchers, and other partners (e.g., individuals with FASDs and their families or caregivers) via publications, presentations, and other methods.

1. Collaborations

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

Funded recipients will work with each other and with CDC to develop methods and protocols for this project, and to carry out project activities.

b. With organizations not funded by CDC:

Recipients may need to consult and communicate with affiliated institutions, referring health care providers or entities, and/or treatment or service providers (e.g., maternal health clinicians, general pediatric providers, behavioral specialists, social service providers) to collect relevant information. Applicants are encouraged to provide letters of support from these organizations or providers, as appropriate. Letters of support should be saved as a PDF file and named “Letters of Support.” They should then be uploaded to www.grants.gov under the "Other Attachments Form."

2. Target Populations

Children age 0 through age 17 diagnosed with an FASD within 5 years of the project start date; children age 0 through 17 who have been referred or evaluated for an FASD within 5 years of the project start date, but not diagnosed with an FASD regardless of reason (e.g., insufficient exposure information, differential diagnosis).

a. Health Disparities

This NOFO will directly address the lack of data sources available for public health surveillance of children with FASDs. Information about the referral, evaluation, diagnosis, and treatment process for children suspected of or diagnosed with FASDs will be collected and can be examined by sociodemographic characteristics, which might uncover health disparities in these processes. Applicants should describe the characteristics of their patient population (e.g., ethnicity, race, gender, socioeconomic status) and geographic location in their application (i.e.,

rural, urban). Applicants with access to or serving diverse patient populations are encouraged to apply.

iv. Funding Strategy

This NOFO intends to fund up to 3 awards for a 3-year period of performance with an average award per budget period of $450,000. Year 2 and Year 3 funding ceilings are not yet set.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

The evaluation and performance measurement strategy will be used to assess the performance of the overall project. The following are the strategies, activities, and outcomes as depicted in the logic model, followed by examples of process measures, outputs, and outcome measures. Measures and outputs are subject to change. CDC will work with recipients to finalize measures and outputs within the first six months of award. Measures and outputs are meant to be collective across sites unless otherwise indicated.

Strategy 1: Identify data sources and data elements (e.g., electronic medical records, diagnostic codes, procedure codes, vital records, school records, as applicable) to inform current and future surveillance of children with FASDs

- Activity 1a. Identify and describe data that contain relevant sociodemographic, clinical encounter, diagnostic, and other health-related information about children referred, evaluated, diagnosed, or receiving care for an FASD.
    - Process measures:
        - Identification and description of data sources at each site
        - Identification and description of data elements at each site
        - Identification and description of procedure, diagnostic, or billing codes at each site
    - Outputs:
        - Report with a compiled list of data sources, data elements, and relevant administrative codes

- Activity 1b. Based on data sources and data elements identified, collaborate with other funded recipients and CDC to develop a plan to collect quantitative information to address Strategy 2 and Strategy 3.
    - Process measures:
        - Definition of subpopulations of interest
        - Participation in development of quantitative data collection tool
        - Participation in development of quantitative data collection protocol
        - Piloting of data collection tool and protocol at each site
        - Determination of number of records to abstract.at each site
    - Outputs:
        - Finalized quantitative data collection tool and protocol

- Activity 1c. Collaborate with other funded recipients and CDC to develop a plan to collect qualitative information to address Strategy 2 and Strategy 3
    - Process measures:
        - Development of key informant list for each strategy at each site
        - Identification of appropriate qualitative methods for each strategy at each site
        - Development of question lists, interview guides, and data collection protocol for each strategy at each site
    - Outputs:
        - Finalized qualitative data collection tools and protocols

Strategy 2: Characterize the availability of information related to FASDs and the quality of this information in health care record systems (e.g., diagnostic and procedure codes and other clinical and administrative data)

- Activity 2a. Using the quantitative data collection tool, abstract linked, standardized data and develop de-identified, non-duplicated, individual-level dataset(s) for populations of interest. Recipients will use the quantitative data collection tool to collect information for children within each subpopulation of interest mentioned above.
    - Process measures:
        - Number of records abstracted per quarter at each site
    - Outputs:
        - Complete dataset of de-identified, de-duplicated, individual-level data from each site
- Activity 2b. Using the qualitative data collection tool for Strategy 2, collect information from key informants about the strengths, challenges, and quality of clinical and administrative data.
    - Process measures:
        - Number of key informant interviews, focus groups, etc., completed at each site
    - Outputs:
        - Report summarizing qualitative data collection process (including number of interviews completed, preliminary/emerging themes) at each site
- Activity 2c. Collaborate with CDC and other funded recipients to analyze and/or interpret quantitative and qualitative data (pooled and/or site-specific), as available.
    - Process measures:
        - Assessment of missing information for each data source and element
        - Assessment of correlates and contributors to missing data or poor data quality
        - Assessment of opportunities, strengths, and challenges related to using clinical and administrative data to advance future surveillance activities

- Outputs:
  - Plans and timelines for data analysis and synthesis of information
  - Analysis plan(s) to address activities
  - Report(s) detailing data sources and elements; rates of missing information; impact of missing information on evaluation and diagnosis process; and correlates and contributors to missing or poor-quality data
  - Report(s) describing opportunities, strengths, and challenges related to using clinical and administrative data to advance future surveillance activities

- Activity 2d. Collaborate with CDC and other funded recipients to communicate project information and results, as appropriate, to healthcare providers, researchers, and other partners (e.g., individuals with FASDs and their families or caregivers) via reports, publications, presentations, and other methods.
  - Process measures:
    - Development of dissemination plan
    - Number of reports or other dissemination products
  - Outputs:
    - Publications, presentations, or other dissemination products describing data sources and elements; rates of missing information; impact of missing information on a referral, evaluation, diagnosis process; and correlates and contributors to missing or poor-quality data
    - Publications, presentations, or other dissemination products describing opportunities, strengths, and challenges related to using clinical and administrative data to advance future surveillance activities

Strategy 3: Describe the process for identifying, referring, evaluating, diagnosing, and caring for children suspected of or diagnosed with FASDs

- Activity 3a. Using the qualitative data collection tool for Strategy 3, collect information from key informants about the identification, referral, evaluation, diagnosis, and care process for children suspected of or diagnosed with an FASD
  - Process measures:
    - Number of key informant interviews, focus groups, etc., completed at each site
  - Outputs:
    - Report summarizing qualitative data collection process (including number of interviews completed, preliminary/emerging themes) at each site

- Activity 3b. Collaborate with CDC and other funded recipients to analyze and/or interpret quantitative and qualitative data (pooled and/or site-specific), as available.
  - Process measures:

        - Description of sequence of healthcare encounters for children referred, evaluated, diagnosed, or receiving care
        - Assessment of diagnostic and treatment delays
    - Outputs:
        - Data analysis plans and timelines
        - Report(s) detailing sequence of healthcare encounters for children referred, evaluated, diagnosed or receiving care for an FASD; clinical services and treatments for children referred, evaluated, diagnosed or receiving care for an FASD; diagnostic and treatment delays (e.g., distribution of time to diagnosis or treatment), potential contributors, and potential solutions

- Activity 3c. Collaborate with CDC and other funded recipients to communicate project information and results, as appropriate, to healthcare providers, researchers, and other partners (e.g., individuals with FASDs and their families or caregivers) via publications, presentations, and other methods
    - Process measures
        - Development of dissemination plan
    - Outputs:
        - Publications, presentations, or other dissemination products describing sequence of health-related encounters for children referred, evaluated, diagnosed or receiving care for an FASD; clinical services, treatments, and health-related or other social services for children referred, evaluated, diagnosed or receiving care for an FASD; diagnostic and treatment delays (e.g., distribution of time to diagnosis or treatment), potential contributors, and potential solutions

Short-term outcome: Increase knowledge of current practices and data sources for identification, evaluation, diagnosis, referral for care and treatment of children with FASDs

- Outcome measures
    - Comprehensive set of documentation that synthesizes results from quantitative and qualitative activities across funded recipients to describe current practices and processes for referral, evaluation, diagnosis, referral for care, and treatment of children with FASDs in order to increase knowledge on these topics
    - Comprehensive set of documentation that synthesizes information collected from across funded recipients about clinical and other administrative data sources and elements that could be used for surveillance of children with FASDs in order to increase knowledge on these topics

Short-term outcome: Increase knowledge of challenges and benefits of using clinical and other administrative data for surveillance of children with FASDs

- Outcome measures

- Comprehensive set of documentation that synthesizes results from quantitative and qualitative activities across funded recipients that describe clinical and other administrative data that could be used for surveillance of children with FASDs as well as related strengths and challenges in order to increase knowledge on these topics

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

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

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

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

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

CDC and recipients may determine the need to update their organization's evaluation and performance measurement plan during the period of performance.

c. Organizational Capacity of Recipients to Implement the Approach
Applicants must describe a level of organizational capacity required to implement and complete the NOFO activities.

Applicants are required to describe their clinical experience and expertise related to referring,

evaluating (including evaluating differential diagnoses), diagnosing and/or providing other FASD-related healthcare services to children with conditions across the FASD continuum. Applicants should describe all project staff regardless of their funding source, including professional titles, relevant qualifications and experience, percentage of time devoted to the project, and portion of the salary to be paid by the cooperative agreement. CVs should be provided for clinical and other key project staff, and an organizational structure should be provided showing the relationship between project staff within the organization. CVs and organizational charts should be saved as PDF files, named "CVs/Resumes" or "Organizational Charts", respectively, and uploaded at www.grants.gov under the "Other Attachments Form".

This NOFO seeks to understand current and available clinical data about children suspected of or diagnosed with FASDs and recognizes various types of organizations might be involved in the referral, evaluation, diagnosis, and care processes for children suspected of or diagnosed with FASDs. Therefore, applicants are also expected to provide a description of their organization. This information should include the type of organization (e.g., private pediatric clinic, academic institution, etc.), size of organization, and affiliations with other relevant healthcare providers/institutions/organizations. Applicants should also describe the types of healthcare services offered by the organization and how care is tailored to the population of interest, such as general pediatric care or services; specialty care or services for children with developmental, cognitive, or behavioral issues; specialty care or services specifically for children prenatally exposed to alcohol or other substances; specialty care or services for children with potential birth defects or genetic conditions. Finally, applicants should describe the population of children served by their organization, including volume of children served, and sociodemographic diversity of the population served (e.g., ethnicity, race, gender, socioeconomic status, geography [i.e., rural, urban]).

Organizational capacity also includes other skillsets necessary to implement the award activities, including information systems access and technical abilities (including data analysis), communication/material development, and program performance management and monitoring. Applicants should describe the ability to administer and manage proposed activities including: accessing relevant clinical and other data systems that contain FASD-related information from their organization; abstracting, linking, de-duplicating, and de-identifying data; using a data collection and management system (e.g., REDCap); and developing reports. If feasible, applicants should demonstrate the ability and legal authority to share de-identified datasets with CDC. Applicants should demonstrate through letters of support the ability to access and share data per the NOFO guidelines. Letters of support should be saved as a PDF file named "Letters of Support" and uploaded to www.grants.gov under the "Other Attachments Form". Furthermore, applicants should describe the capacity to manage resources of the program, specifically demonstrating good financial and procurement practices as well as experience managing federal funds successfully to include financial system and internal controls adequate to establish that funds have been used according to federal statues, regulations, and terms and conditions of the federal award. Finally, applicants should describe the ability to identify and recruit qualified personnel with credentials and appropriate experience to fill key positions, if needed, and should provide position descriptions for proposed project staff as needed.

d. Work Plan

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

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

e. CDC Monitoring and Accountability Approach

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

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

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

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.

- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

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

f. CDC Program Support to Recipients

In a cooperative agreement, CDC staff will be substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program are as follows:

- 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/or in-person to support collaboration and shared learning.
- If needed, provide on-line webinars and in-person training.
- Provide guidance on the implementation of a suitable quantitative data collection system (examples include, but are not limited to, REDCap, Qualtrics, EpiInfo etc.) for recipients to collect abstracted quantitative data, as needed.
- In collaboration with recipients, develop quantitative data collection tools and protocols for collecting and developing de-identified, individual-level data sets.
- Provide other data management support, as needed.
- In collaboration with recipients, develop qualitative interview tools and protocols.
- Assist in performing data analysis and interpretation.
- Work with recipients to develop priority reports and publications.
- Analyze data and author/coauthor reports and publications.
- Assist with planning and assessing performance measures of the project.

B. Award Information

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

2. Award Mechanism:
U84
Cooperative Agreements for Fetal Alcohol Syndrome Prevention Research Programs

3. Fiscal Year:
2022

4. Approximate Total Fiscal Year Funding:

$1,350,000

5. Total Period of Performance Funding:
$4,050,000
This amount is subject to the availability of funds.

Estimated Total Funding:
$4,050,000

6. Total Period of Performance Length:
3
year(s)

7. Expected Number of Awards:
3

8. Approximate Average Award:

$450,000
Per Budget Period

9. Award Ceiling:
$450,000
Per Budget Period

This amount is subject to the availability of funds.

Estimated Year 1 Award Ceiling is $450,000. This amount is subject to the availability of funds.
Future funding levels will be dependent on funding availability. **Therefore, estimated Year 2 and Year 3 Award Ceilings are not yet set.**

10. Award Floor:
$0
Per Budget Period

11. Estimated Award Date:
August 01, 2022

12. Budget Period Length:
12 month(s)

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

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

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

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
01 (County governments)

02 (City or township governments)

04 (Special district governments)

06 (Public and State controlled institutions of higher education)

05 (Independent school districts)

08 (Public housing authorities/Indian housing authorities)

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

07 (Native American tribal governments (Federally recognized))

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

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

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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

00 (State governments)

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

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

Local governments or their bona fide agents

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

State controlled institutions of higher education

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

Non-government Organizations

American Indian or Alaska native tribally designated organizations

Other

Ministries of Health

2. Additional Information on Eligibility

N/A

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

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

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

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

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

a. Data Universal Numbering System:

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

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

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

b. System for Award Management (SAM):

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

c. Grants.gov:

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

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS) (Required until April 4, 2022)	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711

2	System for Award Management (SAM)	1. Retrieve organizations DUNS number (required until April 4, 2022) 2. Go to SAM.gov and designate an E-Biz POC (You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

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

3. Application Package

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

4. Submission Dates and Times

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

a. Letter of Intent Deadline (must be emailed)

Due Date for Letter Of Intent 04/01/2022

b. Application Deadline

Due Date for Applications 05/02/2022

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

Due Date for Information Conference Call
March 14, 2022 - The CDC program will hold an Informational Conference Call for potential applicants to ask questions. Applicants can access the latest information related to the call at https://www.cdc.gov/ncbddd/fasd/nofo.html

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

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

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

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

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal

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

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

6. Content and Form of Application Submission

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

7. Letter of Intent

Letter of Intent (LOI) is due April 1, 2022. This is requested but optional. *The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.*

Please include the following information in the LOI:

- Name and title of this NOFO;
- Descriptive title of the proposed project;
- Name, address, telephone number, and email address of the Principal Investigator or Project Director;
- Name, address, telephone number, and email address of the primary contact for writing and submitting the application;
- Name of applicant's organization, as well as information about the geographic location (e.g., rural vs. urban), size, and type of organization; and
- Brief description of the size and demographic characteristics of the patient population served by the applicant.

The Letter of Intent (LOI) can be sent via email to:

Kellianne King, Project Officer
CDC/NCBDDD/DBDID
Re: CDC-RFA-DD22-2202
Telephone: 404-718-8961
Email: HNH3@cdc.gov

8. Table of Contents

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

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

9. Project Abstract Summary

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

10. Project Narrative

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

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

a. Background

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

b. Approach

i. Purpose

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

ii. Outcomes

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

iii. Strategies and Activities

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

1. Collaborations

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

2. Target Populations and Health Disparities

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

c. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

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

d. Organizational Capacity of Applicants to Implement the Approach

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

11. Work Plan

(Included in the Project Narrative's page limit)

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

12. Budget Narrative

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

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

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

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

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

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

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

13. Funds Tracking

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

subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

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

14. Pilot Program for Enhancement of Employee Whistleblower Protections

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

15. Copyright Interests Provisions

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

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must

identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

16. Funding Restrictions

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

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

17. Data Management Plan

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

18. Other Submission Requirements

a. Electronic Submission:

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

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

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

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

https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t= Get_Started%2FGet_Started. htm

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

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

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

1. Include the www.grants.gov case number assigned to the inquiry

2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

   If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

E. Review and Selection Process

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

a. Phase 1 Review

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

b. Phase II Review

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

i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach

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

i. Approach **Maximum Points:** 40

Overall Strategy (30 points)

- To what extent does the applicant describe an approach to meet the overall strategy and activities of this NOFO? To what extent does the applicant describe an approach that would efficiently and effectively:
  - Identify and describe relevant data sources and data elements? (5 points)
  - Access, abstract, link, de-identify, and de-duplicate all relevant clinical, administrative, and other data related to FASDs? (5 points)
  - Collect qualitative information from key informants? (5 points)
  - Collaborate with funded recipients and CDC to analyze, interpret and disseminate findings, as appropriate? (5 points)
- To what extent does the applicant's described approach seem technically sound and appropriate for meeting the stated strategies and activities? (10 points)

Work Plan (10 points)

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

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

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

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

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

FASD Clinical Capacity and Expertise (15 points)

- To what extent does the applicant:
    - Describe their clinical experience and expertise related to referring, evaluating (including evaluating differential diagnoses), diagnosing, and/or providing other FASD-related healthcare services to children with conditions across the FASD continuum? (6 points)
    - Describe all project staff regardless of their funding source? Descriptions should include professional title, relevant qualifications and experience, percentage of time devoted to the project, as well as the portion of their salary to be paid by the cooperative agreement. Position descriptions of proposed staff must also be provided. (3 points)
    - Provide a description of their organization, including size, type of institution (e.g., private, academic, etc.), and affiliation with other healthcare providers/institutions? Descriptions should include the types of healthcare services offered by the organization, including how care is tailored for specific populations of interest. (6 points)

Patient Population (10 points)

- To what extent does the applicant describe the population of children served by their organization, including estimating the volume of children served and describing the socio-demographic diversity of the population of children being served (e.g., ethnicity, race, gender, socioeconomic status) and geographic location (i.e., rural, urban)?

Administration Abilities (10 points)

- To what extent does the applicant:

- Provide a clear plan for the administration and management of the proposed activities, including accessing clinical and other data systems that contain FASD-related information from their organization (e.g., ability to obtain and execute Data Use Agreements [DUAs] as needed); abstracting, linking, de-duplicating, and de-identifying data; using a data collection and management system (e.g., REDCap); and developing reports? Applicants should include relevant letters of support. If feasible, demonstrate the ability and legal authority to share data with CDC. (6 points)
- Demonstrate the ability to manage resources of the program, including financial reporting, budget management and administration of personnel, as well as management of grants and contracts in a timely manner? (2 points)
- Identify and recruit qualified personnel with credentials and appropriate experience to fill key positions, if needed, and begin project activities in a timely fashion? Does the applicant provide position descriptions for proposed project staff? (2 points)

Budget **Maximum Points:** 0

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

c. Phase III Review

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

- Size and demographic characteristics of patient population served by the applicant (e.g., race/ethnicity, age, socioeconomic status)
- Type and size of applicant's organization (e.g., general pediatric clinic, developmental disability continuity clinic)
- Geographic location (e.g., urban, suburban, rural)

CDC will provide justification for any decision to fund out of rank order.

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

The anticipated announcement date is March 1, 2022.
The anticipated award date is August 1, 2022.
The anticipated project start date is September 2, 2022.

F. Award Administration Information

1. Award Notices

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

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

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

2. Administrative and National Policy Requirements

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

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

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

Generally applicable ARs:

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

ARs applicable to ATSDR Awards:

- *AR-18: Cost Recovery – ATSDR*
- *AR-19: Third Party Agreements – ATSDR*

Organization-specific ARs:

- *AR-8: Public Health System Reporting Requirements*
- *AR-15: Proof of Non-profit Status*
- *AR-23: Compliance with 45 CFR Part 87*

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

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

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

• For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

• HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

• For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

3. Reporting

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

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

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

Performance measures will be assessed annually.

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

Final Performance and Financial Report	90 days after end of period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

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

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

Performance Measurement

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

Evaluation

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

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

the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

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

This report must include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5) Contents of Reports: The reports must contain:

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

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

6. Termination

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

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

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

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

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

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

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Kellianne King
Project Officer

Department of Health and Human Services
Centers for Disease Control and Prevention

Address:
National Center on Birth Defects and Developmental Disabilities
Division of Birth Defects and Infant Disorders
4770 Buford Hwy
MS S106-3
Atlanta, GA 30341

Telephone:
404-718-8961

Email:
HNH3@cdc.gov

Grants Staff Contact

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

Yves Wilkerson
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:
2939 Flowers Road, MS: TV-1
Atlanta, GA 30341

Telephone:
404-498-2057

Email:
QKM9@cdc.gov

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

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

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

H. Other Information

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

- Project Abstract
- Project Narrative

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

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

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

Position descriptions

Non-profit organization IRS status forms, if applicable

Indirect Cost Rate, if applicable

Letters of Support

Organization Charts

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

I. Glossary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and

specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NOFO-specific Glossary and Acronyms