

Centers for Disease Control and Prevention

National Center on Birth Defects and Developmental Disabilities

Public Health Surveillance for the Prevention of Complications of Bleeding Disorders
CDC-RFA-DD20-2004
Application Due Date: 05/11/2020

Public Health Surveillance for the Prevention of Complications of Bleeding Disorders
CDC-RFA-DD20-2004
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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-DD20-2004. 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:

Public Health Surveillance for the Prevention of Complications of Bleeding 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)).

Amendment 1 dated 4/21/20 -section F3 -- Highlights from Information Call dated 3/9 ---

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DD20-2004

E. Assistance Listings (CFDA) Number:

93.080

F. Dates:

1. Due Date for Letter of Intent (LOI):	**03/16/2020**
2. Due Date for Applications:	**05/11/2020**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Date for Informational Conference Call:
3/09/2020

Scheduled for 3:00 pm - 4:00 pm, Eastern Standard Time.

Phone Number: (855) 644-0229

Conference ID Number: 2963605

Highlights from DD20-2004 Information Call

The Program Staff for DD20-2004 would like to highlight the following key points that were discussed on the Information Call Monday March 9th at 3:00 pm ET:

- Program Staff provided an overview of the NOFO pulling directly from the purpose section of the NOFO and the logic model.
- Program and Office of Grants Services staff also re-iterated the required components of

the NOFO, the eligibility criteria, the award information, and the application process by reading exerts directly from the NOFO.

- Program staff pointed out three revisions/edits to the NOFO
    1. In the NOFO we stated that the Work Plan is included in the 20-page limit; however, this is incorrect. The work plan can be uploaded as a separate document that does not count against the 20-page limit.
    2. On page 13 of the NOFO, we removed a bullet from the list of minimum DMP elements and left a dangling "and". The bullet that was removed referred to plans for long-term archiving and preservation of the data; CDC is taking responsibility for those activities for this project.
    3. The Grants Staff Contact information on page 46 of the NOFO has changed. The new information is:

        Darryl Walker, Grants Management Specialist

        Department of Health and Human Services

        Office of Grants Services

        Centers for Disease Control and Prevention

        2939 Flowers Rd MS - TV-2

        Atlanta, GA 30341

        Telephone: 404.498.5602

        Email: lzq7@cdc.gov

- No questions were asked by attendees.

G. Executive Summary:

1. Summary Paragraph:

Hemophilia, von Willebrand disease and other congenital bleeding disorders that decrease normal blood clotting cause significant disease burden and reduced quality of life. The purpose of this NOFO is to build upon the work currently ongoing in the U.S. Hemophilia Treatment Center Network (USHTCN) under DD15-1507 to prevent and reduce the complications of bleeding disorders by supporting the collection, aggregation and use of data and specimens that are representative of the USHTCN for surveillance for inhibitors and other complications of bleeding disorders, including emerging issues. The recipient or recipients are required to collaborate with HTCs and are expected to build upon the structures, processes and instruments implemented under DD15-1507. The recipient or recipients are expected to implement these five strategies and their corresponding activities: 1) establish collaborations with HTCs; 2) data collection and transfer; 3) specimen collection and transfer; 4) data quality evaluation and improvement; and 5) disseminate information. The data will be used to increase awareness of inhibitors and other complications among stakeholders; monitor trends in complications; identify disparities among subpopulations of bleeding disorder patients; identify high risk

populations for interventions; assess gaps in data collection; generate hypotheses for research; and, ultimately, prevent the complications of bleeding disorders.

a. Eligible Applicants: Open Competition
b. NOFO Type: Cooperative Agreement
c. Approximate Number of Awards: 1
CDC will consider making up to three awards under this cooperative agreement to preserve geographic and demographic representativeness.

d. Total Period of Performance Funding: $21,500,000

e. Average One Year Award Amount: $4,300,000

f. Total Period of Performance Length: 5
g. Estimated Award Date: 08/31/2020
h. Cost Sharing and / or Matching Requirements: N
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

Hemophilia, von Willebrand disease (VWD) and other congenital bleeding disorders that decrease normal blood clotting cause significant disease burden and reduced quality of life. These bleeding disorders cause spontaneous or prolonged bleeding, leading to disabling joint disease, intracranial bleeding, miscarriage, bleeding during pregnancy and death. Historically, persons with bleeding disorders have also suffered infection with blood-borne viruses due to contaminated treatment products. About 20,000 people in the United States (US) (mostly males) have hemophilia, with healthcare costs approaching $3 billion annually. VWD occurs in about 1% of the population.

Patients with bleeding disorders are largely treated at specialized hemophilia treatment centers (HTCs) which provide comprehensive care. Since 1975, Congress has provided support for these centers through the Maternal and Child Health Bureau, Health Resources and Service Administration (HRSA) and the CDC. Currently, the federally funded HTC system comprises a network of 141 centers throughout the US and its territories (hereafter, "the US Hemophilia Treatment Center Network" or "USHTCN"). From January 2012 through September 2018, the USHTCN provided care to more than 24,000 patients with hemophilia, 20,000 with VWD and 12,000 with other bleeding disorder diagnoses.

Since the 1980s, CDC has collaborated with the HTCs of the USHTCN to reduce the

complications of bleeding disorders and their treatment. Work from prior cooperative agreements has demonstrated that some complications related to joint disease have decreased over time. The proportion of patients on treatment to prevent bleeding episodes (prophylaxis) has increased. No new hepatitis or HIV infections from contaminated treatment products have been found. However, the percentage of youth with severe hemophilia using prophylaxis varies widely across HTCs and evidence suggested other viruses may still be transmitted in plasma-derived treatment products. Bleeding disorder stakeholders have identified additional health indicators that should be monitored over time in order to protect the health of persons with bleeding disorders, including conditions associated with aging in the general population and inhibitors to clotting factor concentrates. An inhibitor is an antibody to factor which inhibits the action of the factor and decreases its treatment efficacy. Decreased treatment efficacy leads to increased hospitalizations for bleeding and higher healthcare costs. As many as one-third of patients with severe hemophilia A will develop an inhibitor. Additionally, hemophilia treatment is changing. Non-clotting factor products, gene therapy and other new treatment products are changing the frequency and mode of hemophilia treatment. The effects of these new treatments on the hemophilia population need to be monitored to ensure continued progress towards eliminating complications of both the bleeding disorders themselves and their treatment.

This NOFO continues the work ongoing through DD15-1507 to reduce and prevent the complications of bleeding disorders by monitoring treatment and outcomes in order to a) increase knowledge and awareness of inhibitors and other complications, treatment practices and patterns; b) monitor trends in these issues; c) identify potential disparities; d) identify high risk populations for interventions; e) assess gaps in data collection; and f) generate hypotheses for research on inhibitors and other complications. Additionally, this NOFO increases the priority placed on data quality and dissemination.

b. Statutory Authorities

Sections 301(a) [42 USC 241(a)] and 317C of the Public Health Service Act [42 U.S.C. Section 247b-4] as amended.

c. Healthy People 2030

- BDBS-2030-1 (Proposed) Reduce the proportion of persons with severe hemophilia who have more than four joint bleeds per year.
- BDBS-2030-D2 (Proposed, Developmental) Increase the proportion of persons with von Willebrand disease (VWD) seen in speciality care centers who were diagnosed by 21 years of age.

https://www.healthypeople.gov/

d. Other National Public Health Priorities and Strategies

N/A

e. Relevant Work

This NOFO builds on previous projects for the surveillance of complications of bleeding disorders, Prevention of the Complications of Bleeding Disorders through Hemophilia Treatment

Centers (DD06-005, Universal Data Collection) and Public Health Surveillance for the Prevention of Complications of Bleeding and Clotting Disorders (DD11-1103/DD14-1409/DD15-1507, Community Counts). Recipients are expected to build or model upon the structures, processes and instruments implemented under DD11-1103/DD14-1409/DD15-1507.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

CDC-RFA-DD20-2004 Logic Model: *Public Health Surveillance for the Prevention of Complications of Bleeding Disorders*

Bold indicates period of performance outcome

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-term Outcomes
Strategy 1: Establish collaborations with HTCs	**1. Data collection legally and financially enabled** **2. HTCs provide administrative input on existing capacity and barriers for project implementation** **3. HTCs provide multidisciplinary input on project content based on clinical practice and research expertise** **4. Timely review of data proposals and analysis products to facilitate timely analysis and dissemination**	Researchers, providers and other stakeholders: · have increased awareness of inhibitors and other complications, treatment practices and patterns · **monitor trends** · **identify potential disparities** · **identify high risk populations for interventions** · **assess gaps in data collection** · generate hypotheses for research	Reduce and prevent inhibitors and other complications of bleeding disorders
Strategy 2: Data collection and transfer	**1. HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset** **2. At-risk patients receive regular inhibitor screening** **3. At-risk patients receive regular screening for HCV and HIV**		
Strategy 3: Specimen collection and transfer			

Strategy 4: Data quality evaluation and improvement	1. Researchers and other stakeholders have confidence in the quality of data **2. HTCs provide consistently accurate and appropriate data**		
Strategy 5: Disseminate information	**1. HTCs provided with data for continuous improvement of participation and data quality** **2. Researchers and other stakeholders have access to a more comprehensive evidence base for the occurrence of inhibitors and other complications**		

i. Purpose

This NOFO builds upon ongoing work to prevent and reduce complications of bleeding disorders through the collection, aggregation and use of data and specimens representative of USHTCN bleeding disorder patients for surveillance on inhibitors and other complications of bleeding disorders, including emerging issues. These data will be used to increase awareness of inhibitors and other complications; monitor trends; identify disparities and high-risk populations for interventions; assess gaps in data collection; generate hypotheses for research; and prevent complications of bleeding disorders.

ii. Outcomes

Recipients are expected to achieve the following outcomes during the 5-year NOFO period of performance:

1. Data collection legally and financially enabled
2. HTCs provide administrative input on existing capacity and barriers for project implementation
3. HTCs provide multidisciplinary input on project content based on clinical practice and research expertise
4. Timely review of data proposals and analysis products to facilitate timely analysis and dissemination
5. HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset
6. At-risk patients receive regular inhibitor screening through submission of specimens to CDC

7. At-risk patients receive regular screening for Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) through submission of specimens to CDC
8. HTCs provide consistently accurate and appropriate data
9. HTCs provided with data for continuous improvement of participation and data quality
10. Researchers and other stakeholders have access to a more comprehensive evidence base for the occurance of inhibitors and other complications
11. Researchers and other stakeholders monitor trends, identify potential disparities, identify high risk populations for interventions, and assess gaps in data collection

iii. Strategies and Activities

Recipients are expected to implement the following strategies and activities in order to achieve the project outcomes:

Strategy 1: Establish collaborations with HTCs

- Activity 1: Identify and execute needed business agreements with the USHTCN, including regional core centers and HTCs, as appropriate
- Activity 2: Establish or maintain process for regular input from the USHTCN, including regional core centers and HTCs on implementation of project
    - Input on administrative, business, and implementation issues across regions
    - Input on clinical practice and scientific issues across regions

Strategy 2: Data collection and transfer

Recipients must coordinate and facilitate data collection and transfer from HTCs to align with CDC data system and requirements for inclusion in a pooled national data set such that the number of patients represented in the HTC Population Profile data set (Activity 5) is maintained or increased and the number in the Registry (Activity 6) increases relative to the number enrolled at the close of September 2020. Additional information regarding the acceptance testing and data elements referred to in activities 1-4 below can be found in *CDC-RFA-DD20-2004 Supporting Information*.

- Activity 1: Document secure, electronic data collection and transfer mechanism
- Activity 2: Submit sample data files to CDC for acceptance testing.
- Activity 3: Develop data management plan
- Activity 4: Submit timely and correct data files to CDC.
- Activity 5: Coordinate timely collection and transmission of annual minimal patient-level data (HTC Population Profile) on all patients with eligible bleeding disorder diagnoses at HTCs
- Activity 6: Coordinate enrollment of patients and timely collection and transmission of longitudinal, patient-level data (Registry), including seroconversion follow-up, at the HTCs
- Activity 7: Coordinate timely collection and transmission of patient-level data on deaths of bleeding disorder patients at the HTCs (Mortality Reporting)

Strategy 3: Specimen collection and transfer from participants of Strategy 2, Activity 6

(longitudinal patient-level health indicator data/Registry)

- Activity 1: Coordinate at HTCs the collection and transfer of plasma specimens from participants enrolled in Activity 6 of Strategy 2 to CDC for inhibitor testing and seroconversion follow-up
- Activity 2: Coordinate at HTCs the collection and transfer of serum specimens from participants enrolled in Activity 6 of Strategy 2 to CDC for evaluation of treatment product complications and safety issues and seroconversion follow-up

Strategy 4: Data quality evaluation and improvement

- Activity 1: Implement data quality checks to identify and correct data inaccuracies
- Activity 2: Develop and implement process to ensure collection of accurate data
- Activity 3: Develop and implement processes to ensure training of HTC staff on project processes and procedures
- Activity 4: Evaluate feasibility of implement point-of-data entry/submission logical validations within data collection system(s)

Strategy 5: Disseminate Information

- Activity 1: Report on project progress and data quality activities to HTCs
- Activity 2: Facilitate development of web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials
- Activity 3: Ensure that web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials are disseminated to researchers, providers and other stakeholders
- Activity 4: Develop a strategy to promote project findings and products to HTC staff and project participants

1. Collaborations

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

Recipients will be required to collaborate with each other to produce and disseminate public information reports and materials and peer-reviewed manuscripts using the nationally pooled data. Recipients are not expected at this time to collaborate with CDC-funded programs other than those funded by this cooperative agreement to achieve these outcomes.

b. With organizations not funded by CDC:

Recipients are required to collaborate with HTCs that are part of the USHTCN for data and specimen collection. The USHTCN is regionally organized (see *CDC-RFA-DD20-2004 Supporting Information*) and receives funds through Special Projects of Regional and National Significance (SPRANS) administered by the Health Resources and Services Administration (HRSA). The hemophilia regional core centers, the grantees for HRSA SPRANS funds, determine which treatment centers within their geographic region are included in the USHTCN. This determination includes an assessment of whether each center meets the criteria set for HTCs by the Medical and Scientific Advisory Committee of the (US) National Hemophilia Foundation

(MASAC). These criteria are stated in MASAC Recommendation # 132- Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders (Revised April 2002).

CDC will consider making up to three awards under this cooperative agreement to preserve geographic and demographic representativeness. Applicants must specify whether they are collaborating with all of the regions of the USHTCN, or a subset of the regions. If collaborating with a subset of the regions, applicants must specify which regions those are. Recipients must collaborate with USHTCN HTCs within the recipient's proposed geographic area of surveillance.

Applicants must provide documentation that HTCs have agreed to collaborate with the recipient and CDC to carry out the strategies and activities relevant to the HTCs that are proposed for this project. This documentation may be in the form of letters of support, letters of agreement, memoranda of understanding, memoranda of agreement, or contracts from or with collaborating HTCs (hereafter referred to collectively as "letters of support"). Documentation from the regional core center on behalf of the participating HTCs within its region may be provided in place of individual documentation from each HTC.

Applicants must file the letters of support, name the file ?Letters of Support?, and upload it as a PDF file at www.grants.gov.

2. Target Populations

The target populations are people of all ages with congenital bleeding disorders, primarily those due to factor deficiencies such as hemophilia A and B, von Willebrand disease and other clotting factor deficiencies. Inhibitor surveillance is a CDC priority; patients at risk for development of an inhibitor to factor VIII or factor IX are those with a diagnosis of hemophilia A, hemophilia B or type 3 VWD, therefore, these are considered high priority diagnoses for enrollment in the Registry [Strategy 2, Activity 6 (longitudinal patient-level health indicator data)]. Racial and ethnic minorities and persons initiating treatment with clotting factor concentrates, especially young children, are at a higher risk for inhibitor development and should be considered high priority for enrollment. Additionally, patients with any bleeding disorder diagnosis using new non-factor products and other novel treatments (including gene therapy) should be enrolled.

Applicants should describe the geographic catchment area and demographic make-up (diagnoses, gender, race, ethnicity, age: <2 years; 2-10 years; 11-19 years; 20-44 years; 45-64 years; 65+ years and older) of the patient population of the HTCs (in aggregate) with which it proposes to collaborate, as well as the percentage of all USHTCN bleeding disorder patients represented at its collaborating HTCs.

a. Health Disparities

Where such patients are represented in the patient population, applicants are encouraged to include people with disabilities; non-English speaking populations; lesbian, gay, bisexual, transgender, and questioning (LGBTQ) populations; people with limited health literacy; people from geographically underserved communities; or populations that may otherwise be overlooked by the program. Racial and ethnic minorities with a diagnosis of hemophilia A or B or type 3 VWD are a priority for enrollment in the Registry component; however, enrollment of these populations is encouraged for other diagnoses as well.

iv. Funding Strategy

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and Performance Measurement help demonstrate program accomplishments and determine whether the NOFO strategies and activities were implemented as expected. Evaluation and Performance Measurement also tracks if the intended outcomes were achieved during the period of performance. This information is integral to help CDC keep NOFO recipients on track with implementation, to demonstrate the effectiveness of the NOFO on reaching outcomes, and to suggest ways to improve the program.

Evaluation and Performance Measurement will be approached through assessing process and outcome measures. Throughout the period of performance, CDC will work individually and collectively with recipients to track the implementation of recipient strategies and activities and assess progress in achieving NOFO outcomes. Process measures will inform CDC to what extent the recipient has implemented the activities as intended. Outcome measures will inform CDC if the recipient achieved the period of performance outcomes.

Process Measures		
Strategy	**Activity**	**Measure**
1) Establish collaborations with HTCs	Maintain a documented process for gathering input on administrative, business, and implementation issues across regions.	Codify, with key program partners, the purpose, process, and activities for gathering input on administrative, business, and implementation issues.
	Maintain a documented process for gathering input on clinical practice and scientific issues across regions.	Codify, with key program partners, the purpose, process, and activities for gathering input on clinical practice and scientific issues across regions.
2) Data collection and transfer	Document secure, electronic data collection and transfer mechanism.	Submission of documentation.
	Submit sample data files to CDC for acceptance testing.	CDC receives data files with agreed-upon content and format.
	Develop data management plan.	Submission of data management plan within first 6 months.
	Submit timely and correct data files to CDC.	Timely receipt of correct data files at CDC • Timely: Percent of data files received at CDC within the agreed-upon timeframe • Correct: Percent of data files conforming to the file structure

		and data field content agreed-upon by CDC and recipient
	Coordinate timely collection and transmission of annual minimal patient-level data (HTC Population Profile) on all patients with eligible bleeding disorder diagnoses at HTCs. Coordinate enrollment of patients and timely collection and transmission of longitudinal, patient-level data (Registry), including seroconversion follow-up, at the HTCs. Coordinate timely collection and transmission of patient-level data on deaths of bleeding disorder patients at the HTCs (Mortality Reporting)	Percentage of HTCs submitting timely data from Activities 5-7 • Timely: Percent of initial submissions made within the agreed-upon timeframe Percent increase in timely submission of all indicated items (as compared to historical/ baseline).
3) Specimen collection and transfer	Coordinate at HTCs the collection and transfer of plasma specimens from participants enrolled in Activity 6 of Strategy 2 to CDC for inhibitor testing and seroconversion follow-up Coordinate at HTCs the collection and transfer of serum specimens from participants enrolled in Activity 6 of Strategy 2 to CDC for evaluation of treatment product complications and safety issues and seroconversion follow-up	Percent of specimens prepared and shipped according to agreed-upon protocols. Includes collecting correct specimen, appropriate processing, notification to serum bank, completed specimen form (see CDC-RFA-DD20-2004 Supporting Information) and proper shipping
4) Data quality evaluation and improvement	Implement data quality checks to identify and correct data inaccuracies	Percent of data validation queries resolved in a timely manner. Percent of HTCs submitting data validation responses that lead to resolution within the agreed-upon timeframe.
	Develop and implement process to ensure collection of accurate data	Percent decrease in errors among identified problem elements upon initial data quality check (as compared to historical/baseline error rate).
	Evaluate feasibility of implementing point-of-data entry/submission [logical]	Submission of documentation of existing logical validations and what

	validations within data collection system(s)	changes to the system would be required, if any, in order to implement cross item and cross form checks, and other potential validations.
	Develop and implement process to ensure training of HTC staff on project processes and procedures	Submission of training plan including identification of new HTC project staff, onboarding of new HTC project staff, regular refresher training for all relevant HTC project staff, and regular review of expectations and documented project procedures with HTC project staff
5) Disseminate information	Report on project progress and data quality activities to HTCs	Evidence of at least semi-annual reports to the HTCs regarding results of data quality activities and project progress
	Facilitate development of web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials	Number of web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials produced or under development each budget year
	Ensure that web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials are disseminated to researchers, providers and other stakeholders	Number of web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials posted, published, or presented each budget year
	Develop a strategy to promote project findings and products to HTC staff and project participants	Targeted promotion plan for each of the products

Outcome Evaluation Measures	
Outcomes	**Measures**
HTCs provide administrative input on existing capacity and barriers for project implementation	Evidence of implementation of process such as call schedules, agendas, minutes, communications, etc.
HTCs provide multidisciplinary input on project content based on clinical practice and research	Evidence of implementation of process such as call schedules, agendas, minutes, communications, etc.

expertise	
Timely review of data proposals and analysis products to facilitate timely analysis and dissemination	Completion of proposal review process within the agreed upon timeframe
HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset	Number of HTCs submitting timely annual minimal patient-level data of good quality Number of HTCs submitting timely longitudinal health indicator data of good quality Number of HTCs submitting timely mortality data of good quality
At-risk patients receive regular inhibitor screening	Number of participants that qualify for inhibitor screening for whom an appropriate specimen is submitted when indicated
At-risk patients receive regular screening for HCV and HIV	Number of participants that qualify for viral screening for whom an appropriate specimen is submitted when indicated
HTCs provide consistently accurate and appropriate data	Decrease in the number of validation queries from baseline across all form types and all HTCs
Researchers and other stakeholders have access to a more comprehensive evidence base for the occurrence of inhibitors and other complications	Dissemination of at least one public information product per year targeting participants and other consumers or consumer-based organizations Dissemination of at least one public information product per year targeting researchers, providers or policy makers
Researchers, providers and other stakeholders: • monitor trends • identify potential disparities • identify high risk populations for interventions • assess gaps in data collection	Documentation of discussion and review with CDC, the USHTCN and other partners (if applicable) of trends, disparities, high risk populations, potential interventions and gaps in data collection on inhibitors and other complications of bleeding disorders

Since this NOFO involves the generation or collection of public health data, a Data Management Plan is required for this NOFO. At a minimum, the Data Management Plan (DMP) must include:

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

property, or other rights;
- Statement of the use of data standards that ensure all documentation that describes the method of collection, what the data represent, and

Because the data are being submitted to CDC, CDC will take responsibility for plans for archiving and long-term preservation of the data in compliance with federal law and CDC policies, or explaining why long-term preservation and access are not justified. If all of this information is not available when applying, applicants should include a DMP that is as complete as possible. The DMP may be submitted as a checklist, paragraph, or other format. Currently, HHS/CDC does not have a standardized DMP template or checklist. However, below are DMP examples to help guide applicants as they develop their DMP:

- Stanford University DMPTool
- National Network of Libraries of Medicine Data Management Planning Tool

CDC will work with recipients on operationalizing and further defining each performance measure, and guidance will be provided prior to the first report. Reports will be provided to CDC, and CDC will use the reports to assess recipient program improvements and respond to broader technical assistance needs. All evaluation findings produced by the recipients will contribute to: (1) continuous improvement of quality and effectiveness of the program, (2) the evidence base of bleeding disorder surveillance, and (3) future funding opportunities supported by CDC.

CDC will review the work plan and evaluation and performance measurement plan and meet with the recipient to finalize them. Key program partners may include applicant's key program staff, USHTCN regional core center staff, HTC staff and other key partners (for example, federal agencies other than CDC, consumer-based organizations, professional organizations, etc.), as applicable.

ii. Applicant Evaluation and Performance Measurement Plan

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

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP), if applicable, for accuracy throughout the lifecycle of the project. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data

represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

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

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

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

c. Organizational Capacity of Recipients to Implement the Approach

Applicants must have the organizational structure and capacity to execute the CDC strategies and activities and meet outcomes throughout the period of performance. Applicants should address their collaboration with USHTCN regional core center staff, HTC staff and other key partners if applicable (for example, federal agencies other than CDC, consumer-based organizations, professional organizations, etc.); their ability to carry out evaluation, performance monitoring, financial reporting, subcontracting, budget management and administration; and their expertise and experience related to the surveillance of conditions among persons with congenital bleeding disorders. For those capacities that involve collaboration with other organizations (including the USHTCN regional core centers, HTCs and other key partners), existing capacity may be documented within letters of support.

Key capacity considerations to address in the application:

- Applicants must describe their experience related to the surveillance of conditions among persons with congenital bleeding disorders.
- Applicants must specify which regions and HTCs are anticipated to participate in the project.
- Applicants must describe the roles and expertise of their key project staff, USHTCN regional core center staff, HTC staff and other key partners if applicable (for example, other federal agencies, consumer-based organizations, professional organizations, etc.), and their ability to collaboratively implement the NOFO.
- Applicants must provide a staffing plan, describing in detail their own resources and staffing levels for this project, as well as their project management structure, including an organizational chart and resumes/CVs of key project staff. Applicants must name this file "CVs/Resumes" or "Organizational Charts" and upload it at www.grants.gov.
- Applicants must describe their ability to manage the required procurement efforts, including the ability to write and award contracts in accordance with applicable grants regulations.

- Applicants must provide regional data collection projections for the first year of the project for Strategy 2, Activity 6 (Data collection and transfer, longitudinal patient level health indicator data), accounting for both expected initial enrollments and subsequent episodes of participation by patients enrolled previously. These projections should be based on the expectation that any HTC funded under this cooperative agreement will also participate in Activities 5 and 7 of Strategy 2, as well as Activities 1 and 2 of Strategy 3 (Specimen collection and transfer). Projections should be commensurate with available resources and the cost of carrying out the project at each HTC. Applicants should also figure in effort to be spent on ensuring quality data when making these projections.
- Applicants must demonstrate that they have adequate technical resources to meet the project's goals, including informational technology (IT) infrastructure. Applicants must describe how data will be collected and submitted to CDC via a secure, electronic mechanism, including how unique participant identifiers will be assigned and linked to current identifiers, how data will be collected at the HTCs (including how uniform data abstraction and adherence to skip patterns will be ensured), the file type to be used for each data form, and the method and frequency of transmission of data to CDC The applicant must describe the application that they intend to use for data submission and transfer and outline the estimated amount of time before the application and associated documentation can be used for this project.
- Applicants must demonstrate that they have a financial management system that will allow proper funds management and segregation of funds by program, and meet the requirements as stated in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards: CFR 75.302. The financial system should permit the preparation of reports required by general and program-specific terms and conditions; and the tracing of funds to a level of expenditure adequate to establish that such funds have been used according to the federal statutes, regulations, and terms and conditions of the federal award.

d. Work Plan

Applicants must submit a detailed work plan for the first year of the project and a high-level work plan for subsequent years (years 2-5). The work plan should describe how the applicant plans to implement all of the required strategies and activities to achieve NOFO outcomes. A sample work plan format is presented below to show how a traditional work plan aligns with the logical model and narrative. A separate table should be included in the work plan for each of the outcomes that will be addressed during the first year period of performance. If a particular activity leads to multiple outcomes, it should be described under each outcome measure. No specific work plan format is required, as long as it is clear how the components in the work plan crosswalk to the strategies and activities, outcomes, and evaluation and performance measures presented in the logic model and the narrative sections of the NOFO; however, all work plans must contain all of the elements shown in the example (outcome(s), outcome measure(s), etc).

Example Work Plan Table

Period of Performance Outcome:	**Outcome Measure(s):**
HTCs contribute uniform data on bleeding disorders complications to a pooled national	Number of HTCs submitting timely annual minimal patient-

dataset		level data of good quality Number of HTCs submitting timely longitudinal health indicator data of good quality Number of HTCs submitting timely mortality data of good quality	
Strategies and Activities	**Process Measure [from Evaluation and Performance Measurement section]**	**Responsible Position/Party**	**Completion Date**
1. Strategy: Data collection and transfer Activity:Document secure, electronic data collection and transfer mechanism.	Submission of documentation	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)
2. Strategy: Data collection and transfer Activity:Submit sample data files to CDC for acceptance testing.	CDC receives data files with appropriate content and format	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)
3. Strategy: Data collection and transfer Activity:Develop data management plan.	Submission of data management plan within first 6 months	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)
4. Strategy: Data collection and transfer Activity:Submit timely and correct data files to CDC.	Timely receipt of correct data files at CDC - Timely: Percent of data files received at CDC within the agreed-upon timeframe - Correct: Percent of	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)

	data files conforming to the file structure and data field content specified by CDC		
5. Strategy: Data collection and transfer Activity: a.) Coordinate timely collection and transmission of annual minimal patient-level data (HTC Population Profile) on all patients with eligible bleeding disorder diagnoses at HTCs. b.) Coordinate enrollment of patients and timely collection and transmission of longitudinal, patient-level data (Registry), including seroconversion follow-up, at the HTCs. c.) Coordinate timely collection and transmission of patient-level data on deaths of bleeding disorder patients at the HTCs (Mortality Reporting)	Percentage of HTCs submitting timely data from Activities 5-7 - Timely: Percent of initial submissions made within the agreed-upon timeframe Percent increase in timely submission of all indicated items (as compared to historical/ baseline)	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)
6. Strategy: Data	Percent of data	(applicant to fill in appropriate	(applicant to fill in

quality evaluation and improvement Activity: Implement data quality checks to identify and correct data inaccuracies	validation queries resolved in a timely manner. Percent of HTCs submitting data validation responses that lead to resolution within the agreed-upon timeframe.	personnel)	appropriate date)
7. Strategy: Data quality evaluation and improvement Activity:Develop and implement process to ensure collection of accurate data	Percent decrease in errors among identified problem elements upon initial data quality check (as compared to historical/baseline error rate).	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)
8. Strategy: Data quality evaluation and improvement Activity: Evaluate feasibility of implementing point-of-data entry/submission [logical] validations within data collection system(s)	Submission of documentation of existing logical validations and what changes to the system would be required, if any, in order to implement cross item and cross form checks, and other potential validations.	(applicant to fill in appropriate personnel)	(applicant to fill in appropriate date)

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

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

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

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.

- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

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

CDC's priority performance measures to track recipient progress and determine whether the project is achieving NOFO outcomes are:

Strategy 1: Completion of proposal review process within the agreed upon timeframe.

Strategy 2: Timely receipt of correct data files at CDC; Percentage of HTCs submitting timely data from Activities 5-7

Strategy 3: Percent of specimens prepared and shipped according to agreed-upon protocols.

Strategy 4: Percent of HTCs submitting data validation responses that lead to resolution within the agreed-upon timeframe. Percent decrease in errors among identified problem elements upon initial data quality check (as compared to historical/baseline error rate). Submission of documentation of existing logical validations and what changes to the system would be required, if any, in order to implement cross item and cross form checks, and other potential validations. (process)

Strategy 5: Number of web reports, abstracts, posters, surveillance reports, presentations, peer-reviewed manuscripts, and other materials posted, published, or presented each budget year; dissemination of at least one public information product per year targeting participants and other consumers or consumer based organizations; dissemination of at least one public information product per year targeting researchers, providers or policy-makers

CDC will meet with recipient(s) to review progress and provide feedback quarterly or as mutually agreed with recipient(s).

CDC and the recipient(s) will have 6-months after award to finalize the performance monitoring and accountability approach.

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

In a cooperative agreement, CDC and recipients share responsibility for successfully implementing the award and meeting identified outcomes. CDC will:

1. Collaborate with recipient(s) and the USHTCN to balance priorities, and provide technical assistance in adjustment of data collection instruments;
2. Provide technical support for data cleaning;
3. Work with recipient(s) to assess training needs;
4. Submit Office of Management and Budget (OMB) Paperwork Reduction Act (PRA)

Information Collection Clearance package if necessary;
5. Serve as host and steward of data aggregated from HTCs;
6. Prepare surveillance reports and other public health practice reports of data aggregated from HTCs;
7. Provide technical assistance to recipient(s) and USHTCN for analysis of their data as requested;
8. Participate in project site visits and scheduled conference calls as appropriate;
9. Work with recipient(s) to disseminate findings;
10. Coordinate information sharing between recipients (if applicable);
11. Provide guidance for ethical conduct of non-research data collection and patient authorization;
12. Provide guidance on appropriate collection, processing and shipping of blood specimens;
13. Perform, or arrange for, laboratory tests called for by the project;
14. Report test results to the contributing HTC; and
15. Serve as host and steward of specimen repository for future use.

B. Award Information

1. Funding Instrument Type: Cooperative Agreement

CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism: U27

Surveillance of Complications of Hemophilia Cooperative Agreements

3. Fiscal Year: 2020

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

5. Approximate Period of Performance Funding: $21,500,000

This amount is subject to the availability of funds.

Estimated Total Funding: $21,500,000

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

7. Expected Number of Awards: 1

CDC will consider making up to three awards under this cooperative agreement to preserve geographic and demographic representativeness.

8. Approximate Average Award: $4,300,000 Per Budget Period

9. Award Ceiling: $4,300,000 Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor: $100,000 Per Budget Period

11. Estimated Award Date: 08/31/2020

12. Budget Period Length: 12 month(s)

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

13. Direct Assistance

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

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)
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:

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.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

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

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

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM

information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at https://www.sam.gov/SAM/.

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)	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) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/ and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do 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	Same day but can take 8 weeks to be fully registered and	Register early! Log into grants.gov and check AOR status until it shows you have been approved

		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	approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	

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 or postmarked by)

Due Date for Letter of Intent: **03/16/2020**

b. Application Deadline

Due Date for Applications: **05/11/2020** , 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Information Conference Call

3/09/2020

Scheduled for 3:00 pm - 4:00 pm, Eastern Standard Time.

Phone Number: (855) 644-0229

Conference ID Number: 2963605

Highlights from DD20-2004 Information Call

The Program Staff for DD20-2004 would like to highlight the following key points that were discussed on the Information Call Monday March 9th at 3:00 pm ET:

- Program Staff provided an overview of the NOFO pulling directly from the purpose section of the NOFO and the logic model.
- Program and Office of Grants Services staff also re-iterated the required components of the NOFO, the eligibility criteria, the award information, and the application process by reading exerts directly from the NOFO.
- Program staff pointed out three revisions/edits to the NOFO
    1. In the NOFO we stated that the Work Plan is included in the 20-page limit; however, this is incorrect. The work plan can be uploaded as a separate document that does not count against the 20-page limit.
    2. On page 13 of the NOFO, we removed a bullet from the list of minimum DMP elements and left a dangling "and". The bullet that was removed referred to plans for long-term archiving and preservation of the data; CDC is taking responsibility for those activities for this project.
    3. The Grants Staff Contact information on page 46 of the NOFO has changed. The new information is:

       Darryl Walker, Grants Management Specialist

       Department of Health and Human Services

       Office of Grants Services

       Centers for Disease Control and Prevention

       2939 Flowers Rd MS - TV-2

       Atlanta, GA 30341

       Telephone: 404.498.5602

       Email: lzq7@cdc.gov

- No questions were asked by attendees.

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa)) /Homepage.aspx.
Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

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

Risk Assessment Questionnaire Requirement
CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, 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

Applicants are requested, but not required, to submit an LOI.

The LOI should include the following information:

- Descriptive title of proposed project
- Name, address, telephone number, and email address of the Principal Investigator or Project Director, or both
- Name, address, telephone number, and e-mail address of the primary contact for writing and submitting this application
- Number and title of this NOFO

LOI must be sent via U.S. express mail, delivery service, fax, or email to:

Brandi Dupervil

Centers for Disease Control and Prevention/NCBDDD/DBD

4770 BUFORD HWY MS – S106-3

ATLANTA GA 30341-3717

Telephone number: 404-498-6879

Fax number: 404-498-6799

Email: inm4@cdc.gov

An LOI is not required, is not binding, and does not enter into the review of a subsequent application. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

8. Table of Contents

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

9. Project Abstract Summary

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

10. Project Narrative

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

a. Background

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

b. Approach

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

ii. Outcomes

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

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

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

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

c. Applicant Evaluation and Performance Measurement Plan

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

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

data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

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

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

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

d. Organizational Capacity of Applicants to Implement the Approach

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

11. Work Plan

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

12. Budget Narrative

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

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

- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data. Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.
Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.
Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

Budget preparation guidance can be found at: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up

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

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

14. Intergovernmental Review

Executive Order 12372 does not apply to this program.

15. Pilot Program for Enhancement of Employee Whistleblower Protections

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

16. 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.

17. Funding Restrictions

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

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - 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.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional

Requirement (AR) 35 for applicability
(https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant's assurance of the quality of the public health data through the data's lifecycle and plans to deposit data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:
https://www.cdc.gov/grants/additionalrequirements/ar-25.html

19. Other Submission Requirements

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

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 (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

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

a. Phase 1 Review
All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

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

below.
i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach
Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Approach	Maximum Points:35

Background

- To what extent does the applicant provide relevant background information that includes the context of the problem? **(2 points)**

Purpose

- To what extent does the applicant?s 2-3 sentence purpose describe specifically how their application will address the problem as described in the CDC Background Section? **(2 points)**

Outcomes

- To what extent does the applicant clearly identify the outcomes they expect to achieve by the end of the period of performance? **(4 points)**

Strategies and Activities

- To what extent does the applicant describe strategies and activities that align with the CDC logic model, that are achievable, and that will allow for achievement of the outcomes of the project? **(16 points, distributed as indicated below)**
    - To what extent does the applicant describe strategies and activities consistent with the logic model that are appropriate, achievable and will establish collaborations with HTCs? *(4 points)*
    - To what extent does the applicant describe strategies and activities consistent with the logic model that are appropriate, achievable and will enable collecting and transferring data, including the proposed method of data collection and submission? *(4 points)*
    - To what extent does the applicant describe strategies and activities consistent with the logic model that are appropriate, achievable and will enable collecting and transferring specimens? *(4 points)*
    - To what extent does the applicant propose strategies and activities consistent with the logic model that are appropriate and achievable for information dissemination to a) participating HTCs and b) other stakeholders and the public? *(4 points)*

Collaboration

- Does the applicant provide letters of support, letters of agreement, memoranda of understanding, memoranda of agreement, or contracts from or with the USHTCN HTCs or regional core centers they propose to work with? If the applicant proposes to collaborate with a subset of the regions of the USHTCN rather than the entire USHTCN, does the applicant describe how they will collaborate with other recipients under this cooperative agreement? **(3 points)**

Target Population

- To what extent does the applicant describe the geographic catchment area of the collaborating HTCs? **(1 point)**
- To what extent does the applicant describe the demographic make-up (diagnoses, gender, race, ethnicity, age: 0-10 years; 11-19 years; 20 years and older) of the target population within their area of geographic catchment, as well as the percentage of all USHTCN patients represented? **(1 point)**

Work plan

- To what extent does the applicant present a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach? Is the work plan consistent with the content and format proposed by CDC? Are the timeframes proposed for the activities feasible? **(4 points)**
- To what extent does the applicant show that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the period of performance outcomes? **(2 points)**

ii. Evaluation and Performance Measurement Maximum Points:25

- To what extent does the applicant show or affirm the ability to collect data on the process and outcome performance measures specified by CDC in the project description as well as those presented by the applicant in their approach? **(4 points)**
- From the applicant?s description, how clear are the monitoring and evaluation procedures? Specifically, is it clear how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities? **(10 points)**
- To what extent does the applicant describe how performance measurement and evaluation findings will be reported to the relevant audiences, and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement? **(9 points)**
- Does the applicant include a preliminary Data Management Plan (DMP) that addresses the minimum criteria specified in the CDC Evaluation and Performance Measurement Strategy section? **(2 points)**

iii. Applicant's Organizational Capacity to Implement the Approach Maximum Points:40

- To what extent does the applicant describe experience relevant to the surveillance of conditions among persons with congenital bleeding disorders? **(2 points)**
- To what extent does the applicant demonstrate experience that is relevant to execution of the proposed activities and achievement of the project outcomes? **(3 points)**
- Is it clear how the collaborators will collectively implement the project activities? To what extent does the applicant describe the roles and expertise of its own staff, the USHTCN regional core center staff, HTC staff, and the staff of any other key partners (if applicable)? **(5 points)**
- To what extent does the applicant describe the project management structure and staffing for its own organization? Is the staffing plan sufficient to implement the activities and achieve the project outcomes? Are staff roles clearly defined? To what extent is the staffing plan adequate, appropriate and consistent with the work plan? **(6 points)**
- To what extent does the applicant demonstrate their ability to manage the required procurement efforts, including the ability to write and award contracts in accordance with applicable grants regulations? **(3 points)**
- To what extent does the applicant demonstrate that they have a financial management system that will allow proper funds management and segregation of funds by program, and permit the preparation of reports required by general and program-specific terms and conditions; and the tracing of funds to a level of expenditure adequate to establish that such funds have been used according to the federal statutes, regulations, and terms and conditions of the federal award? **(3 points)**
- Does the applicant provide its own organizational chart and resumes/CVs of its staff as well as (if applicable) those for key partners? **(2 points)**
- To what extent does the applicant demonstrate the technical capacity to implement the activities and achieve the project outcomes, including (if applicable): the current status of any proposed data collection and submission application; when it can be used for this project; how unique participant identifiers will be assigned and linked to current identifiers; how data will be collected at the HTCs (including how uniform data abstraction and adherence to skip patterns will be ensured); the file type to be used for each data form; and the method and frequency of transmission of data to CDC **(7 points)**
- To what extent does the applicant demonstrate the experience and capacity to implement the evaluation plan? **(5 points)**
- Does the applicant provide regional data collection projections for the first year of the project for Strategy 2, Activity 6 (longitudinal patient-level health indicator data)? **(4 points)**

Budget

Is the budget prepared according to the CDC Budget Preparation Guidelines? Is the budget aligned with the proposed work plan? Is the proposed use of funds an efficient and effective way to implement the strategies and activities and attain the outcomes during the period of performance? (not scored)

c. Phase III Review

The following factors also may affect the funding decision: Geographic diversity; the number of patients with diagnoses of hemophilia A or B, von Willebrand disease or other clotting factor deficiencies in the geographic catchment area (greater than or less than 5,000); inclusion of populations with diagnoses at risk for FVIII and FIX inhibitors (hemophilia A, hemophilia B, type 3 VWD); inclusion of racial and ethnic minorities; ability to implement data collection with minimal disruption of activities ongoing under DD15-1507.

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

Applicants will be notified whether they are to be awarded funds via email. Awards are anticipated to be made by August 2020. Applicants can get award information from the Grants Staff Contact listed in Section G. Agency Contacts

F. Award Administration Information

1. Award Notices

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

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

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

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.
Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.
The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

- *AR-1: Human Subjects Requirements*
- AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions (June 2012)
- AR-14: Accounting System Requirements
- AR-15: Proof of Non-profit Status
- *AR-16: Security Clearance Requirement*

- AR-21: Small, Minority, And Women-owned Business
- AR-22: Research Integrity
- AR-23: Compliance with 45 CFR Part 87 (faith-based organizations)
- *AR-24: Health Insurance Portability and Accountability Act Requirements*
- AR-25: Data Management and Access
- AR-26: National Historic Preservation Act of 1966
- AR-27: Conference Disclaimer and Use of Logos
- AR-28: Inclusion of Persons Under the Age of 21 in Research
- AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-31: Research Definition
- AR-32: Enacted General Provisions
- AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- AR-34: Language Access for Persons with Limited English Proficiency

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

3. Reporting

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

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

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

Report	When?	Required?

Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Priority Performance Measures	With Annual Performance Report.	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 than120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.
This report must include the following:

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

- Indirect Cost Rate Agreement.

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

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

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

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Brandi Dupervil, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
4770 BUFORD HWY MS – S106-3

ATLANTA GA 30341-3717

Telephone: (404) 498-6879
Email: bdupervil@cdc.gov

Grants Staff Contact

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

Darryl Walker, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
Centers for Disease Control and Prevention

2939 Flowers Rd MS - TV-2

Atlanta, GA 30341

Telephone: (404) 498-5602
Email: lzq7@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
- CDC Assurances and Certifications
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

The following information is required and may be uploaded as separate documents:

- Work Plan
- Resumes / CVs
- Position descriptions (as applicable)
- Letters of Support
- Organization Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate, if applicable
- Bona Fide Agent status documentation, if applicable

I. Glossary

Activities: The actual events or actions that take place as a part of the program.
Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see http:// www.cdc.gov/ grants/ additional requirements/ index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).
Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.
Assistance Listings (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.
Assistance Listings (CFDA) Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency
Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.
Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.
Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.
CDC Assurances and Certifications: Standard government-wide grant application forms.
Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).
Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.
Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.
Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.
Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.
Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally

involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http:// www.cdc.gov /grants /additionalrequirements /index.html.

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.
Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf.
Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.
Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.
Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

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

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

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

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

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

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

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

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

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

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

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

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.
Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.
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