



Centers for Disease Control

National Center on Birth Defects and Developmental Disabilities

Characterizing the Complications Associated with Therapeutic Blood Transfusions for
Hemoglobinopathies

CDC-RFA-DD19-1903

Application Due Date: 05/03/2019

Characterizing the Complications Associated with Therapeutic Blood Transfusions for
Hemoglobinopathies
CDC-RFA-DD19-1903
TABLE OF CONTENTS

[Part I. Overview Information](#)

- A. Federal Agency Name
- B. Funding Opportunity Title
- C. Announcement Type
- D. Agency Funding Opportunity Number
- E. Assistance Listings (CFDA) Number
- F. Dates
- G. Executive Summary

[Part II. Full Text](#)

- A. [Funding Opportunity Description](#)
- B. [Award Information](#)
- C. [Eligibility Information](#)
- D. [Application and Submission Information](#)
- E. [Review and Selection Process](#)
- F. [Award Administration Information](#)
- G. [Agency Contacts](#)
- H. [Other Information](#)
- I. [Glossary](#)

Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-DD19-1903. 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:

Characterizing the Complications Associated with Therapeutic Blood Transfusions for Hemoglobinopathies

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:

Informational Phone call changed to

Conference Number: (770) 488-3600

Conference ID: 4383605

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DD19-1903

E. Assistance Listings (CFDA) Number:

93.080

F. Dates:

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

04/05/2019

2. Due Date for Applications:

05/03/2019, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

A Letter of Intent is requested by not required.

3. Date for Informational Conference Call:

03/14/19

Scheduled for 2:00 - 3:00 pm, Eastern Standard Time.

Conference Number: (770) 488-3600

Conference ID: 4383605

Questions may be submitted to ibx5@cdc.gov as soon as the NOFO is released.

G. Executive Summary:

1. Summary Paragraph:

This funding opportunity is comprised of two components – thalassemia and sickle cell disease.

All applicants must apply for the Thalassemia Component in order to be considered for the Sickle Cell Disease Component via a single application that clearly specifies the activities within each component. Only those successful applicants under the Thalassemia Component will be eligible for additional Sickle Cell Disease Component funding. Applicants must propose a comprehensive work plan that addresses transfusions and their related complications in alignment with the broad strategies indicated in the NOFO.

Thalassemia Component:

- the development and validation of methods for identifying individuals with thalassemia;
- the development and dissemination of information for patients, families, blood banks, and health care providers about the interpretation of laboratory results indicating (1) a potential and (2) a confirmed thalassemia diagnosis and management of transfusions for thalassemia; and
- the collection of biological specimens from individuals with thalassemia.

Sickle Cell Disease Component:

- the development and dissemination of information for patients, families, blood banks, and health care providers about the interpretation of laboratory results indicating (1) a potential and (2) a confirmed sickle cell disease diagnosis and management of transfusions for sickle cell disease and
- the collection of biological specimens from individuals with sickle cell disease.

a. Eligible Applicants:

Open Competition

b. NOFO Type:

Cooperative Agreement

c. Approximate Number of Awards:

2

The awards may be a mixture of Thalassemia Component only and Thalassemia & Sickle Cell Disease Components. Final number of funded award recipients will be determined by the objective review scoring and available funding.

d. Total Period of Performance Funding:

\$3,750,000

e. Average One Year Award Amount:

\$375,000

f. Total Period of Performance Length:

5

g. Estimated Award Date:

09/30/2019

h. Cost Sharing and / or Matching Requirements: N

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

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

Red blood cell (RBC) transfusions are an important part of medical care for many patients with thalassemia or sickle cell disease. Some patients never need a transfusion, others may have infrequent or intermittent needs, and still others may need chronic transfusions every few weeks. Determining which patients need to receive transfusions, when and how often they need to receive them, and what steps minimize complications from the transfusions may lead to improved health outcomes.

In the U.S., individuals with thalassemia and/or their health care providers may be unaware of their diagnosis until overt clinical signs begin to manifest. The initiation of transfusion may be delayed until complications appear. If the diagnosis is never made, patients continue living without the benefits that transfusions could provide. Iron chelation therapy is indicated for all transfused patients when iron measures indicate concentrations that exceed threshold levels. Red blood cell alloimmunization occurs when the immune system is exposed to foreign antigens on red blood cells that are different from its own. Frequent blood transfusions may also expose individuals to infectious agents that may be transmitted through blood. By improving the identification of people who have these conditions and may benefit from appropriately administered transfusions, the understanding of treatment for them, and the standardization of information that is available about them, therapeutic transfusions may be administered in ways that maximize their benefits and minimize their adverse effects.

This NOFO aims to improve access to, coordination of, and continuity of health care for individuals with thalassemia or sickle cell disease which will lead to a decreased occurrence of transfusion-related complications, improved quality and increased length of life. These health care improvements will result from a multi-faceted approach that includes (1) identification of patients, families, communities, and providers who will benefit from increased knowledge about therapeutic transfusions and their potential complications, (2) development and dissemination of materials that will increase understanding of the diagnosis and management of these blood disorders, and (3) development of a biospecimen repository from a sentinel population of transfused patients in which to assess new or emerging pathogens.

This NOFO builds upon findings from the work completed as part of CDC-RFA-DD14-1406. In particular, (1) the difficulty in identifying any thalassemia patient in the U.S. and their health care provider prior to medical complications manifesting, other than those born in states where the condition is a part of the mandatory newborn screening panel, (2) the lack of standardized practices across, and sometimes within, clinical care settings and blood banks for transfusions of patients with thalassemia or sickle cell disease, (3) the need for dissemination of evidence- or consensus-based guidelines about best practices for transfusions, (4) the room for improvement in increasing blood donation from communities most affected by thalassemia or sickle cell disease, and (5) the occurrence of new or emerging pathogens that may arise in the blood supply

and pose a serious potential risk to patients with thalassemia or sickle cell disease who receive multiple therapeutic transfusions.

b. Statutory Authorities

Public Health Service Act Sections 301(a) and 317C (42 U.S.C. Sections 241, 241(a), 243, and 247b-4), as amended.

c. Healthy People 2020

BDBS-17: Increase the proportion of persons who donate blood.

BDBS-18: Reduce the proportion of persons who develop adverse events resulting from the use of blood and blood products.

<https://www.healthypeople.gov/2020/topics-objectives/topic/blood-disorders-and-blood-safety/objectives>

d. Other National Public Health Priorities and Strategies

N/A

e. Relevant Work

This NOFO builds on the accomplishments and outcomes achieved in CDC-RFA-DD14-1406 (<https://www.cdc.gov/ncbddd/hemoglobinopathies/blood-transfusions.html>).

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Develop and validate a method for identifying previously undiagnosed individuals with thalassemia	Improved understanding of the prevalence of thalassemia in the United States	Improved understanding of the natural history of disease for thalassemia	Improved access to, coordination of, and continuity of health care for individuals with thalassemia/sickle cell disease
Develop new processes, or improve upon existing processes, for the dissemination of information pertaining to thalassemia/sickle cell disease	Increased community awareness of the need for blood donation by donors from communities who are most impacted by thalassemia/sickle cell disease	Increased proportion of persons who donate blood Increased standardization of transfusion management for individuals with thalassemia/sickle cell	Improved quality of life for individuals with thalassemia/sickle cell disease
	Increased		

Develop a toolkit of educational materials about the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia/sickle cell disease diagnosis	understanding of the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia/sickle cell disease diagnosis	disease	
Develop a toolkit of educational materials about evidence- or consensus-based management of transfusions for thalassemia/sickle cell disease	Increased understanding of evidence- or consensus-based guidelines on management of transfusions for thalassemia/sickle cell disease	Decreased occurrence of transfusion-related complications for individuals with thalassemia/sickle cell disease	
Collect biological specimens from individuals with thalassemia/sickle cell disease	Improved understanding of how infectious agents play a role in blood transfusion complications in thalassemia/sickle cell disease		

i. Purpose

Individuals with thalassemia or sickle cell disease may require therapeutic blood transfusions. These blood transfusions, in turn, may cause additional complications. This NOFO will support a multifaceted approach towards the development and validation of methods for reducing these complications. The implementation and evaluation of these strategies will lead to a decreased occurrence of transfusion-related complications and improve the quality of life for individuals with thalassemia/sickle cell disease.

ii. Outcomes

This NOFO has two components: (1) a Thalassemia Component that is mandatory for all applicants and (2) a Sickle Cell Disease Component that is optional.

The following short-term outcomes will be achieved by the end of the period of performance:

Thalassemia Component:

- Improved understanding of the prevalence of thalassemia in the United States, including those individuals who do *not* currently receive chronic transfusion therapy

- Increased community awareness of the need for blood donation by donors from communities who are most impacted by thalassemia
- Increased understanding among patients, families, and health care providers of the interpretation of laboratory results (newborn screening, confirmatory diagnosis, etc.) that indicate (1) a potential and (2) a confirmed thalassemia diagnosis and the implications that this result will have on the need for therapeutic transfusion management
- Increased understanding among patients, families, health care providers, and blood banks of evidence- or consensus-based guidelines on management of transfusions for thalassemia
- Improved understanding among patients, families, health care providers, and blood banks of how infectious agents play a role in blood transfusion complications in thalassemia

Sickle Cell Disease Component:

- Increased community awareness of the need for blood donation by donors from communities who are most impacted by sickle cell disease
- Increased understanding among patients, families, and health care providers of the interpretation of laboratory results (newborn screening, confirmatory diagnosis, etc.) that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis and the implications that this result will have on the need for therapeutic transfusion management
- Increased understanding among patients, families, health care providers, and blood banks of evidence- or consensus-based guidelines on management of transfusions for sickle cell disease
- Improved understanding among patients, families, health care providers, and blood banks of how infectious agents play a role in blood transfusion complications in sickle cell disease

These short-term outcomes will lead to the following intermediate outcomes by the end of the period of performance:

Thalassemia Component:

- Improved understanding of the natural history of disease for thalassemia
- Increased proportion of persons who donate blood from communities who are most impacted by thalassemia
- Increased standardization of transfusion management for individuals with thalassemia by health care providers and blood banks

Sickle Cell Disease Component:

- Increased proportion of persons who donate blood from communities who are most impacted by sickle cell disease
- Increased standardization of transfusion management for individuals with sickle cell disease by health care providers and blood banks

iii. Strategies and Activities

The Thalassemia Component and Sickle Cell Disease Component strategies are listed below. Applicants who choose to apply for both components are encouraged to implement strategies in ways that may benefit both communities, when applicable, so that work on these strategies is mutually reinforcing. Complementary strategies should be addressed in a way that benefits both the thalassemia and sickle cell disease communities.

Thalassemia Component:

- Develop and validate a method for identifying previously undiagnosed individuals with thalassemia
- Develop new processes, or improve upon existing processes, for the dissemination of information pertaining to thalassemia
- Develop a toolkit of educational materials about the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia diagnosis
- Develop a toolkit of educational materials about evidence- or consensus-based management of transfusions for thalassemia
- Collect biological specimens from individuals with thalassemia

Sickle Cell Disease Component:

- Develop new processes, or improve upon existing processes, for the dissemination of information pertaining to sickle cell disease
- Develop a toolkit of educational materials about the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis
- Develop a toolkit of educational materials about evidence- or consensus-based management of transfusions for sickle cell disease
- Collect biological specimens from individuals with sickle cell disease

In addition to the above activities, all recipients will be expected to participate in collaborative recipient calls and meetings, site visits by CDC staff at recipient location, as needed, and yearly reverse site visits in Atlanta. All materials developed as part of this project will be share with CDC for use consistent with our federal purposes.

1. Collaborations

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

Applicants are encouraged to collaborate with other related CDC programs or CDC-funded organizations that have a role in achieving the NOFO outcomes. Collaborations may center on shared data; partner organizations; communication approaches/messages; and/or patient identification methodology. Related CDC programs or CDC-funded organizations include, but are not limited to

Thalassemia Component:

- Organization(s) funded under DD14-1405

Sickle Cell Disease Component:

- Organization(s) funded under OT18-1802 or participating in the Sickle Cell Data Collection (SCDC) program

Letters of support are strongly encouraged when the applicant will be working with one of these organizations. These letters should provide detailed information about the nature of the collaborative effort and how the collaboration will help the applicant achieve the objectives of this NOFO. Letters of support should be saved using the name of the agency/organization providing the letter and uploaded as a PDF to www.grants.gov.

b. With organizations not funded by CDC:

Collaborations with a variety of public and private organizations are encouraged to leverage resources and maximize reach and impact for the strategies selected. Applicants should establish or continue strategic partnerships that support the NOFO goals with professional organizations; not-for-profit organizations; community-based organizations; community advocates and members; and other stakeholders that may have a vested interest in improving the health of individuals with thalassemia or sickle cell disease.

Letters of support are strongly encouraged when the applicant will be working with one or more of these organizations. For each organization named as a collaborator, the letter should provide detailed information about the nature of the collaborative effort and how the collaboration will help the applicant achieve the objectives of this NOFO. Letters of support should be saved using the name of the agency/organization providing the letter and uploaded as a PDF to www.grants.gov.

2. Target Populations

The target populations are:

Thalassemia Component:

- Individuals with thalassemia who do not currently have a laboratory-confirmed diagnosis
- Individuals with thalassemia who receive chronic or intermittent transfusions to manage the complications of their disease or who are likely to receive transfusions at a later date
- Families and caregivers of individuals with thalassemia
- Members of populations most commonly affected by thalassemia
- Health care providers of individuals with thalassemia
- Blood bank administrators and transfusion medicine providers

Sickle Cell Disease Component:

- Individuals with sickle cell disease who receive chronic or intermittent transfusions to manage the complications of their disease or who are likely to receive transfusions at a later date

- Families and caregivers of individuals with sickle cell disease
- Members of populations most commonly affected by sickle cell disease
- Health care providers of individuals with sickle cell disease
- Blood bank administrators and transfusion medicine providers

a. Health Disparities

In the United States, both thalassemia and sickle cell disease disproportionately affect individuals of particular ancestry. Moreover, some consider the condition itself, especially sickle cell disease, to be an indicator of a health disparity. This NOFO will address the challenges and health inequities of these two chronic genetic diseases that disproportionately burden certain communities.

iv. Funding Strategy

There are two funding components for this funding opportunity. Applicants must apply for the Thalassemia Component. Additionally applicants can choose to apply for the Sickle Cell Disease Component via a single application that clearly identifies the two components to receive additional funds for these sickle cell disease activities.

Applicants will be placed in a rank order list based on their score on the Thalassemia Component. If any of the applicants who are selected to be funded for the Thalassemia Component also submit an application for the Sickle Cell Disease Component, those scoring highest in the Sickle Cell Disease Component will be selected to be funded for both components.

Applicants applying for both the Thalassemia and Sickle Cell Disease Components:

- Must submit a single application covering both components
- Must clearly label all activities as “thalassemia only,” “sickle cell disease only,” or “combined” in the Work Plan
- Must provide two separate budgets, one for each component
- Must provide an additional letter of support from each collaborator named in the application

Each component will be reviewed and scored separately, with a different score assigned to each component.

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 have been implemented as expected. Evaluation and Performance Measurement also tracks if the intended outcomes have been 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 has the recipient implemented the activities as intended. Outcome measures will inform CDC if the recipient achieved the period of performance outcomes.

The evaluation will be guided by the following evaluation questions. Evaluation questions are pulled from the activities, short-, and long-term outcomes. Both the process and outcome evaluations will seek to answer the following overarching evaluation questions:

1. Approach: To what extent have recipients' implementation approaches been successful in achieving the desired outcomes?
2. Effectiveness:
 1. To what extent has the NOFO increased understanding of the prevalence of thalassemia?
 2. To what extent has implementation of strategies led to increased dissemination of educational information related to the target audiences?
 3. What factors or components were associated with effective implementation of strategies?
 4. What strategies implemented by recipients can be replicated and/or scaled?
3. Impact: To what extent has the intervention contributed to a measurable change in health, behavior, or environment among target audiences?

In order to answer the evaluation questions above, NOFO recipients will provide quarterly reports on the process measures listed below and annual reports on all other process and outcome measures. These reports will be presented during the all-recipient calls or reverse site visits and submitted electronically immediately following the call/site visit. The data collected by CDC for performance measurement and evaluation are directly related to the implementation of the strategies and/or the desired outcomes indicated in the logic model. The data collected for this NOFO for performance measurement do not include any personally identifiable information. Data being collected are strictly related to the implementation of the NOFO strategies and shall be used for assessing and reporting progress and for other pertinent program improvement actions.

Short-term measures for each strategy and intermediate-term measures reported by all recipients are described in the table below. The table aligns with the logic model and shows the alignment between the overarching focus areas, specific strategies, outcomes and performance measures.

Process Measures – Thalassemia Component	
Activity	Measure
Develop and validate a method for identifying previously undiagnosed individuals with thalassemia	Quarterly report on the development and validation of the method to identify previously undiagnosed individuals with thalassemia
Develop new processes, or improve upon existing processes, for the	Quarterly report documenting the development or improvement of a process for the dissemination of

dissemination of information pertaining to thalassemia	information pertaining to thalassemia
Develop a toolkit of educational materials about the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia diagnosis	Quarterly report on the development of the toolkit of educational materials
	# of toolkits delivered to stakeholders [patients, families, health care providers]
	# of people reached by educational materials
Develop a toolkit of educational materials about evidence- or consensus-based management of transfusions for thalassemia	Quarterly report on the development of the toolkit of educational materials
	# of toolkits delivered to stakeholders [patients, families, health care providers, blood banks]
	# of people reached by educational materials
Collect biological specimens from individuals with thalassemia	Quarterly report on the development and implementation of methods for collecting specimens and shipping to CDC
	# of biological specimens collected from individuals with thalassemia and shipped to CDC
Process Measures – Sickle Cell Disease Component	
Activity	Measure
Develop new processes, or improve upon existing processes, for the dissemination of information pertaining to sickle cell disease	Quarterly report documenting the development or improvement of a process for the dissemination of information pertaining to sickle cell disease
Develop a toolkit of educational materials about the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis	Quarterly report on the development of the toolkit of educational materials
	# of toolkits delivered to stakeholders [patients, families, health care providers]
	# of people reached by educational materials
Develop a toolkit of educational materials about evidence- or consensus-based management of transfusions for sickle cell disease	Quarterly report on the development of the toolkit of educational materials
	# of toolkits delivered to stakeholders [patients, families, health care providers]
	# of people reached by educational materials

Collect biological specimens from individuals with sickle cell disease	Quarterly report on the development and implementation of methods for collecting specimens and shipping to CDC
	# of biological specimens collected from individuals with sickle cell disease and shipped to CDC
Short Term Outcome Evaluation Measures – Thalassemia Component	
Outcome	Measure
Improved understanding of the prevalence of thalassemia in the United States, including those individuals who do <i>not</i> currently receive chronic transfusion therapy	[baseline #; XX% increase over baseline] of individuals who are identified with thalassemia that (1) receive chronic transfusion therapy and (2) do not currently receive chronic transfusion therapy
Increased community awareness of the need for blood donation by donors from communities who are most impacted by thalassemia	[baseline #; XX% increase over baseline] of community members who are aware of the need for blood donation by donors from communities who are most impacted by thalassemia
Increased understanding of the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia diagnosis and the implications that this result will have on the need for therapeutic transfusion management by patients, families and caregivers, and health care providers	[baseline #; XX% increase over baseline] of patients who understand the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia diagnosis and the implications that this result will have on the need for therapeutic transfusion management
	[baseline #; XX% increase over baseline] of family members and/or caregivers who understand the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia diagnosis and the implications that this result will have on the

	<p>need for therapeutic transfusion management</p>
	<p>[baseline #; XX% increase over baseline] of health care providers who understand the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed thalassemia diagnosis and the implications that this result will have on the need for therapeutic transfusion management</p>
<p>Increased understanding of evidence- or consensus-based guidelines on management of transfusions for thalassemia by patients, families, health care providers, and blood banks</p>	<p>[baseline #; XX% increase over baseline] of patients who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for thalassemia</p> <p>[baseline #; XX% increase over baseline] of family members and/or caregivers who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for thalassemia</p> <p>[baseline #; XX% increase over baseline] of health care providers who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for thalassemia</p>

	[baseline #; XX% increase over baseline] of health care providers at blood banks who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for thalassemia
Improved understanding of how infectious agents play a role in blood transfusion complications in thalassemia	Biological specimens from a minimum of 25 unique individuals with thalassemia who are chronically or intermittently transfused will be collected and transferred to CDC on an annual basis, along with requested clinical data (minimum of 125 patients during the 5 year period of performance)
Short Term Outcome Evaluation Measures – Sickle Cell Disease Component	
Outcome	Measure
Increased community awareness of the need for blood donation by donors from communities who are most impacted by sickle cell disease	[baseline #; XX% increase over baseline] of community members who are aware of the need for blood donation by donors from communities who are most impacted by sickle cell disease
Increased understanding of the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis and the implications that this result will have on the need for therapeutic transfusion management by patients, families and caregivers, and health care providers	[baseline #; XX% increase over baseline] of patients who understand the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis and the implications that this result will have on the need for therapeutic transfusion management
	[baseline #; XX% increase over baseline] of family members and/or caregivers who understand the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis and the implications that this result will

	<p>have on the need for therapeutic transfusion management</p> <p>[baseline #; XX% increase over baseline] of health care providers who understand the interpretation of laboratory results that indicate (1) a potential and (2) a confirmed sickle cell disease diagnosis and the implications that this result will have on the need for therapeutic transfusion management</p>
<p>Increased understanding of evidence- or consensus-based guidelines on management of transfusions for sickle cell disease by patients, families, health care providers, and blood banks</p>	<p>[baseline #; XX% increase over baseline] of patients who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for sickle cell disease</p> <p>[baseline #; XX% increase over baseline] of family members and/or caregivers who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for sickle cell disease</p>

	[baseline #; XX% increase over baseline] of health care providers who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for sickle cell disease
	[baseline #; XX% increase over baseline] of health care providers at blood banks who are aware of and understand evidence- or consensus-based guidelines on management of transfusions for sickle cell disease
Improved understanding of how infectious agents play a role in blood transfusion complications in sickle cell disease	Biological specimens from a minimum of 50 unique individuals with sickle cell disease who are chronically or intermittently transfused will be collected and transferred to CDC on an annual basis, along with requested clinical data (minimum of 250 patients during the 5 year period of performance)

These short-term outcomes and measures above will lead to the following intermediate outcomes by the end of the period of performance:

Intermediate Outcome Evaluation Measures – Thalassemia Component	
Outcome	Measure
Improved understanding of the natural history of disease for thalassemia	Submission of at least one scientific article per year on new findings regarding the natural history of disease for thalassemia will be submitted for peer-review in years 3, 4, and 5 of the period of performance
Increased number of persons who donate blood from communities who are most impacted by thalassemia	[baseline #; XX% increase over baseline] of persons who donate blood from communities who are most impacted by thalassemia
Increased standardization of transfusion management for individuals with thalassemia by health care providers and blood banks	[baseline #; XX% increase over baseline] of health care providers who adhere to evidence- or consensus-based guidelines on management of transfusions for thalassemia
	[baseline #; XX% increase over baseline] of blood

	banks who adhere to evidence- or consensus-based guidelines on management of transfusions for thalassemia
Intermediate Outcome Evaluation Measures – Sickle Cell Disease Component	
Outcome	Measure
Increased number of persons who donate blood from communities who are most impacted by sickle cell disease	[baseline #; XX% increase over baseline] of persons who donate blood from communities who are most impacted by sickle cell disease
Increased standardization of transfusion management for individuals with sickle cell disease by health care providers and blood banks	<p>[baseline #; XX% increase over baseline] of health care providers who adhere to evidence- or consensus-based guidelines on management of transfusions for sickle cell disease</p> <p>[baseline #; XX% increase over baseline] of blood banks who adhere to evidence- or consensus-based guidelines on management of transfusions for sickle cell disease</p>

CDC will work with recipients on operationalizing and further defining each performance measure, and guidance will be provided prior to the first year of reporting. Quarterly reports on the process measures, as listed above, and annual reports on all other process and outcome measures will be provided annually to CDC, and CDC will manage and analyze the data to assess recipient program improvements, respond to broader technical assistance needs, and report to stakeholders.

All evaluation findings produced by the recipients will contribute to: (1) continuous improvement of quality and effectiveness of recipient program strategies, (2) the evidence base of Thalassemia/Sickle Cell Disease, (3) documentation and sharing of lessons learned to support replication and scaling of these program strategies, and/or (4) future funding opportunities supported by CDC.

CDC will review the work plan and evaluation and performance management plan, meet with the recipient virtually during conference calls every month, and host an annual reverse site visit in Atlanta to discuss progress towards the project outcomes.

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.

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 and for compliance with the monitoring and evaluation guidance established by CDC or other guidance otherwise applicable to this cooperative agreement.

c. Organizational Capacity of Recipients to Implement the Approach

Applicants must describe their organizational capacity to carry out the strategies included in the Component(s). CDC anticipates that all applicants will be able to demonstrate capacity to carry out the activities outlined over the period of performance. Successful applicants will demonstrate the necessary skills and relevant experience and capacity to successfully implement the strategies and activities listed above. Demonstrated readiness to implement the evidence-based strategies includes the ability of applicants to describe the following:

- Evidence that they have the organizational capacity to facilitate the program strategies and meet the period of performance outcomes by describing their program staffing structure, the role of each proposed staff member, their relevant skills, and the percent time expected of each staff for each major activity proposed in the work plan.
- Established partnerships with groups/organizations relevant to the strategies selected, which may include patient and/or community organizations, newborn screening programs, blood banks, professional health care associations, and groups with experience in health education or health promotion.
- Prior experience working on the strategies selected.

- Experience and capacity to conduct program evaluation, both process and outcome, and implement the evaluation plan.
- Sufficient leadership for program planning and development including the identification, hiring, or reassignment and supervision of staff, contractors, and/or consultants that have the knowledge and skills to implement the program and are sufficient in number.
- Proven ability or demonstrate sufficient capacity to develop and execute contracts for program services in an expedient manner and capacity to monitor contracts once implemented.
- Established organizational policies and procedures to ensure sufficient fiscal and budgetary oversight and capacity to provide required reports.
- Ability to participate in project-related meetings and site visits.
- Evidence that they have the capacity to either collect biological specimens from individuals with thalassemia or sickle cell disease or work with partner organizations to facilitate the collection of biological specimens and their shipment to CDC.

Applicants must provide CVs/resumes for key program personnel, name this file "CVs/Resumes", and upload it at www.grants.gov.

d. Work Plan

Applicants must submit a detailed work plan for Year 1 of the award and provide a general summary of work plan activities for Years 2-5 in narrative form. If the applicant is applying for both the Thalassemia and Sickle cell disease components, a single work plan should be used for both components, with clear labeling of which table applies to which component. Additionally, the work plan should demonstrate how any activities that address both component's strategies will be implemented, so that work on these strategies may be mutually reinforcing. Cost sharing of positions to support multiple activities across components is encouraged.

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 logic model and narrative. In this format, **the table would be completed for each period of performance outcome**. If a particular activity leads to multiple outcomes, it should be described under each outcome measure. Applicants are not required to use the example work plan format; 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: (from Logic Model)

Outcome Measure: (from Evaluation and Performance Measurement)

Strategies and Activities	Process Measure (from Evaluation and Performance Measurement)	Responsible Position/Party	Population of focus	Scope	Setting(s)	Completion Date
1.						
2.						

3.						
4.						
5.						

A separate table should be included in the work plan for each of the outcomes that will be completed in Year 1 of the award. If a particular activity leads to multiple outcomes, it should be described under each outcome measure.

Applicants must name this file Project Narrative_ name of applicant and upload it as a PDF file. CDC will provide feedback and technical assistance to award recipients to finalize the work plan activities post-award.

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 will analyze performance measurement data to review progress and identify technical assistance needs for all NOFO strategies on an annual basis. The proposed work plan and performance measures will be reviewed annually by the project officer and evaluation staff and may need to be modified to better reflect program activities as outlined in the NOFO. Findings from the annual analysis of performance measure data will be used to identify areas of program improvement, broader technical assistance needs, and to report to stakeholders. CDC will review the work plan to track implementation of their surveillance system as outlined in recipient strategies and activities (process evaluation) and determine progress on achieving the period of performance outcomes (outcome evaluation). CDC will provide routine feedback to recipients throughout the period of performance using phone calls, emails, and site visits. These

findings may be presented during site visits and recipient meetings.

All evaluation findings produced by CDC and recipients, where appropriate, will contribute to: (1) continuous improvement of quality and effectiveness of program strategies; (2) the evidence base; (3) documentation and sharing of lessons learned to support replication and scaling of these program strategies; and/or (4) future funding opportunities supported by CDC.

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

The CDC programs supporting this NOFO will be substantially involved beyond site visits and regular performance and financial monitoring during the period of performance. Substantial involvement means that the recipient can expect federal programmatic partnership in carrying out efforts under the award. CDC will work in partnership with the recipient to ensure the success of the cooperative agreement by:

- Supporting recipients in implementing cooperative agreement requirements and meeting program outcomes
- Providing technical assistance to revise annual work plans
- Assisting recipients in advancing program activities to achieve project outcomes
- Providing scientific subject matter expertise and resources in support of the selected strategies
- Collaborating with recipients to develop and implement evaluation plans that align with CDC evaluation activities
- Providing technical assistance on recipients' evaluation and performance measurement plans
- Providing technical assistance to define and operationalize performance measures
- Using webinars and social media for recipients and CDC to communicate and share tools and resources
- Participating in relevant meetings, committees, conference calls, and working groups related to the cooperative agreement requirements to achieve outcomes
- Coordinating communication and program linkages with other CDC programs and Federal agencies, such as the Health Resources and Services Administration (HRSA) and the National Institutes of Health (NIH)
- Translating and disseminating lessons learned through publications, meetings, and other means on promising and best practices to expand the evidence base
- Hosting a reverse site visit during each year of the period of performance.
- Encouraging information sharing between recipients: CDC will host quarterly all-recipient calls to allow for information and resource sharing, as well as capacity building and opportunity for collaboration between recipients
- Ensuring that recipients have access to expertise found throughout NCBDDD/DBD. For example, health scientists, epidemiologists, statisticians, policy analysts, communication specialists, and evaluators to provide technical assistance to recipients. Technical assistance teams will also work in collaboration with other programs across NCBDDD/DBD to identify specific actions that improve efficiency and greater public health impact.
- Collaborating with recipients to explore appropriate flexibilities needed to meet public

health outcomes and goals. Flexibility in cooperative agreements includes recipient's ability to propose alternative methods to achieve the outcomes and goals of the cooperative agreement that align with recipient's opportunities for success, infrastructure, partner and stakeholder buy-in, demographics, and burden. This includes bringing together resources from multiple cooperative agreements to jointly advance the goals of each and expanding the dialogue to bring in other CDC and recipient staff to reach a win/win solution.

- Creating greater efficiencies and consistency across NCBDDD/DBD programs for recipients. Examples of how programs work together to achieve this include but are not limited to:
 - Joint site visits that maximize the ability to do collaborative problem solving, offer insights and ideas to strengthen or augment recipient approaches, and increase understanding of recipient's context to accomplish improved health outcomes for thalassemia/sickle cell disease.
 - Jointly developed resources and tools to ensure consistent messages and to meet recipient technical assistance needs.
- Providing packaging materials and technical laboratory assistance to support the collection, processing, and shipment of biological specimens to CDC for the creation of a biorepository that can be monitored for new and emerging pathogens that may pose a serious potential risk to these patient populations.

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:	U58 Chronic Dis
3. Fiscal Year:	2019
4. Approximate Total Fiscal Year Funding:	\$750,000
5. Approximate Period of Performance Funding:	\$3,750,000

This amount is subject to the availability of funds.

Estimated Total Funding: \$3,750,000

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

7. Expected Number of Awards: 2

The awards may be a mixture of Thalassemia Component only and Thalassemia & Sickle Cell Disease Components. Final number of funded award recipients will be determined by the objective review scoring and available funding.

8. Approximate Average Award: \$375,000 Per Budget Period

9. Award Ceiling: \$375,000 Per Budget Period

This amount is subject to the availability of funds.

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

Thalassemia Component: \$50,000

Sickle Cell Disease Component: \$25,000

If funded for Thalassemia and Sickle Cell Disease Components: \$75,000

11. Estimated Award Date: 09/30/2019

12. Budget Period Length: 12 month(s)

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

13. Direct Assistance

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

C. Eligibility Information

1. Eligible Applicants

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
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

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](http://fedgov.dnb.com/webform/displayHomePage.do). The DUNS number will be provided at no charge.

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

b. System for Award Management (SAM):

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

c. Grants.gov:

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

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

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 www.sam.gov and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov	Same day but can take 8	Register early! Log into

		using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	grants.gov and check AOR status until it shows you have been approved
--	--	---	--	---

2. Request Application Package

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

3. Application Package

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

4. Submission Dates and Times

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

a. Letter of Intent Deadline (must be emailed or postmarked by)

Due Date for Letter of Intent: **04/05/2019**

b. Application Deadline

Due Date for Applications: **05/03/2019**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

A Letter of Intent is requested by not required.

Date for Information Conference Call

03/14/19

Scheduled for 2:00 - 3:00 pm, Eastern Standard Time.

Conference Number: (770) 488-3600

Conference ID: 4383605

Questions may be submitted to ibx5@cdc.gov as soon as the NOFO is released.

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\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/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\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/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

The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications. An LOI is requested but not required.

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

Mary Hulihan

Centers for Disease Control and Prevention

National Center on Birth Defects and Developmental Disabilities

Division of Blood Disorders

4770 Buford Highway NE Mailstop E-64

Atlanta, GA 30341-3717

Email: ibx5@cdc.gov

8. Table of Contents

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

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

9. Project Abstract Summary

(Maximum 1 page)

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

10. Project Narrative

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

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

a. Background

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

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the

public health problem as described in the CDC Background section.

ii. Outcomes

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

iii. Strategies and Activities

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

1. Collaborations

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

2. Target Populations and Health Disparities

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

c. Applicant Evaluation and Performance Measurement Plan

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

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see <http://www.hhs.gov/ocio/policy/collection/>.
- 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 Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

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

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

Applicants applying for both the Thalassemia Component and the Sickle Cell Disease Component must provide two separate budgets, one for each component, that are clearly labeled to distinguish the two. Applicants applying for the Sickle Cell Disease Component must clearly differentiate the budget needs for this component and describe them in their budget narrative.

The budget should contain funding for two members of the applicant's team (either internal or

external) team to travel to Atlanta, GA on an annual basis for participation in a two-day reverse site visit.

Costs for the materials necessary for the collection of biospecimens and the shipment of these materials to the CDC laboratory will be covered by CDC and do not need to be included in the applicant's budget.

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.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the OGS TIMS staff at 770- 488-2700 or by e-mail at ogstims@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to OGS TIMS staff for processing from www.grants.gov on the deadline date.

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

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

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

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

All applicants will submit an application for the Thalassemia Component with the option of also applying for the Sickle Cell Disease Component. Although only one application will be submitted, the Thalassemia Component and the Sickle Cell Disease Component will be scored individually. An applicant's score on the Thalassemia Component will be the priority in the ranking process. Applicants also applying for the Sickle Cell Disease Component will be scored for the additional activities necessary for this component separately. Only those applicants whose Thalassemia Component scores rank high enough for funding will be considered for Sickle Cell Disease Component funding.

Applicants should clearly delineate between the two components, or provide an indication of areas that span both components in their Narrative, Work Plan, Organizational Capacity, and Budget sections of the application.

Collaborations (15 points)

Evaluate the extent to which the applicant:

- Provides a plan for communicating and coordinating activities with (1) CDC and (2) collaborating programs and organizations.
- Describes how it will collaborate with related CDC programs or CDC-funded organizations, that have a role in achieving the NOFO outcomes.
- Describes how it will collaborate with at least one of each of the following :
 - professional medical organizations
 - not-for-profit organizations
 - community-based organizations or community advocate organizations.

- Provides letter of support from each collaborator that contains details about the particular role that collaborator will play in achieving the NOFO outcomes

Work Plan (20 points)

Evaluate the extent to which the applicant presents a work plan that:

- Provides detailed information for the first year of the award and a general summary of activities for Years 2-5. The plan should be clear in the narrative approach and reinforced in the work plan.
- Aligns with the strategies/activities, outcomes, and performance measures in the NOFO logic model and Project Description.
- Describes strategies and activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable).
- Specifies the scope, setting(s), and population(s) of focus for work under each strategy and activity.
- Includes a timeline, staff person responsible for oversight, and metric to evaluate effectiveness for each strategy and activity.
- Is consistent with CDC's proposed evaluation questions and process and outcome measures.

ii. Evaluation and Performance Measurement

Maximum Points:25

Partners and Collaborators (5 points)

Evaluate the extent to which the applicant:

- Describes how key program partners will be engaged in the evaluation and performance measurement planning processes.
- Describes how applicants will work with individuals with evaluation experience (either internal or external) to meet the evaluation and performance reporting requirements.

Design (10 points)

Evaluate the extent to which the applicant:

- Describes the type of evaluations to be conducted (i.e. process and/or outcome).
- Describes how key evaluation questions will be answered.
- Describes appropriate data collection approaches, measures, and data sources.
- Describes potentially available data sources for evaluation and performance measurement.

Utilization of Evaluation Findings (10 points)

Evaluate the extent to which the applicant:

- Describes how performance measurement and evaluation findings will be reported, and used to demonstrate the outcomes of the NOFO and for continuous program quality

improvement.

iii. Applicant's Organizational Capacity to Implement the Approach

Maximum Points:40

Organizational Capacity (25 points)

Evaluate the extent to which the applicant:

- Describes its organizational capacity to carry out the project strategies.
- Describes how it will access subject matter expertise (staff and/or contractual) relevant to the strategies selected.
- Demonstrates relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes.
- Demonstrates experience and capacity to implement the evaluation plan.
- Provides a detailed description of previous experience working (internally or with external partners) in the fields of transfusion medicine and clinical care for patients with thalassemia/sickle cell disease
- Provides a detailed description of previous experience working (internally or with external partners) on projects related to the development and testing of materials for public health education and communication
- Provides a detailed description of the ability to document and disseminate findings, outcomes, and recommendations.
- Demonstrates the ability to collect and transfer biological specimens to CDC for storage and potential future use for surveillance of emerging bloodborne infectious agents, including the plan for obtaining and IRB determination and approval from participating institutions

Project Management (15 points)

Evaluate the extent to which the applicant:

- Describes core project management plans and capability to execute project strategies, including roles and responsibilities of project staff.
- Describes who will have day-to-day responsibility for key tasks such as: leadership of the project; monitoring of the project's on-going progress; preparation of reports; program evaluation; and communication with partners and CDC.
- Provides explanation of the extent to which contractual organizations will have a role in implementing program strategies and achieving outcomes and how contracts will be written, executed and monitored to achieve these outcomes.
- Describes how any consultants and/or partner organizations will contribute to achieving project outcomes.
- Provides a detailed description of previous experience in program management including readiness to establish contracts in a timely manner and a long term sustainability plan.

Budget

Evaluate the extent to which the applicant proposes a budget which:

- Aligns with the proposed work plan.
- Shows 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.
- Is accurate and reasonable.

c. Phase III Review

There are two components for this funding opportunity. All applicants must apply for the Thalassemia Component in order to be considered for the Sickle Cell Disease Component via a single application that clearly identifies both components. Only those successful applicants under the Thalassemia Component will be eligible for additional Sickle Cell Disease Component funding. Thalassemia and Sickle Cell Disease Components will be reviewed, scored, and ranked separately. All applications will be funded by score and rank as determined by the objective review panel.

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

By 09/30/2019 all funded recipients will have received a call and entered into budget negotiations with the CDC. All approved but unfunded applicants will receive an email notifying them of the determination.

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>.

The following Administrative Requirements (AR) apply to this project:

<https://www.cdc.gov/grants/additionalrequirements/index.html>

Generally applicable ARs:

- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions (June 2012)
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act Requirements
- AR-25: Data Management and Access
- AR-26: National Historic Preservation Act of 1966
- 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-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 (DP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application	Yes
Data on Performance and Outcome Measures	Quarterly reports - 9 months into award and every 3 months thereafter; Annual reports - 12 months into award and annually thereafter	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 project period	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30, April 30, July 30, and October 30	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)

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

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

Performance Measurement

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

- Other information requested as determined by the CDC program.

Evaluation

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

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

b. Annual Performance Report (APR) (required)

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

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
 - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
 - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
 - Recipients must describe success stories.
- **Challenges**
 - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
 - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**

- Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.
- **Administrative Reporting** (No page limit)
 - SF-424A Budget Information-Non-Construction Programs.
 - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
 - Indirect Cost Rate Agreement.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances); and
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

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:

Mary Hulihan, Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

4770 Buford Hwy MS E-64

Atlanta, GA 30341-3717

Telephone: (404) 498-6724

Email: IBX5@cdc.gov

Grants Staff Contact

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

Ferrinnia (Toni) Augustus-High, Grants Management Specialist

Department of Health and Human Services

Office of Grants Services

2920 Brandywine Rd., MS E/09

Atlanta, GA 30341

Telephone: (770) 488-2906

Email: wef9@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.

For all other **submission** questions, contact:

Technical Information Management Section

Department of Health and Human Services

CDC Office of Financial Resources

Office of Grants Services

2920 Brandywine Road, MS E-14

Atlanta, GA 30341

Telephone: 770-488-2700

Email: ogstims@cdc.gov

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

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. 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

Optional attachments, as determined by CDC programs:

- Resumes / CVs
- Letters of Support
- Indirect Cost Rate, if applicable

For this NOFO, there is a 20 page limit for the Project Narrative, inclusive of the Work Plan, for those applying for only the Thalassemia Component and a 30 page limit for those applying for both the Thalassemia and Sickle Cell Disease Components.

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

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

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

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be

done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

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

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

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

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

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list:

https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-_Review-SPOC_01_2018_OFFM.pdf.

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

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

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

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

Memorandum of Understanding (MOU) or Memorandum of Agreement

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

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