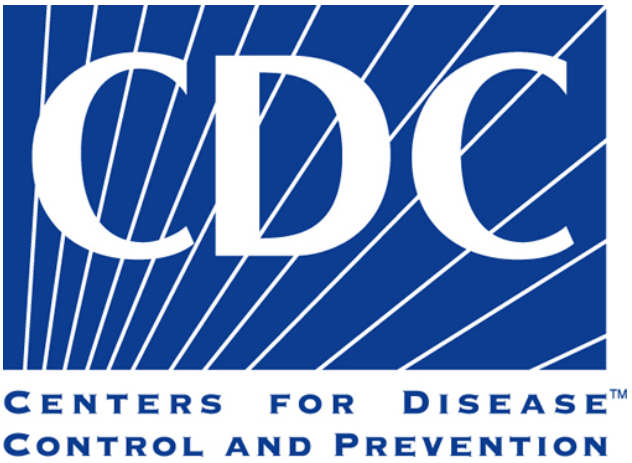



**Centers for Disease Control and Prevention**

National Center for Emerging and Zoonotic Infectious Diseases

# Continuing Enhanced National Surveillance for Prion Diseases in the United States

CDC-RFA-CK22-2202

03/29/2022

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## Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-CK22-2202. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

### A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

### B. Notice of Funding Opportunity (NOFO) Title:

Continuing Enhanced National Surveillance for Prion Diseases in the United States

### C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

### D. Agency Notice of Funding Opportunity Number:

CDC-RFA-CK22-2202

### E. Assistance Listings Number:

93.084

### F. Dates:

**1. Due Date for Letter of Intent (LOI):**
01/28/2022

**2. Due Date for Applications:**

03/29/2022
11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

**3. Due Date for Informational Conference Call:**
N/A

## G. Executive Summary:

**1. Summary Paragraph**
The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2022 funds for a cooperative agreement program to continue enhanced national surveillance for human prion diseases in the United States. The purpose of the funding is to continue an active surveillance program since 1997 to monitor the occurrence of potentially emerging human transmissible spongiform encephalopathies (TSEs) in the United States. In 1997, in collaboration with the American Association of Neuropathologists (AANP), the National Prion Disease Pathology Surveillance Center was established to enhance national Creutzfeldt-Jakob Disease (CJD) surveillance and to make possible laboratory investigation of newly emerging prion diseases. This pathology center provided the services of a cutting edge prion disease laboratory, filling a critical public health gap for monitoring prion diseases in humans. Brain tissues and clinical laboratory information on clinically suspected and diagnosed cases of human prion disease have been evaluated at the NPDPSC for approximately 20 years to confirm diagnoses and determine the type of prion disease, including whether the patients had variant CJD or some other possible emerging prion disease in the United States.

**a. Eligible Applicants:**
Open Competition

**b. Funding Instrument Type:**
CA (Cooperative Agreement)

**c. Approximate Number of Awards**
1

**d. Total Period of Performance Funding:**
$20,000,000

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

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

**g. Estimated Award Date:**
August 31, 2022

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

## Part II. Full Text

## A. Funding Opportunity Description

### 1. Background

**a. Overview**

Prion diseases, also known as transmissible spongiform encephalopathies (TSEs), are a group of animal and human brain diseases that are invariably fatal and often characterized by a long incubation period and a multifocal neuropathologic picture of neuronal loss, spongiform changes, and astrogliosis. Prion diseases that occur in humans include variant Creutzfeldt-Jakob disease (CJD) and classic forms of CJD, including those classified as sporadic or genetic. Classic CJD generally occurs with an incidence between 0.5 and 2 cases per million annually. In recent years in the United States, the annual age-adjusted incidence has been between 1 and 1.4 cases per million. Since US surveillance for CJD began in 1979, the annual number of reported cases has increased substantially although the age-adjusted incidence has remained relatively stable. The increase in numbers of reported cases largely reflects the known increased risk of CJD in people in their 60s and 70s, the aging of the US population and, more recently, the greater use of improved laboratory diagnostic tests (e.g., CSF RT-QuIC and MRIs). Variant CJD (vCJD) was first identified in 1996 in the United Kingdom where, as of June 2021, 178 probable and definite cases have been reported. An additional 54 cases have been identified in residents of 11 countries outside the United Kingdom, including four cases in the United States. In 1976, the occurrence of vCJD surprised most health authorities because it represented infections of humans by a cattle prion, the agent of classic bovine spongiform encephalopathy (BSE). This first recognized zoonotic prion disease led US and Canada to implement measures, such as stopping the feeding of cattle rendered animal protein, to reduce the spread of BSE in cattle in 1997, six years before the first endemic cases of classic BSE in North America occurred. The strict animal feeding restrictions established and maintained in North America has prevented significant spread of BSE, and, as indicated by human disease surveillance, has prevented vCJD. Another prion disease of potential public health concern is chronic wasting disease (CWD) of deer and elk. In 1999, CWD in free-ranging cervids was detected only in Colorado and Wyoming. By 2021 it had been detected in 25 states, two Canadian provinces, South Korea, Norway, Finland and Sweden. Of particular concern are the facts that unlike BSE, CWD is naturally communicable from animal-to-animal, the CWD prions can contaminate the environment from stool, urine, drool and carcasses of infected animals, and humans hunt and consume deer and elk. In addition, multiple strains of CWD have been reported, no highly effective, practical measures for stopping the CWD outbreak in the wild are presently available, and the number of people potentially exposed to CWD is increasing. Although to date, human prion disease surveillance provides evidence against the occurrence of human CWD, the pathogenicity of CWD may not be stable. Consistent with past guidance from a World Health Organization consultation indicating that humans should avoid consumption of any part of an animal with a prion disease, CDC recommends that to be as safe as possible, hunters should minimize their exposures to CWD and avoid consuming meat from any CWD infected animal.

**b. Statutory Authorities**

Sections 301(a) and 317(k)(2) of the Public Health Service Act (42 USC sections 242(a) and 247b(k)(2)), as amended.

**c. Healthy People 2030**
This program addresses the "Healthy People 2030" focus area(s) of Infectious Diseases. www.healthypeople.gov.

**d. Other National Public Health Priorities and Strategies**
Not Applicable

**e. Relevant Work**
The announcement will continue to support and build upon existing CDC activities outlined in CDC-RFA-CK17-1705 (ends August 31, 2022). Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for Emerging and Zoonotic Infectious Diseases. https://www.cdc.gov/ncezid/pdf/ncezid-strategic-plan-2018-2023-508.pdf

## 2. CDC Project Description

**a. Approach**

**Bold** indicates period of performance outcome.

**CK22-2202 – National CJD Pathology Surveillance Project**

| STRATEGIES AND ACTIVITIES | SHORT-TERM OUTCOMES | INTERMEDIATE OUTCOMES | LONG-TERM OUTCOMES |
|---|---|---|---|
| Perform tests necessary to confirm human prion diseases or diagnose them with high specificity and characterize the infecting prions.<br><br>Evaluate the usefulness of new diagnostic methods.<br><br>Periodically contact neurologists and neuropathologists reminding them of the importance of (a) reporting suspected prion disease cases and (b) their helping to arrange for submission to the surveillance center brain tissue from patients with clinically suspected and diagnosed prion disease. | **Improved human prion disease diagnoses and continued monitoring for emerging of new prion diseases in the United States.**<br><br>**Increased awareness of US clinicians, public health personnel and pathologists of available support for them to confirm, by state-of-the-art techniques, the diagnoses of human prion disease and the mechanism for reporting suspected cases of CJD, variant CJD and possibly new human prion diseases.**<br><br>**Maintain improved** | **Improved efficiency of national prion disease surveillance.**<br><br>**Increased submissions of appropriate tissue specimens to confirm the presence or absence of a prion disease in patients clinically diagnosed or suspected to have a prion disease.**<br><br>**Increased availability of surveillance specimens for** | **Provide credible prion disease surveillance to improve the confidence/trust from the US public that if variant CJD or some other new human prion disease, such as human CWD, were to emerge in this country, it would be detected early.**<br><br>**Serve as the ultimate measure of efficacy of the ongoing CDC,** |

| | | | |
|---|---|---|---|
| Collaborate with CDC, state and local HDs, the CJD Foundation and other facilities.<br><br>Enhance the collection, completeness, and reporting of epidemiologic information to CDC.<br><br>Provide consultations to general practice clinicians, neurologists and pathologists.<br><br>Collect autopsy brain tissue specimens on descendants with prion disease.<br><br>Disseminate program findings to the public. | **confirmations (e.g. through brain autopsies) of prion disease cases among physician-diagnosed or suspected prion disease cases and collect autopsy lymphoreticular tissues on any of these decedents known to have had a relatively high risk of exposure to CWD.**<br><br>**Improved pubic access to surveillance information about human prion diseases.** | **prion disease experts to facilitate basic and applied prion disease-related research.** | **USDA, and FDA efforts to reduce to a minimum the risks of iatrogenic and other acquired food and blood-related human prion disease.**<br><br>**Reduce the overall negative impact of prion diseases on US patients, families, and communities.** |

**i. Purpose**

The CDC announces the availability of FY 2022 funds for a cooperative agreement to continue enhanced national surveillance for human prion diseases in the United States. The purpose is to continue an active surveillance program to help confirm suspected and clinically diagnosed cases of human prion disease and to monitor the occurrence of potentially emerging human TSEs in the United States.

**ii. Outcomes**

The recipient is expected to achieve the following short term outcomes:

- Improved prion disease diagnoses and continue monitoring for emerging of new prion diseases in the United States.
- Improved awareness of clinicians, public health personnel and pathologists' awareness of available support for them to confirm, by state-of-the-art techniques, the diagnoses of human prion disease and the mechanism for reporting suspected cases of CJD, variant CJD and possibly new human prion diseases.
- Increased number of confirmed prion disease cases (e.g. through increased autopsies) among physician-diagnosed or suspected prion disease cases.
- Improved public access to surveillance information about human prion diseases.

The recipient is expected to achieve the following intermediate outcomes:

- Improved efficiency of national prion disease surveillance.
- Increased submission of specimens to confirm the presence or absence of a prion disease in patients clinically diagnosed or suspected to have a prion disease.
- Make available surveillance specimens to prion disease experts to facilitate basic and applied prion disease- related research.

The recipient is expected to achieve the following long-term outcomes:

- Provide reassurance to the US public that if variant CJD or some other new human prion disease, such as human CWD, were to emerge in this country, it would be detected early.
- Serve as the ultimate measure of efficacy of the ongoing CDC, USDA and FDA efforts to reduce to a minimum iatrogenic CJD, including the risks of food and blood related human prion disease.
- Reduce the overall negative impact of prion diseases on US patients, families, and communities.

**iii. Strategies and Activities**

Strategy 1: Perform the tests necessary to confirm human prion diseases or diagnose them with high specificity and characterize the infecting prions.

Strategy 2: Evaluate the usefulness of new diagnostic methods.

Strategy 3: Periodically contact neurologists and neuropathologists reminding them of the importance of (a) reporting suspected prion disease cases and (b) their helping to arrange for submission to the surveillance center brain tissue from patients with clinically suspected and diagnosed prion disease.

Strategy 4: Collaborate with CDC, state and local health departments, the CJD Foundation and other facilities

Strategy 5: Enhance the collection, completeness, and reporting of epidemiologic information to the CDC.

Strategy 6: Provide consultations to general practice clinicians, neurologists and pathologists.

Strategy 7: Collect autopsy brain tissue specimens on decedents with prion disease.

Strategy 8: Disseminate program findings to the public.

In addition, the large number of brain tissues and other laboratory samples collected as part of this project are in the public domain and should be made accessible for analysis by other investigators. The applicant should describe a detailed plan on how the samples will be made accessible to other investigators

**1. Collaborations**

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

The recipient is expected to collaborate with CDC funded state and local Health Departments and the CJD Foundation to encourage increased utilization of the prion disease diagnostic services funded by this program.

**b. With organizations not funded by CDC:**

The recipient is expected to collaborate with state and local Health Departments that may not be funded by CDC and other centers as identified and/or recommended by CDC. Some examples include American Academy of Neurology and American Association of Neuropathologists.

**2. Target Populations**

This project does not target specific populations. It collects autopsy brain tissue specimens on decedents with prion disease, provides consultations to general practice clinicians, neurologists and pathologists and disseminates program findings to the public.

**a. Health Disparities**

N/A

**iv. Funding Strategy**

N/A

**b. Evaluation and Performance Measurement**

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

Strategy/Activity 1: Perform the tests necessary to confirm human prion diseases or to diagnose them with high specificity and characterize the infecting prions to monitor for the emergence in the United States of new human prion diseases such as endemic variant CJD or possibly human

CWD.
Measure: # of referrals received from Physicians on patients who die from a clinically suspected prion disease.

Strategy/Activity 2: Evaluate the usefulness of new diagnostic methods to improve the sensitivity of national prion disease surveillance
Measure: assess effects of new methods on the number of identified prion disease cases

Strategy/Activity 3: Periodically contact neurologists and neuropathologists reminding them of the importance of (a) reporting suspected prion disease cases, particularly suspected variant CJD cases and other prion disease cases of increased public health importance (e.g., possible human CWD, iatrongenic disease) and (b) their helping to arrange for submission to the surveillance center brain tissue from patients with clinically suspected and diagnosed prion disease.
Measure: # of neurologists and neuropathologists contacted

Strategy/Activity 4: Collaborate with CDC, state and local health departments and other health facilities to establish effective ways to increase accurate diagnoses of prion diseases, including increasing the number of autopsies among physician-diagnosed or suspected prion disease cases.
Measure: # of Prion diseases cases diagnosed from autopsies
Measure: # of these autopsies specifically coordinated by the recipient

Strategy/Activity 5: Enhance the collection, completeness, and reporting to CDC of epidemiologic information, including copies of the death certificates, on deceased patients with highly probable prion disease based on very specific new diagnostic tests (e.g. RT-QuIC positive cerebrospinal fluid) and/or with brain tissue-confirmed prion diseases.
Measure: # of times RT-QuIC utilized to confirm suspected cases of prion diseases
Measure: proportion of such patients for whom death copies of death certificates were obtained and for whom sufficient information was collected to determine the likely epidemiologic classification of the disease (e.g, iantrogenic or sporadic CJD).

Strategy/Activity 6: Provide consultations as needed, particularly on the clinical and neuropathological manifestations of variant CJD, to neurologists and pathologists in the United States by participating in association conferences, using the internet, publications, phone consultations etc.
Measure: # of conferences, presentations and consultations provided

Strategy 7: Monitor for the potential occurrence of human CWD by collecting and examining relevant tissue specimens on decedents with suspected prion disease who were at increased risk of exposure to the CWD agent as a result of their hunting or venison consumption.
Evaluation: Number of such tissue specimens collected and examined.

Strategy/Activity 8: Disseminate program findings to the public.
Measure: # of presentations and/or publications, providing quarterly updates of the number of referrals and confirmed cases of prion disease to project website.

The recipient is expected to achieve the following short term outcomes:

Short term outcome 1: Improved prion disease diagnoses and continue monitoring for emerging of new prion diseases in the United States.
Measure: Provide state of the art diagnostic services on at least 1000 specimens submitted to the recipient of this contract to help US physicians diagnose~~is~~ prion disease and obtain lymphoreticular tissues at autopsy on at least 5 cases with suspected potentially emerging prion disease (e.g., neurodegenerative illness in a patient with history of exposure to an animal harvested from an area where chronic wasting disease (CWD) has been found).

Short term outcome 2: Improved awareness of clinicians, public health personnel and pathologists' awareness of available support for them to confirm, by state-of-the-art techniques, the diagnoses of human prion disease and the mechanism for reporting suspected cases of CJD, variant CJD and possibly new human prion diseases.
Measure: The recipient of this award should create a website to advertise its prion disease diagnostic services using state-of-the-art techniques and the required protocols for submission of specimens; the website should also provide guidance on the mechanism for reporting suspected cases of CJD, variant CJD and possibly new human prion diseases.

Short term outcome 3: Increased number of confirmed prion disease cases (e.g. through increased autopsies) among physician-diagnosed or suspected prion disease cases.
Measure: Obtain at least 250 diagnostic tissue referrals of physician-diagnosed or suspected prion disease decedents for confirmation of the prion disease diagnosis.

Short term outcome 4: Improved public access to surveillance information about human prion diseases.
Measure: Make results of its surveillance information generally available on its website.

The recipient is expected to achieve the following intermediate outcomes:

Intermediate outcome 1: Improved efficiency of national prion disease surveillance.
Measure: Provide US physicians with a single, centralized place for obtaining prion disease diagnostic information and tests and share results of tests in a timely manner.

Intermediate outcome 2: Increased submission of specimens to confirm the presence or absence of a prion disease in patients clinically diagnosed or suspected to have a prion disease.
Measure: In collaboration with CDC, encourage physicians at professional meetings and through patient support groups to submit specimens on patients for whom prion disease is in the differential diagnosis to help confirm the presence or~~f~~ absence of a prion disease; obtain tissues on at least 250 referrals.

Intermediate outcome 3: Make available surveillance specimens to prion disease experts to facilitate basic and applied prion disease- related research.
Measure: Provide surveillance specimens to support at least 5 reviewed research projects of established prion disease experts, including basic and applied prion disease-related research.

The recipient is expected to achieve the following long-term outcomes:

Long term outcome 1: Provide reassurance to the US public that if variant CJD or some other new human prion disease, such as human CWD, were to emerge in this country, it would be detected early.
Measure: The recipient of this award in collaboration with CDC should interpret the results of

the ongoing prion disease surveillance and both the recipient of this award and CDC should provide to the US public (website/literature/conferences) the interpretation of the evidence obtained for or against the emergence in the US of variant CJD or some other new human prion disease.

Long term outcome 2: Serve as the ultimate measure of efficacy of the ongoing CDC, USDA and FDA efforts to reduce to a minimum iatrogenic CJD, including the risks of food and blood related human prion disease.
Measure: Make available the interpretation of results of human prion disease surveillance to show that the advice of CJD and efforts of USDA and FDA are or are not adequately preventing human chronic wasting disease, iatrogenic CJD cases, and prion disease related to food (variant CJD) or blood. Ideally the number of such CJD cases identified through human surveillance will be zero or close to zero, or if not, this surveillance will reveal the problem that should be addressed.

Long term outcome 3: Reduce the overall negative impact of prion diseases on US patients, families, and communities.
Measure: The recipient of this award in cooperation with CDC a) should enable patients and family members to learn from their physicians based on test results from the recipient of this award about whether they or their loved one has or had a prion disease and b) should enable the community to know with data produced and disseminated by the recipient of this award and CDC, rather than through less reliable sources, whether variant CJD or a more recent new prion disease in the community has emerged.

**ii. Applicant Evaluation and Performance Measurement Plan**

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

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

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

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

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

**c. Organizational Capacity of Recipients to Implement the Approach**

The recipient should describe existing laboratory capacity to perform diagnostic tests for human prion diseases and characterize infecting prions; describe past experience and achievement in successfully completing the types of recipient activities necessary for achieving the purpose of this project; describe the ability to successfully collaborate with state and local health departments and professional associations whose members are involved in the care and diagnosis of CJD patients such as the American Academy of Neurology, the American Association of Neuropathologists, and the United States and Canadian Academy of Pathologists.

**d. Work Plan**

Recipient should submit a proposed workplan for the strategies and/or activities outlined in the logic model section.

**e. CDC Monitoring and Accountability Approach**

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

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

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

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

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

f. CDC Program Support to Recipients

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. The project is divided into eight strategies and/or activities. The recipient will be responsible for all strategies and/or activities outlined below:

CDC staff will provide support by:

- Providing assistance in the dissemination and public health interpretation of results
- Facilitating collaborations with public health officials, neurologists and families of suspected cases to increase the number of referrals
- Providing feedback to the applicant in the formation and execution of their plan to make collected tissue samples available to other investigators

## B. Award Information

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

**2. Award Mechanism:**
U38

**3. Fiscal Year:**
2022

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

**5. Total Period of Performance Funding:**
$20,000,000
This amount is subject to the availability of funds.

Estimated Total Funding:
$20,000,000

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

**7. Expected Number of Awards:**
1

**8. Approximate Average Award:**

$4,000,000
Per Budget Period

**9. Award Ceiling:**
$0
Per Budget Period

This amount is subject to the availability of funds.

**10. Award Floor:**
$0
Per Budget Period

**11. Estimated Award Date:**
August 31, 2022

**12. Budget Period Length:**
12 month(s)

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

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

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

## C. Eligibility Information

### 1. Eligible Applicants

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

00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

06 (Public and State controlled institutions of higher education)

05 (Independent school districts)

07 (Native American tribal governments (Federally recognized))

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

23 (Small businesses)

22 (For profit organizations other than small businesses)

20 (Private institutions of higher education)

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

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

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

08 (Public housing authorities/Indian housing authorities)

Additional Eligibility Category:

Government Organizations:

State controlled institutions of higher education

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

Local governments or their bona fide agents

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

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

Non-government Organizations

American Indian or Alaska native tribally designated organizations

Other

Ministries of Health

**2. Additional Information on Eligibility**

Hospitals, Laboratories and other public and/or private entities may apply.

**3. Justification for Less than Maximum Competition**

N/A

**4. Cost Sharing or Matching**

Cost Sharing / Matching Requirement:
No

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

### 5. Maintenance of Effort

Maintenance of effort is not required for this program

## D. Application and Submission Information

### 1. Required Registrations

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

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

**a. Data Universal Numbering System:**

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

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

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

**b. System for Award Management (SAM):**

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

Knowledge Base.

**c. Grants.gov:**

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

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

| Step | System | Requirements | Duration | Follow Up |
|---|---|---|---|---|
| 1 | Data Universal Number System (DUNS) (Required until April 4, 2022) | 1. Click on http:// fedgov.dnb.com/ webform<br>2. Select Begin DUNS search/request process<br>3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit #<br>4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number | 1-2 Business Days | To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711 |
| 2 | System for Award Management (SAM) | 1. Retrieve organizations DUNS number (required until April 4, 2022)<br>2. Go to SAM.gov and designate an E-Biz POC (You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration. | 3-5 Business Days but up to 2 weeks and must be renewed once a year | For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220 |
| 3 | Grants.gov | 1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR)<br>2. Once the account is set up the E-BIZ POC will be notified via email<br>3. Log into grants.gov using the | Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov) | Register early! Log into grants.gov and check AOR status until it shows you have been approved |

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| | | password the E-BIZ POC received and create new password<br>4. This authorizes the AOR to submit applications on behalf of the organization | | |

## 2. Request Application Package

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

## 3. Application Package

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

## 4. Submission Dates and Times

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

**a. Letter of Intent Deadline (must be emailed)**

Number Of Days from Publication 0

01/28/2022

**b. Application Deadline**

Number Of Days from Publication 60

03/29/2022

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

**Due Date for Information Conference Call**

N/A

## 5. Pre-Award Assessments

**Risk Assessment Questionnaire Requirement**

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

National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

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

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

**Duplication of Efforts**

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

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

## 6. Content and Form of Application Submission

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

## 7. Letter of Intent

N/A

## 8. Table of Contents

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

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

## 9. Project Abstract Summary

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

## 10. Project Narrative

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

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

## a. Background

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

## b. Approach

### i. Purpose

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

### ii. Outcomes

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

### iii. Strategies and Activities

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

### 1. Collaborations

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

### 2. Target Populations and Health Disparities

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

## c. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

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

### d. Organizational Capacity of Applicants to Implement the Approach

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

### 11. Work Plan

(Included in the Project Narrative's page limit)

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

### 12. Budget Narrative

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

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

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

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

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

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

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

## 13. Funds Tracking

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

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

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

## 14. Pilot Program for Enhancement of Employee Whistleblower Protections

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

## 15. Copyright Interests Provisions

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

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

identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

## 16. Funding Restrictions

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

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

## 17. Data Management Plan

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

## 18. Other Submission Requirements

**a. Electronic Submission:**

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

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

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

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

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

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

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

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

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

2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and

3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

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

## E. Review and Selection Process

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

**a. Phase 1 Review**

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

**b. Phase II Review**

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

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

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

**i. Approach** **Maximum Points:** 25

- The extent to which the applicant described in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.
- The extent to which the applicant clearly identified the outcomes they expect to achieve by the end of the period of performance, as identified in the logic model in the Approach section of the CDC Project Description.
- The extent to which the applicant provided a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes.
- The extent to which the applicant selected existing evidence-based strategies.

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

- The extent to which the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- The extent to which key program partners will participate in the evaluation and performance measurement planning processes.
- The extent to which 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) will be utilzed for this project.

**iii. Applicant's Organizational Capacity to Implement the Approach** **Maximum Points:** 50

- The extent to which the applicant described existing laboratory capacity to perform diagnostic tests for human prior diseases and characterize infecting Prions.
- The extent to which the applicant described past experience and successful achievement of recipient activities necessary for achieving the purpose of the project
- The extent to which the applicant described their ability to collaborate with state and local health departments and professional associations whose members are involved in the care and diagnosis of prion disease patients.

**Budget** **Maximum Points:** 0

- The extent to which the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative.

**c. Phase III Review**

Applications will be funded in order by score and rank 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

Applicants will be notified of selection of funding by the Office of Grant Services (OGS) through a Notice of Award, with an anticipated date around August 25, 2022

## F. Award Administration Information

### 1. Award Notices

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

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

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

## 2. Administrative and National Policy Requirements

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

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

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

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

## 3. Reporting

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

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

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

| Report | When? | Required? |
|---|---|---|
| Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP) | 6 months into award | Yes |
| Annual Performance Report (APR) | No later than 120 days before end of budget period. Serves as yearly continuation application. | Yes |
| Federal Financial Reporting Forms | 90 days after the end of the budget period | Yes |
| Final Performance and Financial Report | 90 days after end of period of performance | Yes |
| Payment Management System (PMS) Reporting | Quarterly reports due January 30; April 30; July 30; and October 30 | Yes |

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

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

Performance Measurement

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

Evaluation

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

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

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

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.

- Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
- Recipients must describe success stories.

- **Challenges**
  - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
  - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

- **CDC Program Support to Recipients**
  - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

- **Administrative Reporting** (No page limit)
  - SF-424A Budget Information-Non-Construction Programs.
  - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
  - Indirect Cost Rate Agreement.

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

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

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

**e. Final Performance and Financial Report (required)**
The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report

should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

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

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

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.

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

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

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

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

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

assistance funds"). Outlined below are the specifics of this requirement:

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

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

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

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

5) Contents of Reports: The reports must contain:

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

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

## 6. Termination

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

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

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

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

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

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

## G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

### Program Office Contact

**For programmatic technical assistance,** contact:

First Name:
Tracey

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

Address:
Roybal Bldg 24
MS H24-12
Atlanta, GA 30333

Telephone:
404-639-0953

Email:
TPonder@cdc.gov

### Grants Staff Contact

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

First Name:
Freda

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

Address:
2920 Brandywine Rd
MS TV2
Atlanta, GA 30341

Telephone:
770-488-3107

Email:
WVE2@cdc.gov

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

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

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

## H. Other Information

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

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

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

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

Position descriptions

Organization Charts

## I. Glossary

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

**Administrative and National Policy Requirements, Additional Requirements (ARs):** Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed

in the NOFO. To view brief descriptions of relevant provisions, see .https://www.cdc.gov/grants/additional-requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

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

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

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

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

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

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

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

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

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

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

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

**Direct Assistance:** A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants

and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. https://www.cdc.gov/grants/additional-requirements/index.html.

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

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

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

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

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

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

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

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

administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

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

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

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

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

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

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

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

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

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

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

**Maintenance of Effort:** A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal

grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## NOFO-specific Glossary and Acronyms