Centers for Disease Control

National Center for Environmental Health

Lead Exposure Registry of Flint Residents - Michigan
CDC-RFA-EH17-1704
Application Due Date: 06/28/2017

Lead Exposure Registry of Flint Residents - Michigan
CDC-RFA-EH17-1704
TABLE OF CONTENTS

Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-EH17-1704. 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. Funding Opportunity Title:

Lead Exposure Registry of Flint Residents - Michigan

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 http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-EH17-1704

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.197

F. Dates:

1. Due Date for Letter of Intent (LOI): **N/A**

2. Due Date for Applications: **06/28/2017**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. 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) 2017 funds of approximately $3.6 million to support the City of Flint, MI, and the State of Michigan to build their capacity to: 1) identify communication and training strategies for a registry of residents exposed to lead-contaminated water from the Flint Water System (FWS) during April 25, 2014–October 15, 2015; 2) develop the registry to identify eligible residents; 3) recruit and enroll eligible residents, collect their baseline information, and refer them to services; 4) ensure a referral process to link registrants to comprehensive, coordinated services to mitigate the effects of lead exposure; and 5) select appropriate measures and frequency of follow-up to collect data on exposure, health, and developmental milestones along with choices of interventions, services, and enrichment activities undertaken during the project period.

To maximize the public health benefit to the residents of the City of Flint, MI, the CDC

recommends that the registry be designed to examine whether registrants' choice of referred interventions might be related to better health outcomes and developmental milestones. The registry design should enable important policy and administrative decisions and recommendations for the City of Flint and for the State of Michigan.

a. Eligible Applicants:	Single
b. FOA Type:	Grant
c. Approximate Number of Awards:	1
d. Total Project Period Funding:	$14,400,000
e. Average One Year Award Amount:	$3,600,000
f. Total Project Period Length:	4
g. Estimated Award Date:	08/01/2017
h. Cost Sharing and / or Matching Requirements:	N

Cost sharing or matching funds are not required for this program.

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

During April 25, 2014–October 15, 2015, approximately 99,000 residents of the City of Flint, MI, were exposed to lead when the water source was switched from the Detroit Water Authority to the FWS. Because the FWS did not use corrosion control, the lead levels in Flint tap water increased above the EPA action level of 15 ppb as required by the Lead and Copper Rule. In children, lead exposure can result in serious effects on cognitive and physiological development. Lead can reduce kidney function and increase risk of hypertension and essential tremor among adults. Data from the Michigan Department of Health and Human Services showed an increase in blood lead levels ≥5 µg/dL (CDC reference value) among Flint children, under 5 years of age, after the source water change. Support is needed to assist the City of Flint and the State of Michigan to build their capacity to establish a public health registry.

The Centers for Disease Control and Prevention (CDC) announces the availability of FY2017 funds of approximately $3.6 million to support the City of Flint, MI, and the State of Michigan to build their capacity to: 1) identify communication and training strategies for a registry of residents exposed to lead-contaminated water from the Flint River during April 25, 2014–October 15, 2015; 2) develop the registry to identify eligible residents; 3) recruit and enroll eligible residents, collect their baseline information, and refer them to services; 4) ensure a referral process to link registrants to comprehensive, coordinated services to mitigate the effects

of lead exposure; and 5) select appropriate measures and frequency of follow-up to collect data on exposure, health, and developmental milestones along with choices of interventions, services, and enrichment activities undertaken during the 4 year project period.

This grant requires close collaboration with community leaders, clinical partners and educators, stakeholders, and various entities that serve Flint residents. The applicant, with the network of collaborators, should strive for timely registry planning and development; accurate registrant identification and enrollment; appropriate referral to services; and the collection of both baseline and follow-up information from registrants. Although this NOFO is not intended to fund case-management services for registrants, the applicant should design, establish, and manage a public health registry that links registrants' data about exposure, health, and developmental milestones with their participation in intervention activities and services through a voluntary referral network of external collaborators. This joint effort of shared state and community resources should provide evidence of outcomes for registrants who choose interventions through available health, educational, environmental, and community services for Flint residents.

This non-research NOFO supports state and local capacity to establish a registry to prevent or control disease or injury resulting from exposure to the lead-contaminated FWS. This registry should be used for quality improvement of state and local public health programs and services for residents with lead exposure. Generally, the results and accomplishments from federally-funded grants should be made available to the public. Thus, the ideal applicant should implement a data management plan (DMP) to maximize the utility of the registry data to inform policy and administrative decisions for the benefit of Flint residents and the State of Michigan.

b. Statutory Authorities

This program is authorized under Section 2203(b) of Public Law 114-322, the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016; 42 U.S.C. Section 300j-27(b).

c. Healthy People 2020

The CDC is committed to achieving the objectives of "Healthy People 2020" found at https ://www.healthypeople.gov/. This NOFO is committed to the Healthy People 2020 lead-related goals of reducing: 1) blood lead levels in children aged 1-5 years; 2) mean blood lead levels in children; 3) exposure to lead in the population as measured by blood and urine concentrations; and 4) the proportion of persons who have elevated blood lead concentrations from work exposures. This NOFO also addresses the Healthy People 2020 focus areas of Maternal, Infant, and Child Health.

d. Other National Public Health Priorities and Strategies

The President's Task Force on Environmental Health Risks and Safety Risks to Children reports on "Key Federal Programs to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts" and "Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards." See https:// ptfceh.niehs.nih.gov/ features/ featured-resource/index.htm.

The Occupational Safety and Health Administration (OSHA) Directive No. CPL 03-00-009: National Emphasis Program (NEP) on Lead. See https:// www.osha.gov/ ;OshDoc/ Directive_pdf

/ CPL_03-00-0009.pdf.

e. Relevant Work

On December 14, 2015, lead contamination in the FWS was declared a state of emergency. By January 2016, CDC, led by the Department of Health and Human Services, assisted the City of Flint and the State of Michigan to develop a response and recovery plan. The CDC Emergency Operation Center was activated from February 1, 2016 to March 11, 2016, to coordinate the 2016 Flint Water Contamination Response.

At CDC, NCEH funds 35 childhood lead poisoning prevention programs under NOFO No. CDC-RFA-EH14-1408PPHF14, and the National Institute for Occupational Safety and Health (NIOSH) Adult Lead Epidemiology and Surveillance (ABLES) Program partners with 28 states.

2. CDC Project Description

a. Approach

Bold indicates project period outcome.

The overall NOFO approach is depicted in the following "high-level" logic model, which is elaborated in the sections that follow. A graphic of the full logic model is available in the supporting documents.

CDC-RFA-EH17-1704

Lead Exposure Registry of Flint Residents - Michigan

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Identify communication & training strategies for a registry of residents exposed to lead-contaminated water from the Flint Water System during April 25, 2014–October 15, 2015 • **Community advisory board** • Community outreach • Lead-related community & provider education • Workforce & stakeholder training Develop the registry to identify eligible residents • Define eligibility criteria • Develop protocol to recruit, enroll, and collect information Recruit and enroll eligible residents, collect their baseline information, and refer them to services • Screen for eligible residents • Recruit & Enroll • Collect baseline data/specimen • Refer to services Ensure a referral process to link registrants to comprehensive, coordinated services to mitigate the effects of lead exposure, such as: • Diagnosis & treatment • Therapy • Enrichment • Environmental assessment • Environmental intervention • Data sharing with registry Select appropriate measures and frequency of follow-up to collect data on exposure, health, and developmental milestones along with choices of interventions, services, and enrichment activities • Collect follow-up data/specimen • Analyze laboratory specimens • Manage data • Maintain quality control	**Community & Providers have:** • **Increased awareness of registry goals and scope** • **Increased awareness of eligibility criteria for registry** **Community, Providers & Workforce have increased knowledge of:** • **Adverse health and developmental outcomes from lead exposure** • **Blood lead testing and reporting requirements** • **Medical management recommendations** • **Environmental lead exposure sources and reduction methods** • **Modifiable factors for lead exposure reduction** • **Available preventive referral services and interventions to reduce the impact of lead exposure** **Registry Protocol enables metrics for:** • **Increased registrant referral to services over baseline** • **Target number of registry follow-ups achieved per registrant**	**Registrants:** • **Use preventive services** • **Reduce environmental lead exposures where they live, work, and play** • **Have lower blood lead levels** • **Have better health & fewer developmental delays** **Registry data collection leads to:** • **Increased quality & quantity of data to inform lead poisoning prevention policy & program administration** • **Increased knowledge about the effectiveness of the number of prevention services leading to improved outcomes** • **Increased knowledge about the effectiveness of different types of prevention services leading to improved outcomes** • **Increased knowledge about acute & long-term impacts of lead exposure**	• Residents, healthcare and service providers, & agencies have decision tools to reduce harmful effects of lead exposure • State & local agencies build & sustain the referral network to support lead poisoning prevention • Referral network continuously improves delivery of health, educational, and community services for lead-exposed residents Registry data repository: • Ensures registrant privacy • Establishes information system that informs policy & administrative decisions • Makes registry data available to the public & to agencies • Creates framework for future research

i. Purpose

The purpose of the NOFO is to build local and state capacity to establish a public health registry for residents who were exposed to lead-contaminated water from the FWS during April 25, 2014–October 15, 2015. The registry should include community, tribal, and stakeholder outreach and training; registrant enrollment and baseline data collection; referral of registrants to services to reduce or control lead exposure effects; measurement of registrants' exposure, health, and developmental milestones with their interventions, services, and enrichment activities.

ii. Outcomes

<table>
<tr><td colspan="2">The awardee is expected to achieve the following short-term and intermediate outcomes during the project period:</td></tr>
<tr><td>Short-Term Outcomes</td><td>Intermediate Outcomes</td></tr>
<tr><td>Community and Providers have:
Increased awareness of registry goals and scope
Increased awareness of eligibility criteria for registry
Community, Providers, and Workforce have increased knowledge of:
Adverse health and developmental outcomes from lead exposure
Blood lead testing and reporting requirements
Medical management recommendations
Environmental lead exposure sources and reduction methods
Modifiable factors for lead exposure reduction
Available preventive referral services and interventions to reduce the impact of lead exposure
Registry Protocol enables metrics for:
Increased registrant referral to services over baseline
Target number of registry follow-ups achieved per registrant</td><td>Registrants:
Use preventive services
Reduce environmental lead exposures where they live, work, and play
Have lower blood lead levels
Have better health and fewer developmental delays
Registry data collection leads to:
Increased quality and quantity of data to inform lead poisoning prevention policy and program administration
Increased knowledge about the effectiveness of the number of prevention services leading to improved outcomes
Increased knowledge about the effectiveness of different types of prevention services leading to improved outcomes
Increased knowledge about acute and long-term impacts of lead exposure</td></tr>
</table>

iii. Strategies and Activities

This NOFO supports the following strategies and activities during this four-year program period.

Strategy 1 - Identify communication and training strategies for a registry of residents exposed to lead-contaminated water from the FWS during April 25, 2014–October 15, 2015.

Engaging the public, partners, and stakeholders about lead-related issues will be a key strategy to maximize the public's interest, to promote the registry, and to serve the needs of the registrants. The strategies used by the awardee should be culturally appropriate and include an understanding of the unique demographics and the anticipated challenges of recruiting from targeted Flint neighborhoods and from applicable tribes and tribal members, and the establishment of a community advisory board early in the registry development process. Strategies should also include a commitment to utilize established community social networks and trusted intermediaries to build community, tribal, and audience trust in the registry process.

Techniques such as audience segmentation and social marketing strategies may be used to reach key audiences such as the residents of Flint, including tribal members; health care, educational, and other providers of referral services; the lead prevention workforce; community and agency partners, tribal leaders and tribal public health organizations, and other stakeholders. A robust community outreach plan may use the many communication channels currently available.

Effective strategies may also include organizing regular meetings with partners, tribes, stakeholders, and programs (e.g., early childhood education programs, social services, school systems, tribal public health organizations, etc.) that provide services to mitigate the effects of high blood lead levels.

Effective health education and training among partners and public health professionals is another key to link lead-exposed residents to recommended services. Professional education and training will enhance the provision of state and local technical support and subject matter expertise to systems that identify, refer, provide services to, and follow lead-exposed residents.

Strategy 2 - Develop the registry to identify eligible residents.

The awardee is responsible for developing a registry protocol specifying the methods and materials including strategies, activities, and timeline for the registry and the eligibility criteria for registrants, including potentially affected tribal members.

In developing the registry protocol, the awardee is encouraged to apply the key principles of registry design, operation, and evaluation; and to address common challenges encountered in registry implementation. An example of structured guidelines and recommendations are available in the Agency for Healthcare Research and Quality (AHRQ) "Registries for Evaluating Patient Outcomes: A User's Guide (3rd Edition)" (see general guidelines in the full report at https :// www.ncbi.nlm.nih.gov/ books/NBK208616/ and specific guidelines in Chapter 22 "Quality Improvement Registries" at https:// ;www.ncbi.nlm.nih.gov/ books/ NBK208630/). The awardee is also encouraged to consider principles of a primary, secondary, or tertiary prevention models in the registry framework, activities, and metrics to assess the impact of registry activities at the individual registrant level and at the population level.

The awardee should ensure the protocol adheres to all federal, state, tribal, and local data security and privacy protection requirements; and ensure it complies with State of Michigan, tribal, and

local laws for lead poisoning prevention. The protocol should also describe how and by whom hardcopy and electronic registry records for community and tribal members will be collected, stored, and transmitted.

Prior to implementation, the awardee should have the registry protocol, data collection tools, consent forms, data quality management plan, data security plan, and data management plan finalized and approved by required state, tribal, and local authorities. It is recommended that the protocol clearly list all investigators, their institutions, and their roles and responsibilities, and describe the key partnerships required to implement this registry through the community advisory board and through the referral network and its shared resources.

This activity is funded under a non-research grant; therefore, research activities must not be proposed under this NOFO. The awardee must be aware of and commit to prepare and implement a DMP according to CDC requirements and to describe how and with whom the data will or may be shared. The awardee may choose to allow information from this non-research registry to be used for research by requesters as an additional way to maximize the utility of the registry data in the future. If so, the awardee's consent forms and DMP should reflect this long-term goal beyond the program period.

Strategy 3 - Recruit and enroll eligible residents, collect their baseline information, and refer them to services.

Collection of pertinent registrant information is necessary to accomplish the goals of the registry. The awardee should develop data collection tools that align with the stated goals of the protocol. At enrollment, it is recommended that baseline information be used to establish the registrant's demographics, exposure metrics, health and developmental milestones, housing characteristics, occupational exposures, and other co-factors for lead exposure. Accurate baseline information about the registrants' access to and use of services and diagnosed conditions prior to joining the registry will be needed to track the impact of their referral services sought before and after enrollment and to properly identify registrants who are in need of additional types or increased frequency of select interventions after baseline.

Strategy 4 - Ensure a referral process to link registrants to comprehensive, coordinated services to mitigate the effects of lead exposure.

In a quality improvement registry framework, the awardee should establish the referral network as a vital component of the registry protocol. Active partnership, in the form of support and subject matter expertise, may be the key to including all systems and programs that identify, refer, provide services to, and follow lead-exposed residents. The collaboration with partners, stakeholders, and programs (e.g., early childhood education programs, social services, school systems, etc.) is important to establish because they may provide services to families and households that need to mitigate the effects of high blood lead levels. These partners may be involved in conducting education and outreach to parents and providers of eligible lead-exposed residents.

Along with the provision of services to the registrant, the referral network will be a key source of data about the type of services, about the frequency of service visits, and about changes in health conditions or developmental milestones achieved for each registrant. The referral network should be aware of and agree whether, or under what conditions, their network data linked to the registrant's records may be shared with key partners to inform policy and administrative

decisions, released to the public, or potentially released to researchers in the future. Plans for data release or sharing, including that from the referral network, should be described in the awardee DMP. The CDC is not endorsing any particular mitigation service or providing entity that may be made available to the registrant.

Strategy 5 - Select appropriate measures and frequency of follow-up to collect data on exposure, health, and developmental milestones along with choices of interventions, services, and enrichment activities undertaken during the project period.

The registry protocol should include methods for follow-up data collection from each registrant. Follow-ups are important as results from early vs. later interventions after exposure, or after exposure mitigation, may demonstrate how type of, timing of, and frequency of services result in measurable improvements in health and developmental outcomes.

Data collections in this registry should be designed to inform ways to improve state and local public health programs and referral services for these residents with lead exposure. Therefore, careful consideration of measures of registrants' exposure, health, and developmental milestones is recommended. In addition, measures of registrants' choices of intervention activities and services through the established referral network should be carefully considered. A careful choice of measures of the impact of services on registrants' outcomes will make registry data highly useful to inform policy and administrative decisions for the City of Flint, MI, and the State of Michigan.

1. Collaborations

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

The applicant should engage other CDC-funded programs in its jurisdiction, particularly those with a focus on child health and/or environmental health; and leverage opportunities to reach targeted populations, share databases, deliver services, and achieve outcomes expected under this NOFO. Examples of other CDC-funded programs include, but are not limited to:

- Healthy Homes and Lead Poisoning Prevention Program https://www.cdc.gov/ nceh/ information/ healthy_homes_lead.htm
- Environmental Public Health Tracking Program http://www.cdc.gov/ nceh/ tracking/
- National Center for Birth Defects and Developmental Disabilities (NCBDDD) programs and registries
- National Institute of Occupational Safety and Health's Adult Blood Lead Epidemiology Program (ABLES) https://www.cdc.gov/ niosh/ topics/ ;ables/
- Pediatric Environmental Health Specialty Unit (PEHSU)
- State and local immunization programs and registries

b. With organizations not funded by CDC:

The applicant should work with relevant organizations external to CDC that could extend its reach to targeted populations, interface with other databases, and help facilitate activities under this NOFO. Letters of support, memorandums of understanding (MOU), and memorandums of agreement (MOA) stating agreed upon area of collaboration from state relevant officials and others should be included in the application.

Examples of such organizations are:

- Agency for Healthcare Research and Quality (AHRQ)
- Local health departments
- Michigan Department of Health and Human Services
- Centers for Medicare and Medicaid Services (CMS)
- Special Supplemental Nutrition Program for Women, Infants and Children (WIC)
- Environmental Protection Agency (EPA)
- Health Resources and Services Administration (HRSA) Title V grantees
- HRSA Federal Home Visiting Program
- Healthy Start Association
- Maternal and child health programs
- State of Michigan Department of Education
- Academic institutions
- Community-based, nonprofit and/or faith-based organizations community organizations
- State and local health and housing agencies
- Private and public laboratories
- Hospitals and healthcare systems
- Indian Health Service (IHS)
- Tribes and tribal groups located in Michigan (e.g., Little River Band of Ottawa Indians)
- Tribal organizations (e.g., Inter-Tribal Council of Michigan, National Indian Health Board, or others)
- Flint Kids – The Community Foundation of Greater Flint
- Ruth Mott Foundation
- C.S. Mott Foundation Community Education Initiative
- Tides Foundation (Justice for Flint)
- Michigan Health Endowment Fund
- Community Foundation of Greater Flint
- Great Lake Health Connect
- Flint Now Foundation
- Annenberg Foundation
- American Association of Pediatrics Michigan Chapter
- National Basketball Players Association
- Michigan Fitness Foundation
- Robert Wood Johnson Foundation
- Hagerman Foundation

Strategies should be implemented for leveraging resources that include funds from other allowable federally funded programs and/or state, local, charity, nonprofit or for-profit entities, or internal agency resources. The applicant is expected to partner with a referral network of national, state, or local systems and programs that identify, refer, provide services to, and follow lead-exposed residents. The partnership is important because the referral network provides services to families and households that need to mitigate the effects of lead exposure to contaminated water from the FWS.

The applicant is expected to create a capacity-building mechanism, with partners, that will provide training, education, technical support, mobilization, and consensus to improve the Flint community's ability to detect lead sources and identify risks and provide appropriate and timely interventions.

2. Target Populations

The target population for this program is residents of the City of Flint, MI, who were exposed to lead-contaminated water from the Flint Water System (FWS) during the period April 25, 2014–October 15, 2015. Eligible residents may include Native Americans who are citizens of sovereign tribes.

a. Health Disparities

The applicant should consider underserved populations, including tribal, disabled, and English speakers of other languages (ESOL), as well as other populations that may experience disparities in blood lead levels based on age, race, ethnicity and gender to ensure they benefit from the applicant's activities.

iv. Funding Strategy

NA

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

This section provides measures CDC will use to monitor awardee progress on achieving the project outputs, products, and outcomes. These performance measures and evaluation findings will be used by CDC for continuous program quality improvement during the program period. Database management will be a continuous process during the program period.

CDC Process Evaluation
Budget Year 1 - By 3 months after award **Outputs** • Finalize public health goals for the registry • Finalize organizational structure of registry and referral network • Finalize definition of eligible residents • Estimate number of eligible residents and compile data sources for recruitment
Budget Year 2 - By end of Quarter 2

Outputs

- Establish community advisory board, including key representatives from community groups, tribal membership, and stakeholder organizations
- Finalize scope, methods, and materials for the registry protocol
- Community outreach, health education, and training to target audiences begins and continues as needed during the program period

Products

- Community outreach, health education, and training materials for target audiences are prepared, distributed, and tracked as needed during the program period

Budget Year 2 - By end of Quarter 3

Outputs

- Obtain state and local authority approval for protocol

Products

- Registry protocol finalized

Target - Data collection is approved to begin

Budget Year 2 – By end of Quarter 4

Outputs

- Implement registry strategies for community and stakeholder outreach and communication plan
- Implement registry recruitment, enrollment, and baseline data collection
- Implement DMP, and update as required during program period

Budget Year 3 – By end of Quarter 4

Outputs

- Recruitment, enrollment, and baseline data collection is complete
- Follow-up data collection continues

During Budget Years 2, 3, and part of 4

Outputs - continue registry recruitment, enrollment, and baseline and follow-up data collection

Budget Year 4 - By end of Quarter 2

Outputs

- Registry data collection is completed
- Registry database is prepared for data analysis
- Preliminary data analysis begins

CDC Outcome Measurement

Short-term Outcomes for Community and Providers:

- Increased awareness of registry goals and scope
- Increased awareness of eligibility criteria for registry

Measured by:

- Number of attendees (by type - community, tribe, professional) who attend outreach events
- Percent of attendees of community outreach events (by type) have increased awareness of registry goals, scope, and eligibility criteria
- Number of or percent of registrants who enroll after attending outreach events

Target: At least 80 percent of residents who are contacted for eligibility screening and enrollment report attending at least one outreach event, receiving outreach materials, or hearing about the registry in the media.

Short-term Outcomes for Community, Providers, and Workforce:

- Increased knowledge of adverse health and developmental outcomes from lead exposure
- Increased knowledge of blood lead testing and reporting requirements
- Increased knowledge of medical management recommendations
- Increased knowledge of environmental lead exposure sources and reduction methods
- Increased knowledge of modifiable factors for lead exposure reduction
- Increased knowledge of available preventive referral services and interventions to reduce the impact of lead exposure

Measured by:

- Number of attendees (by type – community, tribe, provider, lead workforce, or stakeholder) who attend education and training events)
- Percent of attendees of education and training events

- Reasons for attendance at education and training events
- Number of or percent of registrants who enroll after attending education and training events

Target: At least 80 percent of registry investigators and collaborators (e.g., public health professionals, lead prevention workforce, partners, and other stakeholders) attend or participate in lead poisoning prevention and intervention training programs.

Short-term Outcomes for Registry Implementation

- Increased registrant referral to services over baseline
- Target number of registry follow-ups achieved per registrant

Measured by:

- Number of types and frequency of services previously accessed and used is recorded at baseline
- Number of types and frequency of referred services accessed and used after baseline is recorded at repeated follow-up
- Percent of increase in use of services by type and frequency

Target:

- At least a 30 percent increase in number of registrant referrals to recommended services over baseline.
- At least a 30 percent increase in number of registrants who use referral services over baseline.
- At least 75 percent of registrants have completed the targeted number of registry follow-ups.

Intermediate Outcomes for Registrants:

- Use preventive services
- Reduce their environmental lead exposures where they live, work, and play
- Have lower blood lead levels over time
- Have better health and fewer developmental delays

Measured by:

- Number and percent of registrants who use follow-up care and referral services (by type of service)
- Reasons that registrants seek or do not seek care from provider and from referral services (by type of service)
- Number and percent of registrants who reduce environmental lead exposures (by type of environmental intervention)
- Reasons that registrants seek or do not seek environmental lead exposures (by type of environmental intervention)

- Number and percent of registrants with lower blood lead levels during follow-up (by type of service, by type of environmental intervention)
- Number and percent of registrants who have better health and fewer developmental delays (by type of service, by type of environmental intervention)

Target:

- At least 85 percent of registrants use preventive services.
- At least 85 percent of registrants take steps to reduce environmental lead exposures.
- At least 60 percent of registrants have lower blood lead levels at their last follow-up.
- At least 60 percent of registrants have better health and fewer developmental delays at their last follow-up.

Intermediate Outcomes for Registry Data:

- Increased quality and quantity of data to inform lead poisoning prevention policy and program administration
- Increased knowledge about the effectiveness of the number of prevention services leading to improved outcomes
- Increased knowledge about the effectiveness of different types of prevention services leading to improved outcomes
- Increased knowledge about the acute and long-term impacts of lead exposure

Measured by:

- Data endpoints to assess if lead poisoning prevention policies or procedures should be updated.
- Data endpoints to analyze effectiveness of frequency and type of prevention services on improved outcomes.
- Data endpoints to assess if registrants who seek referral services earlier have more favorable outcomes (by lead exposure category).

Target: At least three types of referral services have led to better health and fewer developmental delays at registrants' last follow-up through objective measures and reports by providers in the referral network.

ii. Applicant Evaluation and Performance Measurement Plan

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

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.

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

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

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

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

Data Management Plan (DMP): CDC requires the awardee to develop and submit a DMP for each collection or generation of public health data for federally funded projects and programs. For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. The DMP will be required to be evaluated and approved prior to initiation of the data collection.

The DMP may be outlined in a narrative format or as a checklist. In addition to the minimum requirements outlined above, the DMP should include:

- Mechanisms for providing access to and sharing of the data (including collecting provisions for protection of privacy, confidentiality, security, intellectual property, or other rights), including a description of how data for Native American registrants will be managed, including any agreements reached with Tribes;
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified.
- The applicant who contends that the public health data collected or generated are not appropriate for release must justify that contention in the DMP submitted with the application for CDC funds (for example, privacy and confidentiality considerations,

embargo issues).

The DMP should be maintained as a living document that will be updated and revised, as needed, throughout the lifecycle of the data collected within the funding period. Any changes from the original DMP, such as changes to the initial data collection plan, challenges with data collection, and recent data collected, should be justified. The awardee should update the DMP to reflect progress or issues with planned data collections and submit as required for each reporting period.

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in the DMP that is developed during the project planning phase prior to the initiation of data collection or generation. Funding restrictions may be imposed, pending submission and evaluation of a DMP.

The awardee who fails to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: http://www.cdc.gov/ grants/ additionalrequirements/ index.html for revised AR-25.

c. Organizational Capacity of Awardees to Implement the Approach

The organizational capacity statement should describe how the applicant agency is organized to carry out the requirements of this announcement, the nature and scope of its work, and/or its capabilities. The applicant should include a detailed description of the institution's experience, program management components, collection and data reporting requirements, and readiness to establish working agreements, as well as letters of support, MOUs/MOAs, or contracts with collaborating or partner entities. Although this NOFO is not intended to fund referral, follow-up, and case-management of registrants, the applicant should seek to collaborate with other government and non-governmental agencies that will provide preventive, case management, enrichment, educational, or public health services. The applicant must demonstrate that collaborators are willing to provide registrant data. This collaboration is necessary to link registrants' data about exposure, health, and developmental milestones with their participation in intervention activities and services through this voluntary referral network.

Project Management: Key personnel must have the level of education, experience, and/or skills necessary to successfully implement and complete the project. This section should include a clear delineation of the roles and responsibilities of program staff and their qualifications. Specify who will have day-to-day responsibility for key tasks such as: leadership of project; monitoring of project's ongoing progress; management and storage of the data repository, preparation of reports; program evaluation; and communication with other partners and CDC; qualifications, experience, leadership ability, and description of how staff will be used to accomplish the work; and percentage of time the project staff will commit to the project.

Additional information should be provided in the application appendices and labeled as separate appendices (i.e., curriculum vitae, letters of support, MOU/MOA, etc.). The appendices will not be counted toward the narrative page limit.

Additional information includes the following:

- Organizational chart (including voluntary network of collaborators)
- Curriculum vitae for existing key personnel (or job descriptions for planned key personnel)
- Indirect cost rate agreements
- Letters of support and/or MOU/MOA

The applicant must create a separate file for the noted items and must name the file "Organizational Chart," "CVs/Resumes," "Indirect Cost Rate Agreements," "Letters of Support," and/or "MOU/MOA" and upload to www.grants.gov.

d. Work Plan

The applicant must provide a detailed work plan for the first year of the project and a high-level work plan for subsequent years. No specific work plan template is required as long as it is clear how the components in the work plan crosswalk to the strategies and activities, outcomes, and evaluation performance measures presented in the logic model and the narrative sections of this NOFO.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee 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 awardee progress in achieving the desired outcomes.
- Ensuring the adequacy of awardee 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 awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees 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 grantees.

CDC and the awardee will have 6 months after award to finalize the performance monitoring and accountability approach.

B. Award Information

1. Funding Instrument Type: Grant
2. Award Mechanism: Grant
UE2–Studies of Emergency and Environmental Health Services - Grant

3. Fiscal Year: 2017
4. Approximate Total Fiscal Year Funding: $3,600,000
5. Approximate Project Period Funding: $14,400,000

This amount is subject to the availability of funds.

Estimated Total Funding: $14,400,000
6. Total Project Period Length: 4 year(s)
7. Expected Number of Awards: 1

8. Approximate Average Award: $3,600,000 Per Budget Period

9. Award Ceiling: $6,000,000 Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor: $1,200,000 Per Budget Period

11. Estimated Award Date: 08/01/2017
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 awardee (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 project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

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

C. Eligibility Information

1. Eligible Applicants

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

Additional Eligibility Category:

2. Additional Information on Eligibility

This is a single source eligibility NOFO. Funding is limited to Michigan State University.

The award ceiling for this NOFO is $6,000,000. CDC will consider any application requesting an award higher than this amount as nonresponsive and it will receive no further review.

3. Justification for Less than Maximum Competition

During April 25, 2014–October 15, 2015, approximately 99,000 residents of the City of Flint, MI, were exposed to lead when their water source was switched from the Detroit Water Authority to the Flint Water System (FWS). Because the FWS did not use corrosion control, the lead levels in Flint tap water increased above the EPA action level of 15 ppb as required by the Lead and Copper Rule. In children, lead exposure can result in serious effects on cognitive and physiological development. Lead can reduce kidney function and increase risk of hypertension and essential tremor among adults. Data from the Michigan Department of Health and Human Services showed an increase in blood lead levels ≥5 µg/dL (CDC reference value) among Flint children, under 5 years of age, after the source water change. Immediate support is needed to assist the City of Flint and the State of Michigan to build their capacity to establish a public health registry.

Michigan State University (MSU) is already building a registry to support Flint residents. In January of 2017, the Michigan Department of Health and Human Services awarded a one-year grant of $500,000 to MSU College of Human Medicine for the planning of a registry for Flint residents. MSU's plan to build a registry is divided into two phases:

- Phase I of registry planning: clarify registry scope, definition(s), goals and objectives, stakeholders/partners, advisory structure, priorities (by tier) and deliverables.
- Phase II of registry planning: identify and begin to develop infrastructure required for the registry as well as the case management/resource linkages; develop processes for linkage of pre-existing cohorts and environmental data sets; develop guidelines for how registry data will be protected and utilized once operationalized; and develop process for ongoing registry operation and maintenance.

MSU's registry plan supports and builds upon activities contained in this grant. The matrix below provides a comparison of MSU's current registry plan and the activities contained in the CDC registry grant:

MSU Registry Plan to Support Flint Residents	CDC Grant Activities CDC-RFA-EH17-1704
Phase I: Clarify registry scope, definition(s), goals and objectives, stakeholders/partners, advisory structure, priorities (by tier) and	**Activity:** Develop a public health registry of residents who were exposed to lead-contaminated water from the Flint Water System during

deliverables.	the period April 25, 2014 - October 15, 2015
Phase II: Identify and begin to develop infrastructure required for the registry as well as the case management/resource linkages	**Activity:** Implement systems and policies that link lead-exposed residents to comprehensive, coordinated services to mitigate the effects of lead exposure.
Phase I: Clarify registry scope, definition(s), goals and objectives, stakeholders/partners, advisory structure, priorities (by tier) and deliverables	**Requirement:** This work requires close collaboration with community leaders, partners, stakeholders and various entities serving residents to ensure timely and accurate data collection, and a comprehensive system of referral, follow up and evaluation.

This grant requires close collaboration and work with community leaders, partners, stakeholders and various entities serving residents to ensure timely and accurate data collection; and a comprehensive system of referral, follow up, and evaluation of lead-exposed residents. MSU currently has the relationships needed to make this grant successful.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

Cost sharing or matching funds are not required for this program.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

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

a. Data Universal Numbering System:

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

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

If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees 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 an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at ***www.SAM.gov*.**

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

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov	Same day but can take 8	Register early! Log into

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

2. Request Application Package

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

3. Application Package

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

4. Submission Dates and Times

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

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

Due Date for Letter of Intent: **N/A**

b. Application Deadline

Due Date for Applications: **06/28/2017** , 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Information Conference Call

N/A

5. CDC Assurances and Certifications

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

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

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

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

LOI is not requested or required as part of the application for this NOFO.

8. Table of Contents

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

9. Project Abstract Summary

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

10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)
Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include **all** of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period 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 awardees 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 project period 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 awardee 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).

Awardees 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 awardee plans to carry out achieving the project period 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 will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities).
For guidance on completing a detailed budget, see Budget Preparation Guidelines at: http:// www.cdc.gov /grants /interested in applying /application resources.html.
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.
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 Grantees 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). Grantees will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide grantees and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.
Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to

provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

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

14. Intergovernmental Review

The application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372, which established a system for state and local intergovernmental review of proposed federal assistance applications. Applicants should inform their state single point of contact (SPOC) as early as possible that they are applying prospectively for federal assistance and request instructions on the state's process. The current SPOC list is available at: http://www.whitehouse.gov/omb/grants_spoc/.

15. Pilot Program for Enhancement of Employee Whistleblower Protections

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

16. Copyright Interests Provisions

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

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal

publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

17. Funding Restrictions

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

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care except as allowed by law.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, awardees 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 awardee.
- 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 awardees.
- 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.

- Awardees may not use funds for clinical care, case-management, therapy, educational enrichment, environmental assessment or interventions, or other referral services used to mitigate the effects of lead exposure. However, the awardee is expected to create linkages and to enter into data sharing agreements to obtain registrant information from providers of such referral services.
- Awardees may not use funds to include persons in the registry who were not exposed to lead-contaminated water from the Flint Water System (FWS) during April 25, 2014–

October 15, 2015.

18. Data Management Plan

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

19. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by OGS Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov.

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

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

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

application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.
https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t=
Get_Started%2FGet_Started. htm

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

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

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

   If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

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

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

published submission requirements.

b. Phase II Review

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

i. Approach Maximum Points:35

- Evaluate the extent to which the applicant:

  a) **(9 points)** Describes an overall strategy and activities that are achievable, appropriate, and evidence-based (where practicable), and consistent with the CDC Project Description and logic model. Are there plans to:

  - Identify unique demographics of affected Flint neighborhoods and an understanding of potential challenges for recruitment?
  - Include key social networks, social marketing, and audience segmentation techniques to build community trust and support for the registry?
  - Establish a community advisory board early in the registry development process ensuring that the registry activities do not appear to implicate or violate the Federal Advisory Committee Act (FACA) of 1972, by either the grantee or the CDC?
  - Conduct community outreach, training, and education?
  - Develop a registry protocol that will clearly define and identify eligible residents?
  - Recruit and enroll eligible residents, collecting their baseline information, and referring them to services?
  - Establish a referral system of comprehensive, coordinated services to mitigate the effects of lead exposure for registrants that does not provide the appearance that CDC is endorsing any particular mitigation service or providing entity that may be made available to the registrant?
  - Track appropriate measures of registrants' exposure, outcomes, and referral services after enrollment?

  b) **(12 points)** Presents plans for a registry protocol that are consistent with the CDC Project Description and logic model. Are there plans to:

  - Develop a non-research protocol that will address key methods,

management, ethics, legal, and quality assurance for registries in general alignment with guidelines and recommendations (see example at https:// www.ncbi.nlm.nih.gov/ books/NBK208616/)?
- Develop a non-research protocol for a quality improvement registry in alignment with guidelines and recommendations (see example at https:// www.ncbi.nlm.nih.gov/ books/NBK208630/)?

c) **(4 points)** Presents plans for additional outputs, products, and outcomes that are consistent with the CDC Project Description and logic model. Are there plans to:

- Increase awareness and knowledge about the registry among target audiences by planning events and by producing campaign and education materials?
- Establish eligibility criteria, to enumerate or estimate eligible residents, to recruit and enroll registrants, and to collect baseline data?
- Link registrants to comprehensive, coordinated services through a network of collaborating institutions and partners?
- Quantify linkages of enrolled registrants to recommended services, by tracking and collecting referral data at baseline and at follow-up?

d) **(4 points)** Shows that the proposed use of funds is an efficient and effective way to implement the strategies and activities and to attain the project period outcomes.

e) **(3 points)** Presents a work plan that is aligned with the strategies, activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC.

f) **(3 points)** Describes a plan to maximize the utility of the registry data. Are there plans to:

- Share or publically release the registry data to enable policy and administrative decisions and recommendations?

ii. Evaluation and Performance Measurement Maximum Points:30

Evaluate the extent to which the applicant:

a) **(5 points)** Shows the ability to collect data on the process and outcome performance measures specified in the CDC Project Description and presented by the applicant in their approach. Are there plans to:

- Provide a project timeline that demonstrates the ability to achieve outputs, products, and strategic targets in alignment with the CDC Project Description.
- Provide a performance and evaluation plan that aligns with the CDC's eight outcomes of interest including measures and the target performance measures.

b) **(5 points)** Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities.

c) **(5 points)** Describes how performance measurement and evaluation findings will be reported, and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement.

d) **(5 points)** Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base.

e) **(5 points)** Describes any evaluation studies they are to undertake. Describe in sufficient detail to identify the key evaluation questions, and data sources and analysis methods.

f) **(5 points)** Includes a preliminary Data Management Plan (DMP), with the express intention to submit a detailed DMP within 6 months of award and a final DMP with the final report.

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

Evaluate the extent to which the applicant:

a) **(7 points)** Provides a project management structure that will be sufficient to carry out the requirements of this NOFO. Are there plans to:

- Present a project management structure that includes institutions responsible for the registry and the referral network of collaborating services?

b) **(7 points)** Provides a staffing plan that will be sufficient to achieve the project outcomes and which clearly defines staff roles.

- Provides an organizational chart, letters of support, CVs.
- Provides a description of current and potential staff positions.
- If applicable, provides a plan for identifying and hiring qualified applicants on a timely basis.

c) **(12 points)** Demonstrates relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes.

d) **(9 points)** Demonstrates experience and capacity to implement the evaluation plan.

Budget

Reviewed, but not scored:

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the grant. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project. The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the grant funds.

If the applicant requests indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. The indirect cost rate agreement should be uploaded as a PDF file with "Other Attachment Forms" when submitting via Grants.gov.

The applicant can obtain guidance for completing a detailed justified budget on the CDC website at http://www.cdc.gov/funding.

c. Phase III Review

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 Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.
CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.
In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior

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

2. Announcement and Anticipated Award Dates

The anticipated award date is 8/1/2017.

F. Award Administration Information

1. Award Notices

Awardees 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 awardee and CDC. The NOA will be signed by an authorized GMO and emailed to the Awardee Business Officer listed in application and the Program Director.

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

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

2. Administrative and National Policy Requirements

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

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

- AR-7: Executive Order 12372 Review
- AR-8: Public Health System Reporting Requirements

- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions (June 2012)
- AR-14: Accounting System Requirements
- AR-15: Proof of Non-profit Status
- AR-16: Security Clearance Requirement
- AR-20: Conference Support
- AR-21: Small, Minority, And Women-owned Business
- AR 23: Compliance with 45 CFR Part 87 (faith-based organizations)
- AR-24: Health Insurance Portability and Accountability Act Requirements
- AR-25: Data Management and Access
- AR-26: National Historic Preservation Act of 1966
- AR-27: Conference Disclaimer and Use of Logos
- AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-31: Research Definition
- AR-32: Enacted General Provisions
- AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- AR-34: Language Access for Persons with Limited English Proficiency

For more information on the CFR visit http://www. access.gpo.gov/ nara/cfr/cfr-table-search.html

3. Reporting

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

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee 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 project period 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?
a. Awardee Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
b. Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
c. Interim Performance Measure Report (IPMR)	No later than120 days before end of first 6 months of budget period.	Yes
d. Federal Financial Reporting Forms	90 days after the end of the budget period.	Yes
e. Final Performance and Financial Report	90 days after end of project period.	Yes
f. Payment Management System (PMS) Reporting	Quarterly reports due January 30, 2017; April 30, 2017; July 30, 2017; October 30, 2017; January 30, 2018.	Yes

a. Awardee Evaluation and Performance Measurement Plan (required)
With support from CDC, awardees must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees 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.

Awardee 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 awardee must submit the APR via www.Grantsolutions.gov no later than120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but weblinks are allowed.
This report must include the following:

- **Performance Measures:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
    - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
    - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Awardees must describe success stories.
- **Challenges**
    - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.
    - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Awardees**
    - Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period 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 awardee must report annual performance measures no later than 120 days before the end of the budget period, covering the Interim Performance Measure Report (IPMR) period, as described below, and the second half of the budget period.

The APR must be reported using CDC forms approved under OMB Control No. 0920-1132 (expiration date 8/31/2019).

The awardee may submit a carryover request as part of this report. The carryover request must:

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

The awardees 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 awardees at the beginning of the award period.

Interim Performance Measure Report (IPMR): The awardee must submit the IPMR no later than 120 days before end of Month 6 to cover the first six months of the budget period.

The IPMR must be reported using CDC forms approved under OMB Control No. 0920-1132 (expiration date 8/31/2019).

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

e. Final Performance and Financial Report (required)

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

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.
- Impact/Results/Success Stories – Awardees 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).

Awardees must submit their Final Performance and Financial Report via GrantSolutions.

Final Data Management Plan (DMP): Applicants must include an updated final DMP that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data. The final DMP should also indicate that all laws, regulations and rights regarding the data have been complied with.

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 grantee 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 grantee did not pay any taxes during the reporting period.]

2) Quarterly Report: The grantee 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. grantee 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 grantee must include this reporting requirement in all applicable subgrants and other subagreements.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Stephanie Davis, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Telephone: (770) 488-3676
Email: sgd8@cdc.gov

Grants Staff Contact

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

Victoria McBee, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
Time Solutions, LLC Contractor

Centers for Disease Control and Prevention (CDC)

Telephone: (770) 488-2825
Email: yig9@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.
Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

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

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

H. Other Information

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

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

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

CDC/NCEH/Lead website: www.cdc.gov/nceh/lead/about/program.htm

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

- Work Plan
- Data Management Plan
- Table of Contents for Entire Submission
- Resumes/CVs
- Organizational Charts
- Nonprofit Organization IRS Status Forms, if applicable
- Indirect Cost Rate, if applicable
- Letters of Support
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent Status Documentation, if applicable

I. Glossary

Activities: The actual events or actions that take place as a part of the program.
Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; awardees must comply with the ARs listed

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

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

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.

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

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

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

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (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 awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

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

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is

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

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

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

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

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

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

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

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

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

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.
Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.
Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.
Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.
Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.
Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.
Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: http://www.whitehouse.gov/omb/ grants_spoc/.
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.

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.

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

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 project period 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

GrantSolutions: GrantSolutions is a comprehensive grants management system provided by the Grants Center of Excellence (COE) at www.grantsolutions.gov. The system is available to all Federal grant-making agencies as part of the Grants Management Line of Business (GMLOB) initiative. It services all types of grants (service, training, demonstration, social research, and cooperative agreements) across all grant categories (discretionary, formula, block, and entitlement).