

Centers for Disease Control

National Center on Birth Defects and Developmental Disabilities

Surveillance, intervention, and referral to services activities for infants with microcephaly or other adverse outcomes linked with the Zika virus

CDC-RFA-DD17-1702

Application Due Date: 01/26/2017

Surveillance, intervention, and referral to services activities for infants with microcephaly or other adverse outcomes linked with the Zika virus

CDC-RFA-DD17-1702

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-DD17-1702. 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:

Surveillance, intervention, and referral to services activities for infants with microcephaly or other adverse outcomes linked with the Zika virus

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-DD17-1702

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

93.073

F. Dates:

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

2. Due Date for Applications: **01/26/2017**, 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 to establish, enhance, and maintain rapid population-based surveillance of microcephaly and other adverse outcomes (especially central nervous system (CNS) defects) possibly linked to Zika virus infection during pregnancy using an active case-finding methodology; participate in centralized pooled clinical and surveillance data projects; ensure affected infants and families are referred to services; and assess health and developmental outcomes of these children. This aligns with the National Center on Birth Defects and Developmental Disabilities (NCBDDD) performance goal to “enhance birth defects surveillance, research, and prevention.”

This announcement is for non-research activities supported by CDC, i.e., conduct rapid active population-based ascertainment of select major birth defects possibly linked to maternal Zika virus and to use the data for public health action through monitoring, intervention, and referral to services.

Eligibility is limited to the ten (10) identified state, territory, and District of Columbia departments of health,

and their bona fide agents that did not apply to the previous announcement of FOA #DD16-1605 with observed distribution of *Aedes* mosquitoes. FY17 funds are estimated at $1,700,000. Please refer to the Funding Strategy under Section 2.a.iv for a complete list of states, DC, and territories with respective funding amounts.

a. Eligible Applicants:	Limited
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	10
d. Total Project Period Funding:	$8,500,000

This amount is subject to the availability of funds. Although there is no project period ceiling, ceiling amounts may be solicited annually.

e. Average One Year Award Amount:	$170,000
f. Total Project Period Length:	5
g. Estimated Award Date:	03/01/2017
h. Cost Sharing and / or Matching Requirements:	N

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

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

Birth defects are a leading cause of infant mortality in the United States and contribute substantially to health care costs and life-long disabilities. The Birth Defects Prevention Act of 1998 directed CDC to carry out programs to collect data on birth defects and provide information to the public about the prevention of birth defects. The Zika virus is spread to people primarily through the bite of an infected *Aedes* species mosquito, as well as through sexual transmission. The illness is usually mild with symptoms lasting for several days to a week after being bitten by an infected mosquito. However, many infected individuals are asymptomatic.

The Zika virus can also be spread from a pregnant woman to her fetus. Zika virus infection has been linked to microcephaly and potentially other central nervous system (CNS) defects in babies of mothers who had Zika virus while pregnant. The full spectrum of outcomes of children exposed or potentially exposed to the Zika virus is not yet known.

In late 2015, there were reported cases of birth defects associated with the Zika virus occurring in South America with the potential for increased numbers of birth defects cases with the spread of virus to Central and North America and travelers coming from Zika endemic countries. In January 2016, CDC activated the Emergency Operations Center to address national and international public health concerns regarding the spread of the Zika virus and related adverse health outcomes in pregnant women. On February 1, 2016, the World Health Organization declared Zika virus infection a public health emergency of international concern.

An urgent public health response is needed to understand the impact of Zika virus during pregnancy on adverse birth outcomes. Establishing or enhancing existing population-based surveillance systems to rapidly

identify cases of microcephaly and other defects potentially linked to Zika virus from all pregnancy outcomes is key to assessing the impact on communities. However, given the routine lag time in surveillance systems to capture timely case information (from several months up to 1-2 years), rapid reporting and data collection are needed to monitor the impact of Zika virus on pregnancy and infant outcomes as events unfold. These include using a standard case definition across surveillance systems, expanding data sources to include non-traditional sources such as specialty clinics and State Laboratory reports of any pregnancy with positive or inconclusive Zika virus test results, employing innovative and timely approaches to data collection such as remote access to electronic medical records, and participating in CDC centralized pooled clinical and surveillance data projects including the U.S. Zika Pregnancy Registry (USZPR). More information about the USZPR can be found at http://www.cdc.gov/zika/hc-providers/registry.html. This FOA will collaborate closely with the USZPR to ensure any cases of birth defects or Zika virus infection identified through the registry will be included in this project. Grantees are expected to participate in the State-coordinated Zika response, including prevention efforts and reporting bi-weekly the critical information collected from the rapid ascertainment of microcephaly or other adverse outcomes with other health department programs to ensure affected infants and families are referred to health, early intervention, and other social services as well as perform data linkage and evaluation of their health and developmental outcomes. Under this FOA, grantees will submit anonymized, de-duplicated data to CDC on a bi-weekly basis.

b. Statutory Authorities

This program is authorized under sections 311 and 317C of the Public Health Service Act [42 U.S.C. 243 and 247b-4], as amended.

c. Healthy People 2020

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020" found at https://www.healthypeople.gov/. This FOA addresses "Healthy People 2020" priority area of Maternal, Infant, and Child Health, and specifically MICH-1.6, reduce the rate of infant deaths related to birth defects, and MICH-31, increase the proportion of children with special health care needs who receive their care in family-centered, comprehensive, and coordinated systems.

d. Other National Public Health Priorities and Strategies

In January 2016, CDC activated the Emergency Operations Center (EOC) and formed the Pregnancy and Birth Defects Team (and later Task Force) to address national and international public health concerns regarding the spread of the Zika virus and adverse health outcomes in pregnant women. On February 8, 2016 the EOC was designated activation at Level 1 (the highest level). Additionally, on February 1, 2016, the World Health Organization declared the current Zika virus infection a public health emergency of international concern. Because the current Zika virus outbreak is expected to become endemic over the next 3-5 years in the North and South American continents and nearby islands, it is urgent to develop rapid reporting and monitoring of adverse pregnancy outcomes such as microcephaly and other CNS defects that might be associated with Zika virus infection.

CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. One of the many strategies that CDC employs to accomplish this goal includes monitoring health through the use of public health surveillance. Disease specific surveillance systems are critical for the accomplishment of this and other objectives that support CDC's mission. Refer to CDC's website: www.cdc.gov.

e. Relevant Work

For over four decades, CDC has been monitoring the prevalence of and investigating the risk factors for birth defects, as well as developing strategies to prevent these conditions. CDC continues to invest in state and local programs that gather data needed to understand how birth defects can be prevented and to improve the lives of people who have been affected by them.

NCBDDD has funded population-based birth defects surveillance cooperative agreements under FOAs #DD10-1001 and #DD16-1601 to develop and enhance birth defects surveillance, implement population-based programs to prevent birth defects, improve access of children with birth defects to health services and early intervention programs, and use the data for public health action. On August 1, 2016, CDC-RFA-DD16-1605 was awarded to assist 40 state and territory departments of health, American Indian or Alaska Native Tribal Governments, and their bona fide agents to establish surveillance resources necessary to provide surveillance of Zika virus infection and its link to microcephaly and potentially other central nervous system (CNS) birth defect. However, ten (10) eligible state, territory, and District of Columbia departments of health, and their bona fide agents did not apply to this FOA. Several of these eligible non-responding jurisdictions have been identified as having high risk areas with concerns of local transmission (Zika virus transmitted by an infected mosquito).

2. CDC Project Description

a. Approach

Bold indicates project period outcome.

This FOA provides funding to establish a rapid active case ascertainment surveillance system for microcephaly and select CNS defects possibly linked to maternal Zika virus infection. The objective of this surveillance is to determine the impact of maternal Zika virus infection on adverse outcomes in U.S. states and territories with expected endemic transmission or potential cases associated with high volume of travel from endemic countries, i.e. areas with observed distribution of *Aedes Aegypti* and *Aedes Albopictus* mosquitoes. The grantees are expected to work collaboratively with CDC to rapidly monitor the occurrence of microcephaly and select CNS defects possibly linked to maternal Zika virus infection using rapid active case-finding methodologies and to translate the information collected for public health action to better understand the impact of these conditions on communities, drive population-level prevention strategies, improve referral to services for affected individuals and families, and link and evaluate health and developmental outcomes of these children.

Case definitions for birth defects potentially related to Zika virus infection during pregnancy and nationally reported by Zika Pregnancy Registries and monitored and nationally reported by Zika Birth Defects Surveillance.

Adverse Outcomes **Active Birth Defects Surveillance** - All birth defects potentially related to Zika virus infection during pregnancy (with codes noted for case-finding purposes) - Fetuses and infants with these birth defects should be monitored whether or not they had possible Zika virus exposure - Unless otherwise specified, the same defect descriptions and exclusion criteria for the Pregnancy Registries also apply to the Active Birth Defects Surveillance
Brain abnormalities with and without microcephaly

Confirmed or possible congenital microcephaly ICD-10-CM: Q02 CDC/BPA: 742.10, 742.486
Intracranial calcifications ICD-10-CM: No specific code; may be included under Q04.8, Q04.9 CDC/BPA: 742.48
Cerebral / Cortical atrophy ICD-10-CM: No specific code; may be included under Q04.3 CDC/BPA: 742.48
Abnormal cortical gyral patterns: Agyria, lissencephaly, microgyria, polymicrogyria, pachygyria , schizencephaly, gray matter heterotopia ICD-10-CM: Q04.3, Q04.6, Q04.8 CDC/BPA: 742.24, 742.25, 742.28
Corpus callosum abnormalities ICD-10-CM: Q04.0 CDC/BPA: 742.21
Cerebellar abnormalities ICD-10-CM: No specific code; may be included under Q04.3 CDC/BPA: 742.23, 742.31
Porencephaly EXCLUDE: isolated choroid plexus cyst ICD-10-CM: Q04.6 CDC/BPA: 742.41, 742.42
Hydranencephaly ICD-10-CM: No specific code; should be included in Q04.3 CDC/BPA: 742.32
Ventriculomegaly / Hydrocephaly EXCLUDE: isolated “mild” ventriculomegaly without other brain abnormalities ICD-10-CM: Q03.0–Q03.9 CDC/BPA: 742.30, 742.38, 742.39
Fetal brain disruption sequence No specific code. This might be coded as microcephaly or another single brain malformation, or all the components that might be coded individually. ICD-10-CM: Q02, Q04.8, Q04.9 CDC/BPA: 742.10, 742.48

Include the following abnormalities only if co-existing abnormalities of the brain have been diagnosed: ICD-10-CM: Q67.4, Q75.8, Q75.9, Q82.8 CDC/BPA: 754.08, 754.09, 756.08, 756.09, 757.39, 757.80
Other major brain abnormalities ICD-10-CM: Q04.0, Q04.3–Q04.9, Q07.00, Q07.02 CDC/BPA: 742.20, 742.22, 742.29, 742.48, 742.90
Neural tube defects (NTDs) and other early brain malformations
Anencephaly / Acrania ICD-10-CM: Q00.0–Q00.2 CDC/BPA: 740.00-740.10, 740.20-740.29
Encephalocele ICD-10-CM: Q01.0–Q01.9 CDC/BPA: 742.00–742.09
Spina bifida ICD-10-CM: Q05.0–Q05.9, Q07.01, Q07.03 CDC/BPA: 741.00–741.99
Holoprosencephaly / Arhinencephaly ICD-10-CM: Q04.1, Q04.2 CDC/BPA: 742.26, 742.27
Eye abnormalities
Microphthalmia / Anophthalmia ICD-10-CM: Q11.0–Q11.2 CDC/BPA: 743.00, 743.10
Coloboma ICD-10-CM: Q12.2, Q13.0, Q14.1–Q14.8 CDC/BPA: 743.34, 743.43, 743.48, 743.49, 743.51, 743.52, 743.535, 743.58, 743.59
Cataract ICD-10-CM: Q12.0 CDC/BPA: 743.32
Intraocular calcifications No specific code. This might be coded under the affected part of the eye. ICD-10-CM: Q13.8, Q13.9, Q14.1–Q14.9 CDC/BPA: 743.48, 743.49, 743.51, 743.52, 743.58, 743.59

Chorioretinal anomalies involving the macula including chorioretinal atropy and scarring, macular pallor, gross pigmentary mottling and retinal hemorrhage. No specific code. This might be coded under the affected part of the eye. ICD-10-CM: Q14.1–Q14.9 CDC/BPA: 743.51, 743.52, 743.53, 743.58, 743.59
Optic nerve atrophy, pallor, and other optic nerve abnormalities ICD-10-CM: Q14.2, H47.03 CDC/BPA: 743.52
Consequences of central nervous system (CNS) dysfunction
Congenital contractures and joint abnormalities (arthrogryposis, club foot with associated brain abnormalities, congenital hip dislocation with associated brain abnormalities) Include all infants with arthrogryposis or multiple joint contractures. Include talipes equinovarus or clubfoot only with associated brain abnormalities; Include congenital hip dislocation or developmental dysplasia of the hip only with associated brain abnormalities ICD-10-CM: Q65.0–Q65.9, Q66.0–Q66.9, Q68.8, Q74.3 CDC/BPA: 754.30, 754.31, 754.50, 754.73 (excluding 754.735), 755.80
Congenital deafness ICD-10-CM: H90.0–H90.8, H90.A, H91.0-H91.9, Q16.0–Q16.9 CDC/BPA: 744.09

The logic model is a visual depiction of the programmatic approach and reflects how the activities, expected outputs, and outcomes are interrelated to achieve the program goals and objectives. Bolded text indicates outcomes the awardee is expected to achieve during the project period.

Strategies and Activities	**Outcomes**		
	Short-term	**Mid-term**	**Long-term**
Surveillance: Implement strategies for rapid population-based surveillance of microcephaly and select CNS defects *Capacity Development:* Build capacity through collaboration with partners and infrastructure improvements	**Improved rapid and accurate ascertainment of microcephaly and select CNS defects possibly linked to maternal Zika virus approaches by state public health programs**	**Improved use of surveillance data to inform policy among a broad range of stakeholders** Enhanced partnership collaborations to sustain public health response **Improved linkage and**	Improved birth and health outcomes overall, and improved outcomes among children with microcephaly and select CNS defects possibly linked to maternal Zika virus infection

Referral to Services: Connect infants and families to health and social services *Data Reporting:* Participate in CDC centralized pooled surveillance and clinical case project *Health Outcomes:* Examine health and developmental outcomes of selected children born to women with positive or inconclusive Zika virus test	**Improved knowledge about birth defects and Zika virus by partnering organizations, agencies, and individuals** **Increased awareness among at-risk populations about the identification and prevention of maternal Zika virus** **Increased knowledge by public health professionals about pregnancy outcomes, both affected and unaffected as well as percent live born versus pregnancy loss.** **Increased knowledge by affected families about early identification and linkage of infants to health, early intervention, and other**	**evaluation of health and developmental outcomes for children with microcephaly and select CNS conditions with possible link to maternal Zika virus**	improved quality and duration of life for affected children and their families

	services.		

i. Purpose

To establish or enhance rapid active surveillance of microcephaly and select adverse outcomes (CNS defects) with possible association to Zika virus infection for all pregnancy outcomes (live births, stillbirth, and terminations) and to use the data for public health monitoring, prevention, and intervention. Demonstrate data utilization through collaboration with CDC on centralized pooled clinical and surveillance data projects, referral to services, and linkage and evaluation of outcomes of affected children and/or pregnancies with a positive or inconclusive Zika virus test.

ii. Outcomes

As outlined in the logic model, the following are the outcomes the awardee is expected to achieve during the project period:

Short-term:

- Improved rapid and accurate ascertainment of microcephaly and select CNS defects possibly linked to maternal Zika virus approaches by state public health programs.
- Improved knowledge about birth defects and Zika virus by partnering organizations, agencies, and individuals.
- Increased awareness among at-risk populations about the identification and prevention of the Zika virus.
- Increased knowledge by public health professionals about pregnancy outcomes, both affected and unaffected, as well as percent live born versus pregnancy loss.
- Increased knowledge by affected families about early identification and linkage of infants to health, early intervention, and other services.

Mid-term:

- Improved use of surveillance data to inform policy among a broad range of stakeholders.
- Enhanced partnership collaborations to sustain public health response.
- Improved linkage and evaluation of health and developmental outcomes for children with microcephaly and select CNS conditions with possible link to maternal Zika virus.

iii. Strategies and Activities

1) Surveillance: Establish a rapid population-based surveillance of microcephaly and select CNS defects using an active case-finding methodology and standard case definition

- Implement a rapid, active population-based surveillance system to ascertain any potential/possible cases of microcephaly and select CNS defects for all pregnancy outcomes, including live births, fetal deaths, and terminations. States and territories should:
    - Develop active case-finding methodologies for rapid notification and data collection of possible cases from a range of clinical sources including prenatal and hospital champions, and State laboratories that obtain positive or inconclusive maternal Zika virus tests.
    - Employ innovative and timely approaches to data collection in electronic health records, such as remote access to clinical information.
    - Use a standard case definition as defined by CDC. Follow the National Birth Defects Prevention Network (NBDPN) case definition and surveillance notes, available at

http://www.nbdpn.org/zikvbd.php.
- Ensure clinical support for case review.
- Collaborate and coordinate with U.S. Zika Pregnancy Registry effort.
- Collaborate with other health department programs as part of the State coordinated Zika response to ensure that surveillance data are used for public health action.

- Assess administrative datasets as supplemental data sources for the active reporting and notification.

C*apacity Development:*

2) Build capacity through collaboration with partners and infrastructure improvements

- Ensure appropriate partnerships within the State health departments, including the State Laboratory, communicable disease program, state epidemiologist, birth defects surveillance program, State representatives for the U.S. Zika Pregnancy Registry, and the State's organizations receiving Title V federal funds, to develop rapid data collection and reporting of both microcephaly and select CNS defects possibly linked to Zika virus, and any pregnancies with positive or inconclusive Zika virus tests. Also, establish linkages with other programs like Children with Special Health Care Needs (TitleV) and early intervention to improve access for affected children to comprehensive, community-based, family-centered care.
- Identify and engage appropriate clinical partners, especially with prenatal and hospital champions to rapidly report any potential cases. Provide guidance or training to obstetric, pediatric, and other providers as needed.
- Engage the state hospital association, as appropriate.
- Identify and engage appropriate State and local partners to disseminate prevention messages and materials.
- Disseminate results with appropriate organizations within the State and with other States.

3) Referral to Services: Connect children and families to health and social services

- Develop strategies and activities to ensure children with microcephaly and select CNS defects and their families are connected to health, early intervention, and social services in the community. Include a discussion of eligible services the infant/family can apply for.
- Create a plan outlining how the program is working to improve referral to services for affected individuals and families.

4) Data Analyses and Reporting

- Provide support for data analyses to evaluate the data collected and set-up programs for ongoing monitoring of data.
- On a bi-weekly basis, participate in centralized pooled clinical case and surveillance projects via secure transmission, meeting deadlines specified by CDC. This includes contribution of anonymized, de-duplicated data to CDC for projects, such as the Centralized Rapid Microcephaly and Select CNS Defect Outcomes Data System and Detailed Case Diagnosis Project with clinical verbatim diagnosis information. Collaborate with the U.S. Zika Pregnancy Registry.

5) Health and Developmental Outcomes of Children Identified from the Rapid Microcephaly and Select CNS Defect Surveillance System

- Work with the U.S. Zika Pregnancy Registry to ascertain health and developmental outcomes of children with microcephaly and select CNS conditions and those with no apparent birth defects from women with positive or inconclusive Zika virus tests.
- Evaluate the methodologies used and quality of data collected.

1. Collaborations

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

- Work with CDC and other awardees to share strategies and lessons learned to improve rapid reporting and data collection strategies, analyses, utilization, and other activities.
- Participate in a centralized rapid microcephaly and CNS defect surveillance and clinical case projects.
- Participate on all cooperative agreement calls and meetings as identified by CDC program.
- Participate in the State prevention efforts through collaboration with other health department programs, such as vector control and maternal and child health, as part of the State coordinated Zika response.

b. With organizations not funded by CDC:

- Demonstrate effective relationships and cooperation with appropriate partners (e.g., state officials, state government departments, including informatics, state and local laboratories, state epidemiologist; community based organizations; academic medical centers; physician groups; hospitals; prenatal clinics; and/or treatment centers). Letters of support/Memorandums of Understanding/Memorandums of Agreement stating agreed upon area of collaboration from state relevant officials and others should be included in the application.
- Collaborate with other state population-based surveillance programs on collaborative projects. Provide evidence of access to the relevant data sources for identification of cases and evaluation of programmatic activities.
- Collaborate and coordinate across state agencies and clinical settings to evaluate timeliness of reporting, quality of data collected, and the health outcomes identified.
- Involve appropriate within-region partners, such as health care providers, community based organizations, academic medical centers and/or outpatient centers, and other organizations to assist with data collection and utilization.
- Identify and engage appropriate partners within the region to develop, implement, and expand referral to services activities.

2. Target Populations

The surveillance and data utilization activities should focus on a source population (women of child-bearing age, pregnant women, infants with possible microcephaly or other brain abnormalities) in a defined geographic area of the state and any special populations identified by the applicant.

a. Health Disparities

Awardees should consider underserved and high risk populations in their planned activities.

iv. Funding Strategy

Awards will be made to all eligible applicants at the funding level indicated by the formula criteria in this published FOA. The criteria takes in consideration the states and territories with observed distributions of *Aedes Aegypti and Aedes Albopictus* mosquitos and number of live births.

Zika virus cases (11/2/2016)					
State, Territory, District of Columbia	**Mosquito Range**	**Travel-associated**	**Locally acquired**	**2014 Total Live births**	**Base Funds**
Arkansas	Aedes Aegypti	13	0	38,511	**$200,000**
Colorado	Aedes Albopictus	46	0	65,830	**$100,000**
Delaware	Aedes Aegypti	16	0	10,972	**$200,000**

District of Columbia	Aedes Aegypti	25	0	9,509	**$200,000**
Maine	Aedes Albopictus	11	0	12,698	**$100,000**
Nebraska	Aedes Albopictus	12	0	26,794	**$100,000**
Nevada	Aedes Aegypti	15	0	35,861	**$200,000**
Micronesia	Aedes Aegypti	No data	No data	2485 (2003)	**$200,000**
Marshall Islands	Aedes Aegypti	No data	No data	1576 (2006)	**$200,000**
Republic of Palau	Aedes Aegypti	No data	No data	259 (2006)	**$200,000**
Funding Per Year					**$1,700,000**

Notes:

Live births (LB) 2014 data from NCHS http://wonder.cdc.gov/

U.S. Virgin Islands LB http://healthvi.org/assets/documents/2011/2008-natality-and-mortality-indicators.pdf

Micronesia, Marshall Islands, Palau LB http://www.un.org/esa/population/publications/WFD2012/MainFrame.html

ZIKV cases (11/2/2016) http://www.cdc.gov/zika/geo/united-states.html

Aedes distribution in US http://www.cdc.gov/zika/pdfs/zika-mosquito-maps.pdf

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and progress reports

Prepare a written assessment of the accomplishments, challenges and opportunities including a description of the problems encountered, lessons learned, potential improvements, etc.

Strategies/Activities:

1) Surveillance: Implement strategies to improve population-based birth defects surveillance

Indicators for success: a completed surveillance plan outlining approaches for rapid reporting and data collection using active population-based case finding methodologies; documentation of state authority to review and abstract medical records; documentation assessment of the data sources used, their quality, and usefulness; evidence that national guidelines and data quality standards were followed, including use of standard case definitions and clinical support for case review.

2) Capacity Development: Build rapid active population-based surveillance capacity through infrastructure and partner collaborations and infrastructure improvements

Indicators for success: a completed matrix identifying capacity building objectives, strategies, and partners agreed upon by partners and approved by CDC; documentation of ongoing partners meetings, with a summary of the outcomes; documentation of annual review and revisions to plans.

3) Referral to Services: Connect infants and families to health, early intervention and social services

Indicators for success: a completed plan outlining how the program is working to improve referral to services for affected individuals and families; demonstrated availability of data for referral purposes; identification of gaps in referrals using appropriate methods (e.g., surveys, qualitative research using focus groups, follow-up of infants identified).

4) Data Analyses and Reporting:

Indicators for success: documented support for data analyses to evaluate the data collected and set-up programs for ongoing monitoring of data; materials using surveillance data are produced and disseminated; documented data sharing and participation in centralized rapid microcephaly and CNS defect surveillance and clinical case project.

5) Health and Developmental Outcomes of Children Identified from the Rapid Microcephaly and Select CNS Defect Surveillance System

Indicators for success: plan developed outlining approach to collecting health and developmental outcomes data on children with microcephaly and select CNS conditions, and those with no birth defects from women with positive or inconclusive Zika virus tests; evaluation of data collection methodologies and data quality.

Outcomes:

1) Improved approaches to rapidly and accurately ascertaining microcephaly and select CNS defects possibly linked to maternal Zika virus infection.

Indicator for success: evidence of rapid case-finding and assessment of data quality, completeness and timeliness, e.g. products/activities are completed showing improvements in timeliness and accuracy of case ascertainment and data collected.

2) Improved dissemination of accurate and timely information to organizations, agencies and individuals.

Indicator for success: number of publications disseminated, including journal impact/reach; percentage of users/target audiences indicating usefulness of the materials disseminated.

3) Increased awareness about prevention of adverse outcomes with possible link to Zika virus infection.

Indicator for success: evidence of prevention strategies used in targeted communities.

4) Increased knowledge about early identification and linkage of infants to health, early intervention, and other services.

Indicator for success: a completed plan outlining how the program is working to improve referral to services for affected individuals and families.

5) Improved use of surveillance data to inform policy among stakeholders.

Indicator for success: number of instances where decision makers used surveillance data to inform policy.

6) Enhanced partner collaborations to improve rapid reporting and response to emerging issues.

Indicator for success: number of completed projects or joint activities showing collaboration among partners.

7) Improved linkage and evaluation of health outcomes for children with microcephaly and select CNS conditions.

Indicator for success: percentage of affected individuals and families with utilization of health and other services as a result of a programs referral to services activities.

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 FOA. 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 FOA 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 http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-49

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 FOA.

c. Organizational Capacity of Awardees to Implement the Approach

Applicants should possess the capacity and legal authority to collect population-based birth and birth defects data on microcephaly and select CNS defects and obtain State Laboratory reporting of pregnancies with positive or inconclusive Zika test results. There should be a coordinated effort with the U.S. Zika Pregnancy Registry. Applicant must describe the level of organizational capacity necessary to implement the FOA successfully. Organizational capacity includes skill sets to implement the required activities, such as: overall program and performance management, data analysis, data linkage, epidemiologic and clinical expertise, communication/material development, evaluation, performance monitoring, and financial reporting. If there are any vacant positions, the applicant should include a job description (including applicant qualifications) and address both the recruiting strategies and estimated timeline for filling the position.

Eligibility is limited to the ten (10) State/Territorial agencies or their Bona Fide agents that did not apply to the previous announcement of FOA #DD16-1605. These organizations were previously determined eligible and have the public health authority and/or legislative mandate to conduct population-based birth defects surveillance. This authority allows them unique and specific access to datasets from multiple data sources that are required to implement the activities outlined in this FOA. They also have the experience, capacity, expertise, and resources to implement a population-based surveillance program.

d. Work Plan

Applicants are required to provide a work plan consisting of a logic model (specific to their project plans and activities) and related narrative for the five-year program, and a detailed description of the first year of the award, consistent with the project's logic model provided in this FOA.

Applicants are expected to use activities that are consistent with those indicated under the "Program Strategy" section. The work plan should provide outcomes and the related program strategies/activities and should be consistent with the narrative in the Approach and Performance Measurement and Evaluation sections.

Sample Work Plan Template

Project Period Outcome:	Outcome Objective:

Strategies / Activities	Performance Measures	Data Collection, Analysis, Plan	Responsible Person/ Organizational Unit	Status (Update/ Completion Date)

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.

f. CDC Program Support to Awardees (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)
In a cooperative agreement, CDC staff is substantially involved in the program activities above and beyond routine grant monitoring.

1. Provide technical assistance to: establish a rapid active surveillance system to ascertain potential/possible cases of microcephaly and select CNS defects for all pregnancy outcomes; ensure data are used for prevention and intervention activities; and provide other guidance to state agencies and interested parties.
2. Assist in designing, developing, and evaluating methodologies and approaches used for active, rapid population-based birth defects surveillance.
3. Provide standard case definitions for conditions included in the rapid surveillance system. Provide technical assistance for clinical case reviews.
4. Assist with database development and support. Provide database templates and abstraction forms.
5. Assist in analyzing surveillance data.

6. Assist in designing, developing, and evaluating plans to improve the access of children with microcephaly and other birth defects to services.
7. Provide a reference point for sharing grantee and non-grantee state, regional, and national data and contact information pertinent to the surveillance and prevention of birth defects.
8. Assist with linkage strategies and evaluation of health outcomes for children identified with microcephaly and select CNS defects possibly linked to maternal Zika virus infection.

B. Award Information

1. Funding Instrument Type: Cooperative Agreement

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

2. Award Mechanism: U50

3. Fiscal Year: 2017

4. Approximate Total Fiscal Year Funding: $1,700,000

5. Approximate Project Period Funding: $8,500,000

This amount is subject to the availability of funds.

This amount is subject to the availability of funds. Although there is no project period ceiling, ceiling amounts may be solicited annually.

Estimated Total Funding: $8,500,000

6. Total Project Period Length: 5 year(s)

7. Expected Number of Awards: 10

8. Approximate Average Award: $170,000 Per Budget Period

9. Award Ceiling: $200,000 Per Budget Period

This amount is subject to the availability of funds.

Although there is no budget period ceiling, award ceiling amounts may be solicited annually. Please refer to the estimated FY17 award amounts in Funding Strategy - Section 2.a.iv.

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

11. Estimated Award Date: 03/01/2017

12. Budget Period Length: 5 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:

Government Organizations:

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

2. Additional Information on Eligibility

Eligibility is limited to the ten (10) previously identified state, territory, and District of Columbia governments or their bona fide agent (Arkansas, Colorado, District of Columbia, Delaware, Federated States of Micronesia (FSM), Maine, Marshall Islands (RMI), Nebraska, Nevada, and Palau)

Eligible applicants that can apply for this funding opportunity are listed below:

- State governments or their Bona Fide Agents (this includes Arkansas, Colorado, District of Columbia, Delaware, Maine, Nebraska, Nevada, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a letter from the state or local government delegating authority to the applicant to conduct the activities in this FOA is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

The estimated award ceiling for this FOA is $200,000. CDC will consider any application requesting an award higher than this amount as non- responsive and it will receive no further review. If a pre-application is required, then specify here and include it in the special eligibility requirements section. (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf)

3. Justification for Less than Maximum Competition

Eligibility is limited to State, District of Columbia, and Territorial agencies or their Bona Fide agents because they have the public health authority and/or legislative mandate to conduct population-based birth defects surveillance. This authority allows them unique and specific access to datasets from multiple data sources that are required to implement the activities outlined in this FOA.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

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

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

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

a. Data Universal Numbering System:

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

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

If funds are awarded to an applicant organization that includes sub-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 atwww.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	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

		member(s) to obtain DUNS number, verify & update information under DUNS number		
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 using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

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

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this 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 FOA, 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: **01/26/2017** , 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.

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 FOA.

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. 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 FOA. 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 seehttp://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 FOA.

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 FOA 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 FOA. 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. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.
Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.
CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically Pro-Children Act of 2001, 20 U.S.C. Sections 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.

3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http:// www.gsa.gov/ graphics/ pbs/ Guidelines_ for_ Federal_ Concessions_ and_ Vending_ _ Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

http://www.cdc.gov/ nccdphp/dnpao/hwi/ toolkits/ tobacco/index.htm
http://www. thecommunityguide.org/ tobacco/index.html
http:// www.cdc.gov /obesity /strategies /food-serv-guide.html

14. 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.

15. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

16. Intergovernmental Review

Executive Order 12372 does not apply to this program.

17. 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.

18. 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.

19. 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.

To be eligible for receipt of funds, recipients should report information on eligible birth defects on a bi-weekly basis to CDC Zika Birth Defects Surveillance. Reporting should be done within 30 days of identification of birth defects potentially linked to Zika virus. Reporting should be conducted in accordance with CDC case definitions, including cases of possible brain abnormalities or microcephaly diagnosed prenatally or based on prenatal head circumference measurements taken within 24 hours of birth. Recipients must ensure compliance with CDC's approved assurance of confidentiality granted under 308(d) of the PHS Act (42 USC 242m(d)). Recipients should work with CDC to ensure that data reported to Zika Birth Defects Surveillance are timely, accurate and complies with CDC protocol.

20. 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:
http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-49

21. 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 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 FOA. 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. http:// 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:50

Evaluate the extent to which the applicant:

- Demonstrates strategies to implement a rapid, active population-based surveillance system to ascertain any potential/possible cases of microcephaly and select CNS defects for all pregnancy outcomes, including live births, fetal deaths, and terminations.
    - Develops active case-finding methodologies for rapid notification and data collection of possible cases from a range of clinical sources, including prenatal and hospital champions and State laboratories to obtain positive or inconclusive maternal Zika virus tests.
    - Uses a standard case definition as defined by CDC. Follow the National Birth Defects Prevention Network's (NBDPN) case definition and surveillance notes, available at http://www.nbdpn.org/zikvbd.php.
    - Ensures clinical support for case review.
    - Collaborates and coordinates with U.S. Zika Pregnancy Registry effort.
    - Assesses administrative datasets as supplemental data sources for the active reporting and notification

- Demonstrates capacity building through collaboration with partners and infrastructure improvements
    - Ensures appropriate partnerships within the State health departments (e.g. the State Laboratory, communicable disease program, state epidemiologist, birth defects surveillance program, State representatives for the U.S. Zika Pregnancy Registry, the State's organizations receiving Title V federal funds) to develop rapid data collection and reporting of both microcephaly and select CNS defects possibly linked to Zika virus and any pregnancies with positive or inconclusive Zika virus tests. Establish linkages with other programs like Children with Special Health Care Needs (TitleV) and early intervention to improve access for affected children to comprehensive, community-based, family-centered care.
    - Identifies and engages appropriate clinical partners, especially with prenatal and hospital champions to rapidly report any potential cases.

- Develops strategies and activities for children with microcephaly and select CNS defects and their families to connect with health, early intervention, and social services in the community.

- Provides support for data analyses to evaluate the data collected and set-up programs for ongoing monitoring of data. Participates in centralized pooled clinical case and surveillance projects via secure transmission, meeting deadlines specified by CDC. This includes contribution of anonymized, de-duplicated data to CDC for projects, such as the Centralized Rapid Microcephaly and Select CNS Defect Outcomes Data System and Detailed Case Diagnosis Project with clinical verbatim diagnosis information. Collaborate with the U.S. Zika Pregnancy Registry.

- Examines health outcomes of children identified from the rapid microcephaly and select CNS defect surveillance system.

ii. Evaluation and Performance Measurement	Maximum Points:25

Evaluate the extent to which the applicant:

- Presents performance measures and clearly demonstrates how they will meet the measures.
- Includes a work plan that is aligned with the strategies/activities and outcomes with the content and format proposed by CDC including submission of reports and participation in anonymized data projects as outlined by CDC.

iii. Applicant's Organizational Capacity to Implement the Approach — Maximum Points:25

Evaluate the extent to which the applicant:

- Demonstrates appropriate experience, skills, and ability to rapidly develop and improve birth defects surveillance and achieve the project outcomes.
- Demonstrates adequate staffing and/or the capability to assemble competent staff in a timely manner to perform activities outlined in the FOA.
- Provides a staffing plan of current and potential personnel, including qualifications and specific experience as it relates to the requirements set forth in this announcement (e.g., CVs for staff). If applicable, provides a plan for identifying and hiring qualified applicants on a timely basis.
- Provides a management structure and an organizational chart.

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 cooperative agreement funds. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project. Award recipients agree to use cooperative agreement funds for travel by project staff agreed-upon by CDC to participate in CDC-sponsored workshops or other called meetings.

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

All applications that meet the eligibility and responsiveness criteria will receive a technical review by program staff to insure that the proposed project is technically sound and meets the requirements of the FOA. Grant awards will be made to all eligible applicants up to the specific funding level by eligible applicant indicated by the formula criteria in this published FOA.

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 funding opportunity announcement.

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

Awards are anticipated to be announced in February 2017 with a 3/1/2017 project period start date.

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 FOA 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: Generally applicable ARs:

AR-9: Paperwork Reduction Act http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html

AR-10: Smoke-Free Workplace

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-24: Health Insurance Portability and Accountability Act

AR-25: Release and Sharing of Data

AR-33: Plain Writing Act of 2010

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 FOA 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 FOA.

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 FOA copying the CDC Project Officer.

Recipients should report information on eligible birth defects on a bi-weekly basis to CDC Zika Birth Defects Surveillance. Reporting should be done within 30 days of identification of birth defects potentially linked to Zika virus. Reporting should be conducted in accordance with CDC case definitions, including cases of possible brain abnormalities or microcephaly diagnosed prenatally or based on prenatal head circumference measurements taken within 24 hours of birth. Recipients must ensure compliance with CDC's approved assurance of confidentiality granted under 308(d) of the PHS Act (42 USC 242m(d)). Recipients should work with CDC to ensure that data reported to Zika Birth Defects Surveillance are timely, accurate and complies with CDC protocol.

Report	When?	Required?
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	Monthly data reporting of cases directly to CDC program staff; Summarize in Annual Progress Report (continuation application) and also 90 days after budget period end.	Yes
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes
Payment Management System (PMS) Reporting	Quarterly reports.	Yes
Data on Performance Measures	Monthly data reporting of cases; Summarize in Annual Progress Report (continuation application) and also 90 days after budget period end.	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 FOA 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 FOA (e.g., effect on improving public health outcomes, effectiveness of FOA, 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.grants.gov no later than 120 days before 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 awardees must submit the Annual Performance Report via www.grants.gov 120 days before 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.

Monthly data reporting of cases; Summarize in Annual Progress Report (continuation application) and also 90 days after budget period end.

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 calendar quarter in which the budget period ends. 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).

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 FOA.

Program Office Contact

For programmatic technical assistance, contact:

Tineka Yowe-Conley, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Telephone: (404) 498-3941
Email: tay7@cdc.gov

Grants Staff Contact

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

Daryl Barksdale, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
2920 Brandywine Road, MS E-09
Atlanta, GA 30341
Telephone: (770) 488-1087
Email: xxj8@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
- Table of Contents for Entire Submission

For international FOAs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

- Letters of Support
- Indirect Cost Rate, if applicable
- 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 FOA; awardees must comply with the ARs listed in the FOA. 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 FOA 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 FOA 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: Plain Writing Act of 2010, Public Law 111-274 requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.
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 FOA; 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 FOA'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.

FOA-specific Glossary and Acronyms