U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

Centers for Disease Control and Prevention (CDC)
CDC Office of Financial Resources
Guidance for Supplemental Funding
Funding Opportunity Announcement (FOA) Number: **CDC-RFA- CK14-1401PPHF**

Building domestic surveillance, laboratory, vector control, and pregnancy registry capacity to respond to Zika virus

Purpose
This announcement is for approximately 7-months of supplemental funding (to be completed by the ELC budget period ending 7/31/2017) for the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement awardees under CDC-RFA- CK14-1401PPHF. The funding is specifically for Zika Virus activities previously supported under Project M1: West Nile Virus and Other Arboviral Diseases and M2: U.S. Zika Pregnancy Registry.

All ELC grantees are eligible to apply for this supplemental funding. However, in order to optimize funding for greatest public health impact and to address areas at highest risk, some grantees might not receive support under this supplemental action (See ***Funding Strategy*** below). These eligible applicants are uniquely qualified to perform the programmatic activities because the proposed non-research activities build upon the awardees' current activities funded 8/1/2016. These additional funds will further support and strengthen activities to protect the health of the American public, especially pregnant women, including epidemiologic surveillance and investigation, improving mosquito control and monitoring, and strengthening laboratory capacity. It will also support participation in the U.S. Zika Pregnancy Registry to monitor pregnant women with Zika and their infants.

Other current sources of funding available to state and local entities for Zika virus include: FOAs #DD16-1605 and DD16-1606 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 as well as Public Health Preparedness and Response (PHPR) Cooperative Agreement for All-Hazards Public Health Emergencies: Zika 2016; CDC-RFA-TP16-1602. Activities requested under this supplemental announcement should be coordinated with, but not duplicate, these other opportunities.

Recipient Activities
The activities listed below are designed to impact the following outcomes:

- Better trained workforce more prepared to respond to Zika virus cases and outbreaks

- Improved human surveillance and laboratory capacity to monitor the epidemiology, incidence, and geographic distribution of Zika virus
- Improved environmental surveillance to detect and monitor Zika virus vector species distribution and arbovirus activity, and to direct mosquito control and other public health response
- Improved mosquito control and monitoring of insecticide resistance and management
- Improved completeness and timeliness of reporting of Zika virus surveillance data, including clinical, exposure, and laboratory data, to state health departments and CDC
- More rapid and complete identification of Zika virus disease outbreaks to facilitate timely and effective control measures
- Timely and accurate information on Zika virus disease activity provided to healthcare providers, researchers, political leaders, and general public
- Participate in national arboviral diseases meeting proposed for April 11, 2017
- Improved human surveillance and laboratory capacity to monitor the epidemiology, incidence, and geographic distribution of women and infants who meet the U.S. Zika Pregnancy Registry case definition.
- Improved completeness and timeliness of reporting of U.S. Zika Pregnancy Registry data (including all data on the U.S. Zika Pregnancy Registry surveillance forms where reporting is allowable by state laws/regulations) to state health departments and CDC
- More rapid and complete identification of women and infants who meet the U.S. Zika Pregnancy Registry case definition to facilitate timely and effective guidance recommendations
- Timely and accurate information on women and infants who meet the U.S. Zika Pregnancy Registry case definition provided to healthcare providers, researchers, political leaders, and general public
- Improved prenatal care and follow up of pregnant women with any laboratory evidence of Zika virus infection and their infants to assess fetal and infant outcomes
- Translation of public health data real time into clinical and public health recommendations, particularly in the realm of prenatal diagnosis and early detection of developmental delays in infants

All eligible jurisdictions are invited to submit work plans for January 1, 2017–July 2017 for the following activities:

<u>Zika Virus Surveillance and Control Activities</u>:

1. Enhance outbreak investigation response and reporting
    a. Investigate and report Zika virus infections of clinical and public health importance to ArboNET (e.g., pregnant women, in utero or intrapartum transmission, sexual transmission, transfusion- and transplant-associated transmission, local mosquito-borne transmission)
    b. Investigate and report to ArboNET Zika virus disease cases with severe clinical manifestations (e.g., congenital infection with microcephaly or other birth defects, Guillain-Barre syndrome, other neurologic syndromes, deaths)
2. Improve surveillance to drive public health action
    a. Identify and report to ArboNET Zika virus disease cases and congenital infections to ArboNET using standard CSTE case definitions

b. Report Zika virus infections in pregnant women and congenital infections to the U.S. pregnancy registry
c. Initiate a program to systematically map the presence and abundance of *Aedes* aegypti and *Ae. albopictus* mosquitoes

3. Sustain and enhance laboratory diagnostic capacity
   a. Develop laboratory capacity to perform Zika virus RT-PCR and IgM ELISA and participate in annual proficiency testing
   b. Validate currently available Zika virus assays for different diagnostic specimen types (e.g., urine, semen)
   c. Evaluate the presence of viral RNA and IgM antibodies in serum, urine, semen, and other clinical specimens following acute Zika virus infection, to support clinical management and/or public health monitoring and surveillance.
4. Implement and evaluate epidemiologic public health practice, and prevention and control strategies
   a. Educate healthcare providers and public regarding the risk, clinical manifestations, laboratory diagnosis, and prevention of Zika virus infections
   b. Develop and implement vector control capacity
   c. Develop programs for insecticide resistance monitoring and management
5. Coordination and collaboration
   a. Participate in a national arboviral diseases meeting for state and local health departments
   b. Establish regional collaborations between state or territorial health departments to provide clinical diagnostic testing for Zika virus and other arboviral diseases
   c. Attend the national arbovirus meeting at CDC Atlanta on April 11, 2017.

<u>U.S. Zika Pregnancy Registry Activities:</u>

1. Enhance outbreak investigation response and reporting
   a. Coordinate with birth defects surveillance efforts, the investigation and reporting of Zika virus disease cases with severe clinical manifestations (e.g., congenital infection with microcephaly or other birth defects).
2. Coordinate and support local health jurisdictions with conducting outbreak and investigation of potential cases of Zika virus infection among pregnant women and their infants.Improve surveillance to drive public health action
   a. Identify and report all eligible cases that meet U.S. Zika Pregnancy Registry case definition. The Registry case definition includes pregnant women in the U.S. with laboratory evidence of Zika virus (positive or inconclusive tests Zika virus tests regardless of whether they have symptoms) and prenatally or perinatally exposed infants born to these women. In addition, for cases not identified prenatally, the registry definition includes infants with laboratory evidence of congenital Zika virus infection (positive of inconclusive test results, regardless of whether they have symptoms) and the retrospective inclusion of their mothers in the registry.
   b. Coordinate closely with local health departments to ensure that all eligible cases are reported. Implement a strategy for supporting local health jurisdictions to identify and report eligible cases using the US Zika Pregnancy registry case definition and data structures.

c. Establish collaborations among local health jurisdictions as well as between state and local health departments to deepen the understanding and use of the data being collected to support the Zika response for pregnant women and their infants.
d. Participate in the U.S. Zika Pregnancy Registry by collecting follow-up clinical data at designated time points for Registry-eligible pregnant women and infants, including at case identification, the second and third trimesters of pregnancy, at delivery, and for infants, at 2, 6 and 12 months.
e. In collaboration with Registry staff, complete and transmit securely and in a timely manner U.S. Zika Pregnancy Registry forms for maternal and infant follow up (NOTE: while variables of local interest can be added to forms or existing databases, reporting to the registry is expected to include registry data elements in the format required for the registry unless state law forbids transmission of certain Registry data elements).

Funding Strategy

All ELC applicants may request funding for this opportunity; however, funds may be awarded to only a subset of applicants in order to optimize the impact of available funding. The distribution of funding across recipients will be determined by formula that includes the following factors: the quality of application (including a work-plan-- a component of which describes plan to work with local entities within jurisdiction) and current spending of funds awarded for Zika activities under this cooperative agreement in August, 2016; disease burden; current laboratory and vector control capacity; presence of the Zika Virus vector (*Aedes Aegypti* and *Aedes Albopictus* mosquitoes) and local Zika Virus transmission.

Award Information

Type of Award:	Cooperative Agreement
Award Mechanism:	Supplement
Fiscal Year Funds:	2017
Approximate Total Supplemental Funding:	$70,500,000 – 120,500,000

This amount includes $40,000,000 to 70,000,000 for epidemiology and laboratory capacity; $15,000,000 to 35,000,000 for vector control and $15,500,000 for the U.S. Zika pregnancy registry. Awards are subject to availability of funds and includes direct and indirect costs.

Approximate Number of Awards:	Up to 64

Estimated award Ranges:

Epidemiology and laboratory capacity:	$0 - $10,000,000
Vector Control:	$0 - $6,000,000
U.S. Zika Pregnancy Registry:	$0 - $550,000

Anticipated Award Date:	12/30/2016

Budget Period Length: 7 month(s)

Project Period Length: 3 year(s) remaining

Eligibility:

Eligibility is limited to current ELC grantees funded under Cooperative Agreement CK14-1401 for Zika Virus activities. These entities include all U.S. states, 6 large local health departments (Los Angeles County, Philadelphia, New York City, Chicago, Houston, and the District of Columbia), U.S. territories (Puerto Rico, Guam, U.S. Virgin Islands) and other U.S. affiliates in the Pacific (American Samoa, the Republic of Palau, Federated States of Micronesia, Marshall Islands, Mariana Islands and American Samoa).

Application Review Information

Eligible recipients must provide a clear and concise description of the strategies and activities they will use to achieve the project's outcomes, including:

1. Progress on their ELC funded Zika activities to date, including any changes to their approved work-plans.
2. Work-plans for new or enhanced activities to be made possible by the additional funding requested.
3. Plans for how the ELC grantee will work with local jurisdictions to meet local needs. These plans must include: description of activities to be supported at the local level, identification of local partners and localities to be supported, methods to assess local needs, and description of funding mechanisms to support local entities.

Applicants must also submit up to three separate budgets and budget justifications for each of the three available activities: (1) Zika virus epidemiology, laboratory and surveillance; (2) vector control and (2) U.S. Zika pregnancy registry.

Review and Selection Process

Phase I: Applications will be jointly reviewed for responsiveness by **NCEZID and NCBDDD** and CDC Office of Financial Resources (OFR)/CDC Office of Grants Services (OGS), 'Former Procurement and Grants Office (PGO)'.

Phase II: Responsive applications will receive a technical review by subject matter experts for the section(s) applying for. Applications will be reviewed for quality of the proposed work plan (overall approach, evaluation and performance measurement, and capacity-- overall organizational capacity as well as laboratory and epidemiological). Additionally, factors such as disease burden, presence of Zika virus vector, and local transmission of the Zika virus will be noted.

Technical reviews will be provided to applicants as a part of the final notification made by OFR/OGS and/or NCEZID.

Selection
Successful applicants will be notified via email by the OFR/OGS.

Award Administration Information
Successful recipients will receive a Notice of Award (NOA) from the OFR/OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized Grants Management Officer and e-mailed to the program director. A hard copy of the NOA will be mailed to the recipient fiscal officer identified in the application. Unsuccessful recipients will receive notification of the results of the application review by mail.

Reporting Requirements: Supplemental funding must be included in the original award reports. The reports must be submitted to the assigned Grants Management Specialist listed on the notice of grant award.

Due Date for Applications:
Grantees need to email their applications to Anella Higgins at aoh2@cdc.gov and the ELC Program at ELC@CDC.GOV and must be submitted by **November 20, 2016, 11:59pm, Eastern Standard Time**. Late or incomplete reports could result in an enforcement action such as a delay in the award or a reduction in funds. CDC will accept requests for a deadline extension on rare occasions and after adequate justification has been provided.

Checklist of required contents of application packet:
1. SF-424 Application for Federal Domestic Assistance-Short Organizational Form
2. SF-424A Budget Information-Non-Construction Programs
3. Budget Justification
4. Indirect Cost Rate Agreement
5. Project Narrative