

Template for 60-Day FRN

BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-xxxx]

[Docket No. CDC-201x-xxxx]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on CDC Emergency Operations Center

Zika Related Clinical Inquiries and Surveillance which will initiate the collection of urgently needed surveillance data and clinical inquiries in response to the ongoing zika virus outbreak.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-**2016-xxxx** by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.Regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall

have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

CDC Emergency Operations Center Zika Related Clinical Inquiries

and Surveillance - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As of February 2, 2016, twenty-six countries in the Americas have reported local transmission to PAHO. In addition, there have been 39 laboratory-confirmed, travel-associated cases in the United States. There have been an additional 22 confirmed cases in the U.S. territories Puerto Rico and US Virgin Islands.

This ICR includes three projects necessitated by the zika response which all require emergency approval. These projects include:

- Project 1: A call center in the EOC to respond to inquiries on clinical care of persons potentially of interest for zika virus infection.
- Project 2: A registry of pregnant women diagnosed with zika virus infection and their infants in order to better understand the clinical consequences of zika virus infection.
- Project 3: A survey distributed to vector control professionals, entomologists, and public health biologists in order to develop county-level species distribution maps and models for the prevalence of *Aedes aegypti* and *Ae.*

albopictus (the vectors of zika virus) in the contiguous United States.

Project 1: Call center. CDC has set up a call center to respond to inquiries on clinical care of persons potentially of interest for zika virus infection. Respondents to this information collection include the general public, clinicians, and employees at STL health departments. In the beginning of the 2016 zika virus response, the EOC call center was quickly established when the arrival of zika in the Americas was documented and demonstrated the risks posed by this and other exotic viruses. The CDC consultation service was set up to assist in the evaluation of persons thought to be at risk for zika virus. The CDC will begin to collect structured case-patient information from the inquirers using a web-based collection tool under the "Domestic ZIKA Clinical Inquiries Database."

Because clinical data are not systematically collected in the clinical inquiries database currently, information on certain variables might be incomplete, including whether testing occurred. As a result, state health departments and health facilities will be called to collect that missing data including: presence of symptoms, final diagnosis, whether testing was done, pregnancy status, or birth outcome.

The purpose of this project is to document and track clinical inquiries made to the CDC EOC call center related to

Zika virus illness, as well as to systematically collect standardized clinical/demographic/epi information about suspected cases of Zika virus illness, so that the documentation of clinical inquiries may double as a passive surveillance system. Data will provide accountability for services provided to callers and may provide feedback into call center operations, and it will also inform ongoing response activities.

Project 2: Pregnancy Register. As part of the public health response to the Zika virus disease outbreak, CDC also plans to collect data on pregnant women diagnosed with Zika virus infection and their infants to better understand the clinical consequences of Zika virus infection in pregnancy and impact on newborn infants. Information gathered will direct public health messages provided by CDC on reducing the risk of adverse outcomes for pregnant women and their infants.

Registry cases will be identified through one or more mechanisms. Health care providers in the United States report Zika virus disease cases to State and Local Health Departments. Health departments report cases that meet the national case definition to ArboNET, an electronic passive surveillance system for nationally notifiable arboviral diseases. Zika virus disease cases may be identified in this way. In addition, confirmed Zika virus infections in pregnant women may be identified in conjunction with Zika virus testing performed at CDC.

Health department or CDC staff will contact the woman's health care provider and request they ask their patients to voluntarily participate in the national surveillance registry for zika virus infection during pregnancy. The registry will collect information based on tests and procedures conducted as part of the mother and infant's routine clinical care, and in line with recommendations for diagnosis and follow up of women infected with Zika virus during pregnancy. No tests or procedures will be performed specifically for register purposes.

Project 3: Mosquito surveillance survey. The zika virus response necessitates the collection of county level records for *Aedes aegypti* and *Ae. albopictus*, the vectors of zika virus. This information will be used to update species distribution maps for the contiguous United States and to develop a model aimed at identifying where these vectors can survive and reproduce. The resulting maps and models will: inform the public and policy makers of the known distribution of these vectors, identify gaps in vector surveillance, and target allocation of surveillance and prevention resources.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in	Total Burden (in hrs.)

				hrs.)	
State and Local Health Departments	Clinical Inquiries Database	420	1	15/60	105
	Maternal Health History Form	100	5	30/60	250
	Specimen Collection Form	100	1	15/60	25
Clinicians and Other Providers	Clinical Inquiries Database	800	1	15/60	200
	Assessment at Delivery Form	100	1	30/60	50
	Infant Health Follow-Up Form at 2 months of age	100	1	30/60	50
Vector control professionals, Entomologists, and Public health biologists	Survey of county-level surveillance records of <i>Aedes aegypti</i> and <i>Aedes albopictus</i>	500	1	3/60	25
Total					705

Dated:

Leroy A. Richardson
 Chief, Information Collection Review Office
 Office of Scientific Integrity
 Office of the Associate Director for Science
 Office of the Director
 Centers for Disease Control and Prevention

