CDC Emergency Operations Center Zika Related Clinical Inquiries and Surveillance

Request for OMB Approval of a New Emergency Information Collection

February 17, 2016

Supporting Statement A

Justification

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The goal of this information collection request (ICR) is to seek Paperwork Reduction Act (PRA) clearance to carry out zika virus related clinical inquiries and surveillance within the domestic borders of state, tribal, and local (STL) public health authorities and in affected countries.

The information collection is designed to continue CDC assistance in establishing and supporting active surveillance systems for zika virus for STL authorities in the US.

Surveillance activities include monitoring the frequency and types of adverse birth outcomes for women infected with zika virus during pregnancy to strengthen the public health response to the zika virus disease outbreak.

Surveillance activities also include surveys distributed to vector control professionals, entomologists, and public health biologists in order to gather information on the distribution of *Aedes aegypti* and *Ae. albopictus*.

Surveillance for Guillain-Barré Syndrome (GBS) will also be undertaken since GBS can accompany zika virus diagnoses.

The intended use is to continue to provide guidance to STL authorities and health facilities for zika virus clinical inquiries and to carry out necessary surveillance for the ongoing zika virus outbreak.

The respondents are the general public; clinicians, other providers, and workers from healthcare, laboratory, and environmental services; and at times the STL authorities, themselves.

1. Circumstances making the Collection of Information Necessary

Zika virus is spread to people primarily through the bite of an infected Aedes species mosquito. The most common symptoms of zika virus disease (or zika) are fever, rash, joint pain, and conjunctivitis (red eyes). The illness is usually mild with symptoms lasting for several days to a week. There is no vaccine to prevent or medicine to treat zika. Severe disease requiring hospitalization is uncommon and deaths are rare.

Mosquitoes that spread zika virus are aggressive daytime biters, prefer to bite people, and live indoors and outdoors near people. The mosquitoes that spread zika virus also spread dengue and chikungunya viruses.

Zika virus is not currently found in the continental United States, but cases have been reported in returning travelers. Outbreaks of zika have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and most recently in the Americas. Because the mosquitoes that spread zika virus are found throughout the world, it is likely that the outbreak will continue to spread.

In May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed zika virus infection in Brazil. The outbreak in Brazil led to reports of Guillain-Barré Syndrome (GBS) and pregnant women giving birth to babies with birth defects and poor pregnancy outcomes.

Local transmission of zika virus has not been documented in the continental United States. However, zika virus infections have been reported in travelers returning to the United States.

Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for zika virus acquisition. With the ongoing outbreak in the Americas, the number of zika virus disease cases among travelers returning to the United States likely will increase.

In some Brazilian states where zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses in women infected during pregnancy.

In response, CDC has issued travel notices for people traveling to regions and certain countries where zika virus transmission is ongoing.

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:

1. A call center in the EOC 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.
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.
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. albopictu*s (the vectors of zika virus) in the contiguous United States.

<u>Project 1: Call center</u>

CDC has set up a call center to respond to inquiries on clinical care of persons potentially of interest for zika virus infection. 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.

<u>Project 2: Pregnancy Register</u>

As part of the public health response to the zika virus disease outbreak, CDC also plans to collect information from clinicians about pregnant women they treat who are diagnosed with zika virus infection. CDC also plans to collect information from clinicians about their patients' infants in order to better understand the clinical consequences of zika virus infection in pregnancy and its 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.

<u>Project 3: Mosquito surveillance survey</u>

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.

Zika transmission is widespread and the outbreak, ongoing; therefore, the CDC is seeking emergency clearance to carry out information collection activities domestically within the borders of STL public health authorities.

As soon as this emergency ICR is cleared, CDC will begin working on a standard ICR to cover all information collection due to take place beyond the six-month scope of this ICR.

This information collection request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment A**).

2. Purpose and Use of Information Collection

This information collection is designed to allow CDC to provide support for STL authorities and health facilities in responding to the ongoing zika virus outbreak. This purpose is served by all three of the included information collections: the CDC EOC call center, the pregnancy register, and the mosquito surveillance survey.

Project 1: Call center

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" **(Attachment I)**.

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.

STL jurisdictions and healthcare providers call the CDC on their own volition. They are also told that providing patient information to CDC must follow their local requirements for privacy protections of individual cases, patients, and POIs.

HIPAA allows covered entities to disclose a patient's protected health information to a public health authority for public health purposes (including public health investigations) without the

patient's authorization. CDC will only be collecting information from covered entities—health departments and providers.

Project 2: Pregnancy register

Surveillance activities also include a pregnancy registry which will monitor the frequency and types of adverse birth outcomes for women infected with zika virus during pregnancy. This will improve understanding of zika virus infection in pregnancy and strengthen the public health response to the zika virus disease outbreak.

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. CDC has developed interim guidelines for health care providers in the United States caring for pregnant women during a Zika virus outbreak, which include recommendations for screening, testing, and management of pregnant returning travelers. These documents include *Interim Guidelines for Pregnant Women During a Zika Virus Outbreak — United States, 2016* (available at http://www.cdc.gov/mmwr/volumes/65/wr/mm6502e1.htm), and *Interim Guidelines for the Evaluation and Testing of Infants with Possible Congenital Zika Virus Infection — United States, 2016* (available at http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3.htm). Information collected in the registry forms reflects the information that would be available from procedures and tests recommended in line with these guidelines.

For participation in the register, the provider will inform the woman about the register using the information sheet entitled "What you need to know about the United States Registry for Zika Virus Infection During Pregnancy" **(Attachment N)**. The information sheet describes the purpose of the registry and what participation entails, discusses confidentiality and voluntariness, and provides contact information for questions about the registry. As noted in that document, to be involved in the registry, the woman will have to tell her doctor she wishes to participate in the register. The register just collects information already collected as part of routine clinical care. As this is a registry and not a trial or research, the woman will not need to go to any extra appointments or have any extra tests that would not routinely be recommended according to guidelines for women infected with Zika virus during pregnancy.

The provider will document the woman's consent to participate in the registry on the Maternal Health History Form **(Attachment E).** The overview letter **(Attachment D)** states that it is the responsibility of the healthcare provider to obtain consent from the patient in order to participate in the pregnancy registry.

Further information regarding the registry will be available online **(Attachment C)** along with an overview letter **(Attachment D)** so that the physician and/or patient may have immediate access to them in the clinic or home setting. If a woman agrees to participate, healthcare providers will be asked to provide minimal information about the woman's pregnancy **(Attachment E)** by phone, fax, or secured email indirectly through State Health Departments or directly to CDC personnel. Information will again be sought at the time of birth **(Attachment F)** and subsequent to the birth of live-born infants about the infant's health and development **(Attachment G)**. Information regarding infant health will be sought at 2-months after birth (provided this falls within the six-month timeframe for an emergency clearance). This information will be collected by the healthcare provider and transmitted to CDC in the same manner as the Maternal Health History Form. CDC will not follow-up with women to collect this information directly. We recognize that this means there will be postpartum women who may be lost to follow up. However, CDC or State Health Department staff will follow-up with health care providers in an effort to ensure the follow-up information is as complete as possible.

The pregnancy register information sheet **(Attachment N)** instructs mothers who change healthcare providers after giving birth—and want to continue in the registry—to request that their new healthcare providers contact registry staff.

We will not request contact information from pregnant women because of concerns that it will be a deterrent to enrollment which, in the end, may translate into less information. A complete loss of data for a case in a pregnant woman is more important than the loss of small amount of infant follow up data. In addition, contacting pregnant women directly would require additional IRB review and would potentially delay the implementation of this important element of the emergency public health response to Zika.

Published guidelines indicate the procedures and samples that are recommended for collection at or around the time of delivery: infant serum, placental tissue, and umbilical cord tissue (available at http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3.htm). Providers will be supplied with information on how to transport samples for testing to ensure samples are transported at the correct temperature and in the correct way, in line with CDC guidelines (Available at http://www.cdc.gov/zika/hc-providers/tissue-collection-submission.html; copy provided at **Attachment H**). Results from laboratory tests will be included in the register, including from infant serum samples tested for zika virus RNA, and zika and dengue virus IgM and neutralizing antibodies; from histopathological examination, immunohistochemical staining, and RT-PCR on umbilical cord and placental tissue samples, or in the event of fetal demise, zika virus RT-PCR and immunohistochemical staining performed on fetal tissues

An emergency clearance is being sought so that CDC researchers can begin surveillance activities as quickly as possible. As soon as an emergency clearance is obtained from OMB, CDC will begin developing a normal ICR that will cover these surveillance activities beyond the initial six month emergency clearance. All infant health follow-ups due to occur after the expiration of this emergency package will need to be covered by this new ICR.

Project 3: Mosquito surveillance survey

The purpose of the mosquito surveillance survey **(Attachment J)** is to collect county-level records for *Aedes aegypti* and *Ae. albopictu*s, 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.

3. Use of Improved Information Technology and Burden Reduction

One-hundred percent of burden hours will be incurred by respondents using improved information technology.

The CDC EOC call center has developed an electronic data collection tool called the Zika Clinical Inquiries Database using a Microsoft SharePoint platform.

Information associated with the pregnancy register will also be electronically collected through a REDCap database and stored on a secure server.

The mosquito surveillance survey will be distributed via email and carried out using an online survey tool.

4. Efforts to Identify Duplication and Use of Similar Information

Telephone inquiries from STL public health authorities and health facilities to the CDC EOC call center involve discussion about cases under treatment, contacts, and POIs. This information forms a convenience sample of case-, POI-, or patient-level data voluntarily provided and advantageously recorded during the telephone call or entered after the call from handwritten notes. Providing information for all fields is not required by the call center.

The CDC requires immediate information, often daily or weekly, during an emergency response, so even information conveniently collected by the CDC EOC call center can be a useful initial data source.

For the mosquito surveillance survey, data was pulled from ArboNet, This data was found to be lacking for the species of interest.

CDC is not aware of any other systematic collection of vector distribution data or a register of pregnant women with suspected zika virus infections.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities. However, for the small entities involved, the burden imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

6. Consequences of Collecting the Information Less Frequently

CDC activities regarding the domestic zika virus response would be significantly hindered if it were not able to collect the information at the frequency necessary to prohibit the spread of this disease.

Collecting information less frequently than the CDC recommendations will interfere with the public health actions required to contain and respond to zika virus transmission and to do everything possible to limit, if not stop, deaths and birth defects due to this disease.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived.

B. There was no consultation outside of the Agency.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act is applicable. Records are covered under CDC Privacy Act System of Records Notice (SORN) No. 0920-0136 “Epidemiologic Studies and Surveillance of Disease Problems” and SORN No. 09-20-0113, “Epidemic Investigation Case Records Systems Notice.”

Personally identifiable information will be collected from STL authorities and healthcare providers and facility staff. As respondents, domestic public health authorities and healthcare providers will respond as representatives of their agencies or facilities in their business roles. To protect case and POI identities, these entities will be reminded that release of identifiable personal information must be in accordance with the privacy requirements of their own jurisdictions. As an added measure, deidentified data will only be presented in aggregate in reports, and datasets with individual records will not be shared beyond the various partnerships, to the extent allowed by law.

Privacy Impact Assessment

The following information in identifiable form (IIF) will be collected.

IIF CATEGORIES	

Name	X
Date of Birth /Death/Age	X
Address/GPS Coordinates	X
Date of Residence	
Phone Numbers	X
Date of Hospital Admission/Transfer/Discharge	X
Medical Information and Notes	X
Medical Records Numbers/Case ID	X
Biological Specimens	X
Email Address	X
Employment Status	X
Foreign Activities/Travel	X

Information owned by the STL authority may be shared with CDC for assistance with data analysis and publications as agreed.

The CDC will not include information in aggregate datasets that may identify cases or patients, including geographic locations of zika virus diagnosis and clinical treatment, and dates directly related to the patient such as admission dates and dates of diagnosis.

Because the number of cases, patients, and POIs may be small in a given locality or facility, a breach in privacy is a concern. Suppression of data where small numbers occur is another technique to protect privacy. Variables constructed from potentially identifiable elements such as health facility name or location or a patient's country of origin will be anonymized prior to data sharing.

Data will be aggregated to summarize the clinical information for individuals to understand resource needs to assist in the public health response. No information will be released on individuals. All data will be presented in aggregate and will not be stratified into subcategories that might allow for identification of individuals.

The respondents' identities will be known to the CDC. Case, patient, POI, and other respondent data are treated in a private manner, unless otherwise compelled by law. Highly sensitive information is being collected and would affect individual privacy if there were a breach of confidentiality. CDC will make every effort to secure the information.

STL jurisdictions and healthcare providers call the CDC on their own volition. They are also told that providing patient information to CDC must follow their local requirements for privacy protections of individual cases, patients, and POIs, and that information provided is stored securely in a certified Microsoft SharePoint site with limited access to only those who work on the team or manage the data (currently 20 people).

Respondents are told their participation is voluntary. For the purpose of the pregnancy register, CDC will be contacting State and Local Health Departments and providers who will provide information for registry purposes. However, the woman's participation in the registry is voluntary.

Data collected and managed by CDC staff in the field will be strictly under CDC safeguards. Stringent safeguards are in place at CDC to ensure a respondent's privacy including restriction of access to authorized users, physical safeguards, and procedural safeguards.

Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected.

Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters.

Procedural safeguards: Protections for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic media containing Privacy Act information. Finally, CDC and contractor employees who maintain and use records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. CDC employees and contractors are required to be trained on the Privacy Act and receive information security awareness training at least annually.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required for all three projects (Attachments K, L, M).

If the forms are subsequently used for research activities, applicable IRB approvals and PRA clearances must be obtained for these new information collections.

Justification for Sensitive Questions

The forms are used to collect medical and laboratory data which is highly sensitive:

- Epidemiologic data such as clinical signs, symptoms, and laboratory diagnosis; history of illness, pregnancy, and sexual practices to accurately determine a respondent's public health risk for zika virus;
- Demographic data such as age, sex, ethnicity, and religious affiliation.

All of these data elements are essential to meeting the goals of these information collections.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
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,	Survey of county-level	500	1	3/60	25

Entomologists, and Public health biologists	surveillance records of *Aedes aegypti* and *Aedes albopictus*				
Total					705

There will be no anticipated costs to respondents other than time.

Registered nurses are often the persons interviewed at hospitals, so their mean hourly wage ($33.55) is used to represent the hospital staff wages. The mean hourly wage for epidemiologists is $35.63. The mean hourly wage rate for biological scientists ($38.08) was used for the category of vector control professionals, entomologists, and public health biologists. Information on mean wage rates is available at http://www.bls.gov/oes/current/oes_nat.htm.

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State/Local Health Departments	Clinical Inquiries Database	105	$35.63	$3,741.15
	Specimen Collection Form	25	$35.63	$890.75
	Maternal Health History Form	250	$35.63	$8,907.50
Health Facilities	Clinical Inquiries Database	200	$33.55	$6,710.00
	Infant Health Follow-Up Form at 2 months of age	50	$33.55	$1,677.50
	Assessment at Delivery Form	50	$33.55	$1,677.50
Vector control professionals, Entomologists, and Public health biologists	Survey of county-level surveillance records of *Aedes aegypti* and *Aedes albopictus*	25	$38.08	$952.00
Total				$24,556.40

13. Estimates of Other Total Cost Burden to Respondents or Record Keepers

There are no known capital and maintenance costs incurred by respondents or record keepers.

14. Cost to the Government

The cost to the federal government is estimated at $127,839.60. This estimate represents the amount of time for the CDC staff to respond to inquiries, follow protocols, procedures, and communication standard operating procedures (SOPs), enter data, and conduct descriptive statistical analyses, in addition to the time spent managing the response in the EOC. Hourly wage rates were used for step-1 FTEs for the Atlanta locality. These numbers are available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/ATL.pdf.

Project	Grade	Hours	Hourly Wage	Total
EOC call center	GS-11	240	$29.69	$7,125.60
	GS-13	2,400	$42.31	$101,544.00
Pregnancy register	GS-11	80	$29.69	$2,375.20
	GS-13	96	$42.31	$4,061.76
Mosquito surveillance survey	GS-14	80	$50.00	$4,000.00
	GS-13	160	$42.31	$6,769.60
	GS-9	80	$24.54	$1,963.20
Total				$127,839.60

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Over the course of a year, the data collection will occur on a continuous basis for which the timing of inquiries to the CDC EOC Call Center will be determined by the frequency that cases, POIs in applicable risk categories, and contacts occur in a given STL jurisdiction.

This emergency ICR will cover zika-related surveillance activities for six months. After that, a newly developed ICR will be necessary to cover all future information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

A. Public Health Service Act (42 USC 241)
B. Draft 60-day FRN
C. Website information - Zika Virus Disease and Pregnancy Registry
D. Overview letter
E. Maternal Health History Form
F. Assessment at Delivery Form
G. Infant Health Follow-Up Form (for 2 months of age)
H. Specimen Collection Form
I. Domestic ZIKA Clinical Inquiries Database
J. Survey of county-level surveillance records of *Aedes aegypti* and *Aedes albopictus* from 2000 to present
K. IRB Approval – EOC call center
L. IRB Approval – Mosquito surveillance survey
M. IRB Approval – Pregnancy Register
N. Pregnancy Registry Information Sheet