CDC Emergency Operations Center Zika Related Clinical Inquiries and Surveillance

Request for OMB Approval of a New Emergency Information Collection

April 7, 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, territorial, tribal, and local (STTL) 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 STTL 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 STTL 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 STTL 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.

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 other pregnancy problems.

Local transmission of Zika virus has not yet been documented in the 50 US states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands,

and American Samoa. Zika virus infections have also been reported in travelers returning to US states from areas with local transmission of Zika.

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 and local transmission in US states may occur.

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.

Arboviral diseases as a group are nationally notifiable conditions. In recognition of the public health threat from Zika virus, which is an arbovirus, the Council of State and Territorial Epidemiologists (CSTE) has established interim case definitions **(Attachment S)** specifically for Zika virus disease and Zika virus congenital infection. All 50 states, the District of Columbia, and Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands currently participate in notifying CDC of cases of arboviral diseases. State laws mandate reporting of arboviral diseases when identified by a health care provider, hospital, or laboratory. Now that there are specific case definitions for Zika virus disease and congenital Zika virus infection, state and territorial health departments are responsible for determining which reported cases meet the case definitions and notifying CDC of these cases. For an emerging infection like Zika virus, little is known about the spectrum of disease. Case definitions may need to change as more information becomes available about the spectrum of Zika virus disease and congenital infection. The US Zika Pregnancy Registry is designed to allow collection of the clinical and epidemiologic information required to determine whether reported cases meet the case definitions and whether the case definitions accurately capture the spectrum of Zika virus disease. Therefore, the Registry includes pregnant women with laboratory evidence of Zika virus infection who do not meet the current CSTE definition of Zika virus disease, and infants who do not meet the current definition of congenital Zika virus infection and allows mother-infant pairs to be linked, all of which is critical for both fully understanding and responding appropriately to the public health threat from Zika virus.

US states and territories notify CDC of cases of arboviral diseases through ArboNET. However, ArboNET does not capture all the information needed to provide timely situational awareness in the context of the ongoing public health response to the Zika virus outbreak. In particular, ArboNET collects limited data on pregnancy, pregnancy and birth outcomes, and congenital infections, all of which are necessary for informing ongoing response efforts. In addition, to understand the potential for mosquito-borne spread of Zika virus infection, information is needed on the geographic distribution of vectors of Zika virus in the U.S.

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 (POI) for Zika virus infection. Respondents to this information collection include the general public, clinicians, and employees at STTL 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. Respondents to this information collection include the SLTT health authorities, clinicians, and other healthcare providers.
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.

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.

Project 2: Pregnancy Register

Zika virus disease and Zika virus congenital infection are nationally notifiable conditions. Cases reported to CDC will meet the interim case definitions approved by the Council of State and Territorial Epidemiologists for confirmed or probable Zika virus disease in pregnant women and confirmed or probable congenital Zika virus infection. These cases will be included in the U.S. Zika Pregnancy Registry, which will include in addition reported cases of Zika virus infection among pregnant women with laboratory evidence of infection and no reported symptoms, pregnant women with symptoms consistent with Zika virus infection who test positive for an unspecified flavivirus infection (Zika IgM antibodies detected but specific flavivirus infection unable to be determined) and their prenatally and perinatally exposed infants. CDC plans to collect clinical and outcome information from health departments and health care providers regarding these pregnant women and their infants.

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.

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 STTL 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 STTL 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, STTL 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/epidemiologic information about suspected cases of Zika virus illness, so that clinical inquiries can inform future policy. 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.

STTL jurisdictions and healthcare providers call the CDC on their own volition. STLL health departments must follow their local requirements for privacy protections of individual cases, patients, and POIs when providing patient information to CDC.

HIPAA's Privacy Rule establishes conditions under which covered entities (i.e., healthcare providers) may disclose a patient's protected health information (PHI) to a public health authority for public health purposes (including public health investigations) if a public health authority (i.e., CDC) is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability [45 CFR § 164.512(b)]. The Privacy Rule also establishes minimum Federal standards for protecting the privacy of individually identifiable health information and confers to individuals the right to access and amend their health information and to obtain a record of when and why their PHI has been sheared with others for certain purposes. In accordance with HIPAA's Privacy Rule, CDC will only be collecting necessary PHI from other public health authorities, and occasionally from covered entities (i.e., health care providers)—who voluntarily contact the EOC call center.

All documentation provided to healthcare providers and patients regarding the pregnancy registry will include a clear description of the Federal standards and conditions under which healthcare providers may disclose PHI to CDC, and the patients' rights concerning access to their health information and obtaining records of when and why their PHI is shared.

Project 2: Pregnancy registry

A U.S. Zika Pregnancy Registry will provide information to supplement case counts and descriptions from national arboviral disease surveillance on the numbers of cases of Zika virus disease in pregnant women and congenital Zika virus infections in two ways: 1) through inclusion of pregnant women and infants not currently reported to the national arbovirus surveillance system, i.e., pregnant women who have laboratory evidence of Zika infection or unspecified flavivirus infection during pregnancy but who do not report symptoms, symptomatic pregnant women with unspecified flavivirus infection, as well as all infants born to these women regardless of whether they have evidence of Zika virus infection; and 2) through the collection of clinical and outcome information not currently collected for national arboviral disease surveillance, including infant outcomes up to 12 months of age.

To aid the public health response to the Zika virus outbreak, the registry will be used to monitor the frequency and types of adverse outcomes for women infected with Zika virus during pregnancy and their infants. This information will be used to inform ongoing response efforts for this Zika virus disease outbreak, including recommendations for clinical care, planning for services for pregnant women and infants affected by Zika virus, and improved prevention of Zika virus infections during pregnancy.

Health departments report cases that meet the national case definition to ArboNET, an electronic passive surveillance system for nationally notifiable arboviral diseases. Cases may come to the attention of state, tribal, territorial or local health departments through contacts with health care providers, through Zika virus testing performed by CDC, public health, or commercial laboratories (as testing becomes more widely available), or through contacts between health care providers and the EOC Call Center at CDC. ArboNET will serve as the primary means of case identification for follow-up of outcomes among pregnant women and infants through the U.S. Zika Pregnancy Registry. Cases of Zika virus or unspecified flavivirus infection in pregnant women and fetuses/infants may also be identified through existing birth defects surveillance activities.

Health department or CDC staff will contact the woman's health care provider and request the information needed to report clinical and outcomes information for cases eligible to be reported to the US Zika Pregnancy Registry. An overview letter about the registry for health care providers is included in **Attachment D**. Health care providers will be asked to inform their eligible pregnant patients about the registry and provide the information contained in the attached Appendix entitled, "US Zika Pregnancy Registry: What pregnant women need to know" (**Attachment N**). The information sheet describes the purpose of the registry and discusses confidentiality, provides contact information for questions about the registry, and outlines that the information collected is part of routine clinical care. The information sheet indicates that women will not need to go to any extra appointments or have any extra tests that would not be routinely recommended according to national guidelines for women with laboratory evidence of Zika virus during pregnancy or their infants. The general information about the registry and the fact sheets for pregnant women and health care providers will be available on a designated Registry website.

The registry will collect information on tests and procedures conducted as part of the mother and infant's routine clinical care, and in line with CDC, American College of Obstetricians and

Gynecologists and Society of Maternal Fetal Medicine recommendations for evaluation and follow up of women infected with Zika virus or an unspecified flavivirus during pregnancy and their infants who were exposed prenatally or perinatally. No laboratory testing or histopathologic evaluation, procedures or healthcare visits will be performed specifically for registry purposes. CDC has developed interim guidelines for health care providers in the United States caring for pregnant women and infants during a Zika virus outbreak, which include recommendations for screening, testing, and management of pregnant returning travelers and their infants. 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 about the pregnancies of women with laboratory evidence of Zika virus disease will be collected by state or territorial health department staff and transmitted to CDC or by CDC registry staff directly using the maternal history form (**Attachment E**). Information contained in this form will be requested from health care providers during the second and third trimesters of pregnancy. Information will also be requested at the time of expected birth (**Attachment F**) and subsequent to the birth of live-born infants to obtain information about the infant's health and development (**Attachment G**). Information regarding infant health will be sought at 2-months, 6 months and 12 months after birth. No additional clinical visits are required for the collection of data at these timepoints; information may be collected retrospectively if necessary.

CDC U.S. Zika Pregnancy Registry staff will work with Health Departments to make arrangements for gathering this follow-up information, according to Health Department preference. This will include contacting health care providers to collect additional supplemental surveillance data (by phone, secured fax, secured email, or by provision of medical records) for the Registry, i.e. either the health department staff or CDC Registry staff will contact the health care providers to collect this information. The proposed data collection is consistent with efforts to strengthen surveillance in the context of severe disease and emerging infections, which involve working closely with STTL health officials and clinicians who diagnose and treat patients (Chorba TL, Berkelman RL, Safford SK, Gibbs NP, Hull HF. Mandatory Reporting of Infectious Diseases by Clinicians. MMWR Rec Rep 39(RR-9); 1-11, 16-17).

Information will be entered into a secure REDCap Registry database, both through transfer or available information from ArboNET, and through entry of follow-up data by CDC personnel on a shared electronic REDCap database. State or territorial health department staff might also enter data though the same secure REDCap database if so desired; health department representative access to Registry data will be restricted to data from the representative's jurisdiction. A new record will be established for each woman with laboratory evidence of Zika virus or unspecified flavivirus infection during pregnancy and each infant born to these women.

In addition to recommendations for evaluation and treatment of pregnant women with probable and confirmed cases of Zika virus infection, CDC guidelines also recommended collection of samples for testing at or around the time of delivery to establish a diagnosis of maternal, fetal or

infant Zika virus disease. These include: infant serum, placental tissue, and umbilical cord tissue (available at http://www.cdc.gov/mmwr/volumes/65/wr/mm6503e3.htm). Participation in the registry is in no way tied to collection of these samples and collection and submission of samples may vary depending on locality.

CDC has provided information on how to transport samples to CDC in the event samples will be submitted to CDC. These guidelines are available online and include information 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 performed at CDC will be included in the registry, including results from testing of infant serum samples for Zika virus RNA and Zika and dengue virus IgM and neutralizing antibodies; findings from histopathological examination, immunohistochemical staining, and RT-PCR for Zika virus RNA on umbilical cord and placental tissue samples, or in the event of fetal demise, RT-PCR for Zika virus RNA and immunohistochemical staining performed on fetal tissues. For samples tested and performed elsewhere, SLLT health authorities or CDC Registry staff will contact the appropriate laboratory to obtain results to be included in the US Zika Pregnancy Registry.

An emergency clearance is being sought so that CDC researchers can begin surveillance activities as quickly as possible. In conjunction with the emergency clearance application submitted to OMB at this time, CDC will also submit a 3-year ICR that will cover the US Zika Pregnancy Registry activities beyond the initial six-month emergency clearance. Collection of information on infant health follow-up beyond 2 months of age will be included in this new ICR. They are provided here for reference only, as this information will not be collected during the 6-month emergency approval period.

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 registry will be electronically collected through a REDCap database and stored on a secure server. All CDC registry staff accessing REDCAP will have appropriate confidentiality training and Assurance of Confidentiality application is being submitted.

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 STTL public health authorities and health facilities to the CDC EOC call center involve discussion about cases under treatment, contacts, and persons of interest (POI) for arboviral infection. 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.

State and territorial health departments report cases meeting the national case definitions for Zika virus disease, including cases among pregnant women, and congenital Zika virus infection to CDC via ArboNET, an electronic passive surveillance system for nationally notifiable arboviral diseases. ArboNET will serve as the primary means of case identification for follow-up of outcomes among pregnant women and infants through the U.S. Zika Pregnancy Registry. In addition, the Registry will include cases not reportable to ArboNET. Registry cases will therefore be identified through mechanisms in addition to ArboNET. Basic information (**Appendix E**) on Zika virus infections among pregnant women that come to attention through any of these mechanisms will be gathered as part of routine public health follow-up. This information will be entered into the secure REDCap Registry database, both through transfer of available information from ArboNET, and entry of follow-up data not collected for any other purpose.

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 registry for clinical and outcomes follow-up of pregnant women with laboratory evidence of Zika virus infection and their infants.

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 indicate 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. Given the limited information available on Zika virus disease during pregnancy, information is needed to inform CDC recommendations.

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

CDC is collecting clinical information for the U.S. Zika Pregnancy Registry and the Domestic Zika Clinical Inquiries Database in identifiable form as a public health authority, defined in the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations, Standards for Privacy of Individually Identifiable Health Information (45 CFR § 164.501)] ("Privacy Rule").

Pursuant to 45 CFR § 164.512(b) of the Privacy Rule, covered entities such as healthcare providers may disclose, without individual authorization, protected health information to public health authorities "… authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions… ." CDC is requesting these records as a public health authority conducting a public health activity as described by 45 CFR § 164.512(b), and as authorized by section 301 of the Public Health Service Act. The information requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR § 164.514(d) of the Privacy Rule.

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 by CDC from STTL authorities and healthcare providers and health 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, only de-identified data will be presented in case reports and in aggregated reports, and datasets with individual records will not be shared beyond the various partnerships, to the extent allowed by law. In addition, CDC will apply for an Assurance of Confidentiality, authorized under Section 308(d) of the Public Health Service Act, to protect the data collected under this request at the federal level. In accordance with Assurance requirements, all CDC registry staff will have the appropriate confidentiality training.

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 STTL 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 specified dates directly related to the patient such as admission dates, dates of diagnosis or specific procedure dates.

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 origin will be anonymized prior to data sharing.

Data will be aggregated to summarize the clinical information for individuals to understand resource needs and to assist in the public health response. No information that includes personally identifiable information will be released on individuals. Only de-identified data will be presented in case reports or in aggregate. Information that could potentially be used to indirectly identify an individual will be suppressed; for example, aggregated data 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. In addition, an application for an Assurance of Confidentiality, authorized under Section 308(d) of the Public Health Service Act, to protect the US Zika Pregnancy registry and Domestic Zika Clinical Inquiries Database information is in process. The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

STTL jurisdictions and healthcare providers contact the EOC Call Center at 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 (Domestic Zika Clinical Inquiries Database, mosquito survey) with limited access to only those who work on the team or manage the data (currently 20 people).

To collect information for the Domestic Zika Clinical Inquiries Database and the US Zika Pregnancy Registry, CDC will receive data from health care providers who call the Zika Pregnancy Hotline. In addition, basic case data reported to ArboNET and additional information specific to the registry provided to CDC by STTL health departments or health care providers will be received electronically or entered manually into a HIPAA-compliant REDCap database established for the registry.

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, pregnancy and infant outcomes associated with Zika virus exposure

and infection, and infant growth and development; 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, entomologists, and Public health biologists	Survey of county-level surveillance records of *Aedes aegypti* and *Aedes albopictus*	500	1	3/60	25
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 STTL 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
O. Developmental Milestones for Infant
P. Fact Sheet for Obstetric Healthcare Providers
Q. Fact Sheet for Pediatric Healthcare Providers
R. Fact Sheet for Health Care Providers
S. CSTE Case Definition