# US Zika Pregnancy Registry

Request for OMB Approval of a New Information Collection

## Supporting Statement A

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The goal of this information collection request (ICR) is to seek Paperwork Reduction Act (PRA) clearance to monitor the frequency and types of adverse birth outcomes for women with laboratory evidence of Zika virus infection during pregnancy and their infants and to strengthen the public health response to the Zika virus disease outbreak.

The intended use of the resulting data is 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. Information gathered also directs public health messages and counseling messages for pregnant women.

Respondents are state, tribal, territorial, and local health authorities and health care providers.

The latest version of REDCap will be used for data entry and management. SAS, EpiInfo, Microsoft Access and Microsoft Excel will be used for data analysis.

This is a request for a new ICR to continue the emergency information collection approved by OMB in February, 2016 (OMB Control No. 0920-1101). This emergency clearance expires on August 31, 2016. CDC requests an additional three years of clearance to continue this project.

The other two projects that were bundled with this one for the purpose of expediting emergency clearance—a database for the Emergency Operations Center clinical inquiries hotline and the mosquito surveillance survey—are not a part of this ICR. The clinical inquiries hotline and the mosquito surveillance surveys will each pursue their own new ICRs.

**1. Circumstances making the Collection of Information Necessary**

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. As of March 16, 2016, local transmission has been identified in at least 32 countries or territories in the Americas. Further spread to other countries in the region is likely. Local vector-borne transmission of Zika virus has not been documented in the 50 U.S. states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands, and American Samoa. However, Zika virus infections have been reported in travelers returning to the United States from areas with active Zika virus transmission. 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 sexual transmission from male travelers to their sex partners in the United States will likely continue to occur. In addition, mosquito-borne local transmission may occur in states where Aedes species mosquitoes are present.

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 addition to microcephaly, a range of other problems have been detected among fetuses and infants infected with Zika virus before birth, such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth. The Ministry of Health in Brazil, with support from the Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), and other partners, is investigating the association between Zika virus infection and microcephaly, as well as other adverse pregnancy and infant outcomes.

Zika virus disease and Zika virus congenital infection are nationally notifiable conditions for which the Council of State and Territorial Epidemiologists (CSTE) has established interim case definitions. 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 reporting 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. 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.

As part of the public health response to the Zika virus disease outbreak, CDC will conduct supplemental surveillance of antenatal diagnostic testing and clinical outcomes among pregnant women with laboratory evidence of Zika virus or unspecified flavivirus infection and their infants through the U.S. Zika Pregnancy Registry. It is anticipated that the Registry will provide critical information to direct CDC clinical recommendations and public health guidance and messages.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment 1)**.

## 2. Purpose and Use of Information Collection

The objective of this Registry is to monitor the frequency and types of pregnancy and infant outcomes following Zika virus infection during pregnancy, so as 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. Information gathered also directs public health messages and counseling messages for pregnant women.

*Registry Population*
The population eligible for supplemental surveillance through the Registry includes pregnant women with any laboratory evidence of Zika virus infection and their infants in the 50 U.S states, the District of Columbia, the US Virgin Islands, American Samoa, and other U.S. territories as needed. A separate active pregnancy surveillance system will be established for Puerto Rico. The following will be eligible to be included in the Registry:

1. Pregnant women in the United States with laboratory evidence of Zika virus infection (positive or equivocal test results, regardless of whether they have symptoms) and periconceptionally, prenatally or perinatally exposed infants born to these women.
2. Infants with laboratory evidence of congenital Zika virus infection (positive or equivocal test results, regardless of whether they have symptoms) and their mothers.

Unspecified flavivirus infections are included because cross-reactivity in serologic testing will make differentiation between Zika virus and dengue virus infection impossible in some cases; however, in the context of active Zika virus transmission, many infections are likely to be due to Zika virus. Children born to women infected during pregnancy are eligible for follow-up through the Registry, even if they have no apparent congenital infection, because we do not yet know the full spectrum of possible health effects.

At this point, there is no indication of exactly how many U.S. women may become infected with Zika virus during pregnancy. However, there is historical evidence from the existing pregnancy registry to provide insight into how many women and infants may enroll/report to the registry. As of October 13, there are 905 pregnant women with laboratory evidence of possible Zika virus infection. Currently, 23 liveborn infants with birth defects and 5 pregnancy losses with birth defects have been documented. The annual number of respondents was estimated based on the number of respondents reported to the U.S. Zika Pregnancy Registry to date (OMB Control No. 0920-1101, expiration 8/31/2016).

*Identification of Cases and Data Collection*
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. Cases may come to the attention of state 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 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. In addition, the Registry will include cases not reportable to ArboNET, i.e., those among asymptomatic pregnant women with laboratory evidence of Zika

infection or unspecified flavivirus infection, symptomatic pregnant women with unspecified flavivirus infection, and infants born to these women who do not have laboratory evidence of congenital Zika virus infection.

Registry cases will therefore be identified through mechanisms in addition to ArboNET. CDC will ensure that information about cases not reported to ArboNET will be passed on to health departments. CDC has established a designated Registry email, a clinical inquiry system and pregnancy hotline, and is engaged in Zika Virus response activities including case investigation, which may be alternative mechanisms for case identification that trigger reporting to the U.S. Zika Pregnancy Registry, ArboNET, or both. Finally, cases of Zika virus infection in pregnant women and fetuses/infants may be identified for inclusion in the U.S. Zika Pregnancy Registry, ArboNET, or both, through existing birth defects surveillance activities. When a congenitally infected infant is born to a women whose Zika virus or unspecified flavivirus infection has not been previously detected, the woman may be included in the U.S. Zika Pregnancy Registry retroactively.

Basic information 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 through specific follow up activities. CDC U.S. Zika Pregnancy Registry staff will work with Health Departments to make arrangements for gathering this 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 data to be collected for the Registry will include information about Zika infection-related tests and procedures conducted as part of the mother's and infant's routine clinical care, and in line with existing CDC, American College of Obstetricians and Gynecologists and Society of Maternal Fetal Medicine recommendations for evaluation, diagnosis and follow up of women infected with Zika virus during pregnancy. No additional tests or procedures will be performed specifically for Registry purposes.

Since gaining emergency OMB clearance in February 2016 through September 2016, the US Zika Virus Pregnancy Registry has enrolled 905 pregnant women in US states and the District of Columbia, and documented 23 liveborn infants with birth defects and 5 pregnancy losses with birth defects. The information on pregnancies and outcomes has been posted to these CDC websites:

https://www.cdc.gov/zika/geo/pregwomen-uscases.html

https://www.cdc.gov/zika/geo/pregnancy-outcomes.html

**3. Use of Improved Information Technology and Burden Reduction**

The latest version of REDCap software (Vanderbilt University) will be used for data entry and management. Data will be stored on a secure server.

All participant tracking and follow-up (including phone calls, emails, mailings, etc.) will be completed by CDC or state representatives. The Registry data collected by phone, secured fax, or secured email will be uploaded to a secured REDCap database on a central data repository maintained by CDC.

**4. Efforts to Identify Duplication and Use of Similar Information**

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 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.

**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. A 60-day Federal Register Notice was published in the Federal Register on Monday, May 2, 2016, Volume 81, No. 84, p. 26231 (**Attachment 2a**). One non-substantive public comment was received (**Attachment 2b**).

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. 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" and SORN No. 09-20-0113, "Epidemic Investigation Case Records Systems Notice."

The Health Insurance Portability and Accountability Act (HIPAA) permits covered entities such as health care providers 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. Personally identifiable information will only be collected for the Registry if necessary for collection of data from health care providers, and will only be used for the purposes for which it is intended, i.e., supplemental surveillance data collection to inform Zika infection clinical recommendations and the public health response to Zika. As stated in the HIPAA Privacy Rule, individuals participating in this registry have the right to request copies of health records, request that corrections be made to health information, receive notices of how health information is being used and disclosed, specify certain situations that would require the individual's explicit consent prior to disclosure (e.g., marketing), receive a report on why health information is shared for specific purposes, and may file a complaint if the individual believes that her health information is not being protected.

CDC is collecting clinical information for the U.S. Zika Pregnancy Registry 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").

Personally identifiable information will be collected by CDC from state, tribal, territorial and local health department authorities and healthcare providers or health facility staff. To protect the identities of registrants, 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 has obtained 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 (**Attachment 11)**. 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 terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of sensitive surveillance data. 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 such that they 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. In accordance with the Assurance of Confidentiality, CDC registry staff will be trained on confidentiality standards and will be asked to sign a nondisclosure agreement; the confidentiality training will be repeated annually.

Data will be collected and stored in an electronic database on a secure partition of the network with limited user access. All forms and files will be kept confidential to the extent allowed by local, state, and federal law. Whenever possible, to maintain confidentiality, all data, forms, reports, and other records will be identified by the Registry ID number only. Registry documentation will be maintained according to CDC's IRB file management and retention policy. Links to personally identifiable information will be destroyed after Registry data analysis and reporting is completed.

All participant tracking and follow-up (including phone calls, emails, mailings, etc.) will be completed by CDC or state representatives. The Registry data collected by phone, secured fax, or secured email will be uploaded to a secured REDCap database on a central data repository maintained by CDC. REDCap requires identity-proofing for access and is designed to comply with HIPAA regulations. Copies of paper files will be kept on CDC campuses in locked, secured, cabinets, accessible only to authorized Registry coordinators.

The CDC will not include information in reports that may identify cases or patients, including geographic locations of residence, and specified dates directly related to the patient such as admission dates, dates of diagnosis, or specific procedure dates. 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.

## 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 (**Attachment 11**).

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

The table below shows the estimated burden of the US Zika Pregnancy Registry for reporting from 64 state, territorial and local jurisdictions plus 36 additional health care provider respondents. This table reflects the number of respondents after a 1 year start-up period, which is the expected number going forward, and the average number of responses (pregnant women with possible evidence of Zika virus infection) per respondent, which includes the average during the start-up period (which have been entirely travel-associated cases) plus additional responses expected when local transmission occurs in the United States.

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, Territorial and Local Health | Maternal Health History Form | 1100 | 10 | 30/60 | 5500 |

| | | | | | |
|---|---|---|---|---|---|
| Departments | Supplemental Imaging Form | 1100 | 10 | 10/60 | 1833 |
| | Laboratory Results Form | 1100 | 10 | 15/60 | 2750 |
| Clinicians and Other Providers | Assessment at Delivery Form | 1100 | 10 | 30/60 | 5500 |
| | Infant Health Follow-Up Form | 1100 | 30 | 15/60 | 8250 |
| Total | | | | | 23,833 |

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. 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, Territorial and Local Health Departments | Maternal Health History Form | 5500 | $35.63 | $195, 965.00 |
| | Supplemental Imaging Form | 1833 | $35.63 | $65,309.79 |
| | Laboratory Results Form | 2750 | $35.63 | $97,982.50 |

| | | | | |
|---|---|---|---|---|
| Clinicians and Other Providers | Assessment at Delivery Form | 5500 | $33.55 | $184,525.00 |
| | Infant Health Follow-Up Form | 8250 | $33.55 | $276,787.50 |
| Total | | | | $820,569.79 |

**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 $9,921,335.00. 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, reporting and dissemination of information to inform management of the public health response to the Zika outbreak. 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.

| Expense Type | Expense Explanation | | | | Annual Costs |
|---|---|---|---|---|---|
| Direct Costs to the Government--Personnel | Medical Officer | GS-15 | 10% | $101,630.00 | $10,163.00 |
| | Medical Officer | GS-14 | 70% | $86,399.00 | $60,479.30 |
| | Medical Officer | GS-15 | 50% | $101,630.00 | $50,815.00 |
| | IT specialist | GS-11 | 100% | $51,298.00 | $51,298.00 |
| | IT specialist | GS-12 | 50% | $61,486.00 | $30,743.00 |
| | Health Education Specialist | GS-13 | 50% | $73,115.00 | $36,557.50 |

| | | | | | |
|---|---|---|---|---|---|
| | Health Scientist | GS-13 | 100% | $73,115.00 | $73,115.00 |
| | Management and program analysis | GS-9 | 80% | $42,399.00 | $33,919.20 |
| | Medical Officer | GS-13 | 100% | $73,115.00 | $73,115.00 |
| | Associate Service Fellow | GS-12 | 100% | $61,486.00 | $61,486.00 |
| | Health Scientist | GS-12 | 100% | $61,486.00 | $61,486.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |
| | Medical Officer | GS-14 | 100% | $86,399.00 | $86,399.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |
| | Nurse | GS-11 | 100% | $51,298.00 | $51,298.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |
| | Health Scientist | GS-12 | 100% | $61,486.00 | $61,486.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |
| | Nurse | GS-11 | 100% | $51,298.00 | $51,298.00 |
| | Associate Service Fellow | GS-12 | 100% | $61,486.00 | $61,486.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |
| | ORISE Fellow | ORISE | 100% | $74,260.00 | $74,260.00 |

| | | |
|---|---|---|
| | Total Personnel | $1, 374, 964.00 |
| Contractor and Other Expenses | Contract for IT support, area point of contact, epidemiology support | $960,000 |
| | Cooperative Agreement Funds to States and Territories | $7,586,371.00 |
| **TOTAL** | | $9,921,335.00 |

**15. Explanation for Program Changes or Adjustments**

This is a new information collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

CDC will provide weekly updates from the U.S. Zika Pregnancy Registry for U.S. territories (excluding Puerto Rico, which has a separate surveillance system) and U.S. states plus the District of Columbia. These updates will include the number of pregnant women with laboratory evidence of possible Zika virus infection, the number of liveborn infants with birth defects and the number of pregnancy losses with birth defects. Other information from the Registry that is relevant to clinical management or the public health response will be published according to the data release policy in the Assurance of Confidentiality.

*Project Time Schedule*

The US Zika Pregnancy Registry has been operating under an emergency OMB approval (OMB No. 0920-1101) that expired August 31, 2016. Because the infrastructure for this project already exists, no interruption in data collection is anticipated.

| Activities | Time Schedule |
|---|---|
| Data collection | Immediately upon OMB approval |
| Analysis & Publication | Weekly & Episodically* |
| Registry Evaluation | Annually |

*Numbers of pregnant women with any laboratory evidence of Zika infection and outcomes of pregnancies with laboratory evidence of possible Zika virus infection for US states, the District of Columbia, and US territories will be reported weekly; other findings will be released on an ad hoc basis.

The data collected through the US Zika Pregnancy Registry will be used to develop counseling messages for pregnant women, to update recommendations for clinical care, to plan for services for pregnant women and families affected by Zika virus, and to improve prevention of Zika virus infection during pregnancy.

Some results are expected to be useful at the local level while other findings will be more meaningful aggregated across sites. Each participating health department has responsibility for the release of local data. CDC has primary responsibility for the release of cycle-specific data aggregated from all geographic areas. These data are distributed to the participating agencies, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars. Furthermore, CDC will publish weekly surveillance reports using the data collected.

Community members will continue to be informed of the US Zika Pregnancy Registry findings through multiple information conduits. National data results will be released through national publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications and presentations to local medical and service organizations and at local conferences and workshops.

**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**

1. Authorizing Legislation
2a. 60-Day Federal Register Notice
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