Supporting Statement A

Zika Outcomes and Development of Infants and Children (ZODIAC) Investigation

Request for OMB approval of an Emergency ICR

OMB number xxxx-xxxx

New

Georgina Peacock
National Center for Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention
4770 Buford Highway
Atlanta, Georgia 30341
Phone: 404-498-4347
Email: ghn3@cdc.gov

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- **Goal of the study:** To improve understanding of the longer-term health and developmental consequences of congenital ZIKV infection, the impact on affected families, and their care needs.
- **Intended use of the resulting data:** To inform decisions by the CDC and the Ministry of Health of Brazil for the purposes of updating guidelines on care and prevention, control and health promotion, and to plan for the needs of affected children and families.
- **Methods:** Appropriately trained personnel will field test a set of assessment tools and methods to evaluate the health and development of children aged 12-24 months, with evidence of congenital ZIKV infection, with and without microcephaly, in two states in northeastern Brazil. Only children with clinical evidence of congenital ZIKV infection, or ZIKV laboratory test results or stored biological specimens from birth collected for the previous CDC-Brazil MOH case-control study in northeastern Brazil (OMB control no. 0920-1011), or another previous investigation are eligible for enrollment. Their primary caregivers will be interviewed about the child's and family's wellbeing and care needs. All data will be collected under the auspices of the Ministry of Health of Brazil. Data will be collected using a combination of paper and electronic instruments, during one to three visits to a health facility. Investigators will abstract information on neurologic and other clinical findings, and test results for ZIKV infection, if available from medical records and records of previous investigations. ZIKV testing will be performed on stored biologic specimens collected at birth, if not yet tested. Blood will be drawn from participating children, provided parental consent is obtained, for testing of thyroid, liver and kidney function, lead levels and hematocrit, any one of which may contribute to developmental delay.
- **The subpopulation to be studied**: Select cohorts of children 12-24 months of age with congenital Zika infection in two states in northeastern Brazil.
- **How data will be analyzed**: Analyses will be performed to describe the frequencies of clinical and developmental characteristics for groups of children defined by clinical findings and laboratory test results, with statistical testing of equality of percentile distributions of developmental score with those of children in the general population of Brazil.

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

This is a "New" Information Collection Request (ICR) for emergency OMB approval for the "Zika Outcomes and Development of Infants and Children (ZODIAC) Investigation" for three months. This information collection is not expected to require more than three months. However, if more than three months are needed to complete this collection, the National Center on Birth Defects and Developmental Disabilities will submit a full ICR to cover the remaining information collection period. Section 301 of the Public Health Service Act (42 U.S.C. 241) is the authorizing legislation for this information collection (**Attachment 1**).

The current Zika virus disease (Zika) outbreak in the Americas, first identified in March 2015 in Brazil [1-5], has established causal links between congenital infection with Zika virus (ZIKV) and a number of major birth defects, including microcephaly, fetal brain disruption sequence, ocular abnormalities, and other serious central nervous system abnormalities.[6-10] However, the range and specifics of developmental and clinical outcomes are unclear. Babies with microcephaly not related to congenital ZIKV infection are known to be at increased risk for other health problems, including seizures, developmental delays (e.g. speech, motor delays), intellectual disability, problems with movement or balance, feeding difficulties, and hearing or vision problems.[11] These health problems can be mild to severe, are often lifelong, and can be life-threatening in some cases.[7] Some neurologic problems associated with congenital ZIKV infection may not be apparent at birth,[12] and may require new assessment tools or methods to identify and specialized medical or social services to mitigate their effect on the developing child and support achievement of the highest level of function. Early intervention is critical to ensure that children with disabilities achieve their full potential.[13, 14]

Mobilization of enhanced surveillance systems has led to a better, but still incomplete, understanding of symptoms of infants with congenital ZIKV infection, but the impact of congenital ZIKV infection on postnatal and early childhood development has not been assessed. While preliminary case reports from Brazil indicate phenotypes among infants with congenital ZIKV infection consistent with fetal brain disruption sequence, more subtle developmental outcomes are unclear, and may be secondary to hearing, vision or neurologic problems. [15] The presence of a child with a disability and associated long-term home care needs affects the physical and emotional health and well-being of the parents, siblings, and other family members. [16, 17] Parents of a child with a disability have identified several domains in which the child's disability affects family life, including employment, family finances, parental mental and physical health, relationships in the family, loss of social opportunity and time pressures. [18] The impact of congenital ZIKV infection on children and families in countries most affected, like Brazil, has not yet been described.

Comprehensive descriptions of the health and development of children affected by congenital ZIKV infection are needed to help verify preliminary conclusions from sparse data, and to more accurately describe the phenotype, which likely represents a broader spectrum than has been described to date. [15] In addition, knowledge about the frequency with which the various phenotype components co-occur in an infant, as well as whether any component(s) are consistently present, is lacking at this time.

In August, 2016, CDC released guidance for care of infants with congenital Zika syndrome. This guidance recommends a coordinated evaluation by multiple specialists including evaluations for vision, hearing, feeding, growth, and neurodevelopmental and endocrine function during the first year of development, and ongoing monitoring of infants with laboratory evidence of congenital ZIKV infection without microcephaly because of potentially yet-to-be-identified adverse outcomes. If delayed onset of sequelae associated with other congenital infections is any guide, infants with congenital infection but without microcephaly at birth may have numerous latent health and developmental consequences.[19-22]. To date, recommendations for care related to congenital ZIKV infection pertain to infants only, as described above. There is no recommended set of health and developmental assessments to evaluate children with congenital ZIKV infection as they develop past 12 months of age, and to identify delayed consequences. Some existing clinical assessment tools may be adequate for evaluating these children, and others may not, or may have to be adapted to be clinically useful in this population of older children with congenital ZIKV infection.

In addition, parents should be assessed for depression and stress, and field-tested data collection instruments that specifically relate to caregivers and families of children who have been living with congenital ZIKV infection for 12-24 months are not available. Families will need ongoing support and assistance with care coordination in order to support the health and development of their children. Assessing and quantifying the level of need for these services infection is a high priority, not only for Brazil, but for other countries in the Americas, including the United States, where ZIKV arrived later than it did in Brazil, and where the consequences for children and families will be playing out during the coming months and years.

The first wave of Brazilian children congenitally infected by ZIKV during the current outbreak will have reached 12-24 months of age by the summer of 2017. There is an opportunity through future data collection to fill large gaps in our understanding of the impact of congenital ZIKV infection that will inform program development and long-term clinical care. New assessment tools, adaptations of existing tools, and new methods are needed to make the most of the opportunity to learn about the longer term health and developmental outcomes of congenital ZIKV infection among children, and the repercussions of the child's infection on family functioning. The proposed data collection will serve as a formative investigation of such new and adapted tools and methods. Expedited approval for the proposed information collection is requested to begin this formative project, because the findings will be foundational to meeting the urgent needs of children with congenital ZIKV infection and their families.

2. Purpose and Use of Information Collection

The purpose of the proposed information collection is to field test new assessment tools, adaptations of existing tools, and new methods to improve understanding of the longer-term health and developmental consequences of congenital ZIKV infection, the impact on affected families, and their care needs. Children congenitally infected with ZIKV but without clinical signs and symptoms at birth may have developmental issues later in life, but their likelihood of such sequelae is unclear. Furthermore, existing tools and methods for evaluating developmental status may not be applicable to older children with congenital ZIKV infection, and/or may be complex and difficult to apply in low resource settings. This information collection is designed to test new or adapted tools and methods to assess the impact of

congenital ZIKV on children and families. Field testing of these tools is necessary to determine if they are adequate for their intended use: to collect information to update guidelines on care and prevention, identify opportunities for early intervention, develop estimates of the needs of affected children and families for planning purposes, and optimize medical and social services that support affected children and families.

Without field tested tools and methods to assess health, development and family needs, health systems will not be able to plan for health care and social service needs related to congenital ZIKV infection; the inability to plan for these needs could strain existing resources for children with similar care needs, whether or not they are related to congenital ZIKV infection. A more complete understanding of the longer-term consequences of congenital ZIKV infection is urgently needed because early intervention is critical to ensure that children with neurodevelopmental disabilities achieve their full potential [13, 14]. In particular, if delayed consequences of congenital ZIKV infection go unrecognized, these children could miss some of the benefits of early intervention, with lifelong consequences.

The information collection is specifically designed to field test a comprehensive set of assessment tools tailored to the target population, as well as individual tools that are new, adapted from existing tools, have never been validated in Portuguese, or have been tested and validated but are being applied differently. Performance of the assessment tools and methods will be investigated with respect to the following specific questions:

1) What are the long-term (at 12-24 months of age) health and developmental outcomes associated with congenital ZIKV infection among children with laboratory and/or clinical evidence of congenital ZIKV infection?

2) What outcomes are associated with each other, over time? For example:

    - Is head size at birth associated with vision, hearing, cognitive, motor or other outcomes?
    - Is vision associated with motor or other outcomes?
    - Are there patterns of congenital anomalies, developmental delays or other health outcomes?

3) What are the repercussions of congenital ZIKV infection with and without microcephaly on family functioning?

4) What types of care are children with congenital ZIKV receiving?

As detailed in Supporting Statement Part B, the expected number of participants, no more than 235 children aged 12-24 months old, is sufficient to test the ability of the developmental assessment tools to estimate the proportions of children with outcomes of interest with a reasonable level of precision. This sample size is based on the size of the 95% confidence intervals and the expected frequency of the outcomes of interest. Although the available number of cases reduces the power to detect an association between the presence of microcephaly and the assessment of family functioning using our parent questionnaire, the number should be sufficient to pilot test the instrument, and exploratory analyses may generate hypotheses for future investigations.

3. Use of Improved Information Technology and Burden Reduction

The ZODIAC investigation data collection instruments have been designed to collect the minimum amount of information necessary to meet the objectives of this formative investigation. Abstractions of relevant information from medical or previous investigation records and parent interview responses will be collected via a REDCap data entry application on secure, password-protected laptop computers. Developmental assessment findings will be collected on paper instruments, and the resulting scores will be collected in the REDCap data entry application on the laptops. All data will be uploaded via an Secure Socket Layer (SSL)-protected website to the appropriate password-protected database stored on a secure server at the Ministry of Health of Brazil and will be backed-up regularly. Data will be de-identified before transfer to CDC via a secure, encrypted FTP site. Only the minimum information necessary to meet investigation objectives will be collected. Questions about other factors with the potential to have mediating or moderating effects on primary outcomes have been considered and included. The survey instruments will be administered by interviewers and will be presented in a clear and easy-to-answer format based on previous surveys and recommendations from survey methodology research.

4. Efforts to Identify Duplication and Use of Similar Information

While many experts agree that ZIKV causes microcephaly, further investigation is needed to better characterize the full spectrum of developmental outcomes associated with congenital ZIKV infection. This will be the first effort to field test the collection of a full compendium of health and developmental information on children 12-24 months of age with evidence of congenital ZIKV infection at birth, using a combination of previously validated instruments and new application of existing assessment instruments validated for another purpose. CDC is not aware of any other systematic collection of the information described herein.

Below is a list of ongoing projects of the CDC Zika response and how the ZODIAC investigation fills gaps not addressed by these existing efforts.

Project	Contribution added by ZODIAC
Assessment of the Association of Zika Virus Infection and Microcephaly (0920-1011)	This case-control study examined outcomes before 12 months of age associated with congenital ZIKV exposure; ZODIAC will extend this study by documenting developmental outcomes in children aged 12-24 months that may not have been apparent at a younger age.
US Zika Pregnancy Registry (0920-1143)	This project focuses on symptomatic and/or laboratory-confirmed cases of ZIKV in U.S. pregnant women and their infants up to 1 year of age, ascertained from medical records; ZODIAC focuses on longer term developmental outcomes of congenitally exposed children 12-24 months of age ascertained through comprehensive developmental assessment.
Enhanced Surveillance of Pregnancy and Infant Outcomes following with Zika Virus infection in Pregnancy, Colombia (Paperwork Reduction Act not applicable)	This project focuses on symptomatic pregnant women with evidence of ZIKV infection and outcomes in their infants up to 1 year of age, ascertained from medical records; ZODIAC focuses on longer term developmental outcomes

	of congenitally exposed children 12-24 months of age, ascertained through comprehensive developmental assessment.
Zika in Pregnant Women and Children in Colombia (0920-1142)	This project will prospectively identify ZIKV-infected asymptomatic and symptomatic pregnant women in early pregnancy and collect data from maternal questionnaires and medical records, to obtain information on diagnoses, test results, medical procedures, and hospitalizations; infants will be follow up until 6 months of age; ZODIAC focuses on longer term developmental outcomes of congenitally exposed children 12-24 months of age, ascertained through comprehensive developmental assessment
American Samoa Zika Surveillance (0920-1011)	This project focuses on pregnant women with evidence of ZIKV infection and outcomes in their infants up to 1 year of age, ascertained from medical records; ZODIAC focuses on longer term developmental outcomes of congenitally exposed children 12-24 months of age, ascertained through comprehensive developmental assessment.
Collection of serum and plasma from patients with antibodies reactive with Zika virus and other arboviruses (0920-1011)	ZODIAC focuses specifically on children 12-24 months of age.
Persistence of Zika virus in semen and urine of adult men in the United States with confirmed Zika virus infection (0920-1139)	Not applicable—the ZODIAC investigation does not address persistence of ZIKV in body fluids
Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico (ZIPER Study) (0920-1139)	Not applicable—the ZODIAC investigation does not address persistence of ZIKV in body fluids
The Effect of Community-Wide Vector Control Initiatives on Zika Virus Transmission in Puerto Rico, 2016 (0920-1137)	Not applicable – ZODIAC does not address community-wide vector control
Evaluation of In2Care Traps during the Zika Outbreak in Puerto Rico (0920-1071)	Not applicable – ZODIAC does not address community-wide vector control
Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease (0920-0572)	Not applicable – ZODIAC does not address a specific domestic readiness objective
Integrated Aedes aegypti Vector Control Intervention in Caguas City, Puerto Rico to Prevent and Control Zika Virus Infections (Paperwork Reduction Act not applicable)	Not applicable – ZODIAC does not address community-wide vector control
Migrant Farm Workers Understanding and Use of Measures to Prevent Zika Transmission (0920-1126)	Not applicable – ZODIAC does not address prevention of ZIKV transmission in migrant farm workers
Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from	Not applicable – ZODIAC does not assess the effectiveness of specific interventions in

Zika virus infections (0920-1118)	preventing Zika virus infection
Assessment of Zika Prevention Strategies in the U.S. Virgin Islands (0920-1147)	Not applicable – ZODIAC does not assess the effectiveness of specific interventions in preventing Zika virus infection
Assessment of Contraceptive Use and Needs, Puerto Rico, 2016 (0920-1114)	Not applicable – ZODIAC does not assess contraceptive use and needs
Characterization of Guillain-Barré Syndrome Cases in the Setting of Zika Virus Transmission— Colombia, 2016 (0920-1101)	Not applicable--ZODIAC does not focus on Guillain-Barré Syndrome
Formative Evaluation of Zika Prevention Kits for Pregnant Women in Puerto Rico (0920-1071)	Not applicable--ZODIAC does not involve evaluation of Zika Prevention Kits
Mosquito Surveillance Survey (0920-1146)	Not applicable – ZODIAC does not propose to assess mosquito populations
Case-control study of Guillain-Barré Syndrome in Puerto Rico – Surveillance (0920-1011)	Not applicable--ZODIAC does not focus on Guillain-Barré Syndrome
Case-control study of Guillain-Barré Syndrome in Puerto Rico - Records Abstraction (Paperwork Reduction Act not applicable)	Not applicable--ZODIAC does not focus on Guillain-Barré Syndrome
Message testing among partners of pregnant women about Zika in Puerto Rico (0920-0572)	Not applicable – ZODIAC does not include formative evaluation of any programs
Zika Virus Associated Neurologic Illness Case Control Study (0920-1141)	Not applicable – ZODIAC does not focus on ZIKV-associated neurologic illnesses in adults

In addition to these CDC projects, NIH will soon begin a multi-country study to evaluate the magnitude of health risks that Zika virus infection poses to pregnant women and their developing fetuses and infants. The study is opening in Puerto Rico and will expand to several locations in Brazil, Colombia, and other areas that are experiencing active local transmission of the virus. Infants whose mothers consent to their participation in the study will be evaluated within 48 hours of birth and again at three, six and 12 months. ZODIAC is complementary to this effort in that it focuses on longer-term outcomes of congenital ZIKV infection, specifically among children 12-24 months of age.

5. Impact on Small Businesses or Other Small Entities

Medical record data will be collected from private and public health care systems in the participating states in Brazil, including some that may be small businesses. The study data collection elements are the absolute minimum required for the intended use of the data. The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities. Project staff will request the medical records of eligible sampled patients. It is estimated to take an average of 3 minutes to pull each medical record for data abstraction.

6. Consequences of Collecting the Information Less Frequently

For most participants, one to two visits will be required for this information collection. An estimated 5% of children will have a third visit because of the preference of the family and availability of specific professionals.

Collecting information less frequently would not allow investigators to meet study objectives without lengthening the time required for a visit beyond the maximum time children 12-24 months of age have the stamina to tolerate. Failing to complete study objectives would prevent testing of tools and methods to assist health care and public health professionals from taking public health actions to address medical and social needs of children and their families living with the consequences of congenital ZIKV infection.

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

The activities outlined in this package fully comply with all guidelines of 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. A 60-day Federal Register Notice was drafted **(Attachment 2)** and will be sent for publishing in the Federal Register at the same time as OMB's review.

B. There has been ongoing consultation with the Brazil Ministry of Health based on their prior experience with the case-control study, "Assessment of the Association of Zika Virus Infection and Microcephaly" (OMB Control No. 0920-1011). During a site visit from January 11-22, 2017, CDC staff consulted with officials in the states of Ceará and Paraíba, as well as health care facilities in these states. A follow-up visit was conducted from April 17 - 21, 2017 to assess logistical and training needs. Below is a list of individuals consulted.

National Ministry of Health, Brazil

Juliane Maria Alves Siqueira Malta

Technical Consultant

National Dengue Control Program

Address: SRTV 702, Via W 5 Norte, Unidade VI do Ministério da Saúde, Edifício PO 700, 6° andar. Brasília/DF, Brasil

Tel: (61) 3315 - 3122

Email: juliane.malta@saude.gov.br

Isabela Ornela Pereira (ZODIAC Co-Principal Investigator)

Social Policy Technical Analyst

National Dengue Control Program

Address: SRTVN Quadra 701, Via W 5 Norte, Lote D Edifício PO700 – 6° andar CEP: 70719-040, Brasil

Tel. 55 613213.8034

Email: Isabela.opereira@saude.gov.br

State Health Agencies

Henrique Javi

State Health Secretary, Ceará

Address: Avenida Almirante Barroso, 600. Praia de Iracema. Fortaleza/CE Brasil

Tel. (85) 3001 - 5281

Email: henrique.javi@saude.ce.gov.br

Cláudia Veras

State Health Secretary, Paraíba)

Address: Avenida Dom Pedro II, 1836. Torre. João Pessoa/PB, Brasil

Tel. (83) 3218 - 7321

Email:claudiaveras@ses.pb.gov.br

Renata Nobrega

Health Surveillance Lead, Paraiba

Address: Avenida Dom Pedro II, 1836. Torre. João Pessoa/PB, Brasil

Tel: (83) 3218 - 7397

Email: renatavnobrega@ses.pb.gov.br

There were no major problems left unresolved

9. Explanation of Any Payment or Gift to Respondents

Participants' travel to and from the locations where data will be collected and meal vouchers will be provided through a contractor as tokens of appreciation.

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

The Privacy Act is applicable to the proposed data collection. 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." All information collected shall be held in confidence to the extent allowed by law. All staff and contractors involved in data collection and management will be trained concerning procedures and practices to ensure privacy of data. Names will be collected for the purpose of later linking survey responses to information collected by the Brazil Ministry of Health in their SINASC vital records system for newly enrolled participants. Later linkage of these data will allow for analysis of maternal and infant characteristics and outcomes collected on the birth certificate. The participant name will be kept in a separate file from the survey responses. Completed questionnaires and any files with personal identifiers must be kept in a locked file cabinet or a locked room; access to these files will be limited to authorized personnel and will be password-protected. Backup files of data collected for this investigation will also be secured.

The Ministry of Health (MOH) of Brazil will own the data. The Brazil MOH will be responsible for protecting the privacy of respondents and will retain identifying information based on a unique identifier for participants in the project. With the exception of the date of birth, medical information, and caregiver employment status, data will be stripped of PII before it is transferred to CDC via a secure encrypted FTP site so that CDC can assist in finalizing the database and conducting analyses. Date of birth is necessary for deduplication of the data, and medical information and caregiver employment status are necessary to achieve the objectives of this investigation. However, it will not be possible to use these data elements and other information in the dataset sent to CDC to indirectly identify an individual. The CDC will not include information in reports that may identify respondents. 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. Any publication or other use of these data by CDC will contain only aggregated information that could not be used to indirectly identify any individual.

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

IRB Approval

CDC has determined the proposed data collection to be non-research public health practice (**Attachment 12)**. However, the protocol is subject to review and approval by the IRB of the Ministry of Health of Brazil. The informed consent process will be completed prior to data collection. The consent and assent forms will be read by the primary caregiver of an eligible child, or may be read to the primary caregiver by the field staff collecting the data. The consent will include information about the parental interview, the medical record abstraction, and the developmental assessment methods, as well as the purpose and use of this information, including the potential for future data linkage. Respondents will be made aware that participation is purely voluntary. Each primary caregiver will sign the consent form if they agree to participate, or in the case of a primary caregiver who is under that age of 18 years, the parent of the caregiver will sign the consent form, and the primary caregiver will sign the assent form.

Justification for Sensitive Questions

Interviews will be administered by staff who will be trained in the administration of sensitive questions, such as those related to depression, parental stress, income, relationships or coping mechanisms. Sensitive questions are essential to meeting the objectives of this information collection. Staff

interacting with participants will be trained on how to interview participants, and this will include conducting mock interviews.

A Project Operations Manual will be developed that will include steps to protect the privacy and confidentiality of information provided by respondents or collected from medical records.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

To pilot test the assessment methods and instruments, the health and development of a maximum of 235 children with laboratory and/or clinical evidence of congenital ZIKV will be evaluated, and the primary caregiver of each participating child will be interviewed.

Completion of data collection from child-caregiver pairs is estimated to take an average of 155 minutes (2.6 hours). Project staff will request the medical records of eligible children. The average time required for clerks in medical facilities to pull each medical record for data abstraction is 3 minutes. The average time for study staff to record recruitment attempts and participation is 2 minutes per child-caregiver pair. The total number of burden hours is 628.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Project Staff	Recruitment and Participation Log	2	118	2/60	8
Clerk in Medical Facility (to pull records)	Medical Record Abstraction Form	235	1	3/60	12
Primary caregiver of child with evidence of ZIKV	Parent questionnaire	235	1	10/60	39
	Seizure screen	235	1	10/60	39
	Ages and Stages Questionnaire, 3rd Edition	235	1	15/60	59
	Ages and Stages Questionnaire: Social Emotional	235	1	15/60	59
	Patient Health Questionnaire-9	235	1	5/60	20
	Parenting Stress Index – Short Form	235	1	10/60	39
Child with evidence of ZIKV	Growth Exam	235	1	5/60	20
	Physical Health Exam	235	1	15/60	59

	Neurological Exams – Hammersmith Infant Neurologic Exam, Evaluation of Cerebral Palsy	235	1	10/60	39
	Vision Exam	235	1	50/60	196
	Blood draw	235	1	10/60	39
Total					628

B. Estimated Annualized Burden Costs

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

The average annual response burden cost is estimated to be $2,311.04. The hourly wage estimates are based on the Trading Economics Brazil Real Average Monthly Income Indicator http://www.tradingeconomics.com/brazil/wages). For April, 2017, the average monthly income was 2,107.00 BRL. Based on an average work week of 44 hours (http://thebrazilbusiness.com/article/7-things-to-consider-before-hiring-in-brazil), the average hourly wage is 11.97 BRL/hour. Current (06/01/2017) exchange rate is $1 = 3.25 BRL (https://www.google.com/?gws_rd=ssl#q=currency+exchange+rate+dollar+to+brazilian+real).

The mean hourly wage rate for all occupations ($11.97 BRL ($3.68)) was used. For the examinations of the child, costs listed are those of the primary caregiver, who must be present with the child.

Type of Respondent	Form Name	Total burden hours	Hourly Wage Rate	Total Respondent Costs
Project Staff	Recruitment and Participation Log	8	$3.68	$29.44
Clerk in Medical Facility	Medical Records Abstraction Form	12	$3.68	$44.16
Caregiver of child with evidence of ZIKV	Parent questionnaire	39	$3.68	$143.52
	Seizure screen	39	$3.68	$143.52
	Ages and Stages Questionnaire, 3rd Edition	59	$3.68	$217.12
	Ages and Stages Questionnaire: Social Emotional	59	$3.68	$217.12
	Patient Health Questionnaire-9	20	$3.68	$73.60
	Parenting Stress	39	$3.68	$143.52

	Index – Short Form			
Child with evidence of ZIKV	Growth Exam	20	$3.68	$73.60
	Physical Health Exam	59	$3.68	$217.12
	Neurological Exams – Hammersmith Infant Neurologic Exam, Evaluation of Cerebral Palsy	39	$3.68	$143.52
	Vision Exam	196	$3.68	$721.28
	Blood draw	39	$3.68	$143.52
Total				$2,311.04

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The annualized cost to the federal government is $1,188,778, which includes a contract with the implementing partner in Brazil, FIOTEC, and CDC staff time to oversee and collaborate on the study. Annual wages for CDC employees were based on the 2017 General Schedule Salary Table for the Atlanta locality available here: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/ATL.pdf.

Annualized Cost to the Federal Government	
Contract	**Annualized Cost**
1. Total labor	$460,312
2. Total other direct costs	$277,466
3. Total overhead	$115,000
4. General and administrative expense	$197,250
Subtotal	$ 1,050,028
CDC FTEs	**Salary**
1. Developmental Pediatrician (15% time)	$30,000
2. Research Science Officer GS-15 (25% time)	$37,500

3. Behavioral Scientist GS-14 (25% time)	$31,250
4. IT Specialist GS-13 (15% time)	$15,000
5. Medical Officer O-5 (25% time)	$25,000
Subtotal	$138,750
Total Federal Government Cost	**$1,188,778**

15. Explanation for Program Changes or Adjustments

This is a new information collection request, therefore program changes and adjustments do not apply at this time.

16. Plans for Tabulation and Publication and Project Time Schedule

The CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD), in collaboration with the CDC Emergency Operations Center (EOC) will take responsibility for all data tabulations for this assessment. CDC's Division of Human Development and Disability (DHDD) will prepare the data files for analysis. This preparation will include final data cleaning. CDC epidemiologists, including staff in NCBDDD and EOC will develop an analysis plan and table shells during the data collection phase and will perform all data analysis immediately upon availability of final data files. A preliminary report, for internal use at the Brazil Ministry of Health and CDC, will be prepared at the end of data collection. When final tabulations are available, a final report or reports on key findings will be published in a peer-reviewed journal(s) and/or the *Morbidity and Mortality Weekly Report*.

Project Time Schedule	
Begin contact/enrollment	1-2 weeks after OMB approval
Data collection and medical record abstraction	3 weeks to 10 weeks after OMB approval
Complete field work	12 weeks after OMB approval
Data Cleaning	3-5 months after OMB approval
Data Analysis	6-12 months after OMB approval
Publication	18 months after OMB approval

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

The OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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