



July 14, 2017

Dominic Mancini  
Deputy Director  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, the Centers for Disease Control and Prevention (CDC) requests that the proposed information collection project, “Zika Outcomes and Development of Infants and Children (ZODIAC)” be processed in accordance with section 1320.13, Emergency Processing.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to the CDC’s mission to protect America from health, safety and security threats, both foreign and in the U.S.

The current Zika virus disease outbreak in the Americas, first identified in March 2015 in Brazil, has established causal links between congenital infection with Zika virus (ZIKV) and a number of major birth defects. The unanticipated event that prompted this emergency request is the finding that some neurologic problems associated with congenital ZIKV infection may not be apparent at birth. Questions remain about these delayed effects and about progressive neurologic damage in affected children. New or modified assessment tools and/or methods may be needed to identify these sequelae of congenital ZIKV infection; specialized medical or social services may be needed to mitigate their effect on the developing child. The proposed ZODIAC information collection in Brazil is designed to investigate these questions, and is expected to be completed in 3 months. The goal of this 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.

Early intervention is critical to ensure that children with disabilities achieve their full potential. However, to date, recommendations for care related to congenital ZIKV infection pertain to infants only. There is no recommended set of health and developmental assessments to evaluate children with congenital ZIKV infection older than 12 months, 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. Assessing and quantifying the level of need for these services 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 proposed investigation will test a suite of new and adapted tools and methods that could inform the care of these children and the development of programs to support affected families.

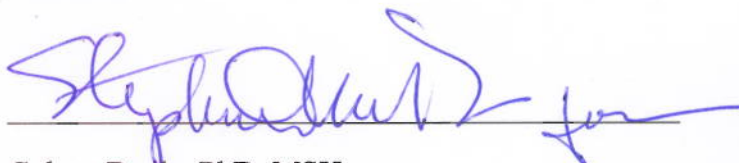
Data collection is to take place in northeast Brazil, where there is a cohort of congenitally infected children at the right age. The first wave of Brazilian children congenitally infected by ZIKV during the current outbreak will have reached 12-24 months of age by the summer of 2017. There is a narrow window of time to complete the data collection on this aging cohort of children and apply what is learned to improve the care of the next wave of children with congenital ZIKV infection to age out of infancy.

Data from the US Zika Pregnancy Registry indicate that 1,687 pregnancies with laboratory evidence of possible Zika infection have been completed in U.S. states and Washington, D.C., from December 1, 2015, to July 6, 2017, and 2,830 have been completed in the U.S. territories. The children from these pregnancies will soon be the age of the children to be assessed in the ZODIAC project. Early intervention during sensitive periods of development, when the brain is developing rapidly, is critical for mitigating disabilities in children, and time is running out as children born with congenital Zika infection age. The children born from the earliest of the completed pregnancies in the United States and its territories will be 2 years old in December 2017. The longer this data collection is delayed, the greater the number of affected toddlers in Brazil, the United States, and elsewhere who will be too old to benefit from any advances in understanding and care that follow from it, with the potential for lifelong consequences. Compliance with normal clearance procedures would therefore result in a lost opportunity to support achievement of the highest level of function among these children. This is the public harm that will result from this request going through the normal clearance process.

Therefore, CDC requests a 90-day emergency clearance to carry out the ZODIAC project, a comprehensive health and developmental assessment of children 12-24 months of age with congenital Zika infection in Brazil.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business July 31, 2017.

Respectfully,

A handwritten signature in blue ink, appearing to read "Coleen Boyle", is written over a horizontal line.

Coleen Boyle, PhD, MSHyg  
Director, National Center on Birth Defects and  
Developmental Disabilities  
Centers for Disease Control and Prevention