



April 27, 2017

Dominic Mancini
Acting 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*, I request that the proposed information collection project, "Zika Virus Enhanced Surveillance of Select Populations" 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 Zika Emergency Response. The Zika Virus Enhanced Surveillance projects aim to define the clinical characteristics and outcomes of Zika virus disease in selected populations, including children, hospitalized patients, and patients with neurologic disease. As routine surveillance data have been reported to CDC, it has become apparent that the full spectrum of Zika virus disease may have been underestimated. In addition, there has been recent recognition that some non-congenital infections are quite severe. Identifying risk factors for developing more severe disease with Zika virus infections and better describing the full spectrum of Zika virus disease is important to obtain prior to the next transmission season in order develop or revise existing guidance used by clinicians and public health officials.

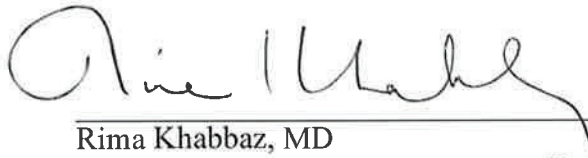
Most Zika virus infections are asymptomatic. Clinical illness, when it occurs, is generally mild and characterized by acute onset of fever, maculopapular rash, arthralgia, and/or nonpurulent conjunctivitis. However, the virus is capable of more severe disease; Guillain-Barre syndrome, other neurologic manifestations, and thrombocytopenia have been reported following Zika virus infections; specific clinical findings and outcomes are not well described. Additionally, there are few published reports describing postnatally-acquired Zika virus disease among children, but there is some indication that the disease presentation in children may differ from that seen in adults.

Zika virus disease cases are reported to CDC through ArboNET. ArboNET is a passive surveillance system that captures selected information on demographics, travel history, clinical features, and laboratory test results. However, reporting of many fields in ArboNET is optional leading to incomplete data, particularly for clinical features. In addition, more specific information regarding reasons for hospitalization, length of hospitalization, specific neurologic findings, and clinical course are not captured in ArboNET. The proposed information collection is for enhanced surveillance of Zika virus disease cases reported to CDC through ArboNET. The objective of this data collection is to collaborate with state health departments to better define the public health burden, clinical characteristics, and risk factors influencing outcomes of Zika virus disease. The identification of persons at higher risk for severe disease is essential for establishing guidance for testing and clinical management of patients infected with Zika virus. Improved clinician awareness of the spectrum of disease presentations will allow for more timely identification of disease cases and improved public health response which should mitigate the risk for local transmission.

CDC cannot reasonably comply with the normal clearance given the need for these data to evaluate and revise existing guidance documents and informational products prior to the summer months, when we anticipate that Zika virus transmission in the Americas will substantially increase. Accelerated OMB review is requested to provide CDC with the ability to rapidly answer urgent remaining questions that will shape the course of this public health emergency response. CDC requests a 180-day emergency clearance to initiate this project to determine the full spectrum of clinical symptoms associated with Zika virus disease and identify populations at risk for most severe disease.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by May 3, 2017.

Respectfully,

A handwritten signature in black ink, appearing to read "Rima Khabbaz", written over a horizontal line.

Rima Khabbaz, MD
Acting Director, National Center for Emerging and Zoonotic
Infectious Diseases (NCEZID), Centers for Disease Control
and Prevention (CDC)