

May 10, 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*, I request that the proposed information collection project, "Zika Virus RNA Persistence in Pregnant Women and Congenitally Exposed Infants in Puerto Rico (ZIRP Puerto Rico)" 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. As the premier public health agency, CDC is looked to for the most up-to-date evidence-based scientific information. As part of its Zika response efforts, CDC is collaborating with the Puerto Rico Department of Health (PRDH) in Puerto Rico where the number of reported cases continue to rise. The large number of cases and stage of the outbreak in Puerto Rico provides an opportunity to collect actionable information on a shorter timeframe than is possible elsewhere. This collaboration is expected to provide critical scientific information to help the United States, Puerto Rico and other countries prepare for the unprecedented challenges posed by Zika.

CDC has been at the forefront of the Zika response; however, many questions still remain unanswered for which studies are needed. Based on information from case reports, case series, and animal models to date, CDC has made the determination that Zika virus is a cause of microcephaly; however, limited epidemiologic data are available to confirm this relationship. As of December 16, 2016, 35,648 confirmed Zika cases had been reported in Puerto Rico, more than any other location in the U.S., and the number is expected to rise. Among the confirmed cases, 2,864 have been among pregnant women, and the first case of microcephaly in a fetus with confirmed Zika virus infection was announced by the PRDH on May 13, 2016. Currently, CDC and the Puerto Rico Department of Health recommend that all pregnant women living in areas with active Zika virus infection transmission such as Puerto Rico be tested. The ZIRP Puerto Rico study involves enrollment and follow-up of 150 Zika virus infection positive pregnant women and their respective infants for a period of 15 months to determine the prevalence and duration of Zika virus RNA persistence among pregnant women infected with Zika virus infection and among infants with congenital infection. This study is designed to answer urgent questions about prevalence and duration of ZIKV RNA persistence in pregnant women and congenitally infected infants as well as to the association between the quantity of Zika virus infection viral load in pregnant women and adverse pregnancy outcomes.

We anticipate new infections with Zika virus to occur in the coming months in Puerto Rico. However, as case management improves so will the number of cases reported. Therefore, launching ZIRP soon is critically important. A delayed start would limit the numbers of infected women that could be enrolled

and the resulting low statistical power would affect our ability to draw meaningful conclusions from the findings. It is critical that the enrollment into the ZIRP Puerto Rico study begins rapidly to ensure that a robust number of pregnant women who have tested positive for Zika virus infection and their infants can be enrolled and followed up to assess outcomes.

Because the enrollment of pregnant women and their respective infants in Puerto Rico is projected to begin on June 1st, 2017, accelerated OMB review is requested. This will provide CDC with the ability to rapidly answer the most urgent remaining questions that will shape the course of this public health emergency response. Therefore, CDC requests a 90-day emergency clearance to launch enrollment of pregnant women and infants within the necessary time frame.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business May 27th, 2017.

Respectfully,



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