

October 5, 2016

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 Associated Neurologic Illness Case Control Study in 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.


CDC cannot reasonably comply with the normal clearance because of the ongoing Zika epidemic in Puerto Rico and multiple clinical findings that are pertinent to public health interventions. One of these has been noted in multiple recent case reports as well as notifications from physicians in Puerto Rico, which have evidenced the association between Zika virus infection and a variety of neurologic illnesses. Most prominent among these is Guillain-Barre syndrome, which was first reported several months ago, but unexpected additional manifestations that have been reported in the past 3 months include cases of myelitis, encephalitis, papilledema, and other severe neurologic illnesses. The role with which Zika virus infection plays in each of these neurologic illnesses is unclear, specifically if the relationship is causative, non-specific, or coincidental. Should collection of data not commence immediately, potential harm to patients with severe neurologic illness may be expected as a result of unnecessary delays in identification of risk factors or interventions that may be associated with developing severe neurologic illness following either infection with Zika virus or other potential exposures

Therefore, CDC requests a 90-day emergency clearance to enroll patients in a case-control investigation that will associate the risk of developing severe neurologic illness following Zika virus infection. Such cases are currently being reported to Puerto Rico Department of Health, and those patients that are enrolled in the case-control investigation will be matched by age and location of residence with control participants. Demographic characteristics, underlying medical conditions, behaviors, and recent illnesses (including diagnostic evidence of infection with Zika, dengue, or chikungunya virus) will be compared between up to 50 cases and 2 controls matched to each enrolled case by age and location of residence in order to determine if there is a significant association between Zika virus infection or other potential exposures and developing severe neurologic illness. Data for the case-control investigation will be collected with a standardized questionnaire and, where applicable, chart abstraction form. Blood and urine specimens will be collected from all consenting participants and tested for evidence of ZIKV infection. Because the unanticipated recent reports of severe neurologic illness associated with ZIKV

infection, earlier submission of data collection materials was unable to be submitted to OMB in sufficient time to avoid the emergency review request.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business October 5, 2016.

Respectfully,



Beth P. Bell, MD, MPH
Director, National Center for Emerging and Zoonotic
Infectious Diseases (NCEZID), Centers for Disease Control
and Prevention (CDC)