March 25, 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
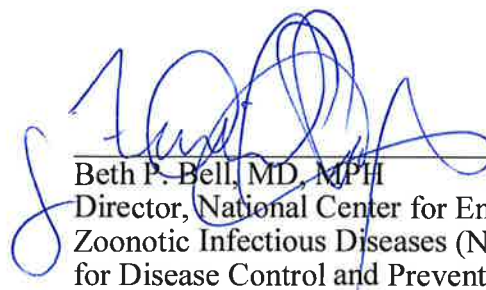
Dear Mr. Mancini:

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 Emergency Package III: Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection" 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 purpose of this study is to enroll adult men with confirmed Zika virus infection and collect serial specimens of semen and urine. This study will fill gaps in the scientific knowledge base for Zika virus regarding the occurrence, persistence, and transmissibility of Zika virus in urine and semen. This information will allow the CDC to target and refine public health interventions to arrest the spread of Zika virus.

CDC cannot reasonably comply with the normal clearance procedures because information on the frequency and duration of Zika virus shedding in semen and urine is needed urgently to inform public health recommendations for infected men and their partners. Therefore, CDC requests a 180-day emergency clearance to begin this study.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business March 30, 2016.

Respectfully,

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