



March 28, 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, "Emergency Zika Package: Zika Reproductive Health Call-Back Survey (ZRHCS), 2017", a population-based telephone survey of women of reproductive age (18-49 years), 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.

In response to the Zika virus outbreak in the Western Hemisphere and evidence that Zika virus infection during pregnancy is a cause of microcephaly and other adverse pregnancy and infant outcomes, CDC's Emergency Operations Center (EOC) has been working at the highest level of activation since February 8, 2016. To date, local transmission has been identified in at least 50 countries or territories in the Americas. Within the United States, widespread mosquito born transmission has been documented in the territories of Puerto Rico and the US Virgin Islands, with more localized transmission in Florida and Texas.¹ Moreover, several jurisdictions within the continental United States have had a large number of travel related cases, with infection occurring through mosquito borne and sexual transmission.

Given the potential for new Zika outbreaks and increases in travel-associated cases as the summer travel and mosquito season approaches,² in March 2017 the CDC EOC provided funding to 14 high-risk states and territories to conduct a population-based telephone survey of reproductive age women (18-49 years) that would provide the information needed for emergency response planning. The 14 funded jurisdictions have had local transmission, are at high risk for local transmission, and/or have a disproportionately high number of travel-related cases of Zika virus infection. The goal of this information collection is to obtain scientifically valid, current information on various aspects of Zika prevention behaviors, including data on: 1) the use of contraception among women wishing to avoid or delay pregnancies that might otherwise be affected by Zika; 2) barriers to access and use of contraception; 3) knowledge of and adherence to mosquito prevention strategies and use of condoms to minimize the risk of sexual transmission; and 4) frequency of travel to Zika areas and knowledge of and adherence to travel recommendations.

For the purpose of emergency response planning, the proposed information collection would ideally begin April 15, 2017. In the event that a jurisdiction has an increase in Zika cases or newly reported local transmission, interim data would be analyzed and provided to the state or territorial health department within 10 business days to aid targeting of prevention messages and distribution of finite resources. For all jurisdictions, interim data and a report will be made available no later than June 2017; a report, reflecting all data gathered through December 31, 2017, will be provided by May 2018. This information will fill a critical gap that is needed for emergency response planning: currently no data exist on the use of Zika protective measures among women of reproductive age within the continental US to prevent sexual or

¹ <https://www.cdc.gov/zika/intheus/maps-zika-us.html>.

² In 2016, the seasonal surge of Zika virus cases in Puerto Rico and the US Virgin Island began in June and July, and a seasonal pattern as has been observed with other infections transmitted by *Aedes aegypti*.

mosquito born transmission, or the frequency of travel to Zika areas and knowledge of and adherence to travel recommendations. Further, the most recent contraceptive use data for 8 of 14 jurisdictions in this request are from 2004. This information will be critical for developing targeted messages and emergency response plans for distribution of finite resources.

Similar data collected in Puerto Rico during July-November 2016 (OMB Control No. 0920-1114) proved to be critical for identifying gaps in knowledge of prevention behaviors and barriers to access and use of contraception among non-pregnant women of reproductive age at risk for unintended pregnancies that could be affected by Zika. This information was essential for developing and targeting prevention messages and strategies, and for developing a program to expand access to contraception for women in Puerto Rico. The currently proposed information collection request will provide an important population-level comparison group for participants in the contraceptive access program, as the evaluation of this program (OMB Control No. 0920-170A) only identifies barriers, facilitators and contraceptive method use among program participants. Moreover, given that Puerto Rico continues to have the largest number of Zika cases of any jurisdiction in the United States, information on adherence to prevention strategies for mosquito and sexual transmission is needed to assess the effectiveness of emergency response efforts from the first season and to further refine and determine where additional efforts and resources are needed. This is particularly important as health officials and clinicians in Puerto Rico have expressed concern about complacency among pregnant women and women of reproductive age in relation to Zika virus despite the causal link between infection during pregnancy and devastating birth defects.

CDC cannot reasonably comply with the normal clearance process and timeline. Given the potential for new outbreaks and increases in cases as we approach the summer travel and mosquito season, a delayed start would mean this critical information would not be gathered in time to implement preparedness and response plans. Therefore, CDC requests a 90-day emergency clearance to launch the Emergency Zika Package: Zika Reproductive Health Survey, 2017. A 60-day notice will be published in the Federal Register to make the public aware of this proposed information collection. Because this is a request for an emergency clearance, CDC requests OMB review without waiting for the 60-day comment period to expire. As more than six months are needed to complete this information collection, CDC will pursue a formal ICR as soon as emergency approval is granted. For this formal, non-emergency ICR, a new 60-day notice will be published in the Federal Register inviting public comment, followed by a 30-day notice and ICR application for three years of OMB clearance.

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

Respectfully,



Ursula E. Bauer, PhD, MPH
Director, National Center for Chronic Disease
Prevention and Health Promotion (NCCDPHP)
Centers for Disease Control and Prevention (CDC)