



October 28, 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, "Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika" 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 goal of this information collection is to qualitatively explore current knowledge, attitudes, and beliefs regarding contraception use, in general, and related to Zika virus exposure, in particular, among women of reproductive age (WRA; 18-44 years) and men of reproductive age (MRA; 18-44 years) in the USVI. This information will be used to develop messages and materials designed to increase knowledge and awareness of the range of available contraceptive methods and to promote access to contraceptive services in the USVI among those who want to delay or avoid pregnancy during the Zika virus outbreak.

As of October 11, 2016, the USVI Department of Health reported 1,320 reported cases, and 524 confirmed Zika cases. The number of cases has increased steadily since the identification of the first case in January 2016. Microcephaly and other problems have been linked to Zika infection during pregnancy and, among fetuses and infants infected with Zika virus before birth, consequences, such as miscarriage, stillbirth, absent or poorly developed brain structures, defects of the eye, hearing deficits, limb abnormalities, and impaired growth have been identified. These adverse pregnancy outcomes highlight the immediate need to facilitate pregnancy planning among women of reproductive age at risk of unintended pregnancy by increasing access to contraception.

In response to the continued impact of the Zika virus in the USVI, CDC staff have conducted preliminary assessments to examine unintended pregnancy in the USVI. Through a variety of data sources, including the National Survey of Family Growth and the Youth Risk Behavior Surveillance System, CDC has determined that more than half of the WRA in the USVI are at risk of unintended pregnancy (WRA who are sexually active and fertile, and not currently desiring a pregnancy). Furthermore, among women at risk of unintended pregnancy, nearly half are not using highly or moderately effective contraception (long acting reversible methods [LARCs], including intrauterine devices [IUDs] and implants, or hormonal methods). These surveillance data, coupled with reports of increased Zika virus transmission in the USVI, underscore the urgent public health need to increase awareness that contraception for those who choose to delay or avoid pregnancy is a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes.

CDC is proposing to develop a comprehensive communication campaign to raise awareness regarding contraception methods and available services in the USVI during the Zika virus outbreak. To ensure the cultural appropriateness and relevance of this approach, CDC plans to conduct a series of focus groups with WRA and MRA in the USVI. No more than 72 individuals will participate in the focus groups, resulting in 6 groups, each with a maximum of 12 individuals. Five groups will be with WRA, whereas one group will be with MRA. Each group will be moderated by an experienced focus group facilitator using a semi-structured interview guide consisting of a series of open-ended questions and probes. The focus groups will be held in a private setting to ensure confidentiality. For those who consent to participate, it is expected that the focus groups will take between 90-120 minutes. The total number of burden hours is 144. There will be no anticipated costs to respondents other than time.

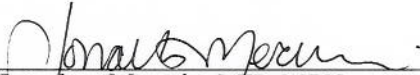
All participants will be recruited by CDC, in partnership with the USVI Department of Health. Two primary modes of recruitment will be utilized: 1) referrals from community-based organizations and health centers and 2) in-person intercepts at health department/health center locations, community-based organizations, and/or venues where the target population may congregate (e.g., nail and hair salons; grocery stores). Eligibility of participants will be determined using a structured screener either by phone or in-person.

The Zika outbreak and its link to birth defects was unanticipated. Before 2007, at least 14 cases of Zika had been documented, although other cases were likely to have occurred and were not reported. Zika outbreaks have probably occurred in many locations but because the symptoms of Zika are similar to those of many other diseases, many cases may not have been recognized. In May 2015, CDC began responding to increased reports of Zika and assisted in investigations with PAHO and countries' ministries of health. In January 2016, CDC activated its Emergency Operations Center (EOC) to respond to outbreaks of Zika occurring in the Americas and increased reports of birth defects and Guillain-Barré syndrome in areas affected by Zika. On February 8, 2016, CDC elevated its EOC activation to a Level 1, the highest level. On February 1, 2016, the World Health Organization declared a Public Health Emergency of International Concern because of clusters of microcephaly and other neurological disorders in some areas affected by Zika.

CDC cannot reasonably comply with the normal clearance procedures because an assessment regarding contraceptive use is immediately needed to guide the prompt development and deployment of a culturally appropriate communication campaign during USVI's Zika virus outbreak to prevent adverse outcomes associated with Zika virus infection during pregnancy. Therefore, CDC requests a 180-day emergency clearance to carry out focus groups involving women and men between the ages of 18 and 44 years living in the USVI who are interested in delaying or avoiding pregnancy during the Zika virus outbreak.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business November 4, 2016.

Respectfully,


Jonathan Mermin, MD, MPH
Director, National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention