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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16ARP]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Zika Virus Persistence in Body Fluids of Patients with Zika Virus Infection in Puerto Rico (ZIPER Study) – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Zika virus (ZIKV) is a mosquito-borne flavivirus that has recently emerged in the Americas. Previously, outbreaks had occurred in Asia and islands in the South Pacific. In addition to mosquito-to-human transmission, ZIKV infections have been documented through sexual transmission, blood transfusion, laboratory exposure, intrauterine transmission resulting in congenital infection, and intrapartum transmission from a viremic mother to her newborn. Along with serum, ZIKV RNA has been detected in semen, urine, breast milk, and amniotic fluid. ZIKV IgM antibodies are generally first detectable at 4 to 8 days after onset of illness and likely persist for weeks to months; however, the duration of persistence of anti-ZIKV IgM antibodies is unknown as well as the timing from infection to the development of IgG antibodies. The prevalence of ZIKV RNA in various body fluids among patients with acute ZIKV infection and the length of time that ZIKV RNA might persist in these body fluids is not well understood, nor the frequency with which it is infectious. Characterizing these parameters has implications both for diagnosis of ZIKV infection using specimens other than blood than may be more convenient to collect, as well as for potential human-to-human transmission.

The Zika PERsistence (ZIPER) study will help inform the presence and duration of ZIKV shedding in several body fluids

among RT-PCR-positive ZIKV cases from Puerto Rico. It will also provide information regarding the duration of detection of anti-ZIKV IgM antibodies and the time for development of IgG antibodies among the same population. In addition, this protocol will determine the prevalence of anti-ZIKV IgM and IgG, and virus shedding in body fluids among household contacts of ZIKV cases.

We propose to investigate the persistence (shedding) of ZIKV in different body fluids and its relation to immune response to provide a basis for development of non-blood-based diagnostic tools, and target and refine public health interventions to arrest ongoing spread of infection. To do so, we will conduct a prospective cohort study of individuals with reverse transcription-polymerase chain reaction (RT-PCR) positive ZIKV infection and a cross-sectional study of their household contacts. Results and analyses will be used to update relevant counseling messages and recommendations from the CDC.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 374.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses	Avg. Burden per

			per Respondent	Response (in hrs.)
Public Health Personnel	Shedding Questionnaire (Symptomatics)	200	8	10/60
	Shedding Questionnaire (Cross-Sectional Asymptomatics)	400	1	10/60
General Public	Shedding Eligibility Form	1,000	1	2/60
	Contact Information Form	200	1	2/60

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