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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16ASR]

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

Persistence of Zika Virus in Semen and Urine of Adult Men in the United States with Confirmed Zika Virus Infection - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Zika virus is an arthropod-borne flavivirus that has recently emerged in the Americas. Maternal infection has been linked to congenital microcephaly, fetal loss, and other adverse reproductive health outcomes. Although spread primarily by mosquitoes, recent reports have highlighted the potential for sexual transmission of Zika virus through the semen of infected men. Detection of viral RNA in semen 62 days after illness onset has been reported; however the frequency and duration of virus shedding is largely unknown. Information on these parameters is needed urgently to better inform public health recommendations, particularly for couples contemplating pregnancy.

This study will fill gaps in the scientific knowledge base for Zika virus regarding the persistence and transmissibility of Zika virus in body fluids, and determine the frequency and duration of Zika virus shedding in semen and urine of infected men. Minimal health information and specimens from consenting men with recent Zika virus infection will be collected once every two weeks for up to 6 months post onset of symptoms (or up to 12 collections). Specimens will be tested for Zika RNA by reverse transcriptase polymerase chain reaction assay (RT-PCR) at CDC; those testing positive may be further evaluated by virus isolation techniques. Zika virus disease is a nationally

notifiable condition, and participants will be recruited through contact with CDC personnel. Urine and semen specimens will be self-collected using home collection kits, a short questionnaire will be self-administered, and participants will be compensated for their time. Results of testing will be provided to participants at the conclusion of testing. The results of this study are expected to have immediate implications for public health recommendations and disease prevention.

This is a prospective, descriptive cohort study. The prospective nature of the proposed cohort study allows for determining the persistence of shedding Zika virus in semen and urine through serial specimen collection from individuals with confirmed Zika virus.

The results of this study will be of great relevance to provide evidence-based information to circumvent Zika virus transmission. They will inform the development of recommendations used in the current epidemic setting, as well as in future Zika virus situations. Results and analysis will be used to update and refine relevant counseling messages and recommendations. Potential products include scientific abstracts and manuscripts, presentations, and guidance documents.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 134.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
General Public	Introductory Survey	250	1	20/60
	Follow-up survey	250	12	1/60

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