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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-1140]

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) (OMB Control Number 0920-1140, Expiration Date 10/31/2017) – Revision – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking a one-year OMB approval to extend the ZIPER Study information collection.

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 study 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.

The study will include baseline and follow-up questionnaires and the collection of the following specimens:

blood, saliva, urine from participants of all ages, and semen/vaginal secretions from adults (ages 21 years or older) and legally emancipated minors (support themselves financially, live independent of their parents, are pregnant, or have children).

Individuals with RT-PCR positive ZIKV infection will be recruited through the Sentinel Enhanced Dengue Surveillance System (SEDSS) at Saint Luke's Episcopal Hospital in Ponce, Puerto Rico and through passive surveillance in selected municipalities in Puerto Rico. SEDSS was established in 2012 through a cooperative agreement between the hospital in Consortium with the Ponce School of Medicine and Ponce Research Institute from the Ponce Health Sciences University and the CDC (Protocol #6214).

Specimens will be tested for the presence of ZIKV RNA by RT-PCR at the CDC Dengue Branch Laboratory in San Juan, and positive specimens will be further tested for virus isolation to evaluate infectivity. Each body fluid will be collected on a weekly basis for four weeks and biweekly thereafter until two consecutive negative RT-PCR results are obtained from all specimens. Irrespective of RNA detection, body fluids will also be collected for RT-PCT at 2, 4, and 6 months to investigate intermittent shedding. Analyses of antibody response through

titers of IgM and IgG will be performed at baseline and repeated at 2, 4, and 6 months.

Among symptomatic participants seven milliliters of blood will be drawn at each study visit split into a tiger top tube (5ml) and a purple top tube (2ml) for a total not to exceed 50 ml during any given 8-week period. At enrollment healthy non-pregnant adults will have 20 ml of blood collected following standard procedures. Two tiger top tubes of 8.5 ml and one 3ml purple top tubes will be collected. These procedures will be repeated at each follow-up visit.

RT-PCR-positive participants will be asked to refer up to five household members to establish the percentage of household members with detectable and potentially infectious Zika virus RNA in body fluids. Household members who are found to be ZIKV RT-PCR-positive in any body fluid will be invited to participate in the cohort study. A second study visit will be scheduled with household contact at 2 or 4 months, to detect new infections and estimate incidence. Because the original study consent forms do not include this visit, household contacts will be contacted by study staff and will be consented again using the same consent form.

Since gaining OMB approval in October 2016, the project has enrolled 295 Zika virus-infected individuals into the Zika virus

Persistence study, which is 55 individuals below the target enrollment of 350 individuals.

Preliminary findings have been published in New England Journal of Medicine, where we also expect that the final report that includes the full sample size will be published.

This is a request to continue information collection with minor modifications. Modifications have been made to reflect the developing nature of the science surrounding Zika virus infection and potential outcomes associated with infection, as well as additional questions that were best answered by taking advantage of the existing study platform. Specifically, CDC proposes the addition of two components to the collection of data under this study, one of which has already begun:

1. A follow-up household visit has been added to determine how many household members of Zika virus-infected participants become infected during the 4 months following initial screening. For any household members that had no evidence of Zika virus infection at the initial visit, the same questionnaires used at the initial household visit will again be completed ~4 months later. Such information will provide additional information regarding the incidence of Zika virus infections among households with a Zika-positive household member.

2. Additionally, CDC proposes following up with men with Zika virus-positive semen specimens to better understand the effect of Zika virus infection on sperm. To do this, 8-14 semen ejaculates from 10-20 men participating in the ZIPER study will be used to determine the presence and/or detection of the Zika virus in different fractions of the semen ejaculate (i.e., seminal plasma, cellular debris, including White Blood Cells and spermatozoa). CDC has received Institutional Review Board approval for this modification, but information collection has not begun.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 USC 241). The total estimated annualized number of burden hours is 243. There is no cost to respondents other than the time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Public health personnel	Shedding Questionnaire	18	30	15/60
General public	Shedding Questionnaire (Symptomatics)	55	8	10/60
	Shedding Questionnaire (Cross-Sectional Asymptomatics)	100	1	10/60

	Questionnaire for men in Semen sub-study	30	1	20/60
	Shedding Eligibility Form	160	1	2/60
	Contact Information Form	32	1	2/60

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