BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-xxxx]

[Docket No. CDC-2016-xxxx]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Emergency zika package II: Persistence of zika virus in body fluids and case-control investigation of etiologic agents associated with Guillain-Barré

Syndrome.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-201x-xxxx by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information

collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information

to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Emergency zika package II: Persistence of zika virus in body fluids and case-control investigation of etiologic agents associated with Guillain-Barré Syndrome – New – National Center for Emerging and Zoonotic Diseases (NCEZID), Centers for Disease

Control and Prevention (CDC).

Background and Brief Description

This information collection request consists of two separate projects dealing with the CDC's response to the zika virus outbreak:

1. Persistence of Zika virus(ZIKV)RNA and IgM in body fluids of patients with acute Zika virus infection in the United States

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 though their duration in serum is unknown. 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. Characterizing these parameters has implications both for potential human-to-human

transmission and for diagnosis of ZIKV infection.

CDC proposes to investigate the persistence of ZIKV in different body fluids (shedding) 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 symptomatic individuals with reverse transcription-polymerase chain reaction (RT-PCR) positive ZIKV infection and a cross-sectional study of their asymptomatic household contacts. Results and analyses will be used to update relevant counseling messages and recommendations from the CDC.

2. Case-Control Investigation of Etiologic Agents Associated with Guillain-Barré Syndrome

There is an urgent public health need to understand the potential association between GBS and ZIKV infection. Currently, increased numbers of GBS cases have been reported in ZIKV-affected contexts, but it is not known if this is due to ZIKV, another etiologic agent, or some combination/interaction thereof. PRDH is establishing GBS surveillance and defining baseline incidence toward investigating the association between GBS and ZIKV infection in Puerto Rico. More broadly, the results of this investigation would be relevant to other ZIKV-affected contexts, serving toward enabling clinical and/or public health action to

manage and prevent additional cases.

A case-control investigation will be conducted to identify potential risk factors for the development of GBS. As part of the investigation, blood specimens will be collected from GBS cases and matched controls to evaluate for antibodies against several pathogens known to cause GBS (e.g., influenza) or pathogens hypothesized to contribute to this illness cluster (e.g., ZIKV, dengue virus, chikungunya virus, HIV, Campylobacter jejuni, Leptospira species bacteria).

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Public health personnel	Shedding Questionnaire (Symptomatics)	350	8	10/60	467
	Shedding Questionnaire (Cross-Sectional	1,000	1	10/60	167

	Asymptomatics)				
	GBS Chart abstraction questionnaire	10	6	1	60
General public	GBS Questionnaire for cases and controls	120	1	15/60	30
	Shedding Eligibility Form	1,350	1	2/60	45
Total					769

Dated:

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Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention