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 Zika Emergency Package III: Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection which will determine the frequency

and duration of Zika virus RNA in bodily fluids of infected adult men.

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-2016-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

Zika Emergency Package III: Persistence of Zika virus in semen and urine of adult men 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.

The purpose of this study is to 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 receive a token of appreciation. 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.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
General public	Introductory survey	250	1	2/60	8.5
	Follow-Up survey	250	12	1/60	50
Total					58.5

Dated:

_____

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