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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-1143; Docket No. CDC-2019-0009]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled US Zika Pregnancy registry, is to seek Paperwork Reduction Act (PRA) clearance to monitor the frequency and types of adverse birth outcomes for women with laboratory evidence of Zika virus infection during pregnancy and their infants and to strengthen the public health response to the Zika virus disease outbreak.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0009 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Lead, 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

Proposed Project

US Zika Pregnancy Registry (OMB Control No. 0920-1143, Expiration 11/30/2019) - Extension - National Center on Birth Defects and

Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. As of March 16, 2016, local transmission has been identified in at least 32 countries or territories in the Americas. Further spread to other countries in the region is likely. Local vector-borne transmission of Zika virus has not been documented in the 50 U.S. states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands, and American Samoa. However, Zika virus infections have been reported in travelers returning to the United States from areas with active Zika virus transmission. Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for Zika virus acquisition. With the ongoing outbreak in the Americas, the number of Zika virus disease cases among travelers returning to the United States likely will increase, and sexual transmission from male travelers to their sex partners in the United States will likely continue to occur. In addition, mosquito-borne local transmission may occur in states where Aedes species mosquitoes are present.

In some Brazilian states where Zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses in women infected during pregnancy. In addition to microcephaly, a range of other problems have been detected among fetuses and infants infected with Zika virus before birth, such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth. The Ministry of Health in Brazil, with support from the Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), and other partners, is investigating the association between Zika virus infection and microcephaly, as well as other adverse pregnancy and infant outcomes.

Zika virus disease and Zika virus congenital infection are nationally notifiable conditions for which the Council of State and Territorial Epidemiologists (CSTE) has established interim case definitions. All 50 states, the District of Columbia, and Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands currently participate in reporting of arboviral diseases through ArboNET. However, ArboNET does not capture all the information needed to provide timely situational awareness in the context of the ongoing public health response. In particular, ArboNET collects limited data on pregnancy, pregnancy and birth outcomes, and congenital infections, all of which are necessary for informing ongoing response efforts.

As part of the public health response to the Zika virus disease outbreak, CDC will conduct supplemental surveillance of antenatal diagnostic testing and clinical outcomes among pregnant women with laboratory evidence of Zika virus or unspecified flavivirus infection and their infants through the U.S. Zika Pregnancy Registry. It is anticipated that the Registry will provide critical information to direct CDC clinical recommendations and public health guidance and messages.

The data to be collected for the Registry includes information about Zika infection-related tests and procedures conducted as part of the mother's and child's routine clinical care, and in line with existing CDC, American College of Obstetricians and Gynecologists and Society of Maternal Fetal Medicine, and American Academy of Pediatrics recommendations for evaluation, diagnosis, and follow-up of women infected with Zika virus during pregnancy and their children. No additional tests or procedures will be performed specifically for Registry purposes.

This request is submitted to extend the collection period of collection OMB number 0920-1143 for an additional three years. The total estimated annual burden hours are 23,833. There are no costs to the respondents other than their time.

Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in	Total Burden Hours

				hours)	
State, Territorial and Local Health Departments	Maternal Health History Form	1100	10	30/60	5500
	Supplemental Imaging Form	1100	10	10/60	1833
	Laboratory Results Form	1100	10	15/60	2750
Clinicians and Other Providers	Assessment at Delivery Form	1100	10	30/60	5500
	Infant Health Follow-Up Form	1100	30	15/60	8250
Total					23,833

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity

Office of Science

Centers for Disease Control and Prevention

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