ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Women with recent births	Maternal hospital-based questionnaire.	2,760	1	25/60	1,150
Fathers with recently born infants	Father hospital-based questionnaire	1,104	1	15/60	276
Women with live births 2–10 months prior.	Follow-up phone questionnaire	2,868	1	15/60	717
Total					2,143

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.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17NF; Docket No. CDC–2017–0006]

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 a proposed information collection project titled ''ZIRP Puerto Rico Study: Zika Virus RNA Persistence in Pregnant Women and Congenitally-Infected Infants in Puerto Rico.''

DATES: Written comments must be received on or before June 19, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0006 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., 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 Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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

ZIRP Puerto Rico Study: Zika Virus RNA Persistence in Pregnant Women and Congenitally-Infected Infants in Puerto Rico—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Zika virus (ZIKV) infection is a mosquito-borne flavivirus transmitted by *Aedes* species mosquitoes, and also through sexual and mother-to-child transmission; laboratory-acquired infections have also been reported. Evidence of human ZIKV infection was observed sporadically in Africa and Asia prior to 2007 when an outbreak of ZIKV caused an estimated 5,000 infections in the State of Yap, Federated States of Micronesia.

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; however, the duration of persistence of anti ZIKV IgM antibodies is unknown as well as the timing form infection to the development of IgG antibodies. 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, nor the frequency with which it is infectious.

A few small studies have suggested that testing pregnant women for Zika virus (ZIKV) more than seven days from symptom onset might detect women with persistence of ZIKV RNA. Less is known about persistent ZIKV RNA in congenitally-infected infants.

The Puerto Rico Department of Health (PRDH) reported the first case of autochthonous transmission of Zika Virus (ZIKV) in December 2015. As of December 16, 2016, 35,648 confirmed ZIKV cases had been reported in Puerto Rico, more than any other location in the U.S., and the number is expected to rise. Among the confirmed cases, 2,864 have been among pregnant women, and the first case of microcephaly in a fetus with confirmed ZIKV infection was announced by the PRDH on May 13, 2016. Currently, testing for ZIKV infection can be done by either using rRT–PCR to detect the presence of ZIKV RNA or by serologic testing to detect IgM and neutralizing antibodies. rRT–PCR testing has been the preferred and suggested method for diagnosing ZIKV infection, but has a shorter testing window.

ZIKV RNA typically only persists in serum for 3–7 days and is thought to be cleared by 10 days. Currently, CDC recommends that all pregnant women living in areas with active ZIKV transmission such as Puerto Rico be tested. Symptomatic pregnant women should have serum and urine tested for the presence of ZIKV RNA by rRT–PCR within two weeks of symptom onset. Symptomatic pregnant women being tested more than two weeks after symptom onset and symptomatic women with negative rRT–PCR test results should have serologic testing. Asymptomatic pregnant women are recommended to have serologic testing at the initiation of prenatal care and again during their first and second trimesters as a part of routine care; serum and urine rRT–PCR testing should be done after a positive or equivocal serological test result.

Limited data from human studies suggest that pregnant women have persistent detection of ZIKV RNA. In one case report, a pregnant woman became symptomatic at 11 weeks gestation and was rRT–PCR-positive at 16 weeks gestation. In another case report, a pregnant woman tested positive by rRT–PCR 107 days after symptom onset. A recent case series found persistent detection of ZIKV RNA in five pregnant women. Symptomatic women had detectable virus at 17, 23, 44, and 46 days post symptom onset and one asymptomatic woman was still rRT–PCR positive 53 days after returning from travel. This pattern has led to the hypothesis that persistent detection of ZIKV RNA in pregnant women may be a marker of fetal infection and thus potentially a marker of adverse fetal outcomes including microcephaly.

Additionally, researchers have speculated that fetal infection might be influenced by viral load as well as persistence. The increasing number of cases and stage of the outbreak in Puerto Rico provide an opportunity to collect actionable information on a shorter timeframe than is possible elsewhere.

The ZIRP Puerto Rico study aims to determine the prevalence and duration of ZIKV RNA persistence in pregnant women and congenitally infected infants. This information will be essential for establishing guidance for testing and clinical management of pregnant women and congenitally infected infants with exposure to ZIKV. Moreover, this study is expected to provide critical scientific information to help the United States prepare for the unprecedented challenges posed by Zika and possible clinical guidelines related to ZIKV RNA testing.

CDC is requesting emergency OMB review for six months of clearance. However, because information collection is expected to take two years, CDC will submit a non-emergency information collection request to OMB for an additional two years of clearance.

Authorizing Legislation for this information collection comes from Section 301 of the Public Health Service Act (42 U.S.C. 241)

There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
ZIKV positive Pregnant women	Pregnant women screening form	150	1	2/60	5
	Pregnant women enrollment questionnaire.	150	1	8/60	20
	Pregnant women symptom questionnaire.	150	1	8/60	20
	Pregnant women follow-up questionnaire.	150	48	8/60	960
Parents of ZIKV positive Infants	Infant enrollment questionnaire	150	1	8/60	20
	Infant sample collection questionnaire.	150	1	8/60	20
	Infant follow-up questionnaire	150	6	8/60	120
Total					1,165

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–17ABB]

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.* Direct written comments and/or suggestions regarding the items contained in this notice 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

ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia—New—Pregnancy and Birth Defects Task Force, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Zika virus (ZIKV) infection is a mosquito-borne flavivirus transmitted by *Aedes* species mosquitoes, and also through sexual and mother-to-child transmission; laboratory-acquired infections have also been reported. Evidence of human ZIKV infection was observed sporadically in Africa and Asia prior to 2007, when an outbreak of ZIKV caused an estimated 5,000 infections in the State of Yap, Federated States of Micronesia. Since then, evidence of ZIKV has been found in 65 countries and territories, mostly in Central and South America. Common symptoms of ZIKV in humans include rash, fever, arthralgia, and nonpurulent conjunctivitis. The illness is usually mild and self-limited, with symptoms lasting for several days to a week; however, based on previous outbreaks, some infections are asymptomatic. The prevalence of asymptomatic infection in the current Central and South American epidemic is unknown.

Although the clinical presentation of ZIKV infection is typically mild, ZIKV infection in pregnancy can cause microcephaly and related brain abnormalities when fetuses are exposed *in utero.* Other adverse pregnancy outcomes related to ZIKV infection remain under study, and include pregnancy loss, other major birth defects, arthrogryposis, eye abnormalities, and neurologic abnormalities.

As the spectrum of adverse health outcomes potentially related to ZIKV infection continues to grow, large gaps remain in our understanding of ZIKV infection in pregnancy. These include the full spectrum of adverse health outcomes in pregnant women, fetuses, and infants associated with ZIKV infection; the relative contributions of sexual transmission and mosquito-borne transmission to occurrence of infections in pregnancy; and variability in the risk of adverse fetal outcomes by gestational week of maternal infection or symptoms of infection. There is an urgency to fill these large gaps in our understanding given the rapidity of the epidemic's spread and the severe health outcomes associated with ZIKV to date.

Colombia's Instituto Nacional de Salud (INS) began surveillance for ZIKV in 2015, reporting the first autochthonous transmission in October 2015 in the north of the country. As of October 2016, Colombia has reported over 105,000 suspected ZIKV cases, with over 19,000 of them among pregnant women. With a causal link established between ZIKV infection in pregnancy and microcephaly, there is an urgent need to understand: How ZIKV transmission can be prevented; the full spectrum of adverse maternal, fetal, and infant health outcomes associated with ZIKV infection; and risk factors for occurrence of these outcomes. To answer these questions, INS and CDC will follow 5,000 women enrolled in the first trimester of pregnancy, their male partners, and their infants, in various cities in Colombia where ZIKV transmission is currently ongoing.

The primary research questions we aim to address with the ZEN Colombia study are:

1. Evaluate associations between ZIKV in pregnancy and adverse pregnancy or maternal outcomes, such as preterm birth, preeclampsia, maternal death, postpartum hemorrhage, and intrapartum fetal demise, among others. Effect modification by gestational age of infection will also be explored.

2. Quantify the magnitude of the association between ZIKV infection in pregnancy and major birth defects, with specific focus on microcephaly and congenital Zika syndrome. The prospective design of the study will allow estimation of both absolute and relative risk for microcephaly for women with ZIKV infection during pregnancy.

3. Identify risk factors for symptomatic ZIKV infection in pregnancy among all women with laboratory-confirmed ZIKV in pregnancy. A spectrum of risk factors will be considered, including maternal demographics, ZIKV infection characteristics, and other potential risk factors such as smoking and medication use.

4. Identify risk factors for ZIKV infection in infancy. A spectrum of risk factors will be explored, including maternal infection factors and birth and pregnancy factors.

5. Identify risk factors for symptomatic ZIKV infection in infancy among infants with laboratory-confirmed ZIKV born to women enrolled in the study. A spectrum of risk factors will be considered, including maternal ZIKV infection in pregnancy factors, co-infections, sociodemographic characteristics and birth factors.