



**BILLING CODE: 4163-18-P**

**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 the U.S. Centers for Disease Control and Prevention (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 study objectives are to: 1) Describe the

sociodemographic and clinical characteristics of the study population; 2) Identify risk factors for ZIKV infection in pregnant women and their infants. These include behaviors such as use of mosquito-bite prevention measures or condoms, and factors associated with maternal-to-child transmission; 3) Assess the risk for adverse maternal, fetal, and infant outcomes associated with ZIKV infection; 4) Assess modifiers of the risk for adverse outcomes among pregnant women and their infants following ZIKV infection. This includes investigating associations with gestational age at infection, presence of ZIKV symptoms, extended viremia, mode of transmission, prior infections or immunizations, and co-infections.

The project aims to enroll approximately 5,000 women, 1,250 male partners, and 4,500 newborns. Pregnant women will be recruited in the first trimester of pregnancy for study enrollment, followed by assessments during pregnancy (every other week until 32 weeks gestation and monthly thereafter), and within 10 days postpartum. At all visits, participants will complete visit-specific questionnaires. In addition to the questionnaires, at all pregnancy and delivery visits, participants will receive Colombian national recommended clinical care and provide samples for laboratory testing.

Male partners will be recruited around the time of the pregnant partners' study enrollment, followed by monthly visits

until his pregnant partner reaches the third trimester (approximately 27 weeks gestation). If the male partner contracts ZIKV during this time, visits will occur every other week until the partner has two negative consecutive tests for ZIKV or the pregnancy ends. At all study visits, male partners will complete visit-specific questionnaires and provide samples for laboratory testing.

All newborns of mothers participating in the study will be followed every other week from birth to 6 months of age. At all visits, infants will receive national recommended clinical care (at birth and clinic visits at 1, 2, and 6 months), provide samples for laboratory testing, and mothers will complete study-specific questionnaires about infant ZIKV symptoms and developmental milestones. During follow-up, infants will also have cranial ultrasounds, their head circumference measured, and hearing and vision tests. For mothers and their infants, relevant information collected as part of clinical care will be abstracted from medical records. Study results will be used to guide recommendations made by both INS and CDC to prevent ZIKV infection; to improve counseling of patients about risks to themselves, their pregnancies, their partners, and their infants; and to help agencies prepare to provide services to affected children and families. Participation in this study is voluntary. The estimated number of annual Burden Hours are

20,548 and there are no costs to participants other than their time.

Estimated Annualized Burden Hours

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Pregnant women	Pregnant women eligibility questionnaire	3,125	1	5/60
	Pregnant women enrollment questionnaire	2,500	1	35/60
	Adult symptom questionnaire	2,500	15	10/60
	Pregnant women follow-up questionnaire	2,500	8	15/60
	Infant symptoms questionnaire	2,250	14	10/60
	Infant Ages and Stages Questionnaire : 2 Month	2,250	1	15/60
	Infant Ages and Stages Questionnaire : 6 Month	2,250	1	15/60
Male partners	Male partner eligibility questionnaire	2,500	1	5/60
	Male enrollment questionnaire	625	1	25/60
	Adult symptom questionnaire	625	7	10/60

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