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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.

6. Investigate associations between ZIKV infection in utero or in infancy and hearing loss and other physical, neurologic, and neurodevelopmental outcomes at 6 months of age.

7. Estimate survival of infants born to ZIKV infected mothers.

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

1. Identify risk factors for ZIKV infection in pregnant women, partners and infants. A spectrum of risk factors will be explored, including mosquito bites and mosquito bite preventive measures, sexual transmission, sociodemographic characteristics, and medical risk factors. The results of this analysis will provide information on the reduction in risk associated with adherence to recommended preventive measures and risk factors for infection in pregnant women.

2. Identify characteristics associated with taking preventive measures (mosquito bite prevention, sexual transmission) against contracting Zika virus among pregnant women and their partners. The results of this analysis will assist in targeting education or intervention to individuals at greatest risk for Zika infection.

3. Describe symptoms associated with ZIKV and estimate the positive predictive value of certain symptoms or constellations of symptoms in pregnant women, men, and infants to allow for refinement of clinical diagnosis of ZIKV infection in a setting in which testing and/or results might not be readily available.

4. Assess the duration of viremia following ZIKV infection and investigate risk factors (such as sociodemographics, comorbidities, and co-infections) associated with prolonged viremia among pregnant women, men, and infants with laboratory-confirmed ZIKV infection in blood.

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 at or within 72 hours of delivery. 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, 3, and 6 months), provide samples for laboratory testing, and mothers will complete study-specific questionnaires about infant ZIKV symptoms. Infants will also have cranial ultrasounds at birth, their head circumference measured (birth, 72 hours, 1, 2, 3, and 6 months of age), and enhanced hearing/vision tests at 1 and 6 months old. 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 total estimated annualized burden hours are 19,415, and there are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number 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
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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications/contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications/contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; HPV Review.

Date: May 10, 2017.