investigation. After clinical reports and field observation of a broader range of health endpoints, this larger investigation is now being undertaken to expand the exploration of the association of Zika virus infection with not only Guillain-Barre syndrome but also other severe neurologic illnesses.

Under this request, case and control interviews similar to those conducted under the previously approved information collection will be conducted using the questionnaire developed by the investigation team. All cases and controls will be asked questions about activities, antecedent signs and symptoms of illness, and exposures in the two months prior to onset of neurologic illness for cases and the same time period for their matched controls. A calendar will be used to orient cases and controls to the time period of interest.

As in the previously approved information collection activities, sera, urine, and saliva will be collected from cases and controls at the time of interview using standard techniques. The sera will be tested for antibodies against suspected infectious pathogens, such as ZIKV, dengue virus, chikungunya virus, influenza virus, human immunodeficiency virus, and Leptospira species bacteria. Urine specimens will be tested by rRT–PCR to identify ZIKV, dengue virus, or chikungunya virus.

If any residual specimens are available from cases, those will also be obtained and undergo testing for infectious pathogens. It is not expected that matched controls will have any previously collected clinical specimens; however, in cases where controls had specimens collected while seeking medical care for an acute illness experienced within two months of GBS symptom onset of the matching case, these specimens will also be collected and tested for evidence of infection with the aforementioned pathogens.

Residual samples will be stored after infectious testing is complete at the U.S. CDC with an identification number for possible additional testing for GBS-associated biological markers or other infectious pathogens as clinically indicated. If a participant does not provide consent to store the specimens, all specimens for that participant will be destroyed once testing for infectious disease pathogens has been completed. As with cases, written consent will also be obtained to review controls' medical records, where applicable and available, using a standardized chart abstraction form. Diagnostic test results will be securely transmitted from CDC to PRDH, which will then transmit diagnostic test results to participants by telephone or mail, as they prefer.

Data analysis will focus on potential demographic, environmental, and/or medical risk factors for developing neurologic illness, as well as laboratory evidence for infection with the aforementioned pathogens.

The total number of estimated annualized burden hours for this project is 90. There are no other costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Personnel	Severe Neurologic Illness Chart Abstraction Questionnaire.	10	6	1	60
General Public	Severe Neurologic Illness Questionnaire for Cases and Controls.	120	1	15/60	30
Total					90

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.

[FR Doc. 2016–27692 Filed 11–16–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–16BGA; Docket No. CDC–2016–0106]

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 entitled ''ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia.'' This collection intends to identify risk factors for Zika virus (ZIKV) infection in pregnant women and their infants, assess the risk for adverse maternal, fetal, and infant outcomes associated with ZIKV infection and, assess modifiers of the risk for adverse outcomes among pregnant women and their infants following ZIKV infection.

DATES: Written comments must be received on or before January 17, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0106 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 the 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

ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia—New—Pregnancy and Birth Defects Task Force, 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; sexual transmission, mother-to-child transmission, and 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 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; 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 August 2016, Colombia has reported over 102,000 suspected ZIKV cases, over 18,000 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 two to four cities in Colombia where ZIKV transmission is currently ongoing.

The primary objectives of the study are to (1) 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; (2) Assess the risk for adverse maternal, fetal, and infant outcomes associated with ZIKV infection and; (3) 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.

Pregnant women will be recruited in the first trimester of pregnancy at participating clinics in Colombia's private and public health care systems and followed through their pregnancy, delivery, and immediate postpartum period. Study visits will coincide with routine prenatal care clinic visits (monthly), and at these visits, mothers will be monitored for incident ZIKV infection by collection of blood. In addition, women will be asked to complete a questionnaire about behavioral, sexual, environmental, or other risk factors for ZIKV or adverse pregnancy outcomes and a ZIKV symptoms questionnaire. In between clinic visits (approximately two weeks after the clinic visit), a home visit will be conducted where a urine sample from the pregnant woman will be collected. Mothers will complete a ZIKV symptom questionnaire at the time of the home visit. Fetal ultrasound evaluation will occur once per trimester. If ZIKV is detected during pregnancy, monthly fetal ultrasounds will be conducted and women will provide

blood biweekly at the clinic or hospital until there are 2 consecutive negative blood tests for ZIKV. Fetal tissue will be collected for pregnancy losses to assess fetal ZIKV infection. All pregnancy outcomes and any additional testing during pregnancy or in the immediate neonatal period as part of clinical care will be abstracted from medical records.

Male partners will be recruited via their pregnant partners around the time of their pregnant partners' enrollment into the study. At enrollment, men will complete a baseline questionnaire and ZIKV symptom questionnaire and provide a blood sample. Urine samples in men will be collected at home every 2 weeks through the second trimester of pregnancy to monitor for incident ZIKV infection. Men will complete a ZIKV symptom questionnaire at the time of each specimen collection. If a man becomes symptomatic, he will be asked to provide a blood sample at the clinic for ZIKV testing. If ZIKV is detected, semen collection at home will be scheduled every two weeks until there are 2 consecutive negative tests, or the end of pregnancy. In addition, if a man's at-home urine sample is positive, he will again be asked to participate in semen collection at home every two weeks until there are 2 consecutive negative tests, or the end of pregnancy.

All newborns of mothers participating in the study will be followed from birth to 6 months of age. A blood sample will be collected at delivery or no later than 3 days after delivery. Urine samples and information on infant's symptoms will be collected every 2 weeks at home visits to monitor for ZIKV infection in infancy. Additionally, any infant health conditions or results from medical testing during this 6-month period conducted as part of routine clinical care will be abstracted from medical records.

INS and CDC will use the study results to guide their recommendations 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.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Pregnant women	Pregnant women eligibility questionnaire.	6,250	1	5/60	520
	Pregnant women enrollment questionnaire.	5,000	1	20/60	1,666
	Adult symptom questionnaire	5,000	12	5/60	5,000
	Pregnant women follow-up questionnaire.	5,000	12	15/60	15,000
	Infant symptoms questionnaire	4,500	4	5/60	1,500
Male partners	Male partner eligibility questionnaire	5,000	1	5/60	417
	Male enrollment questionnaire	1,250	1	15/60	312
	Adult symptom questionnaire	1,250	12	5/60	1,250
Total					25,665

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

[60Day–17–0881; Docket No. CDC–2016–0109]

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 ''Data Calls for the Laboratory Response Network'' collected from its members concerning their capacity to respond to public health threat emergencies.

DATES: Written comments must be received on or before January 17, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0109 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 the 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