releases and determine their health statuses;

2. Identify needs (*i.e.,* medical and basic) of those exposed during the releases to aid in planning interventions in the community;

3. Assess the impact of the incidents on health services use and share lessons learned for use in hospital, local, and state planning for chemical incidents; and

4. Identify cohorts may be followed and assessed for persistent health effects resulting from acute releases.

Because each chemical incident is different, it is not possible to predict in advance exactly what type of and how many respondents will be consented and interviewed too effectively evaluate the incident. Respondents typically include, but are not limited to emergency responders such as police, fire, hazardous material technicians, emergency medical services, and personnel at hospitals where patients from the incident were treated. Incidents may occur at businesses or in the community setting; therefore, respondents may also include business owners, managers, workers, customers, community residents, pet owners, and those passing through the affected area.

The multidisciplinary ACE team consisting of staff from ATSDR, the Centers for Disease Control and Prevention (CDC), and the requesting agencies that will be collecting data. ATSDR has developed a quickly tailored series of draft survey forms used in the field to collect data that will meet the goals of the investigation. ATSDR collections will be administered based on time permitted and urgency. For example, it is preferable to administer the general survey to as many respondents as possible. However, if there are time constraints, the shorter household survey or the ACE Short Form may be administered instead. The individual surveys collect information about exposure, acute health effects, health services use, medical history, needs resulting from the incident, communication during the release, health impact on children and pets, and demographic data. Hospital personnel are asked about the surge, response and communication, decontamination, and lessons learned.

Depending on the situation, data collected by face-to-face interviews, telephone interviews, written surveys, mailed surveys, or on-line surveys can be consider collected. Medical and veterinary charts may also be consider for review. In rare situations, an investigation might involve collection of clinical specimens.

ATSDR anticipates up to four ACE investigations per year. The number of participants has ranged from 30–715, averaging about 300 per year. Therefore, the total annualized estimated burden will be 591 hours per year. Participation in ACE investigations is voluntary and there are no anticipated 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)
Residents, first responders, business owners, employees, customers.	General Survey	800	1	30/60	400
	ACE Short Form	50	1	7/60	6
Residents	Household Survey	120	1	15/60	30
Hospital staff	Hospital Survey	40	1	30/60	20
Staff from state, local, or tribal health agencies.	Medical Chart Abstraction Form	250	1	30/60	125
	Veterinary Chart Abstraction Form	30	1	20/60	10
Total					591

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. 2017–18404 Filed 8–29–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–1190; Docket No. CDC–2017–0073]

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 the proposed project titled ''ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia.''

DATES: Written comments must be received on or before October 30, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0073 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

ZEN Colombia Study: Zika in Pregnant Women and Children in Colombia, (OMB No. 0920–1190, expires 07/31/2019)—Revision—Pregnancy and Birth Defects Task Force, National Center for 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 through sexual and mother-to-child transmission. Laboratory-acquired infections have also been reported.

Health officials observed sporadic evidence of human ZIKV infection 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, health officials have found evidence of ZIKV 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 December 2016, Colombia has reported over 106,000-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 to prevent ZIKV transmission; 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 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, 4,500 newborns, and a subset of 1000 infants/children. 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.

Researchers will recruit male partners 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.

Researchers will follow all study-participating mothers' newborns every other week from birth to 6 months of age. At all visits, infants will receive national recommended clinical care (at birth and follow-up 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, researchers will abstract relevant clinical care information from medical records.

The revised information collection package includes the following changes. During the data collection period, researchers will follow a subset of 300 infants until 2-years of age. These infants will have answer questionnaires at 6, 12, 18, and 24 months, as well as have other clinical assessments performed to exam developmental delays.

Researchers will use the study results use 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 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)	Total burden hours
Pregnant women	Pregnant women eligibility questionnaire	3,125	1	5/60	260
	Pregnant women enrollment questionnaire	2,500	1	35/60	1,458
	Adult symptoms questionnaire	2,500	15	10/60	6,250
	Pregnant women follow-up questionnaire	2,500	8	15/60	5,000
	Infant symptoms questionnaire	2,250	14	10/60	5,250
	Ages and Stages Questionnaire: 2, 4, 6 Month.	2,250	2	15/60	1,125
		300	3	15/60	225
	Ages and Stages Questionnaire: 12, 18, 24 Month.	300	3	5/60	75
	Center for Epidemiologic Studies Depression—10.				
Male partners	Male partner eligibility questionnaire	2,500	1	5/60	208
	Male enrollment questionnaire	625	1	25/60	260
	Adult symptoms questionnaire	625	7	10/60	729
Total					20,840

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. 2017–18405 Filed 8–29–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–0004]

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.* Written comments and/or suggestions regarding the items contained in this notice should be directed 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

National Disease Surveillance Program II. Disease Summaries (OMB Control Number 0920–0004, Expires 10/31/2017)—Revision—National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC requests a three-year approval for the proposed revision of the ''National Disease Surveillance Program II. Disease Summaries'' information collection project.

As with the previous approval, these data are essential for measuring trends in diseases, evaluating the effectiveness of current preventive strategies, and determining the need to modify current preventive measures.