

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
	Ages and Stages Questionnaire: 12, 18, 24 Month.	300	3	15/60	225
	Center for Epidemiologic Studies Depression—10.	300	3	5/60	75
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.*

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**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](mailto: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.

Diseases included in this surveillance program are Influenza Virus, Caliciviruses, Respiratory and Enteric Viruses, Foodborne Outbreaks, Waterborne Outbreaks and Enteroviruses.

Proposed revisions include form consolidation, minor revised language and rewording to improve clarity and readability of the data collection forms and the discontinuation of multiple previously approved influenza collection instruments, and the National

Respiratory & Enteric Virus Surveillance System (NREVSS) Laboratory Assessment (CDC 55.83). CDC also requests the use of a new form, Suspect Respiratory Virus Patient Form, to assist health departments and clinical sites when they submit specimens to the CDC lab for viral pathogen identification. The data will enable rapid detection and characterization of outbreaks of known pathogens, as well as potential newly emerging viral pathogens.

The frequency of response for each form will depend on the disease and surveillance need. This represents a 7,116 burden hour reduction since last approval. This reduction in burden hours is attributed primarily to the discontinuation of previously approved forms and formatting changes to existing forms. The total time burden estimate for all collection instruments in this revision request is 24,805.

There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Epidemiologist .....	NORS Foodborne Disease Transmission_Person to Person Disease Transmission_Animal Contact_Environmental Contamination_Unknown Transmission Mode 52.13.	54	37	20/60
Epidemiologist .....	WHO COLLABORATING CENTER FOR INFLUENZA Influenza Virus Surveillance.	53	52	10/60
Epidemiologist .....	U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment.	113	1	10/60
Epidemiologist .....	US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly_CDC 55.20.	1,800	52	10/60
Epidemiologist .....	US Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder 55.20E.	1800	1	5/60
Epidemiologist .....	Influenza-Associated Pediatric Mortality Case Report Form .....	57	2	30/60
Epidemiologist .....	Human Infection with Novel Influenza A Virus Case Report Form ....	57	2	30/60
Epidemiologist .....	Human Infection with Novel Influenza A Virus Severe Outcomes .....	57	1	90/60
Epidemiologist .....	Novel Influenza A Virus Case Screening Form .....	57	1	15/60
Epidemiologist .....	Antiviral Resistant Influenza Infection Case Report Form .....	57	3	30/60
Epidemiologist .....	National Respiratory & Enteric Virus Surveillance System (NREVSS) (55.83A, B, D) (electronic).	550	52	15/60
Epidemiologist .....	National Enterovirus Surveillance Report: (CDC 55.9) (electronic) ....	20	12	15/60
Epidemiologist .....	National Adenovirus Type Reporting System (NATRS) .....	13	4	15/60
Epidemiologist .....	Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form.	57	3	25/60
Epidemiologist .....	Viral Gastroenteritis Outbreak Submission Form .....	20	5	5/60
Epidemiologist .....	NORS Waterborne Disease Transmission Form 52.12 .....	59	1	20/60
Epidemiologist .....	Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements.	57	52	5/60
Epidemiologist .....	Influenza virus (electronic, year round) (PHIN-MS) .....	3	52	5/60
Epidemiologist .....	Suspect Respiratory Virus Patient Form .....	10	5	30/60

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 Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier CMS-10239]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.