

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

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**

Data Calls for the Laboratory Response Network, (OMB Control No. 0920-0881 exp. 4/30/2017)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

The Laboratory Response Network (LRN) was established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to acts of biological, chemical, or radiological terrorism and other public health emergencies. Federal, state and local public health laboratories voluntarily join the LRN.

The LRN Program Office maintains a database of information for each member laboratory that includes contact

information as well as staff and equipment inventories. However, semiannually or during emergency response the LRN Program Office may conduct a Special Data Call to obtain additional information from LRN Member Laboratories in regards to biological or chemical terrorism preparedness.

LRN has used the currently approved generic information collection plan twice during the last three years. Once in 2014, LRN surveyed its members to ascertain which, if any, labs would be willing to test clinical specimens for Ebola virus.

The information gathered led to an emergency deployment of a new Ebola assay for LRN members. It is critical for the LRN to know which labs have equipment to support an agent specific assay during an emergency. In 2015, LRN surveyed members via broadcast email asking how many facilities had a specific version of an instrument. The information was used to help the LRN program office determine if new procedures should be written and made available to members to support the instrument in question.

Special Data calls may be conducted via queries that are distributed by broadcast emails or by survey tools (*i.e.* Survey Monkey).

This is a request for a three year extension to this generic clearance.

The only cost to respondents is their time to respond to the data call. Authorizing legislation comes from Section 301 of the Public Health Service Act.

**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 Laboratorians .....	Special Data Call .....	136	1	30/60	68
<b>Total .....</b>	.....	.....	.....	.....	<b>68</b>

**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 Medicare & Medicaid Services**

[Document Identifier CMS-10169]

**Agency Information Collection Activities: Proposed Collection; Comment Request; Correction**

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

**ACTION:** Correction of notice.

**SUMMARY:** This document corrects the information provided for [Document Identifier: CMS-10169] titled "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program; Change of Ownership Forms."

**FOR FURTHER INFORMATION CONTACT:** William N. Parham, III, (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the October 14, 2016, issue of the **Federal Register** (81 FR 71100), we