



This document is scheduled to be published in the Federal Register on 11/17/2016 and available online at <https://federalregister.gov/d/2016-27692>, and on [FDsys.gov](https://fdsys.gov)

BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17ZQ]

[Docket No. CDC-2016-0107]

**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 Zika Virus Associated Neurologic Illness Case Control Study. This collection intends to identify potential risk factors for the development of severe neurologic

illnesses using a case-control investigation.

DATES: Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0107 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, N.E., 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, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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

Zika Virus Associated Neurologic Illness Case Control Study -
New - National Center for Emerging and Zoonotic Infectious

Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

There is an urgent public health need to understand the potential association between neurological illness and Zika Virus (ZIKV) infection. Currently, increased numbers of neurologic illness cases have been reported in ZIKV-affected contexts, but it is not known if this is due to ZIKV, another etiologic agent, or some combination/interaction thereof. The Puerto Rico Department of Health (PRDH) is establishing neurologic illness surveillance and defining baseline incidence toward investigating the association between neurologic illness and ZIKV infection in Puerto Rico. More broadly, the results of this investigation would be relevant to other ZIKV-affected contexts, serving toward enabling clinical and/or public health action to manage and prevent additional cases.

A case-control investigation will be conducted to identify potential risk factors for the development of neurological illness. As part of the investigation, blood specimens will be collected from cases and matched controls to evaluate for antibodies against several pathogens known to cause neurological illness (e.g., influenza) or pathogens hypothesized to

contribute to this illness cluster (e.g., ZIKV, dengue virus, chikungunya virus, HIV, Campylobacter jejuni, Leptospira species bacteria).

This information collection request is a continuation on the work begun under the following Emergency Clearance: OMB 0920-1106 (Expiration date 9/30/16). Specifically, beginning in March 2016, CDC collaborated with the PRDH on the collection of very similar data for a Guillain-Barre syndrome case-control 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	120	1	15/60	30

	Questionnaire for Cases and Controls				
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: 11/16/2016 8:45 am; Publication Date: 11/17/2016]