



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20ND; Docket No. CDC-2020-0044]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting*. CDC will, at the request of state and local health departments, collect epidemiological data and blood samples from households to determine the extent of COVID-19 infection in communities as determined by overall SARS-CoV-2 seroprevalence.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0044 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments 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 Jeffrey M. Zirger, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting - New - National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for Immunization and Respiratory Diseases (NCRID), Division of Viral Diseases (DVD) requests approval for a new information collection, "Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting." Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first reported in Wuhan, Hubei Province, China in late December 2019. On February 26, 2020, CDC announced that an infection with the novel coronavirus had been confirmed "in a person who reportedly did not have relevant travel history or

exposure to another known patient with COVID-19," making this the first suspected United States (U.S.) case of community transmission.

We propose to conduct an investigation to (1) determine the extent of infection in communities as determined by overall SARS-CoV-2 seroprevalence; and (2) determine factors associated with SARS-CoV-2 seropositivity among persons residing in areas with evidence of community transmission. The data collected under this information collection request (ICR) will be used immediately by CDC's emergency COVID-19 response at the national level, and by state and local health departments, to understand the cumulative incidence in a given population within their jurisdiction. A cross-sectional household survey design will be used to measure SARS-CoV-2 seroprevalence at one or more time points in ≥ 1 U.S. areas with evidence of community transmission of SARS-CoV-2. Areas with existing population-based surveillance platforms with well-defined catchment areas will be preferentially selected. The investigation population will consist of all persons residing in selected households from selected defined geographic areas, according to the sampling framework. CDC and health departments alike will use this seroprevalence data to prioritize the allocation of resources and response efforts.

CDC will collect epidemiological information in the form of a standardized questionnaire which will capture information on household characteristics, age, sex, race, ethnicity, exposures, underlying medical conditions and symptoms consistent with COVID-19 infection that occurred prior to the survey. One respondent in each household (an adult who knows all residents of the household) will provide responses for the household questionnaire. The household questionnaire will capture information on household characteristics and document all household members, whether they are present at the time of the visit or not. Blood samples will be collected by trained phlebotomists from all individuals in the household and tested for antibodies to SARS-CoV-2 using an enzyme-linked immunosorbent assay with confirmatory microneutralization testing as needed. Investigations will be conducted at a total of four sites throughout the clearance period. There are no costs to respondents other than their time to participate. The total estimated annualized burden hours requested for this collection is 2,420.

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)
Household	Individual	4,000	1	20/60	1,333

Participants	Questionnaire				
	Household Questionnaire	1,680	1	15/60	420
	Blood collection (no form)	4,000	1	10/60	667
Total					2,420

Jeffrey M. Zirger,

Lead,

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Centers for Disease Control and Prevention.

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