



April 20, 2020

Dominic Mancini
Acting Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to the Office of Management and Budget (OMB) procedures established at 4 CFR 1320, Controlling Paperwork Burdens on the Public, I am writing to request that the following collection of information, *Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting*, be processed in accordance with section 1320.13 Emergency Processing.

I have determined that the information must be collected prior to the expiration of time period established under Part 1320, and that this information is essential to CDC's ability, as well as that of state and local health departments, to effectively respond to the national public health crisis caused by the Novel Coronavirus (COVID-19). As rates of infection and resulting deaths continue to rise across the nation, healthcare facilities and public health departments are facing significant strain on patient care and infection prevention efforts. CDC plans to collect data 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. Data collected during this study is essential to developing and assessing public health prevention measures by contributing to modeling estimates to inform decisions about prevention and control strategies as well as community mitigation interventions in the U.S. response to COVID-19; thus, improving the overall public health response.

CDC cannot reasonably comply with the normal clearance procedures due to the public harm that could escalate if routine processing of this request is required. Current epidemiologic data in the U.S. suggests that sustained community transmission of SARS-CoV-2 is occurring in certain areas. The extent of transmission of SARS-CoV-2 in community settings is currently unknown, so it is critical to collect the information needed to fully understand the scope of community transmissions. CDC requests authorization to use information collection instruments for 180 days to immediately enable CDC and public health departments to investigate the extent of transmission of SARS-CoV-2 in communities. The data collection instrument consists of a household and individual standardized questionnaire which will capture information on household characteristics, demographics, underlying medical conditions and symptoms consistent with COVID-19 infection that occurred prior to the survey. 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.

Please provide an approval/ disapproval determination of this request to collect information under an emergency clearance by close of business April 24, 2020.



Respectfully,

A handwritten signature in blue ink, appearing to read "Anne Schuchat".

Anne Schuchat, MD
Incident Manager, 2019 Novel Coronavirus Response
Principal Deputy Director, Centers for Disease Control and
Prevention (CDC)