

born, and (3) 2–4 maternal dietary data recalls. The data from IFPS III will be used to: Fill research gaps on how feeding behaviors, patterns, and practices change over the first two years of life and the health-related impacts; inform multiple federal agency efforts targeting maternal and infant and

toddler nutrition through work in hospitals, with health care providers, with early care and education providers, and outreach to families and caregivers; and provide context to policy level documents such as the *U.S. Dietary Guidelines for Americans*, which will include pregnant women and children

birth to 24 months of age for the first time in 2020–2025. CDC requests approval of 5,051 annualized burden hours for this collection. There is no cost to respondents 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 annualized burden hours	
Pregnant/Postpartum Women .....	Study Screener .....	7,477	1	3/60	125	
	Study Consent .....	4,711	1	5/60	131	
	Prenatal Survey .....	4,239	1	20/60	471	
	24-Hour Dietary Recall—Prenatal ....	2,756	1	24/60	367	
	Replicate 24-Hour Dietary Recall—Prenatal.	269	1	24/60	36	
	Request for notification of child's birth.	4,239	1	2/60	47	
	Birth Screener .....	4,103	1	2/60	46	
	1-Month Survey .....	3,693	1	20/60	410	
	2-Month Survey .....	3,575	1	15/60	298	
	3-Month Survey .....	3,460	1	15/60	288	
	24-Hour Dietary Recall—Month 3 ....	2,249	1	24/60	300	
	Replicate 24-Hour Dietary Recall—Month 3.	219	1	24/60	29	
	4-Month Survey .....	3,350	1	15/60	279	
	5-Month Survey .....	3,243	1	15/60	270	
	6-Month Survey .....	3,139	1	15/60	262	
	8-Month Survey .....	3,038	1	15/60	253	
	10-Month Survey .....	2,941	1	20/60	327	
	12-Month Survey .....	2,847	1	15/60	237	
	15-Month Survey .....	2,756	1	15/60	230	
	18-Month Survey .....	2,668	1	15/60	222	
	21-Month Survey .....	2,582	1	15/60	215	
	24-Month Survey .....	2,500	1	15/60	208	
	Total .....	.....	.....	.....	.....	5,051

**Jeffrey M. Zirger,**  
*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket No. CDC–2020–0047]

**Healthcare Infection Control Practices Advisory Committee (HICPAC); Cancellation of Meeting**

Notice is hereby given of a change in the meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC); [Docket No. CDC–2020–0047]; May 15, 2020, 3:00 p.m. to 4:30 p.m., EDT, which was published in the **Federal Register** on April 30, 2020,

Volume 85, Number 84, pages 23965–23966.  
 This meeting is being canceled in its entirety.

**FOR FURTHER INFORMATION CONTACT:** Koo-Whang Chung, M.P.H., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE, MS H16–3, Atlanta, Georgia 30329–4027; Telephone: 404–639–4000; Email: [hicpac@cdc.gov](mailto:hicpac@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 11, 2020.  
**Kalwant Smagh,**  
*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*  
 [FR Doc. 2020–10417 Filed 5–14–20; 8:45 am]  
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**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 July 14, 2020.

**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 NE, 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 NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto: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 (NCIRD), 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  $\geq 1$  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 Participants .....	Individual Questionnaire .....	4,000	1	20/60	1,333
	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, Information Collection Review Office,  
 Office of Scientific Integrity, Office of Science,  
 Centers for Disease Control and Prevention.*  
 [FR Doc. 2020-10411 Filed 5-14-20; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket No. CDC-2020-0051]

**Request for Information Concerning Personnel and the Retention of Next Generation Sequencing Data in Clinical and Public Health Laboratories**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with request for comment.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on personnel performing bioinformatics activities in clinical and public health laboratories; storage and retention of next generation sequencing (NGS) data files; and maintenance of sequence analysis software. The comments will be used by the Clinical Laboratory Improvement Advisory Committee (CLIAC) for deliberation and possible recommendations about future changes to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

**DATES:** Written comments must be received on or before July 14, 2020.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2020-0051 by any of the following methods. CDC does not accept public comment by email.

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Heather Stang, MS, MT, Division of Laboratory Systems, Centers

for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, GA 30329, Attn: Docket No. CDC-2020-0051.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Heather Stang, MS, MT, Center for Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4018, telephone (800) 232-4636; email: [dlsinquiries@cdc.gov](mailto:dlsinquiries@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

**Public Participation**

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data about topics related to personnel performing informatics activities, as well as data storage and retention practices related to the use of next generation sequencing (NGS) technology. In addition, CDC invites comments specifically on the following questions:

- (1) What are the roles and responsibilities for all personnel performing bioinformatics or pathology/laboratory informatics activities? What training is considered essential for each of the roles? What competencies are considered essential for each of the roles? What minimum educational requirements (degrees or courses) are required for each of the roles?
- (2) What are the challenges for recruitment and retention of bioinformatics or pathology/laboratory informatics personnel?
- (3) What are examples of how NGS data files are used in addition to generating a clinical test result?
- (4) What NGS data files should be retained for quality assurance, repeat

analyses, or subsequent analyses? How long should these NGS data files be retained?

(5) What are the challenges and approaches for laboratories to maintain and utilize previous versions of sequence analysis software?

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. Do not submit public comments by email. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

**Background and Brief Description**

Clinical laboratory testing technology has advanced significantly since the CLIA regulations were first implemented approximately 30 years ago. Next generation sequencing (NGS) technologies provide the high-throughput capability to rapidly and cost-effectively sequence large regions and mixed populations of DNA and RNA, when compared to traditional sequencing methods. This technology results in a significant increase in data that requires specialized analysis to derive a clinically meaningful result. NGS has led to improvements in diagnoses and patient care in many areas of medicine that include medical genetics, pediatrics, oncology, and microbiology. In some instances, NGS has led to life-saving diagnoses and treatment pathways, not achievable using other testing modalities. One element that differentiates NGS from most laboratory methodologies is its