Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting

Request for OMB approval of a New Information Collection

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Supporting Statement B

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The data collection involves statistical methods and the purpose of the collection is not to make statistical generalizations beyond the respondents.

1. Respondent Universe and Sampling Methods

A cross-sectional household-based survey design will be used to measure SARS-CoV-2 seroprevalence at one point in time. The investigation will be implemented in ~~3~~up to 4 U.S. locations with evidence of community transmission of SARS-CoV-2. Locations with pre-existing surveillance platforms in place to capture COVID-19 hospitalization rates and well-defined geographically bound catchment areas will be preferentially selected for implementation. The investigation population will consist of all persons residing in selected households from selected defined geographic areas. Individuals of all ages residing within an eligible household will be assessed for eligibility. An eligible household participant will be defined as an individual who spends an average of ≥2 nights per week in the home. Households will be defined as a shared living space between ≥1 people, excluding correctional facilities, long-term care facilities, boarding schools, hostels, dormitories, or other similar institutionalized settings. Households in which English is not the primary language spoken may be excluded from the survey if translation services are not available.

At the request of state and local health departments, seroprevalence investigations will be conducted in selected areas to understand the SARS-CoV-2 seroprevalence in this community. The sampling methodology for this investigation will be based on a modified CDC Community Assessment for Public Health Emergency Response (CASPER) framework (https://www.cdc.gov/nceh/casper/default.htm). The primary investigations in this ICR will select Census blocks using Probability Proportional to Size (PPS) sampling without replacement, as described here (https://v8doc.sas.com/sashtml/stat/chap63/sect20.htm). Some investigations that will be included in the ICR may use other sampling methods or existing population-based surveillance platforms.

The seroprevalence investigations will employ a multistage cluster sampling design to obtain a representative sample of households. Counties within a selected catchment area will be identified. Catchment areas are defined by hospital service areas. Adjacent hospital service areas may be combined to create a contiguous geographic area. Using the most updated census data, census blocks will be selected according to probability proportional to size (PPS) within each catchment area. Maps will be

obtained for each of these census blocks and based on visual inspection, households will be manually labeled and numbered within each of these census blocks. A list of all the households will be created for each census block (i.e., cluster) and seven households will be randomly selected using a random number generator. Selected households will be approached on at least three separate occasions before replacement due to non-availability. Additional details on systematic random sampling methods can be found in Attachment 4a.

At least 210 households will be included in each catchment area sample but may vary based on location of the investigation. All eligible participants within a household will be approached for recruitment. A fixed household sample size will be used regardless of the number of households within a catchment area for logistical reasons (the sample size is based off of the number of samples that can be collected by a single research team). As a result, the precision of the estimates will depend on the size of the catchment area. This effect on precision will be considered during the construction of catchment areas to prevent creating catchment areas that are so large that the fixed sample size will not be capable of providing the desired level of precision.

2. Procedures for the Collection of Information

The investigation organizers will work with county and state officials to notify the selected areas about the investigation using their recommended communication networks and routes, as well as through locally relevant social media networks. In some areas they may also have provided flyers or informational leaflets to households.

Quality Control Procedures

Prior to the investigation, data collection teams (consisting of two members each: an interviewer and a phlebotomist) will attend the scheduled training specific to the investigation, deployer training (specifically to cover Personal Protective Equipment (PPE) donning and doffing) if applicable (CDC staff) and a review of the investigation's Standard Operating Procedure (SOP). The interviewer will be trained to administer the consent and questionnaire. The list of questions and individuals' answers will be recorded using REDCap and will be stored in a secure database. The privacy of the information given by respondents will be protected to the extent allowed by law, and respondents can withdraw from participation in the investigation at any time without penalty.

The trained interviewer will verbally consent individuals and conduct the interviews and the phlebotomist will obtain blood samples by venipuncture. The phlebotomists will be professionals who are qualified to perform phlebotomy, and many include phlebotomists contracted by CDC to participate in the investigation.

Two standardized questionnaires will be administered: a household level questionnaire (Attachment 3a) and an individual level questionnaire (Attachment 3b). One respondent in each household (an adult who knows about all of the residents of the household) will provide responses for the household level questionnaire and each household member (or parent guardian in the case of a child too young to answer) will provide responses for the individual level questionnaire. The household level questionnaire

will capture information on household characteristics and document all household members whether they are present at the time of the visit or not. The individual-level questionnaire will capture information on age, sex, race, ethnicity, exposures, underlying medical conditions and symptoms consistent with COVID-19 since January 2020 for each available and consenting household member. The questionnaire will be administered in person by a trained interviewer. Team phlebotomists will collect up to 10mL of venous blood (or for children the recommended volume per age and weight) from each consented participant in an enrolled household (see specimen collection section below).

Questionnaire responses will be collected using REDCap, including possibly mobile data collection software. Paper forms will be used to collect consent (Attachment 4b) and may be used to track visited households within a selected cluster or census block.

- A 10 mL volume of blood will be collected from each adult participant using standard venipuncture techniques and following recommended PPE guidelines. Blood volume collected from children under the age of 18 years will not exceed the recommended amount per age and weight.
- Once collected, blood samples will be stored in closed cooler boxes in team vehicles and then transported to the local collaborating laboratory for processing.
- Testing will be done at CDC using serologic assays that test for SARS-CoV-2 antibodies. Serologic assays will likely include enzyme-linked immunosorbent assays (ELISA), and when necessary, microneutralization testing (MNT). As serologic tests are further developed, it is possible that additional serologic tests and quantitative testing for different classes of serum antibody might be performed. Note that all serologic tests have associated error (false positives and false negatives). This error will combine with the sampling error in this investigation to affect the accuracy and precision of the final estimates. CDC will include information about the error associated with the serological tests employed in this investigation whenever results are disseminated.
- All personnel involved in the investigation will be trained in infection prevention and control procedures. Recommended PPE, which may include a surgical mask, N95 respirator, gown, face shield and gloves will be used by staff and phlebotomists entering households according to the SOP. Procedures will include proper hand hygiene and the correct donning and doffing of PPE
- The CDC Emergency Operations Center will supply the pre-determined PPE to data collection teams specifically for these investigations.

3. Methods to Maximize Response Rates and Deal with No Response

If a household refuses to participate or appears vacant/unoccupied there are two methods (immediate or delayed replacement) for the household described in Attachment 4a. If the team is unable to enroll seven households in the cluster, they can revisit the cluster during the mop-up period at the end of the data collection period, if deemed necessary. If they cannot access a particular subdivision of a cluster, the team will re-allocate the targeted number of households to other areas of the cluster so that they can still enroll seven households. If an area or home has a “No trespassing sign” or potential hazards (e.g., need to enter a fence with unrestrained dog to access front door), they will not enter the area to avoid risk of harm. These procedures are considered to result in a pseudorandom sample, and any resulting departures from a truly random sample will not be accounted for.

4. Tests of Procedures or Methods to be undertaken

The investigators will use the questionnaires provided in Attachments 3a and 3b.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

It is the responsibility of the COVID-19 Epidemiology Task Force staff to manage and analyze data collected through the studies. Also, state and local health departments can analyze their data for their purposes. Additional statistical resources are available at CDC.

Attachments

Attachment 1 – Authorizing Legislation

Attachment 2 – 60-day FRN

Attachment 3a – Individual Questionnaire

Attachment 3b – Household Questionnaire

Attachment 4a – Field Team SOP

Attachment 4b – Consent Form

Attachment 5 – Investigation Protocol

Attachment 6 – Letter of Invitation

Attachment 7 – IRB Non-Research Determination