

SARS-CoV-2 Epidemiologic Data Collections

Request for OMB approval of a New Information Collection

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Supporting Statement A

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Table of Contents

1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of Information Collection.....	4
3. Use of Improved Information Technology and Burden Reduction.....	9
4. Efforts to Identify Duplication and Use of Similar Information.....	10
5. Impact on Small Businesses or Other Small Entities.....	11
6. Consequences of Collecting the Information Less Frequently.....	11
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	11
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	11
9. Explanation of Any Payment or Gift to Respondents.....	12
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	12
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	13
12. Estimates of Annualized Burden Hours and Costs.....	13
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	15
14. Annualized Cost to the Government.....	15
15. Explanation for Program Changes or Adjustments.....	15
16. Plans for Tabulation and Publication and Project Time Schedule.....	15
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	16
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	16
Attachments.....	16

- **Goal of the study:** These tools serve a variety of purposes, specifically to fill gaps in knowledge around COVID-19 case characteristics, infection rate, point prevalence in people experiencing homelessness, risks for severe illness or adverse outcomes among pregnant individuals and their newborns, and risk factors for severe illness.
- **Intended use of the resulting data:** Inform guidance on COVID-19
- **Methods to be used to collect:** Variety of methods will be used including interviews and chart abstractions.
- **The subpopulation to be studied:** General public, pregnant women, prison staff, incarcerated peoples, and homeless shelter staff and people experiencing homelessness.
- **How data will be analyzed:** Variety of methods.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a one-year approval for a new information collection, “SARS-CoV-2 Epidemiologic Data Collections.”

This is a new information collection request for a bundle of epidemiologic tools that will help CDC’s efforts to slow and stop the spread of SARS-CoV-2. Some of the data collection instruments for which OMB approval is sought were initially approved under OMB control no. 0920-1011 (exp. date 4/23/2020). This ICR will continue those forms’ clearance and add additional tools.

The 0920-1011 gen-IC approved in January 2020 (exp. date 4/23/2020) included three data collection instruments: (1) COVID-19 case report form, whose data elements have been inherited by the NNDSS ICR (0920-0728); (2) persons under investigation form, which has been discontinued; and (3) a household transmission questionnaire, which is included in this ICR to extend its OMB clearance.

As CDC’s response to the pandemic evolved over the last 90 days, the OMB-approved forms from the 0920-1011 gen-IC were repurposed for the ongoing studies and uses described in this ICR. The purpose of this ICR is to bring these new collections into compliance.

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 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. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and President Trump proclaimed the outbreak a national emergency on March 13, 2020. As of April 20, 2020, more than 700,000 cases of SARS-CoV-2 have been confirmed in the U.S.

Current epidemiologic data in the U.S. suggest 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.

Forms for six epidemiologic projects are included in this ICR:

1. COVID-19 Case Investigation Form. Ongoing use. Adapted from approved 0920-1011 form.
2. Household transmission questionnaires. Ongoing use. Extension of 0920-1011 approval.
3. Homeless shelter study forms. This project is a continuation of ongoing work. We anticipate being done with the first round of screening/testing and associated two-week follow-up of positives by 5/22. This ICR will bring this data collection into compliance.
4. COVID-19 pregnancy module. This project began in April 2020. This ICR will bring this data collection into compliance.
5. Risk factor investigation forms. These are being used in an ongoing study in Colorado. This ICR will bring this study into compliance. Future studies are also possible. Non-substantive change requests will be submitted for any future study.

These tools are authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of Information Collection

This ICR includes a bundle of epidemiologic data collection instruments for six distinct, but complementary, purposes. The objectives of these tools are to help CDC identify cases and contacts of cases who are at risk for illness, understand the risk factors for disease and transmission, describe the clinical characteristics of disease, and identify potential ways to control transmission. The data gathered with these tools will be used to inform the U.S. public health response to COVID-19, including guidance, and aid efforts to prevent and control the spread of the virus.

1. Case investigation form being used nationally

- Attachment 3.
- Initially approved under OMB control number 0920-1011 (exp. date 4/23/2020).
- CDC aims to gather information from approximately 5-10 cases (or more if feasible) in each state or jurisdiction from different age groups and of different disease severities. In total, we hope to collect information on approximately 300 cases.
- Information collected will be used to provide an in-depth descriptive summary of case characteristics, including demographics, and epidemiologic and clinical characteristics.
- This evidence-based assessment of COVID-19 disease epidemiology and clinical characteristics is essential to inform decisions around timely preventive recommendations to reduce illness and death.
- Jurisdictions have been approached through various means, including outreach via CSTE, CDC field teams and State Liaisons.
- Data are being collected by either CDC field staff or staff at state and local health departments. Data are collected from a combination of chart reviews and patient interviews, and sometimes completed from data that are already available within the state (from prior interviews).
- Type of respondent: COVID-19 cases, including individuals and healthcare personnel.

- Estimated number of annual respondents: Approximately 300 respondents, each completing the form once.

2. Household transmission studies

- *Five instruments:*
 - Att. 4: Household transmission contact questionnaire: Questions focus on individual household members/contacts (one completed/household member) and include exposure history, interactions with index case in the household, and demographic and clinical characteristics.
 - Att. 5: Household transmission questionnaire: Questions focus on the entire household (one completed/household at time of enrollment) and include size of house, number of rooms, makeup of household, etc.
 - Att. 6: Household transmission member symptom diary: Questions focus on ongoing symptoms for each household member (one completed/household member) to be captured daily for 14 days from the time of enrollment.
 - Att. 7: Household transmission animal questionnaire: Questions focus on household pets (one completed/household pet) and includes questions about the pets' health status, interactions with index case, etc.
 - Att. 8: Household transmission close out form: Questions focus on the entire household (one completed/household at completion of 14 day follow-up) and include changes in behaviors intended to mitigate transmission, final status of household members, and field team assessments of the household's possible transmission.
- There are four objectives attached to these collections:
 1. Estimate the household secondary infection rate of SARS-CoV-2 and/or COVID-19.
 2. Identify factors associated with secondary household infection.
 3. Compare results of paired self-collected nasal swabs with NP swabs collected by public health personnel.
 4. Identify pre-symptomatic viral shedding amongst household contacts.
- We are doing enhanced contact investigations in household contacts of confirmed cases. In short, this is a convenience sample of households based on those that have a confirmed case of COVID-19, more than one household member, and largely is based on convenient times when our CDC teams are in the field working with local health department(s). The timing and locations of households enrolled depends largely on requests for technical assistance that CDC receives from state or local health departments. This convenience sampling approach allows us flexibility to accommodate different local needs or preferences. This includes collecting household-level data, index case data, household contact data, and pet data. Specimens are also collected (NP swabs, self-collected nasal swabs, and blood) from each household member in their household. CDC or local health department personnel visit the household in full COVID-19 PPE given there is a confirmed COVID-19 patients in the household. The PPE and infection

control guidelines for this project as per those outlined by CDC guidelines for home specimen collection (<https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.html>).

- Data are collected on paper forms in the field and later entered into an electronic RedCap database. Each questionnaire/form captures data from a slightly different aspect of the household that may contribute to transmission of SARS-CoV-2.
- Lab data are sent in Excel spreadsheets and merged into an electronic dataset at CDC. This comprehensive dataset will be housed at CDC but may be shared with partners (i.e. state or local health departments participating in this investigation).

3. *Homeless shelter study in Atlanta, GA*

- Two instruments:
 - Att. 9: Screener
 - Att. 10: Symptom follow-up instrument
- The purpose of this project is to investigate the point prevalence of SARS-COV-2 in people experiencing homelessness and to assess the ability of a symptom-based screening tool to effectively cohort individuals within a shelter.
- Shelters have been using CDC intake symptom screening tools to assign persons experiencing homeless to general shelter areas or to symptomatic areas. Data from this project will be used to evaluate effectiveness of screening tools in identifying individuals with COVID-19 infection.
- CDC will request verbal consent from staff members and each client entering each of the shelter locations, or encountered on homeless outreach outside, to conduct a brief survey and test for SARS-CoV-2 (att. 23). All potential participants will be advised that their participation is voluntary and with whom the data will be shared.
- CDC will conduct a brief survey (attachment 9 and 10) to collect demographic data, underlying condition information, and information on current symptoms. Data elements will include:
 - Identifier code (to link to positive results)
 - Date and location
 - Demographics (age, sex, race)
 - Current symptoms (fever, cough, shortness of breath)
 - Underlying conditions
- Two weeks of data from daily symptoms screenings will be collected for people who are isolated after testing positive. We will also access medical records for retrospective review of clinical course for those who test positive and are hospitalized.
- Specimen collection will be conducted by healthcare workers in accordance with the procedures outlined in CDC guidance at one point in time and one follow-up point in time, if deemed necessary. Whether this follow-up data collection is needed will be determined by the epidemic curve in the Atlanta metro area and in discussion with Mercy Care and local county public health department (if there is a suspected increase in infections). If necessary, the same protocol as described herein will be followed.

Laboratory testing will be conducted by a commercial laboratory contracted by Mercy Care of Atlanta. Positive test results will be provided to the individual and public health departments through standard healthcare facility procedures. Negative test results will not be provided; however, clients will be notified that they did not test positive.

- Specimens will be collected by physician-volunteer staff with support of Mercy Care of Atlanta Mobile Clinics. Tests (Real Time- PCR) will be performed at Grady Memorial Hospital.
- Data will be collected on paper forms and stored on a secure Access database.
- The approximate 2400 individuals experiencing homelessness and shelter staff in Atlanta area will complete the modified screener up to two times. If determined to be necessary, the second completion of the form will occur 2-4 weeks after the initial completion among all individuals experiencing homelessness (to assess prevalence of infection at different points in the epidemic).
- Two weeks of data from daily symptoms screenings will be collected for people who are isolated after testing positive.

4. *COVID-19 pregnancy module (a supplement to the standard COVID-19 case report form)*

- Att. 11: Pregnancy Module
- The COVID-19 Pregnancy Module will collect data on the pregnant individual's obstetric history and pregnancy complications, as well as the outcome of the pregnancy and basic information about the neonate.
- Health departments can choose to participate in this optional information collection.
- Data collected for the COVID-19 Pregnancy Module will be used to describe risk for severe illness or adverse outcomes among pregnant individuals with COVID-19 during pregnancy, or their newborns. Aggregate data will be shared with jurisdictions and CDC COVID-19 Response leadership to better inform clinical guidance and risk communication messages.
- The standard COVID-19 Case Report Form (data covered under OMB Control No. 0920-0728) asks whether an individual is currently pregnant at the time of COVID-19 infection. If the individual is pregnant, the COVID-19 Pregnancy Module is an optional data collection that consists of two forms: 1) Pregnancy form and 2) Neonate form. For multiple gestation pregnancies, multiple neonate forms should be completed.
- Data will be collected electronically from jurisdictions through one of the following methods:
 - Direct Data Entry in DCIPHER online data collection system
 - CSV File sent through SAMS secure file transfer
 - Integrating COVID-19 variables into currently funded Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET) sites through the Epidemiology Laboratory Capacity Cooperative Agreement: Project W.

5. *Risk Factor investigation*

- Two instruments:

- o Att. 12: Risk factor interview
- o Att. 13: Risk factor chart abstraction instrument (no public burden; not in burden table)
- Information about risk factors for hospitalization COVID-19 illness is sparse, limiting public health and clinical decision-making. With this investigation, we plan to explore risk factors for hospitalization among COVID-19 cases by comparing demographics, underlying medical conditions, and current medications in hospitalized and non-hospitalized patients with 2019 novel coronavirus disease (COVID-19).
- Understanding patient risk factors for hospitalization will directly inform clinical and public health guidance for higher risk groups and is necessary for assessing potential clinical and public health needs.
- These forms are currently being used in a Colorado study to identify risk factors for severe illness. If other studies are initiated, a non-substantive change will be submitted.
- Data will be collected via patient interview and chart abstractions. CDC staff are calling known COVID-19 cases to ask about symptoms, exposures, and medications taken. If relevant, charts are then abstracted (also by CDC staff).
- These two data collection tools were adapted from the Case Investigation Form (Att. 3) and include additional key information on underlying conditions and medications taken.
- Data will be collected on paper forms and entered in a secure REDCap database.
- Respondents include COVID-19 cases, including individuals and healthcare personnel.
- The current investigation may need to be repeated in other locations to capture higher numbers for better statistical power. In the current location (Colorado), we are aiming for approximately 600 respondents (200 hospitalized and 400 non-hospitalized), each completing the patient interview once. A proportion (approx. 400) will have charts abstracted.

3. Use of Improved Information Technology and Burden Reduction

Use of improved information technology will vary with these instruments. Data will be collected using a variety of techniques including paper forms, electronic forms, and chart abstractions.

1. COVID-19 Case Investigation Form: Paper form, scanned and submitted to CDC securely via SAMS
2. Household transmission questionnaires: Paper forms collected in the field and later entered into electronic RedCap database. Lab data sent in Excel spreadsheets and merged into electronic dataset.
3. Homeless shelter intake form: Paper forms.
4. COVID-19 Pregnancy module. Electronic: Direct Data Entry in DCIPHER online data collection system; CSV File sent through SAMS secure file transfer; and integrating COVID-19 variables into currently funded Surveillance for Emerging Threats to Mothers and Babies Network (SET-NET) sites.
5. Risk factor interview: Paper forms and later entered into a secure RedCap database.

Always, the minimum amount of information necessary will be collected.

4. Efforts to Identify Duplication and Use of Similar Information

The instruments proposed for this ICR are being used or are designed to be used for investigations of distinct populations deemed high priority for the COVID-19 response. These investigations are primarily led by the Epidemiologic Studies Task Force. However, this Task Force consults with other task forces and outside partners when topics or activities overlap.

Other forms are not duplicative of other US government data collections. The homeless study uses components of the case investigation form and the household transmission questionnaire to ensure it is capturing equivalent data. This population is distinctly different from household, pregnant studies. The Epidemiology Task Force is in contact with the Community Intervention/At-Risk Task Force related to other homeless population studies and state requests related to this population.

For the household transmission study, our field teams have attempted to embed these questionnaires into the general contact tracing questions and efforts at the local health department level.

5. Impact on Small Businesses or Other Small Entities

The only data collection included in this ICR that will include small entities is the homeless shelter patient intake form. We will request verbal consent from staff members to conduct a brief survey and test for Sars-CoV2. All potential participants will be advised that their participation is voluntary and with whom the data will be shared. They are free to decline participation. The minimum amount of information necessary will be collected in order to keep burden to a minimum.

6. Consequences of Collecting the Information Less Frequently

Health department staff from participating jurisdictions will complete the pregnancy module supplement once for every pregnant individual with confirmed COVID-19. Data collected for the COVID-19 Pregnancy Module will be used to describe risk for severe illness or adverse outcomes among pregnant individual's with COVID-19 during pregnancy, or their newborns. Aggregate data will be shared with jurisdictions and CDC COVID-19 Response leadership to better inform clinical guidance and risk communication messages.

The homeless shelter intake form (att. 9) could be completed up to two times. If determined to be necessary, the second completion of the form will occur 2-4 weeks after the initial completion in order to assess prevalence of infection at different points. Whether this follow-up data collection is needed will be determined by the epidemic curve in the Atlanta metro area and in discussion with Mercy Care and local county public health department (if there is a suspected increase in infections). If necessary, the same protocol as described herein will be followed.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on February 5, 2020, vol. 85, No. 24, pp. 6546 (Attachment 2). CDC received three non-substantive public comments (att. 2a, 2b, 2c).

B. We have coordinated outreach to state and local health departments via CSTE. The pregnancy module form was shared with the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

The homeless study works with a local partner which provides health services to individuals experiencing homelessness (MercyCare). CDC Field team consults and coordinates with MercyCare to access shelters, set up screening and testing, and follow-up of positives. Homeless study is also coordinating with local county public health department (Fulton County) who has performed similar screening and testing in smaller shelters.

We are specifically partnering with state and local health departments to ensure our investigations are linked to their local response efforts. This include integrating into their normal flow of contact tracing activities as well as trying to align data capture into the local context and flow. We also are aligning lab testing with testing indicated/required for the local health response (i.e. one specimen is collected for both rather than requiring two specimens).

9. Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. The applicable SORN is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems." This record system enables CDC officials to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

- Case investigations: Scanned forms are being entered into DCIPHER for long term storage and analysis. Scanned forms are saved in the Epi Task Force secure server.
- Household transmission: Data will be stored in a REDCap database. Paper forms will initially be stored in field lockboxes that will be transitioned to CDC HQ locked files.
- Homeless study: Data will be stored on a secure Access database.
- Pregnancy module: Data will be stored using DCIPHER and on CDC encrypted shared drive
- Risk factor: Data are entered in a secure REDCap database. Paper forms are stored securely in locked cabinets. No PII is collected.

Consent forms are included as follows:

- Att. 17 – Household transmission consent (Parent)
- Att. 18 – Household transmission consent (Household member)
- Att. 19 – Household transmission consent (Case)
- Att. 20 – Household transmission consent (Child)
- Att. 23 – Homeless project verbal consent

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not research involving human subjects [attachments 22a (broad epi non-research determination); 22b (homeless shelter screening); 22c (pregnancy module)]. IRB approval is not required.

Justification for Sensitive Questions

There are no sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The table below provides an annualized estimate for the burden of these instruments. Total estimated burden is 19,362 hours.

The burden of the homeless shelter screener is estimated at two responses per respondent. However, this is likely an over-estimation. A second collection will only be done if determined necessary in response to an increase in observed SARS-CoV-2 infections among persons in the Atlanta metro-area and in consultation with partners (Mercy Care and Fulton county local health department).

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
General public	Case investigation form	300	1	1	300
General public	Household contact questionnaire instrument	200	1	10/60	34
General public	Household questionnaire	60	1	10/60	10
General public	Household member symptom diary	200	1	10/60	34
General public	Household animal questionnaire	60	1	10/60	10
General public	Household close-out form	60	1	10/60	10

Homeless shelter staff	Homeless shelter modified screener	2400	2	15/60	1,200
Homeless shelter staff	Homeless symptom follow-up	50 (estimated positives)	14 (two weeks of daily symptom checks)	5/60	59
Epidemiologist	Pregnancy module	20	1000	45/60	15,000
General public	Risk factor interview	600	1	30/60	300
Total					16,957

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	Case investigation form	300	\$25.72	\$7,716.00
General public	Household contact questionnaire instrument	34	\$25.72	\$874.48
General public	Household questionnaire	10	\$25.72	\$257.20
General public	Household member symptom diary	34	\$25.72	\$874.48
General public	Household animal questionnaire	10	\$25.72	\$257.20
General public	Household close-out form	10	\$25.72	\$257.20
Homeless shelter staff	Homeless shelter modified screener	1,200	\$25.72	\$30,864.00
Homeless shelter staff	Homeless symptom follow-up	59	\$25.72	\$1,517.48
Epidemiologist	Pregnancy module	15,000	\$37.64	\$564,600.00
General public	Risk factor interview	300	\$25.72	\$7,716.00
Total				\$614,934.04

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

In the table below, estimated staff time is multiplied by the wage rate for GS-13 federal employees. Staff time includes time for data collection, entry, and analysis.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost

Staff time – Case investigation (650 hours x \$46.06)	\$29,939.00
Staff time – Household transmission (8,500 x \$46.06)	\$391,510.00
Staff time – Homeless study (2,968 hours x \$46.06)	\$136,706.08
Staff time – Pregnancy module (8,320 hours x \$46.06)	\$383,219.20
Staff time – Risk factors (1,800 hours x \$46.06)	\$82,908.00
Total	\$1,024,282.28

15. Explanation for Program Changes or Adjustments

This is a new information collection request. Some of these forms were included in an “Emergency Epidemiologic Investigations” gen-IC (0920-1011), exp. date 4/23/2020. This ICR extends the clearance of those approved forms.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Case investigation	6 months
Household transmission	Complete enrollment in first two states (UT and WI) May 1; primary analysis and publications to be completed by June 1.
Homeless study	By May 2020 first round of screening complete; By June 2020 two week follow-up of positives complete; mid-May- June 2020 preliminary data analysis to inform response and second round of screening, if deemed necessary; July 2020 data analysis; 2021 publication of results
Pregnancy module	Data collection through April 2021 with initial reporting in June 2020; final analyses and report in May 2021
Risk factors	3 months; if used in locations besides Colorado, the timeline will be extended and a nonsub change will be sought from OMB.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing Legislation
2. 60-Day FRN
 - a. Public comment
 - b. Public comment

c. Public comment

3. Case investigation form
4. Household contact questionnaire
5. Household questionnaire
6. Household member symptom diary
7. Household animal questionnaire
8. Household close out form
9. Homeless shelter modified screener
10. Homeless symptom follow-up instrument
11. Pregnancy module
12. Risk factor interview
13. Risk factor chart abstraction
14. No File
15. No File
16. No File
17. Household transmission consent (Parent)
18. Household transmission consent (Household member)
19. Household transmission consent (Case)
20. Household transmission consent (Child)
21. No File
22. Non-research determinations
 - a. Broad
 - b. Homeless shelter screening
 - c. Pregnancy module
23. Homeless project verbal consent