Contact Investigation Outcome Reporting Forms

(OMB Control No. 0920-0900)

Expires 05/31/2021

Request for Revision of a Currently Approved Data Collection

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Supporting Statement A

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- The goal of this information collection is to obtain sufficient information on the results of contact investigations carried out by state and local public health professionals or maritime medical crews to assess the impact of a confirmed communicable disease of public health concern in a traveler, both in terms of spread and health outcomes and to determine if further public health intervention is appropriate.
- The information will be used to assist and collaborate with state health departments, conveyance operators, port of entry partners, and international public health authorities to identify potential exposures, to determine risk of infection and whether public health interventions are needed.
- Methods to be used to collect information are basic surveys of respondents that record information about location and activities on the conveyance, other potential exposures, symptoms occurring after the potential exposure, prior history of vaccination or disease, and other medical conditions that could influence the risk of infection or severity of illness.
- The respondent universe is state/local public health officials and airline or maritime conveyance operators who assist CDC by making contact with potentially exposed travelers within their states or on maritime conveyances, or airline or ship crew members.
- No statistical methods will be used in this information collection.

1. Circumstances Making the Collection of Information Necessary

This is a request for revision to a currently approved information collection, OMB Control No 0920-0900, Contact Investigation Outcome Reporting Forms. CDC is requesting a three-year approval for the contact investigation outcome reporting information collection tools to continue the CDC's routine contact investigation activities. These collections enable CDC to better assess the risk to individuals who may have been exposed to a confirmed case of a communicable disease of public health concern while traveling to or within the United States.

CDC is requesting changes to some of the forms in use under this control number, primary concerning the General Contact Investigation Outcome Reporting Form for Land and Air. The changes are being requested to better tailor the form for use in the land and air border environment when conducting contact investigations, including updating to better capture vaccination records for COVID-19. CDC is also updating estimates of burden to account for increasing numbers of contact investigations over the last 3 years.

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A.1) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Under its delegated authority, CDC works to fulfill this responsibility through a variety of activities, including the operation of Quarantine Stations at ports of entry and administration of foreign and interstate quarantine regulations; 42 CFR Parts 70 and 71 (Attachment A2 and A3), respectively. These regulations require conveyances to immediately report an ill person or any death to the Quarantine Station of jurisdiction prior to arrival in the United States.

CDC's activities with regard to communicable diseases and travel generally occur sequentially. When an illness or death suggestive of a communicable disease is reported during travel (reported under 0920-0134 Foreign Quarantine Regulations by airlines or Customs and Border Protection for international travelers arriving to the United States; or 0920-0488 Restrictions on Interstate Travel of Persons for interstate flights) Quarantine Officers or our port partners respond to carry out an onsite public health assessment and collect pertinent information using "Illness Response and Investigation Forms," OMB 0920-0134. In other cases, CDC is notified via other channels after travel by public health departments that a person was ill and infectious during their flight or maritime voyage. The public health response may differ depending upon the assessment of an ill/deceased person. One such response is determining that passengers need to be notified if they were exposed to the communicable disease during travel. This notification of passengers is critical to preventing the spread of communicable disease because it allows for timely implementation of public health measures needed to mitigate or stop further spread of disease.

CDC is then responsible for providing state and local public health authorities with adequate contact information, such as phone numbers and addresses included in manifests, to facilitate successful notification of the exposed passengers. After CDC has collected the flight or maritime vessel manifest information and sent this information via Epi-X (a secure public health messaging system) to the state health department or via secure email to the maritime vessels, the responsibility for contacting exposed passengers typically falls with state or local health departments or with maritime operators. The extent of the contact investigation is determined by which passengers are believed to have been exposed to a communicable disease and is based on CDC investigative protocols. The success of preventing the spread of a communicable disease is due in large part to the effectiveness of the CDC's investigative protocols and the provision of contact information. CDC's ability to control the spread of communicable disease through implementing effective investigative protocols is impaired without comprehensive feedback indicating the outcome of the notification and contact investigation received from state and local health departments or from maritime conveyance operators after the investigation has concluded.

2. Purpose and Use of Information Collection

The information collected on the outcome reporting forms by state health departments and maritime operators enables CDC to more fully understand the extent of disease spread and transmission during travel. This information assists in the development and/or refinement of investigative protocols, aimed at reducing the spread of communicable disease.

The purpose of the proposed contact investigation outcome reporting forms is to uniformly collect information from state and local health department officials as well as maritime operators conducting contact investigations on behalf of CDC. This information enables CDC to assess, detect, and respond efficiently and accurately to communicable disease threats of potential public health concern at ports of entry. The information collected is also necessary for public health surveillance (tracking) and follow-up purposes. The forms collect the following categories of information: demographics, pertinent clinical and medical history, and epidemiologic and travel history.

This information enables CDC staff to assist conveyances and border agents in the public health management of ill persons at U.S. ports and plan the appropriate response. This data is then entered into the Quarantine Activities Reporting System (QARS), a secure web-based, data-management system used by all Quarantine Stations to record information about the daily activities of Quarantine Station staff.

3. Use of Improved Information Technology and Burden Reduction

The majority of responses (outcome reporting forms) are submitted using secure e-mail or fax. CDC also introduced an excel version of the maritime outcome reporting forms to reduce burden and ease the submission of data for multiple individuals using one format. CDC has also modified the air-related forms to be more easily accessible to users by making use of simpler, more compatible format. CDC is investigating a process by which the following air related forms could be digitized in some manner requiring a public health follow-up. When this format is ready to be submitted CDC will submit a change form request to OMB.

4. Efforts to Identify Duplication and Use of Similar Information

CDC retains the regulatory authority for performing quarantine-related activities at U.S. ports of entry (42 part 71) and related to interstate travel (42 part 70). One such activity is providing pertinent passenger information to state and local health departments and maritime operators for the notification of those who may have been exposed to communicable disease during travel. CDC is the only agency that provides this information, and the health department of jurisdiction or maritime operator is the only entity that conducts the contact investigations. In addition, CDC works in collaboration with its international, federal, state, and local partners to ensure all contact investigations due to a communicable disease exposure during travel are done in a coordinated manner. There is no duplication of data regarding the outcome of contact investigations initiated by the CDC for international or interstate travelers.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

The proposed information collection request does not impact small businesses or other small entities. Respondents are primarily state and local health department officials, and cruise ship medical staff or cargo ship managers.

6. Consequences of Collecting the Information Less Frequently

Frequency of the proposed data collection is determined by the incidence of travelers who develop an illness or die from a communicable disease of public health concern. Information will only be collected if these incidences occur during travel by air, land, or maritime conveyance and reported to a quarantine station at a port of entry. Control of communicable diseases of public health concern is dependent on

rapid identification and immediate response when identified. Information will only be collected when it is essential to protect the public's health. Further reduction of required reporting would prevent CDC from meeting its legislative mandate, thereby endangering the public's health.

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 March 8, 2021, vol. 86, No. 43, pp. 13390 (Attachment B). CDC received one public comment. Please see Attachment B1 for the comment and response.

B. CDC did not formally consult with outside persons on the development of these forms; however, CDC does take into account public health partners needs and requests when formatting or other technological problems with the forms or their function arise. In response to some problems with the integrity of the forms after transmission via Epi-X, CDC recently changed the format to an HTML version make them easier to use.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondent

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

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases and determined that the Privacy Act does apply to some aspects of this information collection request. The applicable System of Records Notice is 09-20-0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

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 (Attachment C). IRB approval is not required.

Justification for Sensitive Questions

These forms collect three types of data: 1) Epidemiologic data such as travel itinerary, clinical signs and symptoms, exposure to ill people or animals, history of illness are essential to accurately determining the public health risk; 2) Demographic data such as age, race, sex, and geographic location are routinely collected as part of standard public health surveillance; and 3) Clinical information (symptom development, medical evaluation, lab testing, etc.) All of these data elements are essential to efficiently

detect a public health threat and rapidly implement appropriate public health control measures to prevent the introduction and spread of communicable disease in the U.S.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The number of times these data are collected remains dependent upon the number of exposure events of public health concern that occur within each data collection period. For the standard contact investigation forms, the number of times these data are collected remains dependent upon the number of exposure events of public health concern that occur within each data collection period, and the number of times the state decides to respond to CDC with the follow up information.

Additionally, because contact investigations involving ships almost always occur on the ship prior to making port, only one form is needed per investigation. In an air contact investigation, one form is requested per contact given how dispersed travelers are after termination of travel.

CDC estimated the number of respondents by reviewing respondent data in 2019, before the COVID-19 pandemic, and for 2020 during the pandemic and averaging the difference. In cases where there was very little data for 2019, CDC used the upper-bound estimate. These estimates result in a total of 1,422 burden hours for this information collection. If there is a significant increase in volume, CDC will submit a change request to account for that burden.

CDC is requesting approval for the use of the following forms and associated burden:

1. Clinically TB Contact Investigation Outcome Reporting Form – Maritime (Attachment D): 15 respondents and 20 minutes per response, for a total of 5 burden hours.
2. Varicella Investigation Outcome Reporting Form (Attachment E): 20 respondents and 20 minutes per response, for a total of 7 burden hours
3. Influenza Like Illness Investigation Outcome Reporting Form (Attachment F): 30 respondents and 20 minutes per response, for a total of 10 burden hours
4. General Contact Investigation Outcome Reporting Form – Air (Attachment G): 16,672 respondents and 5 minutes per response, for a total of 1,389 burden hours.
5. TB Contact Investigation Outcome Reporting Form – Air (Attachment H): 38 respondents and 5 minutes per response, for a total of 3 burden hours.
6. Measles Contact Investigation Outcome Reporting Form – Air (Attachment I): 73 respondents and 5 minutes per response, for a total of 6 burden hours.
7. Rubella Contact Investigation Outcome Reporting Form – Air (Attachment J): 5 respondents and 5 minutes per response, for a total of .4 burden hours.
8. General Contact Investigation Outcome Reporting Form – Land (Attachment K): 15 respondents and 5 minutes per response, for a total of 1.25 burden hours.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per	Average Burden per Response	Total Burden Hours
Cruise Ship Physicians/Cargo Ship Managers	Clinically Active TB Contact Investigation Outcome Reporting Form - Maritime	15	1	20/60	5
Cruise Ship Physicians/Cargo Ship Managers	Varicella Investigation Outcome Reporting Form	20	1	20/60	7
Cruise Ship Physicians/Cargo Ship Managers	Influenza Like Illness Investigation Outcome Reporting Form	30	1	20/60	10
State/Local public health staff	General Contact Investigation Outcome Reporting Form -Air	16,672	1	5/60	1,389
State/Local public health staff	TB Contact Investigation Outcome Reporting Form - Air	38	1	5/60	3
State/Local public health staff	Measles Contact Investigation Outcome Reporting Form - Air	73	1	5/60	6
State/Local public health staff	Rubella Contact Investigation Outcome Reporting	5	1	5/60	.4

	Form - Air				
State/Local public health staff	General Contact Investigation Outcome Reporting Form -Land	15	1	5/60	1.25
Total					1,422

B. Estimated Annualized Burden Costs

To estimate annualized burden cost for standard contact investigation reporting forms, we have taken the median income of Epidemiologists, which is $40.20 per hour (according to the U.S. Department of Labor Statistics, http://www.bls.gov/oes/current/oes191041.htm), and then adjusted x 2 for non-wage benefits and overhead for a total of $80.40 per hour.

Payment can vary widely depending on country of origin and training level, doc vs nurse or other mid-level staff. We feel reporting the Epidemiologist costs from US trained epidemiologists is a reasonable approximation. Doing so results in an estimate annualized burden cost of approximately $114,322.10.

Type of Respondent	Form Name	Total Burden Hours	Wage Rate	Costs
Cruise Ship Medical Staff/Cargo Ship Managers	Clinically Active TB Contact Investigation Outcome Reporting Form - Maritime	5	$80.40	$402
Cruise Ship Medical Staff/Cargo Ship Managers	Varicella Investigation Outcome Reporting Form - Maritime	7	$80.40	$536
Cruise Ship Medical Staff/Cargo Ship Managers	Influenza Like Illness Investigation Outcome Reporting Form - Maritime	10	$80.40	$804
State/Local public health staff	General Contact Investigation Outcome Reporting Form - Air	1,389	$80.40	$111,702.40
State/Local public health staff	TB Contact Investigation Outcome Reporting Form -	3	$80.40	$254.60

	Air			
State/Local public health staff	Measles Contact Investigation Outcome Reporting Form - Air	6	$80.40	$489.10
State/Local public health staff	Rubella Contact Investigation Outcome Reporting Form - Air	.4	$80.40	$33.50
State/Local public health staff	General Contact Investigation Outcome Reporting Form - Land	1.25	$80.40	$100.50
Total				**$114,322.10**

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

There is no total annual cost burden to respondents or record keepers other than their time.

14. Annualized Cost to the Government

As defined by CDC's regulatory authority and responsibility, routine contact investigations are ongoing. For routine costs, CDC estimates that it requires the equivalent of approximately 2 hours of CDC staff (GS-13 base, Atlanta locality x 2 to adjust for non-wage benefits and overhead) time to distribute and collect the CI follow up forms, along with some basic data transcription of the data into QARS. The COVID-19 pandemic has required the most significant public health response and routine burden is not anticipated to be as large going forward. Total costs for these activities within the routine CIs are as follows:

Staff	Pay Scale	# of Contact Investigations	Time/Contact	Total Cost
Public Health Advisor	GS13 base, ATL Locality ($46.52 x2 = $93.04)	32,956	Two Hours	**$3,035,907**

Finally, there are systems and personnel costs associated with the use, development, and maintenance of QARS, which will store information concerning individuals who are contacted in relation to a communicable disease confirmed in a traveler. These costs include the IT and associated staffing expenses that are impossible to apportion to CI's specifically, but are integral to operations involving illnesses in travelers. These costs are for the QARS system as whole, which is also used for other activities, but whose costs cannot be divided according to function. The costs for the QARS system is as follows.

QARS System Costs	$321,129
Staff Costs: 1xGS-13 (50% base *2 to adjust for non-wage benefits and overhead) 1xGS-9 (75% base *2 to adjust for non-wage benefits and overhead)	 $97,078 $84,443
Total	**$502,650**

The total annual cost for routine contact investigations included in this information collection is $502,650

15. Explanation for Program Changes or Adjustments

CDC has updated the burden to account for changes after the COVID-19 pandemic.

Additionally, the following changes are requested to the forms under this control number:

- General Contact Investigation Outcome Reporting Form -Air:
  - Section 5 – Immunity
    - Add a box for "Does not apply" to allow for accurate data collection point
    - Add a line for "Vaccination Type:_____" to allow for explanation of vaccine type
    - Add a line for "Manufacturer:_____"
    - Add a line for multiple "Date of Doses __/__/__; __/__/__; __/__/__ " in case more than one dose of vaccine is needed.
  - Section 6 – Health Since Travel
    - Add "Date of earliest symptom onset __/__/__" if Yes to signs or symptoms
    - Add check box for "Loss of sense of smell", "Loss of sense of taste" or "Fatigue" to account for other signs or symptoms related to COVID-19.
- General Contact Investigation Outcome Reporting Form - Land
  - Section 1 – Travel Information:
    - Country is added to add clarification to where the traveler is coming from or going to
    - Port of Entry or Border Patrol Sector is added as there are so many places along the border that the traveler could cross into the US
    - Other is added in case of other mode of transportation such as POV or Pedestrian
  - Section 2 – Index Case
    - Add a line for whether the illness is suspected/probable/confirmed for entry in QARS and to gather better data points
    - Separated out a space for Clinical Information vs Laboratory information as they are two different types of information that might be collected.

- Section 3 – Change title to Information for Exposed (Contact) Passenger/Traveler for clarity
- Section 4 – Contact Interview Information
    - Where there is a “no” box, change “why not?” to “due to:” This keeps language more professional.
    - Add “unknown” and “Does not apply” to end of “was contact interviewed section” as these are choices in QARS.
    - Add “specify” if person was known close contact of index case outside of this travel
- Section 5 – Immunity
    - Add a box for “Does not apply” to allow for accurate data collection point
    - Add a line for “Vaccination Type:_____” to allow for explanation of vaccine type
    - Add a line for “Manufacturer:_____”
    - Add a line for multiple “Date of Doses __/__/__; __/__/__; __/__/__ “ in case more than one dose of vaccine is needed.
- Section 6 – Health Since Travel
    - Add “Date of earliest symptom onset __/__/__” if Yes to signs or symptoms
    - Add check box for “Loss of sense of smell”, “Loss of sense of taste” or “Fatigue” to account for other signs or symptoms related to COVID-19.
- Section 7 – Public Health Intervention
    - Where there is a “no” box, change “why not?” to “due to:” This keeps language more professional.

16. Plans for Tabulation and Publication and Project Time Schedule

The proposed activities are routine and reoccurring data collections, the time schedules for which are determined by the frequency of exposure to a communicable disease resulting in a contact investigation. Both daily and incident specific reports are generated for CDC staff using QARS data. Quarantine staff plan to use the data, aggregated to protect the privacy of any individually identifiable information, to provide the public, partners, and other stakeholders information about contact investigation and to evaluate and improve CDC’s investigative protocols. Data are not collected for statistical use. There are no current plans to publish any information collected in this request.

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

Attachment A1: Section 361 of the Public Health Service (PHS) Act (42 USC 264)

Attachment A2: 42 CFR part 70

Attachment A3: 42 CFR part 71

Attachment B: 60 Day Federal Register Notice

Attachment B1: Response to 60 Day Federal Register Notice Comment

Attachment C: Non-research Determination

Attachment D: Clinically TB Contact Investigation Outcome Reporting Form – Maritime

Attachment E: Varicella Investigation Outcome Reporting Form

Attachment F: Influenza-Like Illness Investigation Outcome Reporting Form

Attachment G: General Contact Investigation Outcome Reporting Form – Air

Attachment H: TB Contact Investigation Outcome Reporting Form – Air

Attachment I: Measles Contact Investigation Outcome Reporting Form – Air

Attachment J: Rubella Contact Investigation Outcome Reporting Form – Air

Attachment K: General Contact Investigation Outcome Reporting Form – Land

Attachment L: QARS PIA