Contact Investigation Outcome Reporting Forms

(OMB Control No. 0920-0900)

Expires 06/30/2018

Request for Revision of a Currently Approved Data Collection

1/12/2018

Updated 3/28/2018 and 4/20/2018

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 a number of changes in this iteration of 0920-0900 resulting in 673 fewer burden hours. All changes and adjustments are based on reassessments of which pieces are data are critical to understanding outcomes and data on responses from previous years. They are as follows:

- As directed by OMB/OIRA, CDC has determined that the Ebola specific forms included in previous versions of this information collection are no longer needed, and so CDC is requesting the removal of those forms and the associated burden, 534 hours.
- CDC has re-evaluated information collections involving maritime communicable diseases and is requesting the following changes:
    - Removal of all current maritime-related forms except a condensed maritime TB contact investigation follow-up form in an excel format. Of the current maritime forms, only TB exceeds the threshold of more than 9 respondents in 12 months.
    - A downward revision of the estimated number of TB contact investigation forms used annually from 150 to 15, but an upward revision of the amount of time requested from each respondent from 5 to 20 minutes per response.

- The addition of varicella and influenza like illness outbreak contact investigation follow up forms

- No changes are requested of the Air or Land associated forms; however adjustments in burden are requested, as described in section 15.

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 0920-0821. 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.

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 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 October 13, 2017, vol. 82, No. 197, pp. 47743 (Attachment B). CDC did not receive public comments related to this notice.

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 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): 29 respondents and 20 minutes per response, for a total of 10 burden hours
3. Influenza Like Illness Investigation Outcome Reporting Form (Attachment F): 45 respondents and 20 minutes per response, for a total of 15 burden hours
4. General Contact Investigation Outcome Reporting Form – Air (Attachment G): 34 respondents and 5 minutes per response, for a total of 3 burden hours.
5. TB Contact Investigation Outcome Reporting Form – Air (Attachment H): 547 respondents and 5 minutes per response, for a total of 46 burden hours.
6. Measles Contact Investigation Outcome Reporting Form – Air (Attachment I): 324 respondents and 5 minutes per response, for a total of 27 burden hours.
7. Rubella Contact Investigation Outcome Reporting Form – Air (Attachment J): 27 respondents and 5 minutes per response, for a total of 2 burden hours.
8. General Contact Investigation Outcome Reporting Form – Land (Attachment K): 15 respondents and 5 minutes per response, for a total of 1 burden hour.

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	29	1	20/60	10
Cruise Ship Physicians/Cargo Ship Managers	Influenza Like Illness Investigation Outcome Reporting Form	45	1	20/60	15
State/Local public health staff	General Contact Investigation Outcome Reporting Form -Air	34	1	5/60	3
State/Local public health staff	TB Contact Investigation Outcome Reporting Form - Air	547	1	5/60	46
State/Local public health staff	Measles Contact Investigation Outcome Reporting Form - Air	324	1	5/60	27
State/Local public health staff	Rubella Contact Investigation Outcome Reporting Form - Air	27	1	5/60	2
State/Local public health staff	General Contact Investigation	15	1	5/60	1

	Outcome Reporting Form -Land				
Total					109

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 $37.37 per hour (according to the U.S. Department of Labor Statistics, http://www.bls.gov/oes/current/oes191041.htm)

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

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	$37.37	$187
Cruise Ship Medical Staff/Cargo Ship Managers	Varicella Investigation Outcome Reporting Form - Maritime	10	$37.37	$374
Cruise Ship Medical Staff/Cargo Ship Managers	Influenza Like Illness Investigation Outcome Reporting Form - Maritime	15	$37.37	$561
State/Local public health staff	General Contact Investigation Outcome Reporting Form - Air	3	$37.37	$112
State/Local public health staff	TB Contact Investigation Outcome Reporting Form - Air	46	$37.37	$1,719

State/Local public health staff	Measles Contact Investigation Outcome Reporting Form - Air	27	$37.37	$1,009
State/Local public health staff	Rubella Contact Investigation Outcome Reporting Form - Air	2	$37.37	$75
State/Local public health staff	General Contact Investigation Outcome Reporting Form - Land	1	$37.37	$37
Total				**$4,074**

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) time to distribute and collect the CI follow up forms, along with some basic data transcription of the data into QARS. 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 ($43.14)	186	Two Hours	**$16,048**

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	$134,554
Staff Costs:	$45,012

1xGS-13(50% base) 1xGS-9(75% base)	 $26,102
Total	**$ 205,668**

The total annual cost for routine contact investigations included in this information collection is $221,716.

15. Explanation for Program Changes or Adjustments

CDC is requesting a number of changes in this iteration of 0920-0900. They are as follows:

- As directed by OMB/OIRA, CDC has determined that the Ebola specific forms included in previous versions of this information collection are no longer needed, and so CDC is requesting the removal of those forms and the associated burden: 534 hours.
- CDC has re-evaluated information collections involving maritime communicable diseases and is requesting the following changes:
    - Discontinuation of all current non-TB maritime-related forms. None of these investigations exceeds the threshold of more than 9 respondents in 12 months. This is a reduction of 28 burden hours.
    - Discontinuation of the word version TB Contact Investigation Outcome Reporting Form. Changes include a revised excel format Clinically Active TB Contact Investigation Outcome Reporting Form, and a downward revision of the estimated number of Clinically Active TB Contact Investigation Outcome Reporting Forms used annually from 150 to 15, but an upward revision of the estimated time requested of the respondents to complete the form and send to CDC. This results in a reduction of 21 burden hours. This is due to a clarification that only one form is needed per investigation, not per contact in an investigation. The changes ask for the bare minimum necessary info for a TB CI in the maritime environment, (decrease burden), and parallel our TB CI Recommendation Letter sent to ship when CI criteria are met
    - The following changes are being requested to the Clinically Active TB Contact Investigation Outcome Reporting Form
        - Decrease in the pieces of data requested from the maritime operator respondent: **43** data-entry fields/columns to **15**. The following have been removed:
            - Gender (not necessary for public health decision-making)
            - Date contacted (not necessary for public health decision-making)
            - Unnecessary contact details (e.g. Was this person a known close contact of the index case outside of this voyage?; Specify types of contact this person had with index case?). Not necessary for public health decision-making

- Unnecessary medical history of contact (e.g. other TB exposures, history of incarceration, IV drug use, BCG vaccine, previous TST or IGRA testing, etc)

- Modifications
  - "Were you able to contact this person? Y/N If no, why not? (contact disembarked in another country, transferred to another ship, etc) (If no, stop here)" to "Is this contact still on this vessel?
    - Sometimes crew disembark to work on other ships of the same cruise line
  - "Was a review of signs and symptoms completed?" to "Does this person have any signs or symptoms of TB?
    - Critical clinical and public health information needed, i.e. the results of the disease screening/CI)
  - "If x-ray done, was result Normal, abnormal, non-cavitary or Abnormal cavitary?" to "If a chest X-ray was done, did it show any signs of TB?"
  - IGRA screening test results…to "If a high-risk contact* without TB signs/symptoms, how was contact assessed for latent TB (LTBI)?"
    - This modified question clarifies what the critical information is and is less confusing to the respondent. The question now also parallels the recommendations sent to ship in our TB CI Recommendation Letter
  - Multiple columns asking TST vs. IGRA screening test results….to "Results of high-risk contact LTBI screening"
    - This modified question clarifies what the critical information is and is less confusing to the respondent. The question now also parallels the recommendations sent to ship in our TB CI Recommendation Letter

- The addition of varicella and influenza like illness contact investigation follow up forms. This is an addition of 25 hours.
- No changes to the form content are requested for the Air or Land associated outcome reporting forms.
- The following adjustments are requested for the Air forms, all are the result of revised estimates based on QARS data and including reporting forms returned to CDC, not those that are sent as part of the Epi-X notification after confirmed case of illness is reported to CDC.
  - General Contact Investigation Outcome Reporting Form – Air: an increase of 22 respondents and 2 burden hours
  - TB Contact Investigation Outcome Reporting Form – Air: a decrease of 697 respondents and 58 burden hours
  - Measles Contact Investigation Outcome Reporting Form – Air: a decrease of 640 respondents and 53 burden hours
  - Rubella Contact Investigation Outcome Reporting Form – Air: a decrease of 68 respondents and 6 burden hours.

Table A.15-1. Summary of changes to Burden Table

		Previous OMB Approval Period		Proposed for This Revision		Net Change	
Type of Respondents	Form Name	No. of Responses	Total burden (in hours)	No. of Responses	Total burden (in hours)	Change in responses	Change in burden hours
State/local health department staff	General Contact Investigation Outcome Reporting Form (Air)	12	1	34	3	+22	+2
Cruise Ship Physicians/Cargo Ship Managers	General Contact Investigation Outcome Reporting Form (Maritime – word version)	100	8	N/A		-100	-8
Cruise Ship Physicians/Cargo Ship Managers	General Contact Investigation Outcome Reporting Form (Maritime – Excel version)	100	8	N/A		-100	-8
State/local health department staff	General Contact Investigation Outcome Reporting Form (Land)	12	1	15	1	+3	0
State/local health department staff	TB Contact Investigation Outcome Reporting Form (Air)	1,244	104	547	46	-697	-58
Cruise Ship Physicians/Cargo Ship Managers	TB Contact Investigation Outcome Reporting Form (Maritime -	150	13	15	5	-135	-8

	word version)						
Cruise Ship Physicians/Cargo Ship Managers	TB Contact Investigation Outcome Reporting Form (Maritime - Excel version)	150	13	N/A		-150	-13
State/local health department staff	Measles Contact Investigation Outcome Reporting Form (Air)	964	80	324	27	-640	-53
Cruise Ship Physicians/Cargo Ship Managers	Measles Contact Investigation Outcome Reporting Form (Maritime – word version)	63	5	N/A		-63	-5
Cruise Ship Physicians/Cargo Ship Managers	Measles Contact Investigation Outcome Reporting Form (Maritime – excel version)	63	5	N/A		-63	-5
State/local health department staff	Rubella Contact Investigation Outcome Reporting Form (Air)	95	8	27	2	-68	-6
Cruise Ship Physicians/Cargo Ship Managers	Rubella Contact Investigation Outcome Reporting Form (Maritime – word version)	12	1	N/A		-12	-1

Cruise Ship Physicians/Cargo Ship Managers	Rubella Contact Investigation Outcome Reporting Form (Maritime – excel version)	12	1	N/A	-12	-1
Passenger	Ebola Airline Exposure Assessment Passenger	340	113	N/A	-340	-113
Flight Crew	Ebola Airline Exposure Assessment Flight Crew	240	80	N/A	-240	-80
Cleaning Crew	Ebola Airline Exposure Assessment Cleaning Crew	120	40	N/A	-120	-40
Airport or Other Port of Entry Staff	Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff	100	33	N/A	-100	-33
Passengers on other commercial conveyances	Ebola Exposure Questionnaire for Passengers on other commercial conveyances	180	60	N/A	-180	-60
Traveler	Script – Introduction and Confirmation	2500	208	N/A	-2500	-208
Cruise Ship Physicians/Cargo Ship Managers	Varicella Investigation Outcome Reporting Form	N/A		29	10	+29	+10

Cruise Ship Physicians/Cargo Ship Managers	Influenza Like Illness Investigation Outcome Reporting Form	N/A		45	15	+45	+15
Total		6457	782	1036	109	-5421	-673

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 C: Non-research Determination

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

Attachment D 1: Summary of changes: 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