**Contact Investigation Outcome Reporting Forms**

**(OMB Control No. 0920-0900)**

**Expires 10/31/2017**

**Request for Revision of a Currently Approved Data Collection**

**June 16, 2015**

**Contact:**

**Amy McMillen**

**Office of Policy and Planning**

**National Center for Emerging and Zoonotic Infectious Diseases**

**Centers for Disease Control and Prevention**

**1600 Clifton Road, N.E., MS C12**

**Atlanta, Georgia 30333**

**Phone: (404) 639-1045**

**Email:** [**auh1@cdc.gov**](mailto:auh1@cdc.gov)

**Table of Contents**

Contents

[A. Justification 4](#_Toc407702666)

[1. Circumstances Making the Collection of Information Necessary 4](#_Toc407702667)

[2. Purpose and Use of Information Collection 6](#_Toc407702668)

[3. Use of Improved Information Technology and Burden Reduction 7](#_Toc407702669)

[4. Efforts to Identify Duplication and Use of Similar Information 7](#_Toc407702670)

[5. Impact on Small Businesses or Other Small Entities 8](#_Toc407702671)

[6. Consequences of Collecting the Information Less Frequently 8](#_Toc407702672)

[7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5 8](#_Toc407702673)

[8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency 8](#_Toc407702674)

[9. Explanation of Any Payment or Gift to Respondents 8](#_Toc407702675)

[10. Assurance of Confidentiality Provided to Respondents 8](#_Toc407702676)

[11. Justification for Sensitive Questions 12](#_Toc407702677)

[12. Estimates of Annualized Burden Hours and Costs 12](#_Toc407702678)

[B. Estimates of annualized burden cost 16](#_Toc407702679)

[13. Estimates of Other Total Annual cost burden to Respondents or Record Keepers 19](#_Toc407702680)

[14. Annualized Cost to the Government 20](#_Toc407702681)

[15. Explanation for Program Changes or Adjustments 21](#_Toc407702682)

[16. Plans for Tabulation and Publication and Project Time Schedule 22](#_Toc407702683)

[17. Reason(s) Display of OMB Expiration Date is Inappropriate 22](#_Toc407702684)

[18. Exceptions to Certification for Paperwork Reduction Act Submissions 23](#_Toc407702685)

[List of Attachments: 24](#_Toc407702686)

**Contact Investigation Outcome Reporting Forms**

**(OMB Control No. 0920-0900)**

**Request for Revision of an Approved Data Collection (expiring 10/31/2017)**

* The goal of this information collection is to contact and assess travelers who may have been exposed to a person contagious with a communicable disease of public health concern while traveling to or within the United States, and provide preventive treatment if available and 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, carry out initial investigations to determine risk of infection and whether public health interventions are needed, and monitor the status of at-risk travelers after exposure until the end of the potential incubation period (e.g. 21 days for Ebola or measles) to ensure that any developing symptoms are identified as early as possible to prevent further spread.
* 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 travelers who may have been exposed to an infectious disease while aboard a conveyance traveling to or within the United States, as well as 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.

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 the addition of a one year approval for Ebola-specific information collection tools to supplement the Centers for Disease Control and Prevention’s (CDC) routine contact investigation activities so that CDC can better assess the risk to individuals who may have been exposed to a confirmed case of Ebola while traveling to or within the United States. These forms were previously granted approval under OMB Control No. 0920-1032. After one year, CDC will re-evaluate the need for these forms. CDC is requesting a three year approval for the use of the routine contact investigation outcome reporting forms.

The Ebola-specific forms proposed for inclusion are as follows:

* Ebola Airline passenger exposure questionnaire (Attachment P) - This contact investigation form gathers information from airline passengers who traveled on plane(s) and sat within a 3 foot area around the suspected case and travel companions of the suspected case to determine the level of exposure and risk, as well as other passengers who may have had contact with the case’s bodily fluids. Information gathered in this form is shared with the CDC to determine risk level. Risk levels are outlined in [CDC’s Movement and Monitoring Guidance](http://www.cdc.gov/vhf/ebola/pdf/monitoring-and-movement.pdf). The number of respondents and burden associated with this tool is 170 and 113, respectively.
* Ebola exposure Assessment Flight Crew (Attachment Q) – The flight exposure questionnaire is used to ascertain the same relevant information included in the passenger questionnaire for all crew who worked on flight(s) and came into contact with Ebola patient(s). The number of respondents and burden associated with this tool is 120 and 80, respectively.
* Ebola exposure Assessment Cleaning Crew (Attachment R) – This form collects the same information as the flight crew exposure questionnaire, used to determine the level of exposure a member of the cleaning crew who serviced a flight with an ill patient(s). The number of respondents and burden associated with this tool is 60 and 40, respectively.
* Ebola exposure Assessment Airport or other port of entry staff (Attachment S) – This questionnaire is utilized for airport staff who may have come into contact with a person ill with Ebola. Airport staff are identified through conversations with airport authority to determine which employees carried out tasks that would have put them in contact with the ill person or their body fluids. The number of respondents and burden associated with this tool is 50 and 33, respectively.
* Passengers of other commercial conveyance Ebola exposure questionnaire (Attachment T) – This questionnaire collects the same information as the airline passenger questionnaire but will be utilized for passengers of commercial conveyance that is land- or waterborne. The number of respondents and burden associated with this tool is 90 and 60, respectively.
* Finally, the introduction and confirmation script (Attachment U) is to be used by CDC staff manning open call lines available for persons who traveled on planes that carried suspected or confirmed patients with Ebola. As with the other questionnaires, this script assesses the risk of a plan passenger who was not in the immediate vicinity of the Ebola patient but still has concerns about the level of exposure and risk of contracting the virus. The number of respondents and burden associated with this tool is 2500 and 208, respectively.

CDC is not proposing any changes to the number of respondents or burden hours associated with the routine contact investigation forms already approved under this information collection request.

The total burden associated with this revision is 782 hours.

# A. Justification

# 1. Circumstances Making the Collection of Information Necessary

Background

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.

When an illness or death suggestive of a communicable disease is reported during travel (reported under 0920-0134 Foreign Quarantine Regulations), Quarantine Officers respond to carry out an onsite public health assessment and collect pertinent information using “Illness Response and Investigation Forms,” OMB 0920-0821. 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 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.

The responsibility for contacting exposed passengers typically falls with state or local health departments or with maritime operators, if travel occurred on a ship. The extent of the contact investigation that determines which passengers are believed to have been exposed to a communicable disease is based on CDC investigative protocols. CDC is also responsible for providing state and local public health authorities with adequate contact information, such as phone numbers and address, to facilitate successful notification of the exposed passengers. 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 from state and local health departments or from maritime conveyance operators.

In addition to the standard contact investigation forms described above, CDC has proposed to add an additional five contact investigation forms and one contact investigation script specifically for use in situations where there is a confirmed case of Ebola on a commercial conveyance, e.g. airline, but, train, etc. CDC, in coordination with state and local health departments, will perform contact investigations of individuals who may have come into contact with travelers that are confirmed to have Ebola infection. CDC will collaborate with state health departments, conveyance operators, port of entry partners, and international public health authorities to identify potential exposures, carry out initial investigations to determine risk of infection, and monitor status for 21 days after exposure to ensure that any developing symptoms are identified as early as possible and prevent further spread. CDC relies on established public and private sector partnerships to complete contact investigations. CDC’s response to the current outbreak of Ebola requires incorporating forms recently approved under OMB 0920-1032 into the standing information collection request OMB Control No 0920-0900. The additional burden estimate for the 5 additional forms and 1 additional script is 2,990 persons and 534 hours, bringing the total number of respondents and burden requested to 5,967 persons and 782 hours, respectively.

# 2. Purpose and Use of Information Collection

The information collected on the forms 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. CDC is not requesting any changes to the following forms in this revision:

* General Contact Investigation Outcome Reporting Form – Air (Attachment C)
* General Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment D)
* General Contact Investigation Outcome Reporting Form –(Excel version) (Attachment E)
* General Contact Investigation Outcome Reporting Form – Land (Attachment F)
* TB Contact Investigation Outcome Reporting Form – Air (Attachment G)
* TB Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment H)
* TB Contact Investigation Outcome Reporting Form –(Excel version) (Attachment I)
* Measles Contact Investigation Outcome Reporting Form – Air (Attachment J)
* Measles Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment K)
* Measles Contact Investigation Outcome Reporting Form –(Excel version) (Attachment L)
* Rubella Contact Investigation Outcome Reporting Form – Air (Attachment M)
* Rubella Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment N)
* Rubella Contact Investigation Outcome Reporting Form –(Excel version) (Attachment O)

Along with the standard forms described above, the addition of five Ebola contact investigation questionnaires enable CDC to gather necessary information from travelers entering and traveling in the United States. These forms are as follows:

* Ebola Airline passenger exposure questionnaire (Attachment P)
* Ebola exposure Assessment Flight Crew (Attachment Q)
* Ebola exposure Assessment Cleaning Crew (Attachment R)
* Ebola exposure Assessment Airport or other port of entry staff (Attachment S)
* Passengers of other commercial conveyance Ebola exposure questionnaire (Attachment T)
* Script: Introduction and Confirmation (Attachment U)

Passenger data collected, including recent travel history, explanation of exposure to persons ill with Ebola or their bodily fluids, allows the CDC and its partners to assess the risk that passengers on commercial transit have of contracting Ebola, as well as their risk to spreading the disease in the receiving communities. Data uniformity is important for the ongoing Ebola outbreak not only to maintain equal information access with partner organizations, but also to provide solid data for future analysis to improve the American public health safety and response system for future global health threats.

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.

QARS is a secure intranet system implemented in June 2005 to track the number of illnesses and deaths reported to Quarantine Stations that occurred on conveyances and land border crossings entering the United States. In addition, QARS is used to store information on Quarantine Station activities such as: emergency preparedness and partnership activities, interaction with public health and other port partners, medical paperwork processing for aliens and immigrants, the importation of nonhuman primates and other animals, and drug releases (botulism and diphtheria anti-toxins and malaria treatment).

# 3. Use of Improved Information Technology and Burden Reduction

The majority of responses 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.

# 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 71). 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.

# 5. Impact on Small Businesses or Other Small Entities

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 physicians 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 notice detailing the proposed data collection activities was published in the Federal Register on December, 15, 2014, Vol. 79, No. 240, p. 74099 (Attachment B). No public comments were received.

B. CDC did not consult with outside persons on the development of these forms. The forms represent data that is already captured by state and local health departments and maritime operators. CDC collects these data on a voluntary basis. The forms are tools to facilitate transfer of this information to CDC.

# 9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondent

# 10. Assurance of Confidentiality Provided to 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.

**Privacy Impact Assessment**

1. Overview of the Data Collection System

CDC’s Division of Global Migration and Quarantine has developed contact investigation outcome reporting forms for the different types of contact investigations. These forms are used to collect information on the outcome of contact investigations so that CDC can determine if adequate information was provided to those responsible for contacting passengers believed to have been exposed to a communicable disease during travel. These forms include:

* General Contact Investigation Outcome Reporting Form – Air (Attachment C)
* General Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment D)
* General Contact Investigation Outcome Reporting Form –(Excel version) (Attachment E)
* General Contact Investigation Outcome Reporting Form – Land (Attachment F)
* TB Contact Investigation Outcome Reporting Form – Air (Attachment G)
* TB Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment H)
* TB Contact Investigation Outcome Reporting Form –(Excel version) (Attachment I)
* Measles Contact Investigation Outcome Reporting Form – Air (Attachment J)
* Measles Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment K)
* Measles Contact Investigation Outcome Reporting Form –(Excel version) (Attachment L)
* Rubella Contact Investigation Outcome Reporting Form – Air (Attachment M)
* Rubella Contact Investigation Outcome Reporting Form – Maritime (Word version) (Attachment N)
* Rubella Contact Investigation Outcome Reporting Form –(Excel version) (Attachment O)
* Ebola Airline Exposure Assessment – Passenger (Attachment P)
* Ebola Airline Exposure Assessment – Flight Crew (Attachment Q)
* Ebola Airline Exposure Assessment – Cleaning Crew (Attachment R)
* Ebola Airline Exposure Assessment – Airport or other Port of Entry Staff (Attachment S)
* Ebola Exposure Questionnaire for Passengers on other commercial conveyances – (Attachment T)
* Ebola Script – Introduction and Confirmation – (Attachment U)

Each of these data collection tools reflect specific questions unique to the communicable disease of public health concern specified. These forms provide the means for state and local public health officials, as well as cruise ship physicians and cargo ship managers to communicate information to CDC information regarding contact investigations. The method of collecting information is determined by those conducting the contact investigation.

Data collected from state and local health departments or maritime operators will be maintained by CDC in accordance with the CDC records retention schedule: *Communicable Disease Case Study Files (NC1-90-83-2, Item 1*).

2. Items of Information to be Collected

These forms include the following information in identifiable form: medical information, date of birth, gender, country of birth, and country of residence. These data are compiled from existing sources. The forms provide a uniform approach for relaying information pertinent to communicating the outcome of each investigation.

3. A description of how the information will be shared and for what purpose

Any records shared will be transmitted using secure fax or encrypted email.

* Records may be disclosed to contractors to handle program work duties, performing many of the same functions as FTEs within DGMQ in situations where additional staff is required. Contractors are required to maintain Privacy Act safeguards with respect to such records.
* Records may be disclosed to state and local health departments and other cooperating medical and public health authorities and their counsel to more effectively deal with outbreaks and other significant public health conditions.
* Personal information from this system may be disclosed as a routine use to appropriate conveyance personnel, Federal agencies, state and local health departments, Department of State and embassy personnel (U.S. and foreign), and health authorities in foreign countries for contact tracing investigations and notifications of possible exposures to serious communicable diseases in connection with   
  travel.
* Records may be disclosed to the Department of Homeland Security to restrict travel of persons who pose a public health risk and in the instance of suspected domestic or international terrorism.
* Disclosure may be made to medical personnel providing evaluation and care for ill or exposed persons, including travelers.
* Records may be disclosed to the World Health Organization in accordance with U.S. responsibilities as a signatory to the International Health Regulations or other international agreements.
* Personal information may be disclosed to federal, state, and local authorities for taking necessary actions to place someone under quarantine or isolation, for enforcement of other quarantine regulations, or to protect the public's health and safety.
* Records may be disclosed to cooperating state and local legal departments enforcing concurrent legal authority related to quarantine or isolation activities.

4. A statement detailing the impact the proposed collection will have on the respondent’s privacy.

For routine contact investigations, respondents to this data collection are state and local health departments and maritime conveyance operators. Their PII is not collected and so a breach of this information would have no effect. The information collected by the state and local health departments may include PII and be highly sensitive, which would affect a respondent’s privacy if there were a breach of security.

CDC will assure the security of respondents based on procedures implemented in accordance with the Privacy Act. These forms are maintained as a system of records under the Privacy Act system notice 0920-0171, “Quarantine and Traveler Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71, published in the Federal Register, Vol. 72, No. 238, December 13, 2007, pp. 70867-70872. Stringent safeguards are in place to ensure a respondent’s privacy including authorized users, physical safeguards, and procedural safeguards.

5. Whether individuals are informed that providing the information is voluntary or mandatory.

In general, for the routine and Ebola contact investigations, respondents to this data collection are state and local health departments and maritime conveyance operators and response to these forms is voluntary. However, if respondents refuse to answer questions related to a communicable disease exposure, other measures may be taken by public health authorities to collect enough information to determine that the contact either is, or its not, a risk to other individuals. Under 42 CFR 70 and 71, CDC can take measures if an individual is infected with a quarantinable disease, which include TB and Ebola. State and local health departments have their own authorities for control of infectious disease.

6. Opportunities to consent, if any, to sharing and submission of information.

Respondents to this data collection are state and local health departments and maritime conveyance operators and response to these forms is voluntary. CDC generally is not collecting data directly from the ill traveler or contact; therefore, no consent or script to conduct such an interview is needed.

7. How the information will be secured

Highly sensitive information is being collected that would affect a respondent’s privacy if there were a breach of security. However, stringent safeguards are in place to ensure a respondent’s privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC’s computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations which are located in a secure area of the airport. Procedural safeguards: Protections for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic medical containing Privacy Act information. Finally, CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts and the CDC Project Director, contract officers and project officers oversee compliance with these requirements.

8. Parts of this data collection are subject to the Privacy Act. The existing applicable systems of Records Notice for this revision is 09-20-0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

IRB Approval

CDC’s National Center for Emerging and Zoonotic Infectious Diseases has determined that this project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment V).

# 11. 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

1. Estimate of Annualized Burden Hours

The number of times these data are collected remains dependent upon the number of outbreaks 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 outbreaks of public health concern that occur within each data collection period.

No changes to the burden for routine contact investigations already approved in this information collection are requested. Based on the average of the routine contact investigations conducted between 2011 and 2014, CDC still estimates that the number of contacts will be approximately 2,977 annually. The estimated time to complete the forms remains approximately five minutes. Completion of each form is dependent upon the ability to contact the individual believed to have been exposed to a communicable disease. If contact was made, the burden estimates below are based upon the time it would take to relay the pertinent information they have collected to the CDC standardized forms. The total burden hours are approximately 248 hours, if outcome forms are submitted for each contact.

In addition to the burden calculation for routine contact investigation forms, CDC has completed an additional assessment of burden hours for the additional Ebola Contact Investigation forms and script that were approved by OMB through an emergency clearance in Control No 0920-1032. Below are the estimates of the annualized burden that are not already included in the OMB No. 0920-0900. This estimate of 534 burden hours represents a reasonable estimate based on recent experience with contact tracing for Ebola in the United States, but was not arrived at through epidemiological modeling or other scientific techniques. The estimate is a contingency to ensure that CDC has requested adequate public burden in the event that more contact investigations for Ebola are needed. If addition burden is needed, CDC will submit a change request to OMB for additional hours.

This estimate is based on the following assumptions and estimates:

1. It is common for index case to connect from an international flight to a domestic flight, since international flights often do not land at the airport closest to index’s home.  This will result in double the amount of potential contacts. This estimate also includes flights that originate and terminate within the United States.
2. In the past CDC has requested the ability to contact at least 17 passengers on a flight who may have had close contact with an ill traveler. The generally covers 14-15 travelers who are sitting in the close contact zone as well as other individuals who may have had close contact. CDC requests the ability to use the already approved contact investigation forms, with the change of temperature notice, for five contact investigations.
3. CDC anticipates that every individual on a flight with a confirmed case will call CDC and will respond to questions in Script – Introduction and Confirmation. This is approximately 250 individuals per flight, multiplied by two flights per index case, multiplied by five contact investigations. This comes to a total of 2,500 total respondents.
4. Of those 2,500 respondents CDC, anticipates that 170 travelers who are in a close contact zone or otherwise had contact with the ill traveler may need to be contacted using the Ebola Airline Exposure Assessment Passenger Form.
5. CDC anticipates that 120 flight crew may need to be contacted using the Ebola Airline Exposure Assessment Flight Crew Form. This is approximately 12 per flight for each of the five contact investigations.
6. CDC anticipates that 60 cleaning crew may need to be contacted using the Ebola Airline Exposure Assessment Form. This is six crew members per flight for each of the five contact investigations.
7. CDC anticipates that 50 port of entry staff may need to be contacted using the Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff Form. This is five staff per flight, for five contact investigations.
8. To account for the potential that an index case may expose fellow travelers on another mode of travel, CDC is requesting the addition of a tool to follow up with passengers on buses, trains, or other conveyances. CDC estimates 18 contacts per contact investigation, for a total of 90 contacts.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Number of Respondents** | **Number of Responses per** | **Average Burden per Response** | **Total Burden Hours** |
|
| State/local health department staff | General Contact Investigation Outcome Reporting Form (Air) | 12 | 1 | 5/60 | 1 |
| Cruise Ship Physicians/Cargo Ship Managers | General Contact Investigation Outcome Reporting Form (Maritime – word version) | 100 | 1 | 5/60 | 8 |
| Cruise Ship Physicians/Cargo Ship Managers | General Contact Investigation Outcome Reporting Form (Maritime – Excel version) | 100 | 1 | 5/60 | 8 |
| State/local health department staff | General Contact Investigation Outcome Reporting Form (Land) | 12 | 1 | 5/60 | 1 |
| State/local health department staff | TB Contact Investigation Outcome Reporting Form (Air) | 1,244 | 1 | 5/60 | 104 |
| Cruise Ship Physicians/Cargo Ship Managers | TB Contact Investigation Outcome Reporting Form (Maritime - word version) | 150 | 1 | 5/60 | 13 |
| Cruise Ship Physicians/Cargo Ship Managers | TB Contact Investigation Outcome Reporting Form (Maritime - Excel version) | 150 | 1 | 5/60 | 13 |
| State/local health department staff | Measles Contact Investigation Outcome Reporting Form (Air) | 964 | 1 | 5/60 | 80 |
| Cruise Ship Physicians/Cargo Ship Managers | Measles Contact Investigation Outcome Reporting Form (Maritime – word version) | 63 | 1 | 5/60 | 5 |
| Cruise Ship Physicians/Cargo Ship Managers | Measles Contact Investigation Outcome Reporting Form (Maritime – excel version) | 63 | 1 | 5/60 | 5 |
| State/local health department staff | Rubella Contact Investigation Outcome Reporting Form (Air) | 95 | 1 | 5/60 | 8 |
| Cruise Ship Physicians/Cargo Ship Managers | Rubella Contact Investigation Outcome Reporting Form (Maritime –word version) | 12 | 1 | 5/60 | 1 |
| Cruise Ship Physicians/Cargo Ship Managers | Rubella Contact Investigation Outcome Reporting Form (Maritime – excel version) | 12 | 1 | 5/60 | 1 |
| Passenger | Ebola Airline Exposure Assessment Passenger | 170 | 2 | 20/60 | 113 |
| Flight Crew | Ebola Airline Exposure Assessment Flight Crew | 120 | 2 | 20/60 | 80 |
| Cleaning Crew | Ebola Airline Exposure Assessment Cleaning Crew | 60 | 2 | 20/60 | 40 |
| Airport or Other Port of Entry Staff | Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff | 50 | 2 | 20/60 | 33 |
| Passengers on other commercial conveyances | Ebola Exposure Questionnaire for Passengers on other commercial conveyances | 90 | 2 | 20/60 | 60 |
| Traveler | Script – Introduction and Confirmation | 2,500 | 1 | 5/60 | 208 |
| **TOTAL** |  | **5967** |  |  | **782** |

1. Estimates of annualized burden cost

To estimate annualized burden cost for non-Ebola, standard contact investigation reporting forms, we have taken the average wage or median income of Epidemiologists, which is $35.11 per hour (according to the U.S. Department of Labor Statistics, http://www.bls.gov/oes/current/oes191041.htm). Assuming an hourly respondent labor wage of $35.11 for the epidemiologists’ time, the estimated annual cost to respondents total $8,707.

In addition to non-Ebola, standard reporting forms, the table below reflects the estimates for cost to respond to the Ebola specific contact tracing forms. All wages are from the Bureau of Labor Statistics Occupational Employment and Wages, May 2013. CDC estimates an additional $12,190 of respondent cost as a result of this revision. The total estimated cost to respondents is $20,897.

* Wages for Passengers were gathered from 00-0000 All Occupations (<http://www.bls.gov/oes/current/oes_nat.htm#00-0000>)
* Wages for Flight Crew were gathered from 53-2011 Airline Pilots, Copilots, and Flight Engineers (<http://www.bls.gov/oes/current/oes532011.htm>) and 53-2031 Flight Attendants (<http://www.bls.gov/oes/current/oes532031.htm>). A weighted average wage taking into account a full crew per flight of three pilots and nine flight attendants is used for the hourly wage column.
* Wages for Airline Cleaning Crew were gathered from 53-7061 Cleaners of Vehicles and Equipment (<http://www.bls.gov/oes/current/oes537061.htm>)
* Given the variety of professional staff who may interact with a potential case at a port of entry, the estimated hourly wage used is 00-0000 All Occupations (<http://www.bls.gov/oes/current/oes_nat.htm#00-0000>)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Total Burden Hours** | **Wage Rate** | **Costs** |
| State/local health department staff | General Contact Investigation Outcome Reporting Form (Air) | 1 | $35.11 | $35 |
| Cruise Ship Physicians/Cargo Ship Managers | General Contact Investigation Outcome Reporting Form (Maritime – word version) | 8 | $35.11 | $281 |
| Cruise Ship Physicians/Cargo Ship Managers | General Contact Investigation Outcome Reporting Form (Maritime – Excel version) | 8 | $35.11 | $281 |
| State/local health department staff | General Contact Investigation Outcome Reporting Form (Land) | 1 | $35.11 | $35 |
| State/local health department staff | TB Contact Investigation Outcome Reporting Form (Air) | 104 | $35.11 | $3,651 |
| Cruise Ship Physicians/Cargo Ship Managers | TB Contact Investigation Outcome Reporting Form (Maritime - word version) | 13 | $35.11 | $456 |
| Cruise Ship Physicians/Cargo Ship Managers | TB Contact Investigation Outcome Reporting Form (Maritime - Excel version) | 13 | $35.11 | $456 |
| State/local health department staff | Measles Contact Investigation Outcome Reporting Form (Air) | 80 | $35.11 | $2,809 |
| Cruise Ship Physicians/Cargo Ship Managers | Measles Contact Investigation Outcome Reporting Form (Maritime – word version) | 5 | $35.11 | $176 |
| Cruise Ship Physicians/Cargo Ship Managers | Measles Contact Investigation Outcome Reporting Form (Maritime – excel version) | 5 | $35.11 | $176 |
| State/local health department staff | Rubella Contact Investigation Outcome Reporting Form (Air) | 8 | $35.11 | $281 |
| Cruise Ship Physicians/Cargo Ship Managers | Rubella Contact Investigation Outcome Reporting Form (Maritime –word version) | 1 | $35.11 | $35 |
| Cruise Ship Physicians/Cargo Ship Managers | Rubella Contact Investigation Outcome Reporting Form (Maritime – excel version) | 1 | $35.11 | $35 |
| Passenger | Ebola Airline Exposure Assessment Passenger | 113 | $22.33 | $2,523 |
| Flight Crew | Ebola Airline Exposure Assessment Flight Crew | 80 | $31.29 | $2,503 |
| Cleaning Crew | Ebola Airline Exposure Assessment Cleaning Crew | 40 | $11.05 | $442 |
| Airport or Other Port of Entry Staff | Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff | 33 | $22.33 | $737 |
| Passengers on other commercial conveyances | Ebola Exposure Questionnaire for Passengers on other commercial conveyances | 60 | $22.33 | $1,340 |
| Traveler | Script – Introduction and Confirmation | 208 | $22.33 | $4,645 |
| **Total** |  | **782** |  | **$20,897** |

# 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. Also, due to the current outbreak of Ebola, CDC has included above estimates of potential numbers of contacts that may need to be reached should a case of Ebola be confirmed on a commercial conveyance arriving to or traveling within the United States. For additional clarity in terms of likely annual cost to the government, routine and response related costs are being separated here.

For routine costs, CDC estimates that it requires the equivalent of approximately 2 hours of CDC staff (GS-13 base, Atlanta locality) time to initiate and follow up on the contacts involved in the types of CIs described in this information collection. This includes confirming passenger contact information, communicating with state, local, and private sector partners, information collection from state, local, and private sector partners, and management of various federal staff. Total costs for routine CIs are as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Staff | Pay Scale | # of Contacts for Routine CIs | Time/Contact | Total Cost |
| Public Health Advisor | GS13 base, ATL Locality ($41.38) | 2,977 | Two Hours | **$246,377** |

Total costs for Ebola related contact investigations include the costs to CDC if the maximum number of contacts requested in this revision responded to the relevant Ebola Assessments. CDC estimates the same amount of staff time would be required.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Staff | Pay Scale | # of Contacts for Ebola CIs | Time/Contact | Total Cost |
| Public Health Advisor | GS13 base, ATL Locality ($41.38) | 490 | Two Hours | **$40,552** |

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 entire QARS system is as follows.

|  |  |
| --- | --- |
| QARS System Costs | $218,172 |
| Staff Costs:  1xGS-12(50% base)  1xGS-9(75% base) | $73,868 |
| **Total** | **$** **292,040** |

The total annual cost for routine contact investigations included in this information collection is $538,417. The total cost annual for routine and Ebola related contact investigations is $578,969.

# 15. Explanation for Program Changes or Adjustments

There are no proposed changes to the standard contact investigation forms for Tuberculosis, Measles, and Rubella.

Five additional investigation forms and an investigation script are proposed for use in contact investigations by airlines, airports, and other commercial conveyances in the United States. The information gathered will allow for detailed risk assessment of populations entering the U.S. from West Africa and improved ability of CDC and state public health departments to follow up with persons over the 21-day Ebola incubation period if persons came into contact with symptomatic Ebola patients. The forms include:

* Airline passenger exposure questionnaire (Attachment P) – This contact investigation form gathers information from airline passengers who traveled on the plane with and sat within a 3 foot area around the suspected case, and his/her travel companions. Answers collected include relevant contact information, flight number(s) seat location, a description of contact the person had with the sick passenger, any symptoms the interviewee has had that align with Ebola symptoms, and any travel in the past 21 days before the flight with a symptomatic passenger. If the passenger answered ‘yes’ to travel in Sierra Leone, Guinea or Liberia, the public health department is instructed to call the CDC EOC immediately to complete an additional risk assessment with CDC staff. After completing the questionnaire, state health department officials will determine the risk level, and based on their determination passengers will be followed up with either active monitoring or direct active monitoring. Depending on the follow up determination, the state health department will continue contact with persons interviewed including symptom monitoring, voluntary quarantine, travel restriction or other public health measures, as appropriate. All questionnaires also include questions to identify the interviewer, in case updates are needed from them to clarify answers recorded.
* Flight crew exposure questionnaire (Attachment Q) – The airline staff questionnaire collects the same information as the passenger questionnaire. In addition, the questionnaire asks for a description of personal protective equipment utilized by airline staff. Follow up items are identical, including categorization of risk, follow up with CDC, and determination of necessity of monitoring.
* Flight cleaning crew questionnaire (Attachment R) – This form collects the same information as the flight crew exposure questionnaire, used to determine the risk of exposure, the necessity for monitoring and other quarantine activities, including the use of personal protective equipment. As with the flight crew, interviewees are asked about any use of personal protective equipment when coming into contact with bodily fluids. Because the cleaning crew does not come into contact a symptomatic Ebola patient; instead the questions ask for contact with only body fluids, not the person who was symptomatic.
* Airport Staff exposure questionnaire (Attachment S) – As with the other questionnaires, the questions included in this form align with attachments A, B and C. Interactions and flight numbers are collected along with travel information to the affected countries and symptoms the interviewee may have that align with the symptoms of Ebola. As with the flight crew, interviewees are asked about any use of personal protective equipment when coming into contact with bodily fluids.
* Passengers of other commercial conveyance Ebola exposure questionnaire (Attachment T) – This questionnaire collects the same information as the airline passenger questionnaire. It asks for the trip information including type of travel conveyance (train, bus etc.) as well as the city/state that the travel occurred between and any other relevant information (bus number) and location on the conveyance medium. This form is more general (not specific to trains, buses) because there is a very low expectation of travel exposure on alternative commercial means of conveyance; however, the questionnaires collect all necessary information to determine risk, contact passenger if necessary, and continue monitoring if necessary.

The script (Attachment U) that CDC is requesting will be used in the following manner.

* If a traveler calls CDC, CDC staff will use Script – Introduction and Confirmation. This script will ask the respondent to provide name and contact information, flight information, a phone number where they can be reached in case the call is disconnected, and seat number. Travelers will also be informed that their state or local health departments will be following up with them.

CDC is not proposing any changes to the number of respondents or burden hours associated with the routine contact investigation forms already approved under this information collection request.

# 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 appropriate. No exemption requested.

# 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

# List of 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: General Contact Investigation Outcome Reporting Form (Air)

Attachment D: General Contact Investigation Outcome Reporting Form

(Maritime – word version)

Attachment E: General Contact Investigation Outcome Reporting Form

(Maritime – Excel version)

Attachment F: General Contact Investigation Outcome Reporting Form (Land)

Attachment G: TB Contact Investigation Outcome Reporting Form (Air)

Attachment H: TB Contact Investigation Outcome Reporting Form

(Maritime - word version)

Attachment I: TB Contact Investigation Outcome Reporting Form

(Maritime - Excel version)

Attachment J: Measles Contact Investigation Outcome Reporting Form (Air)

Attachment K: Measles Contact Investigation Outcome Reporting Form

(Maritime - word version)

Attachment L: Measles Contact Investigation Outcome Reporting Form

(Maritime - Excel version)

Attachment M: Rubella Contact Investigation Outcome Reporting Form (Air)

Attachment N: Rubella Contact Investigation Outcome Reporting Form

(Maritime - word version)

Attachment O: Rubella Contact Investigation Outcome Reporting Form

(Maritime - Excel version)

Attachment P: Ebola Airline Exposure Assessment Passenger

Attachment Q: Ebola Airline Exposure Assessment Flight Crew

Attachment R: Ebola Airline Exposure Assessment Cleaning Crew  
Attachment S: Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff

Attachment T: Ebola Exposure Questionnaire for Passengers on other commercial conveyance

Attachment U: Script – Introduction and Confirmation

Attachment V: Non-research Determination