

Nonmaterial/non-substantive change to Emergency Submission to Supplement OMB Control Number 0920-0900 in the context of Contact Investigations to Determine Ebola Risk (OMB Control No 0920-1032

Expiration date 4/30/2015

Program Contact

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Circumstances of Change Request for OMB 0920-1032

CDC requests approval for a nonmaterial/non-substantive change to Emergency Submission to Supplement OMB Control Number 0920-0900 in the context of Contact Investigations to Determine Ebola Risk (OMB Control No 0920-1032, expiration 4/30/2015).

After potential Ebola exposure occurred during a commercial air flight in the United States, the CDC, in coordination with airlines and state health departments, developed questionnaires specific to passengers and staff that may have been exposed to the virus. This contact investigation tool is utilized if and when a passenger has been diagnosed with Ebola travels on commercial conveyance in the US to determine the level of risk of exposure and establish contact information for ongoing direct and, where necessary, active monitoring of temperature and symptoms. The information collected helps CDC in determining whether or not CDC recommendations for movement restrictions and monitoring are being followed by state and local health departments, and further enables CDC to determine if enhanced federal participation in monitoring travelers is warranted. The health departments of the receiving states generally decide what actions will be taken with regard to each passenger. Although CDC encourages that these actions be consistent with CDC recommendations, this is not always the case. Requirements about quarantine and other restrictions vary not only by state, but also by jurisdiction. In addition, if any contacts are deemed to be in the high risk category, the actions outlined in the movement and monitoring guidance may be required. If appropriate restrictions were not put in place at the state or local level, there may be a need for enhanced federal participation in public health measures. Additionally, CDC is often asked to report to several audiences, sometimes daily, statistics describing how many passengers are being actively monitored, restricted from traveling, etc. If we cannot get access to these pieces of information, CDC will not be able to accurately report on a timely basis. The state and local health departments should be aware of the specific actions they are taking with regard to passengers who are within their jurisdiction, and be able to report this activity to CDC so that additional action can be taken, if needed.

CDC has identified specific elements in the investigation tools that need to be modified in order to more quickly and effectively assess the risk for Ebola in travelers in the United States who were exposed to the disease in commercial travel conveyance. The majority of these changes do not have an impact on respondents, but instead focus on improved instructions for state health department personnel concerning how to complete the forms, operational refinements to improve processing of information and paperwork, and modifications to risk categorization by CDC officials based on CDC's revised Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure (available here: <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>.)

Description of Changes

No changes are being requested to the Introduction and Confirmation Script (Attachment A)

CDC is requesting an update to the following forms OMB Control No 0920-1032, Ebola Exposure Questionnaires for Airline Passengers (Attachment B), flight crew (Attachment C), cleaning crew (Attachment D) and airport staff (Attachment E) to improve collection of essential information regarding the risk exposure of all travelers on flights where a suspected or confirmed case of Ebola has occurred. The changes made align with the updated Monitoring and Movement (M&M) guidance released by the CDC on October 27, 2014.

The following changes are consistent across questionnaires 0920-1032 for passengers, flight crew, airport staff and flight cleaning crew.

- CDC requests a change in the title of the forms, removing the word ‘assessment’ to make the title more concise and to reduce redundancy with the word ‘questionnaire’.
- CDC requests the addition of ‘other symptoms of Ebola’ and the replacement of the words ‘determined to have’ with ‘develops’ to broaden the scope of symptoms relevant to State Public Health Department staff conducting screenings and provide more accurate verbiage to urge the notification of CDC officials when symptoms are evident.
- Based upon feedback during contact investigations conducted in October 2014, CDC is requesting the inclusion of more identifying information of the public health official conducting the questionnaire, including the interviewer’s agency, phone number, and email. This will improve the ability of state health departments and the CDC to find interviewers should follow up questions be necessary after completion of the initial screening.
- CDC recommends the inclusion of additional identifying questions to improve the record keeping and contact tracing information should further follow up be needed for any passenger or airline staff aboard a commercial airline flight with possible Ebola exposure. These additional questions include:
 - Date of Birth
 - Country of Citizenship
 - What are interviewee’s travel plans through the next 21 days post-exposure?
 - Street address *for the next 21 days*, including city and zip code (neither were included previously)
 - For improved flight information, the questionnaire now asks for details of the flight in which the index case traveled on (for both passengers, cleaning crew and flight crew), including the flight number, flight origin, and flight destination.
- If the interviewee did come in contact with the index case, they are now asked to both describe the ill passenger as well as the interaction, including the location, type and extent of exposure. These changes were added to provide greater context of exposure to determine the risk level of the passenger. Questions are adjusted slightly depending on the respondent (passenger, crew or cleaning staff) but are used to determine the same context of exposure.
- In question number 3 (question 4 on flight crew questionnaire), a description of bodily fluids that passengers came into contact with expanded to include feces, saliva, sweat, urine and vomit, so those determining risk levels are able to better understand the level and type of exposure each passenger had.
- Question #5 (question #6 on flight crew questionnaire) has been expanded to include a list of the potential symptoms -fever, body aches, abdominal pain, diarrhea, rash, sore throat, severe headache, vomiting, weakness, unusual bruising or bleeding. The questionnaire asks the interviewee to select the symptom, and now also includes information on the symptom onset and duration of symptoms since their onset.
- CDC requests that a gateway question be included when discussing the interviewee’s travel to West Africa to determine the necessity of selecting one or more of the three countries currently experiencing transmission of Ebola (Sierra Leone, Liberia, Guinea, or Other, should additional countries be affected).
- CDC has proposed an update to the risk classification of interviewees with a potential Ebola exposure on commercial flights. This update improves the clarity of the process each health department interviewer must complete after interviews of exposed passengers and airline staff/crew are conducted. This includes calling the EOC Air Contact investigation Team after the interview to receive the risk classification from CDC. Previously the Health Departments were

asked to assign risk level but in an effort to maintain uniformity in identification, the CDC is now the determining body of risk identification.

- The Health Department conducting the interview is asked to monitor and record follow up actions taken after the initial interview. These were updated to both comply with updated M&M guidance and reduce burden on the interviewer by listing more specific questions and yes/no answers. The list of follow up actions is requested to be expanded to include the following:
 - Check box to indicate: Active Monitoring: state or local public health authority checks with potentially exposed individual daily to assess for the presence of symptoms and fever (i.e., via phone or other communication).
 - Check box to indicate: Direct Active Monitoring: public health authority conducts active monitoring through direct observation
 - Check box to indicate: Was (s)he tested for Ebola? Yes or No reply, added to collect information about this important follow-up item that was previously not requested.
 - Check box to indicate: Controlled movement: exclusion from all long-distance and local public conveyances (aircraft, ship, train, bus and subway)
 - Check box to indicate: Exclusion from public places (e.g., shopping centers, movie theaters), and congregate gatherings
 - Check box to indicate: Exclusion from workplaces for the duration of the public health order
 - Check box to indicate: Federal public health travel restrictions -[Do Not Board](http://www.cdc.gov/quarantine/quarantineisolation.html) (<http://www.cdc.gov/quarantine/quarantineisolation.html>)
- CDC recommends an update to the ‘final disposition’ follow up section to include a list of possible symptoms that interviewers should check after the 21 day monitoring period, including fever, sore throat, body aches/muscle pain, severe headache, abdominal pain, vomiting, diarrhea, weakness, rash, and unusual bleeding or bruising.

Updates to Cleaning Crew, Flight Crew, and Airport Staff Form:

- The cleaning crew, flight crew, and airport staff forms have updated personal protective equipment (PPE) questions, now including check-boxes to select the type of PPE used, including masks, gloves, eye protection, gown or rubber boots/shoe covers and nothing. The inclusion of check boxes reduces burden on the interviewer.

CDC is requesting the use of an additional form: Ebola Exposure Questionnaire for Passengers on other Commercial Conveyances (including bus, ship, and train travel)

- In order to be fully prepared for all potential contact investigations on transportation vehicles in the United States, the CDC recommends the adoption of a new form, created based on the original forms outlined above, to perform contact investigations of any and all passengers travelling via commercial transit (boat, bus or train, but not via commercial aircraft) with a person diagnosed with Ebola. This form contains identical questions to determine contact information, type of exposure, extent of risk and follow-up actions. It includes additional questions to classify the type of transportation utilized, like a Greyhound bus or an Amtrak train, for example. While CDC does not anticipate numerous investigations of non-airplane commercial transport exposures, this form is proposed to improve the preparedness of both state and local public health departments should an investigation of this nature become necessary.

To replace the risk stratification section included in the previous versions of the questionnaires, CDC is including a supplemental attachment that outlines how each interviewee will be categorized according to

their risk (Attachment G). This is in line with the revised Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure.

Burden

The questionnaire changes for airline passengers, flight crew, cleaning staff and airport staff are not expected to increase the time or burden on state health departments; questions added provide greater clarification but do not increase time of interview, as they are highly specific and simplify the investigation process by providing necessary and clear information to assess risk.

The addition of the Ebola Questionnaire for Passengers on other Commercial Conveyances is expected to have a similar estimated time burden per interview, as the questionnaire is nearly identical to the others listed above. The table below includes burden estimates for all forms, including an additional form. Burden is adjusted based on the addition of this fifth form. Burden is estimated based on previous estimates of other transportation questionnaires included here, as the length of each interview is identical, as is the estimated hourly wage of the respondent.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Passenger	Ebola Airline Exposure Assessment Passenger	1700	2	20/60	1133
Flight Crew	Ebola Airline Exposure Assessment Flight Crew	1200	2	20/60	800
Cleaning Crew	Ebola Airline Exposure Assessment Cleaning Crew	600	2	20/60	400
Airport or Other Port of Entry Staff	Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff	500	2	20/60	333
Traveler	Script – Introduction and Confirmation	25000	1	5/60	2083
Passengers on other commercial conveyances	Ebola Exposure Questionnaire for Passengers on other commercial conveyances	900	2	20/60	600
Total		34800			5349

The table below reflects financial burden equivalent to the previous submission of airline-related exposure. Additional cost attributed to the new form for non-airplane commercial conveyance is noted in the table below, as well.

Type of	Form	Total	Hourly	Total Respondent Costs
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Respondent		Burden Hours	Wage Rate	
Passenger	Ebola Airline Exposure Assessment Passenger	1133	\$22.33	\$25,300
Flight Crew	Ebola Airline Exposure Assessment Flight Crew	800	\$31.29	\$25,032
Cleaning Crew	Ebola Airline Exposure Assessment Cleaning Crew	400	\$11.05	\$4,420
Airport or Other Port of Entry Staff	Ebola Airline Exposure Assessment Airport or Other Port of Entry Staff	333	\$22.33	\$7,436
Traveler	Script – Introduction and Confirmation	2083	\$22.33	\$46,513
Passengers on non-flight commercial conveyance	Ebola Exposure assessment for Passengers on other commercial conveyances	600	\$22.33	\$13,398
Total		5349		\$122,099

Privacy Impact Assessment

1. Respondents to this data collection will be informed whether or not providing the data described in this supporting statement is mandatory or voluntary.
2. Respondents indicate their consent by verbally agreeing to participate in the screening program.
3. Highly sensitive information is being collected and would affect a respondent's privacy if there were a breach of confidentiality. This information is collected under the Privacy Act system of records notice 09200171, "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. However, stringent safeguards are in place to ensure a respondent's privacy including restriction of access to 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. 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 media containing Privacy Act information. Finally, CDC and contractor employees who maintain and use 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, the CDC Project Director, contract officers and project officers oversee compliance with these requirements, and CDC employees and contractors are required to be trained on the Privacy Act and receive information security awareness training at least annually.

4. This data collection is subject to the Privacy Act. The existing applicable Systems 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.