Quarantine Station Illness Response Forms:
Airline, Maritime, and Land/Border Crossing
(0920-0821 expires 08/31/2015)

Request for OMB Approval of a Revision for an Existing Information Collection Request

February 10, 2015

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Supporting Statement A

- The goal of this information collection is to accurately assess risk for infectious disease in travelers coming to, or traveling within, the United States. In addition to the current set of tools already approved by OMB under this control number, the Centers for Disease Control and Prevention (CDC) is requesting the addition of tools to collect contact information for and assess the risk for Ebola in travelers coming to the United States from certain countries, as well as the addition of tools to assist in active monitoring of these travelers after they arrive in the United States.
- The information will be used to determine if individuals meet risk thresholds for further medical evaluation or public health follow-up according to guidance developed by the CDC, and to help state health departments to contact these travelers reliably for active monitoring.
- Travelers will be interviewed by the CDC and the Department of Homeland Security (DHS) using screening and risk assessment tools developed by CDC. To facilitate active monitoring for Ebola, individual travelers coming to the United States from affected countries will be able to call a phone number daily during their 21-day monitoring period and respond to a survey asking for any signs or symptoms of Ebola.
- The respondent universe for this information collection request is travelers coming to, or traveling within, the United States who are reported as having certain signs and symptoms of illness prior to or after arrival, as well as those travelers coming to the United States from countries affected by the current Ebola outbreak.
- No statistical methods will be used

CDC is requesting a revision to a currently approved information collection, Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing (OMB Control No 0920-0821). This revision seeks to incorporate the changes that are the result of activities undertaken during the response to Ebola. These changes include two major components, both of which have been given previous emergency clearance by OMB under control numbers 0920-1031 and 0920-1034, and both with an expiration date of April 30, 2015. As a part of this revision, CDC is requesting the full three year approval for the following:

1. The incorporation of two public health screening forms that are currently used to assess risk for Ebola in travelers coming to the United States from countries experiencing widespread transmission of the disease, or countries that have Ebola in urban areas and are implementing uncertain control measures. These forms are the slightly revised United States Traveler Health Declaration and a completely revised Ebola Entry Screening Risk Assessment Form (forms approved under OMB Control No 0920-1031). The additional burden requested for the English versions of the health declaration and the risk assessment form, as well as the

French and Arabic translation guides for the health declaration and risk assessment forms, is 13,664 hours.

a. CDC maintains the ability to use the Ebola Entry Screening Risk Assessment Form in the event that a traveler is identified as ill on a U.S.-bound flight prior to arrival. In the no material or nonsubstantive change to a currently approved collection granted by OMB on 9/18/2014, CDC requested 100 respondents and 5 hours of burden. Because the form is more comprehensive, it requires more time for traveler to complete the assessment (A full outline of the changes is found in section c below). CDC is requesting an additional 20 hours of burden for the purpose of assessing ill travelers, for a total of 25 hours of burden. No additional respondents are requested.
b. Since the approval of the United States Traveler Health Declaration on 11/20/2014 and its use in the screening process, CDC has recognized that a few changes are necessary to make the form more useful from a follow-up standpoint and easier for the respondents to complete the process. These changes are as follows:
    i. Renamed "Departure date" as "Departure date from affected country"
    ii. Renamed "1st email address" and "2nd email address" as "Email address" and "Alternate email address"
    iii. Renamed "1st telephone number" and "2nd telephone number" as "Telephone number" and "Alternate telephone number". Added a check box for number provided to indicate whether it is a mobile phone.
    iv. Reversed the order of "Home address" and "Address(es) for next 21 days".
    v. Added two addresses (for next 21 days)
    vi. Added dates fields, e.g. Dates at address: [date] to [date] for 21 day period.
    vii. After "Gave tear sheet", added "(if CARE Kit not available)".
    viii. In the disposition section of the form, "Referred to CDC" has been changed to "Referred to Tertiary" for increase clarity in record keeping and communication between DHS and CDC.
    ix. Revised the instructions to DHS on visual observation for signs of illness to further clarify that this is an action to be taken by DHS and not a question to be asked of the traveler.
c. Since the approval of the Ebola Entry Screening Risk Assessment Form on 11/20/2014 and its use in the screening process, CDC has recognized that a few changes are necessary to make the form more sensitive to risk and easier to administer. These changes are mainly concerned with the instructions so that individuals who meet certain risk thresholds are assisted according to the most updated version of the CDC's revised Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure. The changes, in detail, are as follows:
    i. A revised title, which is now the Ebola Entry Screening Risk Assessment Form.

ii. A clarification of the instructions on how to complete the form correctly. This information is intended for the CDC official conducting the assessment and constitutes no burden to the individual being screened.
iii. Instructions for consulting with CDC headquarters (CDC Ebola Consultant) have been removed, because these instructions have been included in the general Quarantine Station Guidance.
iv. Instructions for documentation have been made more explicit to ensure a more complete record of the assessment. A separate "definitions" section has been created. "Blood" has been included in list of body fluids in the definition.
v. Clinical section/symptoms questions have been moved to the beginning of the form so that Medical Officer can make a more informed decision about personal protective equipment use. Similarly, instructions for completing clinical section of the assessment have been moved to top of the instructions section for improved use by the assessors.
vi. A qualifying statement about the use of fever reducing medication *within the last 12 hours* has been added to limit questions to this time period thus minimizing the response burden of this question.
vii. In question one, CDC has clarified several points, including asking about "other potential exposures" (besides contact) and stating that the question includes situations while wearing personal protective equipment (PPE). CDC additionally added: *Note to interviewer: As applicable, ask about activities such as cleaning/disinfecting contaminated areas or spraying in HCF doffing areas (i.e. before PPE removal) or of dead bodies/body bag*. This is to better ascertain potential exposures. This is being included based on common interactions with individuals who relay this useful information to CDC without being specifically prompted to do so in order not to miss individuals who do not volunteer the information without prompting.
viii. In question two, CDC has added phlebotomist to the description of patient care, to better identify these individuals who might not consider themselves as having taken care of patients.
ix. In question three, CDC has added: *Note to interviewer: Please clarify context; for travelers that report visiting Ebola treatment units (ETUs) this question refers only to areas of the ETU where PPE is typically required, such as direct patient care areas*. This is to assist CDC is assessing the level of exposure risk and to minimize the response burden to people who entered a facility designated as an ETU but in a capacity that did not put them at risk for exposure to Ebola patients, e.g. administrators. In the documentation (check boxes), "nonclinical activities" has been added to "observer" to capture people who did not provide patient care but who entered into a patient care area in an occupational capacity rather than as an observer.

x. In question number four, CDC added a field for the name of lab where an individual may have worked. Assessors were previously asked to find out the name of the lab; the field is added for improved documentation. Obtaining the name of the lab minimizes the response burden as individuals who worked in labs that CDC has inspected and determined that appropriate biosafety precautions are routinely followed do not require additional questioning about lab-related activities.

xi. In question number four, the instructions have been changed to include an option for a "Some Risk" assessment.

xii. Question five has been altered to include a simpler, more overarching question "Were you around dead bodies or did you attend a funeral?" This should limit the additional time to ask the more detailed exposure questions to only those people who were in this situation.

xiii. Documentation for question six has been clarified to require recording of time living in the household of a person with Ebola to only the period that the person was symptomatic/infectious.

xiv. Question number seven has been re-worded in an attempt to more accurately discern if any exposures have occurred in locations other than in an ETU or a household, which would have been discovered in answering either question three or six. This question is less redundant and more sensitive to potential unprotected exposures.

xv. A new question eight was added to ask explicitly about PPE breaches if PPE was worn in situations where there was a potential exposure to Ebola (as determined through questions one and three-five). This question should function as a sub-part to questions one and three-five, so should not add any additional burden to respondents.

xvi. Several changes have been made to improve documentation and notation during the assessment. These include:

1. New space to provide more detailed description of any symptoms
2. More space for detailed narrative information to describe the assessment
3. A section for outlining a justification for the traveler disposition has also been added
4. The positioning of spaces for free text transcription are moved so that they are more likely to be used by assessment staff.

xvii. The rest of the changes are simple wording changes to improve ease of use and understanding

d. Through experience at the ports of entry where screening is being conducted and discussions with our port partners, CDC has determined that the French and Arabic versions of the health declaration and risk assessment would be more efficiently used as aides for translation, and not stand alone versions. Currently, the interviews and assessments are

carried out by English-speaking Department of Homeland Security (DHS) officers and CDC medical officers with assistance from translators. CDC is now seeking approval to remove the English instructions from the forms, and keep the French and Arabic questions and definitions as a guide for translation, with the English translations appearing to the side. The actual answers and narrative derived from the interviews and assessments will be written on the English versions of the forms. No change to burden is requested, and the French and Arabic translation guides will remain accounted for in the burden tables in Sections 12a and 12b.

2. The incorporation of a telephonic, automated survey administered through the Interactive Voice Response (IVR) phone system, referred to as the CARE Hotline, which would ask travelers if they have developed a fever or any other symptoms potentially indicative of Ebola exposure (OMB Control No 0920-1034). This system would be used as a tool to assist public health authorities in maintaining contact with returning travelers to ensure that signs and symptoms of disease are reported as soon as possible. The additional burden requested for the use of the IVR system is 71,400 hours.

No revisions are requested to the Air Travel, Maritime Conveyance or Land Travel Illness and Death Investigation forms or burden associated with these information collections. The current burden associated with these forms is 314 hours.

The total additional burden requested for this revision is 105,571 respondents and 85,063 burden hours. The estimated total burden for 0920-0821 is 109,429 respondents and 85,382 burden hours.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A1) 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, the Division of Global Migration and Quarantine (DGMQ) works to fulfill this responsibility through a variety of activities, including the operation of Quarantine Stations at ports of entry and administration of domestic and foreign quarantine regulations; 42 Code of Federal Regulation parts 70 and 71 (Attachment A2 and A3). These regulations authorize quarantine officers to inspect and undertake necessary control measures with respect to conveyances (e.g., airplanes, cruise and cargo ships), persons, and shipments of animals and etiologic agents in order to protect the public's health. This information collection concerns CDC's statutory and regulatory authority, and public health mission, of assessing individual travelers for public health risk following a report of illness from a conveyance, as well as conducting public health screening of travelers upon arrival to the

United States e.g., the type of process currently being undertaken with respect to travelers from countries with widespread transmission of Ebola.

U.S. Quarantine Stations are located at 20 ports of entry and land-border crossings where international travelers arrive. The jurisdiction of each station includes air, maritime, and/or land-border ports of entry. Quarantine Station staff work in partnership with international, federal, state, and local agencies and organizations to fulfill their mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations. This work is performed to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or from one State or possession to another State or possession. When an illness suggestive of a communicable disease is reported, Quarantine Officers respond to carry out an onsite public health assessment and collect data from the individual. This response may occur jointly with port partners. The collection of comprehensive, pertinent public health information during these responses enables Quarantine Officers to make an accurate public health assessment and identify appropriate next steps. For this reason, quarantine station staff need to systematically interview ill travelers and collect relevant health and epidemiologic information.

When Quarantine Officers are present at the port of entry, they may often respond in person to conduct assessment of an ill traveler. However, there are many instances in which a Quarantine Officer may not be able to meet a conveyance or border crosser in person, including (but not limited to) the following: the conveyance arrives at a port of entry that does not have a Quarantine Station on site; a maritime vessel is still out at sea when the report comes in; Quarantine Officers are already responding to another illness report; or the illness may be reported after hours and Quarantine Officers cannot arrive in time to meet the conveyance or border crosser without causing substantial delays to travel. If Quarantine Officers are unable to respond in-person, they provide phone consultation to port partners (e.g., Emergency Medical Services (EMS), DHS and Border Protection Officers (CBP), and maritime partners) on the scene, to determine the public health importance of the illness. In both circumstances, an interview of the ill person(s) is required to conduct the public health assessment, whether in-person, by phone, or through a trained responder (in consultation with the Quarantine Officer).

As of October 2014, CDC has been tasked with performing public health screening at U.S. ports of entry to mitigate the risk of a traveler infected with Ebola coming to the United States. CDC relies on its federal partners in DHS to assist in the screening process because of their presence at the ports entry. CDC develops the tools and training to facilitate the screening process and works collaboratively with DHS to ensure that any individual who is identified as at risk or needing further evaluation is followed-up with appropriately. This may involve medical evaluation by CDC and transport to health care facilities, or communication via phone with CDC or state and local health departments to see if the travelers develop symptoms after arrival.

Data collected by Quarantine Station staff using the illness response forms and screening tools are entered into the Quarantine Activity Reporting System (QARS). QARS is a secure internet database implemented in June 2005 to track the number of illnesses and deaths reported to Quarantine Stations that occurred on conveyances entering the United

States and at land border crossings. In addition, QARS is used to record 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 regulated by CDC, and emergency releases of drugs and immunobiologics controlled by CDC (artesunate; botulism, diphtheria and tetanus antitoxins).

There have been no changes to the currently approved Air Travel, Maritime Conveyance or Land Travel Illness and Death Investigation forms (Attachments C, D, E respectively).

However, CDC is seeking to include information collection tools that were approved in OMB Control No 0920-1031 and 0920-1034, as they are set to expire 4/30/2015. These included:

- OMB Control No 0920-1031: two tools for screening travelers coming to the United States from countries with wide spread transmission of Ebola, or from countries with Ebola in urban areas who are implementing uncertain control measures; and
- OMB Control No 0920-1034: one IVR-based information collection script, currently available in English and French, that would provide travelers with an interactive phone system to report any signs or symptoms of disease, while under active monitoring.
    - The system as approved under 0920-1034 was never fully implemented, as State public health authorities implemented their own active monitoring systems. The system was only used by federal employees returning from the affected countries.
    - However, the need for such a system on a federal level remains in the event that states are unable or would prefer not to perform active monitoring in the future. CDC is proposing here a baseline tool for active monitoring for Ebola in the event that active monitoring becomes a federal responsibility and is led by CDC staff. While the current need is for Ebola, future responses may require a federally led active monitoring system to prevent the spread of a different disease within the United States. If the need for modifications to the IVR tool arises, CDC will submit the requisite documentation to OMB to obtain approval to collect that information.
    - The current IVR system is based on free, open source IT architecture developed by private sector partners and is made available via Amazon Web Services. States public health authorities are able to use this system independent from CDC and make modifications as their active monitoring needs require. Any data collected via an IVR system is de-identified, aggregated, and stored outside federal control.

2. Purpose and Use of Information Collection

For routine response to illnesses associated with travel, the purpose of the Air, Maritime, and Land Illness and Death Investigation forms is to systematically collect information, thereby enabling Quarantine Station staff to assess, detect and respond rapidly, efficiently and accurately to communicable disease threats of potential public health importance at ports of entry. The information collected is also necessary for public health surveillance

and follow-up purposes. The forms collect the following categories of information: identifying and contact information, demographics, mode of transportation, pertinent clinical and medical history, epidemiologic history, other relevant facts (e.g., travel history, traveling companions, etc.), and information specific to the traveler's conveyance or mode of travel. This information is used by Quarantine Station staff to identify specific signs and symptoms common to the nine quarantinable diseases (Pandemic influenza; severe acute respiratory syndromes; Cholera; Plague; Diphtheria; Infectious Tuberculosis; Smallpox; Yellow fever; and Viral Hemorrhagic Fevers), as well as other communicable diseases or conditions of public health concern which may be transmissible in a conveyance setting.

Information collected on these forms are used by Quarantine Station staff to make decisions about a traveler's suspected illness as well as its communicability. This information enables Quarantine Station personnel to assist conveyances and border agents in the public health management of ill persons at U.S. ports and plan the appropriate response. These data are then entered into QARS.

In the current response to Ebola, approval of this information collection request would continue to provide CDC with the tools and appropriate burden to conduct entry screening of individuals coming to the United States from countries affected by the current Ebola outbreak, as well as give CDC the ability to assist state and local health departments in conducting active monitoring of travelers from those areas who meet the risk threshold identified under 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). This revision can be broken down into two categories of information collection tools: screening tools at ports of entry, and surveys/scripts for asking questions of individuals who call the IVR CARE Hotline as part of a CDC-led active monitoring program.

1. For this revision, the purpose and use of the United States Traveler Health Declaration (Attachment F1a English hard copy, Attachment F1b English electronic portal, Attachment F1c English fillable PDF, Attachment F2 French, Attachment F3 Arabic) and Ebola Entry Screening Risk Assessment Form (Attachment G1 English, Attachment G2 French, Attachment G3 Arabic) are as follows:
    a. United States Traveler Health Declaration:
        i. The United States Traveler Health Declaration form is designed for rapid use in briefly ascertaining if an individual has any symptoms of Ebola or potential exposures, and contains questions that are limited in scope so as not to subject travelers to unnecessarily onerous and intrusive questions and not unduly obstruct the flow of travel. Additionally, the United States Traveler Health Declaration, while developed by CDC, will be implemented by DHS at international airports. This form is designed to be used by DHS with basic training. The United States Traveler Health Declaration will be administered to every traveler arriving at a U.S. airport from certain countries. DHS will assist CDC by completing the United States Traveler Health Declaration

and temperature screening based on responses from the traveler and the use of a non-contact thermometer.

If a traveler answers in the affirmative to experiencing any of the specified symptoms or exposures, appears visibly ill, or has a fever, the risk threshold for a further public health evaluation is met. DHS will then contact CDC who will use the revised Ebola Entry Screening Risk Assessment Form to conduct a detailed medical evaluation to determine if further intervention is necessary. French and Arabic translations guides for the risk assessment form are available as needed.

Three different formats of the health declaration are available; however, CDC anticipates the primary mode of respondent interaction with the health declaration will be the portal version. The fillable PDFs and hard copy versions are provided only as back up in case of problems with IT or access at ports of entry or in the event travelers requiring screening arrive at ports of entry other than the five airports where enhanced entry screening is being conducted. Therefore, only one IC with a combined burden is listed in the burden tables in section 12.

b. Ebola Entry Screening Risk Assessment Form

   i. If a traveler answers in the affirmative to experiencing any of the specified symptoms or exposures included in the United States Traveler Health Declaration, appears visibly ill, or has a fever, the risk threshold for a further public health evaluation is met. DHS will then contact CDC who will use the revised Ebola Entry Screening Risk Assessment Form to conduct a detailed medical evaluation to determine if further intervention is necessary.

   This form will still be used to evaluate travelers for risk of Ebola infection or exposure who are reported to CDC as ill prior to arrival, according to CDC regulations at 42 Code of Federal Regulations 71.21.

While cooperation with CDC during this public health screening is voluntary, if an individual refuses to provide the requested information, or is not truthful about the information provided during screening of an illness investigation, CDC may, if it is reasonably believed that the individual is infected with or has been exposed to Ebola, quarantine, isolate, or place the individual under surveillance under 42 CFR 71.32 and 71.33.

2. For this revision, the purpose and use of IVR (Attachment H – IVR Script English, Attachment I – IVR Script French, Attachment K – IVR Script Arabic) is to assist public health authorities with active monitoring of individuals coming to the United States from countries affected by the current Ebola outbreak. This information collection tool would provide a cost- and time-saving mechanism for supporting states with their active monitoring responsibilities. The IVR phone line asks questions that are limited in scope so as not to subject travelers to an unnecessarily onerous and intrusive interview. The interview would only ask the minimum number of questions required to assess if the traveler is presenting symptoms indicative of Ebola. English and French scripts are currently available given the larger numbers of English and French speakers coming from the Ebola

affected region. There are some very limited numbers of Arabic speakers coming from the region affected by the Ebola outbreak, and translation services could be made available for those individuals.

Active monitoring is being conducted by state and local public health authorities for 21 days on every traveler arriving at a U.S. airport from an affected country, including a small number making connections outside of an affected country. Should the CDC-led IVR system be implemented, CDC would provide information on accessing and using the system to travelers via a CARE Card provided during the entry screening process at the airport. As is currently being done at ports of entry, DHS staff members would affix a sticker with the CARE ID to the Traveler Health Declaration Form. Also as is currently being done, the ID would be added to QARS along with the other information from the form. When using the system, and reporting no symptoms, the negative response would be recorded, stored in an appropriate data format (e.g. comma separated values (CSV) file), and made available to the authorized health official in the jurisdiction in which the traveler is staying. That jurisdiction will record this person as having been actively monitored for that day. If a traveler answers in the affirmative to experiencing any of the specified symptoms, the system would automatically connect the traveler to a public health professional (either at CDC or the state health department), who can connect them immediately to the proper medical personnel and/or the health department. If the caller is connected to the CDC, the health department will also be notified to ensure the traveler's call went through successfully and follow-up occurred.

While use of the CDC active monitoring system would be voluntary, if an individual failed to check in via the system, an alert would be sent to the public health entity responsible for active monitoring (e.g, the state health department). The health department of their state of residence could follow up with the traveler via phone or in person.

3. Use of Improved Information Technology and Burden Reduction

CDC is making use of information technology for several of the information collections described in this revision. The Air, Maritime, and Land Illness and Death investigation forms can be emailed to CDC if the documents are encrypted. Final forms can be printed and faxed securely to CDC if the respondent does not have access to email. The maritime form, Attachment D, is available as a fillable PDF.

The United States Traveler Health Declaration is primarily administered via an online portal system that DHS uses in order to ensure rapid screening data sharing with the CDC. The health declaration is also available in hard copy and fillable PDF as a backup.. The portal system and fillable PDF have built in data validation processes so that if a field is missing data or appears inaccurate, the form cannot be transmitted. Because DHS is entering the information on the fillable PDF and portal versions of the health declaration, these versions are only available in English. The French and Arabic health declaration translation guides will assist travelers with limited English proficiency, as well as DHS, in completing the interview.

The use of the IVR technology instead of an interview with a live person would reduce burden in the following manner:

- Travelers can call in at their convenience instead of potentially being told to report daily to the health department at a specified time to have their temperature taken.

- Use of a phone line to capture information about non-symptomatic travelers – the vast majority of respondents – exponentially reduces the labor involved with staffing a state or CDC-level call center.

- Electronic reporting improves data quality and increases the speed at which data can be made available to the states.

- Travelers avoid long waits associated with using live interviewers.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has the regulatory authority for performing quarantine-related public health evaluation activities at U.S. ports of entry (42 Part 71). This includes responding to a report of an ill traveler or death of a traveler on a conveyance, or, when requested by DHS personnel at a land border crossing. As a result, CDC is the only agency collecting illness or death reports related to the introduction and transmission of communicable diseases at ports of entry. CDC works in collaboration with its international, federal, state, and local partners at ports of entry to ensure all illness responses are done in a coordinated manner.

With regard to screening and active monitoring of travelers who are coming to the United States from countries with widespread transmission of Ebola, CDC worked very closely with DHS and state and local health departments in creating and revising the screening tools and IVR scripts. The information required and requested from respondents has been kept to the minimum necessary to evaluate them for risk of Ebola, and provide state and local health departments with sufficient information to enable them to make contact with their residents if they need to be monitored for potential symptoms of Ebola. If a state opts for an alternative active monitoring strategy, the traveler residing in that state will not participate in this system. The state will inform the traveler during their first contact that the traveler should not use the IVR line for daily reporting.

5. Impact on Small Businesses or Other Small Entities

Some of the respondents may be considered small businesses. However, data collection variables are kept to an absolute minimum to minimize burden on these entities.

6. Consequences of Collecting the Information Less Frequently

The frequency of information collection is determined by the frequency that illnesses or deaths on conveyances or at land borders are reported to Quarantine Stations at ports of entry. Control of communicable diseases or conditions of public health interest is dependent on rapid identification and immediate response when identified. If data are not collected immediately, there is a risk of introduction and spread of disease to the U.S. public.

Failure to collect this information for a public health risk assessment, either at the port of entry or during active monitoring via an IVR system could lead to an increased risk of ill travelers coming in contact with the general public. There are no legal obstacles to reducing the burden.

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

Frequency of data collection is inconsistent with the guidelines, as discussed in Section A6. The frequency of data collection is determined by the frequency that illnesses or deaths on conveyances or at land borders are reported to Quarantine Stations at ports of entry; this could occur more often than quarterly. This is similarly the case for screening and follow-up through the IVR system.

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

A. A notice was published in the Federal Register (Vol. 79, No. 231 / Tuesday, December 2, 2014) (Attachment B) announcing the proposed data collection and requesting public comment. One non-substantive comment (Attachment B1) was received and CDC's standard response was sent.

B. CDC is the primary authority with responsibility to prevent the introduction and spread of communicable disease in the U.S. through air, land and sea ports of entry. No other entity collects the type and quantity of information from ill travelers. While the respondents to this data collection are individual travelers, not industry, CDC does work with the air and cruise industries on the information collection process outlined in this Supporting Statement to ensure that these industries are able to operate with the least interference possible, while also maintaining the ability to collect the information needed to protect public health.

CDC has fielded requests for additional fields to the public health screening forms from both DHS and state and local health departments. For the most part CDC has complied with these requests to make the forms more usable for both our federal and state and local partners.

9. Explanations of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents.

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 it has been 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.

Information submitted will be entered into a computer system for analysis and later retrieved if necessary. Data containing personal identifiers and source documents will be retained until the event prompting the collection of data has concluded in accordance with DGMQ's records retention schedule. Data not containing personal identifiers will be retained indefinitely for statistical and historical documentation purposes. Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide "need to know" in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special "certified" process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

IRB Determination

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 J).

10.1 Privacy Impact Assessment Information

Privacy Impact Assessment Information

1. An overview of the data collection system

- For routine operations at ports of entry and for reports of illness that come to CDC after travel has been completed, DGMQ has developed illness response forms for the three different types of ports of entry – air, maritime, and land border. These forms include 1) the Air Travel Illness or Death Investigation Form, 2) the Maritime Conveyance Illness Investigation or Death Report Form and 3) the Land Border Travel Illness or Death Investigation Form. All three forms collect pertinent demographic, clinical, and epidemiologic information on travelers suspected of being infected with a communicable disease, and who may be (or may have been) contagious during travel. The forms are also used by Quarantine Station staff to collect information for follow-up and tracking (surveillance) purposes. The differences between the forms reflect the unique public health risks associated with specific modes of travel and the response to illness at each of the three types of ports.

  It is not always necessary to obtain complete epidemiologic information from every ill traveler; therefore, a two-tiered approach has been used in the development of these forms – Info Only and Response reports. When Quarantine Station staff respond to a situation that is not of public health interest (e.g., chronic skin condition, heart attack, etc.) only general information is collected. This information includes: contact information, date, and complaint. These non-public health-interest situations are referred to as Info Only responses.

  Response reports require obtaining full epidemiologic information from the ill

traveler. Quarantine Station staff will use the entire form to collect information and will follow up with the ill traveler.

This tiered approach to data collection during illness investigations will reduce the burden on the public by collecting only information appropriate for the situation.

- The United States Traveler Health Declaration and Ebola Entry Screening Risk Assessment Form are used at U.S. ports of entry to screen all travelers coming to the United States from countries experiencing widespread transmission of Ebola. DHS will be the primary administrator of the health declaration, and versions will be available primarily via electronic systems, but also in hard copy for English, French, and Arabic. Some of the personal identifying and travel related information will be pre-populated in the electronic portal version of the health declaration using passenger name record data collected by DHS. If a traveler answers in the affirmative to experiencing any of the specified symptoms or exposures, appears visibly ill, or has a fever, the risk threshold for a further public health evaluation is met. DHS will then contact CDC who will use the revised Ebola Entry Screening Risk Assessment Form to conduct a detailed medical evaluation to determine if further intervention is necessary. An English version of the risk assessment, as well as French and Arabic translation guides will be available for travelers. Information collected by DHS and CDC at the ports of entry will be stored in the QARS database.

  The United States Traveler Health Declaration is primarily completed by interviewing the traveler and entering responses into an electronic portal administered by DHS. The portal system and fillable PDF will have built in data validation processes so that if a field is missing data or appears inaccurate, the form cannot be transmitted. Data entered into the electronic portal by DHS will be securely transferred within 72 hours to CDC's QARS database for retention. The PDFs will be transferred by encrypted flash drive to DHS server, and there will be batch transfers of PDFs to CDC via secure file transfer protocol. Hard copy versions will primarily be used at ports of entry other than the five airports where enhanced entry screening is being conducted, in the event that travelers requiring screening arrive at those ports. Data will be provided to CDC by fax or secure email of scanned documents.

  The travelers contact information is collected on the health declaration and is sent to the State health departments via a secure public health messaging system. This contact information includes the number to the pre-paid cell phone provided by CDC. The states then make contact with the travelers every day for 21 days to complete the recommended 21 days of active monitoring.

- Currently, the IVR system is a telephonic tool that would assist state and local public health authorities with active monitoring of recent arrivals from countries with widespread transmission of Ebola, and the provision of Ebola related information to travelers who may have questions. The IVR system, and the burden estimates, could be adapted for other public health responses involving

different diseases or populations, if needed. In this scenario CDC would submit a change to make transparent the rationale for the change, as well as the anticipated burden.

In the IVR system, travelers who are identified as needing active monitoring would dial the number and respond to a series of questions posed either by an automated system or operator, according to the traveler's choice. When using the system and reporting no symptoms, the negative response would be recorded, stored by CDC in an appropriate format, and made available to the authorized health official in the jurisdiction they are staying. That jurisdiction would record this person as having been actively monitored for that day. If a traveler answers in the affirmative to experiencing any of the specified symptoms, the system would automatically connect the traveler to a public health professional (either at CDC or the state health department), who can connect them immediately to the proper medical personnel and/or the health department. If the caller is connected to the CDC, the health department would also be notified to ensure the traveler's call went through successfully and follow-up occurred.

The data collected through the IVR would be processed in the following way for Ebola:

- The traveler would call the line and identify who they are through a unique CARE ID (produced through random number generation) provided on their CARE card.
- The traveler would be asked if they checked their temperature and if they have, they will be advanced to two questions about the presence of a temperature over 100.4 F and the presence of other symptoms indicative of possible exposure to Ebola.
- If the traveler reported a fever or other symptom, the system would immediately advance them to a live call center representative for connection to the health department or urgent medical care (no data collection occurs).
- If a traveler reported "no" to both questions, the call would end and their responses would be saved with their ID number.
- Upon request, states would be provided with a file at a frequency of their preference that indicates which CARE IDs had reported and their symptom-development status. The states would have a list of all returning travelers in their state during the 21-day monitoring period and would be able to connect the CARE ID from the IVR report to the CARE ID in their report.

2. A description of the information to be collected

Each information collection tool in this request asks for personally identifiable information, occupation description, to include name, contact information, and travel related information, such as flight number, to ensure accurate identification of travelers. The presence of symptoms and history of exposures to disease is also collected to assist CDC in making a risk assessment and determine if further public health measures are needed.

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

- 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.

Information is being collected that may have an impact on an individual if the information was disclosed. CDC will only share the information for the specific purposes, and with the specific agencies, outlined in section three above

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

Respondents to this data collection will be informed whether or not providing the data described in this supporting statement is mandatory or voluntary prior to providing the information to CDC. In the health declaration, there is specific language outlining that the submission of information is voluntary. However, if an individual refuses to provide the requested information, or is not truthful about the information provided during screening or an illness investigation, CDC may, if it is reasonably believed that the

individual is infected with or has been exposed to Ebola, quarantine, isolate, or place the individual under surveillance under 42 CFR 71.32 and 71.33.

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

Respondents indicate their consent by verbally agreeing to participate in the screening program and illness and death investigations. Additionally, by calling the CARE Hotline to participate in the IVR, individuals indicate their consent.

7. How the information will be secured

Several safeguards are in place to prevent unauthorized disclosure.

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 the Centers for Disease Control and Prevention (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.

Access to the CDC Clifton Road 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 keypad) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The local fire department is located directly next door to the Clifton Road facility. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) 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.

Protection for computerized records, both on the mainframe and the National Center Local Area Network (LAN), 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. Additional safeguards may be built into the program by the system analyst, as warranted by the sensitivity of the data.

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. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

8. Whether a system of records is being created under the Privacy Act.

No system of records is being created for this information collection. This information is collected under the Privacy Act system of records notice 09-20-0171, "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.

11. Justification for Sensitive Questions

This information collection requests certain personally identifying information of both imports and travelers. Some personally identifying information will be collected during the proposed risk assessments in order to identify ill travelers. Some travelers might find these questions sensitive in nature, but this information is necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.

12. Estimates of Annualized Burden Hours and Costs

Below are the estimates of the Annualized Burden Hours that CDC is requesting for this revision to the OMB No. 0920-0821, which seeks to incorporate several information collections that were approved by OMB under control numbers 0920-1031 and 0920-1034. This includes the United States Travel Health Declaration, the Ebola Entry Screening Risk Assessment Form, the IVR system, as well as a request for burden estimates to account for the full 12 months of information collection.

The total additional burden requested for this revision is 105,571 respondents and 85,063 burden hours. The estimated total burden for 0920-0821 is 109,429 respondents and 85,382 burden hours.

This estimate is based on the following assumptions and available data:

- Since OMB approved 0920-1031, CDC has received updated data on arrivals from the affected countries; these countries currently include Guinea, Sierra Leone, and Liberia. Based on aviation data from Data in. Data out., LLC, CDC assumes there will be approximately 51,000 travelers per year from the affected countries who are coming to the United States and who will be screened using the United States Travel Health Declaration in any language (English, French or Arabic) or version (hard copy, fillable PDF, or portal version). This form requires 15 minutes of respondent time.
    - Based on the screening and language data collected from 11/22/2014 to 12/30/2014, CDC estimates that of these 51,000 arrivals, 49,238

respondents will use the English language version of the health declaration with an anticipated burden of 12,310 hours per year.

- While it is anticipated that the English language portal version of the health declaration will be most commonly used, CDC is including the English language hard copy, fillable PDF, and portal versions in one information collection in the table, because it is impossible to determine a proportion for each version, each version contains the same data elements, and each version requires the same length of time to complete. As described above, the portal version is anticipated to be the primary method of data capture, with hard copy and fillable PDF available as back-up.

  - Of these 51,000 annual arrivals, approximately 1,586, or approximately 3% of respondents may require the use of a French translation guide of the United States Travel Health Declaration. CDC estimates that the total burden for French speaking respondents will be 397 hours of additional burden requested in this revision.
  - A small number, less than 1%, of travelers from the region may require an Arabic translation guide for the health declaration. CDC is requesting approval to use the Arabic version with an approximately 176 respondents and 44 hours of burden.

- A small subset of this group will be referred by DHS to CDC based on their responses to the United States Travel Health Declaration. Based on referrals to CDC during the current screening process, CDC estimates that approximately 7% of travelers, on average, will require a public health assessment using the Ebola Entry Screening Risk Assessment Form, and other Illness and Death Investigation forms, if necessary. This form requires 15 minutes of a respondent's time. This equates to 3570 responses and an additional 893 hours for the use of the revised Ebola Entry Screening Risk Assessment Form. (Any discrepancies between the 3570 respondents calculated above and the number of respondents provided below is due to rounding.)
  - The largest group of respondents, slightly less than 97%, will use the English version of the risk assessment form. This is 3447 respondents and 862 burden hours.
  - Of these 3570 respondents, we anticipate that 111, or slightly more than 3%, will need the French translation guide for the Ebola Entry Screening Risk Assessment Form to assist an in depth medical evaluation. This is an estimated burden of 28 hours of the total 862 hours.
  - A small number of travelers may require Arabic translation guide for the risk assessment form to assist an in depth medical evaluation. CDC is requesting 3 hours of burden to cover an estimated 13 Arabic speaking travelers, less than 1 % of respondents.
- CDC is maintaining the ability to use the Ebola Entry Screening Risk Assessment Form in the even that a traveler is identified as ill on a flight prior to arrival in the United States. In the no material or nonsubstantive change to a currently approved collection granted by OMB on 9/18/2014, CDC requested 100 respondents and 5 hours of burden to assess ill travelers for risk of Ebola. CDC is maintaining the number of respondents at 100, but because the risk assessment form is more comprehensive and requires more time to complete, CDC is

requesting an additional 20 hours of burden for this purpose. The new total burden is 25 hours. This risk assessment may be done in English, French, or Arabic depending on the language need of the individual passenger. If other languages are needed, translation services will be provided.

2) Currently, CDC estimates that the addition of the IVR system to this information collection will add approximately 51,000 respondents and 71,400 burden hours above what is already approved in 0920-0821. It is important to note that, given the currently affected countries, this is the maximum estimate for respondents and hourly burden as CDC does not anticipate every individual from every state using the IVR system. In the even that an IVR system is activated, some states will develop their own systems to accomplish active monitoring.

This estimate is based on the following assumptions and estimates:

- Based on aviation data from Data in. Data out., LLC, CDC assumes there will be approximately 51,000 travelers per year from the affected countries who are coming to the United States who will be screened, and who will be provided information about the active monitoring IVR line. This means that 51,000 people per year will be participating in active follow-up for 21 days, with an approximately 71,400 burden hours associated with the use of the IVR script. (Differences in burden hours in the table are attributed to rounding)
    - Of these 51,000 respondents, slightly less than 97% will require an English version of the script, or 49,238 respondents. CDC estimates that the total burden for English speaking respondents will be 68,993 out of the approximately 71,400 hours of additional burden requested in this revision.
    - Slightly more than 3% of the incoming travelers will need a French translation. This equals 1,586 respondents and 2,220 hours of burden.
    - CDC estimates that less than 1% will need Arabic translation assistance. This estimate corresponds to 176 respondents and 246.
- As stated above, if responding to a different disease outbreak or other public health emergency, CDC will submit a change to account for different estimates of burden.

3) There are no changes in the number of requested respondents or burden to the Land Travel Illness or Death Investigation Form, Maritime Conveyance Illness or Death Investigation Form, or Airline Travel Illness or Death Investigation Form.

12 A. Estimates of Annualized Burden Hours

Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours

Traveler	Airline Travel Illness or Death Investigation Form	1,626	1	5/60	136
Traveler	Maritime Conveyance Illness or Death Investigation Form	1,873	1	5/60	156
Traveler	Land Travel Illness or Death Investigation Form	259	1	5/60	22
Traveler	Ebola Entry Screening Risk Assessment Form (Ill traveler interview: English, French, Arabic, or other as needed)	100	1	15/60	25
Traveler	United States Travel Health Declaration (English: Hard Copy, fillable PDF, electronic portal)	49,238	1	15/60	12,310
Traveler	United States Travel Health Declaration (French translation guide)	1,586	1	15/60	397
Traveler	United States Travel Health Declaration (Arabic translation guide)	176	1	15/60	44

Traveler	Ebola Entry Screening Risk Assessment Form (English hard copy)	3,447	1	15/60	862
Traveler	Ebola Entry Screening Risk Assessment French translation guide	111	1	15/60	28
Traveler	Ebola Entry Screening Risk Assessment Arabic translation guide	13	1	15/60	3
Traveler	IVR Active Monitoring Survey (English: Recorded)	49,238	21	4/60	68,933
Traveler	IVR Active Monitoring Survey (French: Recorded)	1,586	21	4/60	2,220
Traveler	IVR Active Monitoring: Arabic translation assistance (no script)	176	21	4/60	246
Total		**109,429**			**85,382**

Estimates of Annualized Cost of including the estimates from emergency requests 0920-1031 and 0920-1034 into 0920-0821 Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing, with the updated annualized estimate, are included in the table below. Wages for travelers were gathered from BLS category 00-0000 "All Occupations" (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). The estimated additional cost is $1,899,456, and the total estimated cost is $1,906,579.

12 B. Estimates of Annualized Cost

Respondent	Form	Total Burden	Hourly Wage	Total Respondent

		Hours	Rate	Costs
Traveler	Airline Travel Illness or Death Investigation Form	136	$22.33	$3,037
Traveler	Maritime Conveyance Illness or Death Investigation Form	156	$22.33	$3,483
Traveler	Land Travel Illness or Death Investigation Form	22	$22.33	$491
Traveler	Ebola Entry Screening Risk Assessment Form (Ill traveler interview: English, French, Arabic, or other as needed)	25	$22.33	$558
Traveler	United States Travel Health Declaration (English: Hard Copy, fillable PDF, electronic portal)	12,310	$22.33	$274,882
Traveler	United States Travel Health Declaration (French translation guide)	397	$22.33	$8,865
Traveler	United States Travel Health Declaration (Arabic translation guide)	44	$22.33	$983
Traveler	Ebola Entry Screening Risk Assessment Form (English hard copy)	862	$22.33	$19,248
Traveler	Ebola Entry	28	$22.33	$625

	Screening Risk Assessment French translation guide			
Travler	Ebola Entry Screening Risk Assessment Arabic translation guide	3	$22.33	$67
Traveler	IVR Active Monitoring Survey (English: Recorded)	68,933	$22.33	$1,539,274
Traveler	IVR Active Monitoring Survey (French: Recorded)	2,220	$22.33	$49,573
Traveler	IVR Active Monitoring: Arabic translation assistance (no script)	246	$22.33	$5493
Total		**85,382**		**$1,906,579**

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

There are no costs to respondents other than the time necessary to respond to the information collection

14. Annualized Cost to the Government

***All General Schedule wages are estimated using Atlanta locality adjustment.*

1) The routine costs for using the air, sea, and land illness and death investigation forms are as follows. This estimate represents the amount of time for the staff at the Quarantine Stations, to complete the forms and input them into QARS, in addition to the costs of printing the forms. The total staff hours used for this estimation correlate to the total hours requested from the public to respond to the data, plus an additional 50% to account for variation in the amount of time it takes CDC to collect and review the initial information in responses to illness or death in a traveler. Also included is the time for a

Quarantine Medical Officer to review and confirm the information. This cost accounting is for routine annual activities and does not include activities other than processing the data.

Personnel	Time in hours required to review and collect illness or death investigation forms	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost
Quarantine Public Health Officer (GS12)	314+(.5x314)=471	$34.80	$16,391
Quarantine Medical Officer (GS14)	314+(.5x314)=471	$48.90	$23,032
Total			**$39,423**

2) Public health screening at ports of entry is not a routine activity, but is instead an action begun in response to the widespread transmission of Ebola in specific countries in West Africa and is currently limited to five ports of entry with co-located CDC Quarantine Stations. CDC is providing the costs incurred for the screening program since its inception in early October and projecting out 12 months at the same five locations.

Expense Type	**Government Related Expenses**	**Annual Costs (dollars)**
Direct cost to the Federal Government – Screening Personnel		
	5 Quarantine Medical Officers (GS-14, 100%)	$510,225
	16 Public Health Associates (GS7, 100%)	$655,025
	10 Quarantine Public Health Officers (GS12, 100%)	$726,200
	5 Quarantine Public Health Officers (GS13, 100%)	$431,775
	15 Public Health Advisors (GS13, 100%)	$1,295,325
Direct cost to the Federal Government – Support Personnel		
	7 QMO's (GS14, 100%)	$714,315
	7 QPHO's (GS12, 100%)	$508,340
	7 OIC's 100% time (GS14, 100%)	$714,315
Contractor and		

other expenses		
	Contracts for public health surge support o 16 Medical Officers 100% time o 28 PHAs 100% time	$18,532,230
	Data Management Support	$450,000
	Ancillary Costs (Printing, travel, PPE, supplies, equipment, etc.)	$6,000,000
	TOTAL COST TO THE GOVERNMENT	**$30,537,750**

3) The IVR system is not a routine activity performed by CDC, but is instead a system initiated during the response to Ebola. The majority of the system costs have been donated from CDC partners. Costs for the IVR system supported by CDC are as follows:

Expense Type	**Government Related Expenses**	**Annual Costs (dollars)**
Direct cost to the Federal Government		
	CDC Project Manager (GS-14, .20 FTE)	$20,409
	CDC Call Center Operators (GS-12, 2 FTE)	$ 145,240
	CDC Health Communication Specialist (GS-13, .15 FTE)	$ 12,953
Contractor and other expenses		
	Data Management Support (estimated at .5 GS-13 equivalent plus contract costs)	$ 54,036
	TOTAL COST TO THE GOVERNMENT	**$232,638**

4) Finally, there are systems and personnel costs associated with the use and maintenance of QARS, which will store information concerning travelers who are screened and who require public health follow up. These costs include the IT and associated staffing expenses. 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 are as follows.

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

5) The total annual cost for this information collection is $31,101,851. As explained above, only the costs for illness and death investigations and the cost of the QARS IT system and administration are routine costs. The screening and IVR system were initiated to improve CDC's public health response to Ebola.

15. Explanation for Program Changes or Adjustments

This revision seeks to incorporate the changes that resulted from activities undertaken during the response to Ebola. These changes include two major components, both of which have been given previous emergency clearance by OMB under control number 0920-1031 and 0920-1034, with an expiration date of April 30, 2015. As a part of this revision, CDC is requesting the full three year approval for the following:

1. The incorporation of two public health screening forms that are currently used to assess risk for Ebola in travelers coming to the United States from countries experiencing widespread transmission of the disease, or countries that have Ebola in urban areas and are implementing uncertain control measures. These forms are the slightly revised United States Traveler Health Declaration and a completely revised Ebola Entry Screening Risk Assessment Form (forms approved under OMB Control No 0920-1031). The additional burden requested for the English versions of the health declaration and the risk assessment form, as well as the French and Arabic translation guides for the health declaration and risk assessment forms, is 13,664 hours.
    a. CDC is maintaining the ability to use the Ebola Entry Screening Risk Assessment Form in the event that a traveler is identified as ill on a U.S.-bound flight prior to arrival. In the no material or nonsubstantive change to a currently approved collection granted by OMB on 9/18/2014, CDC requested 100 respondents and 5 hours of burden. Because the form is more comprehensive, it requires more time for traveler to complete the assessment (A full outline of the changes is found in section c below). CDC is requesting an additional 20 hours of burden for the purpose of assessing ill travelers, for a total of 25 hours of burden. No additional respondents are requested.
    b. Since the approval of the United States Traveler Health Declaration on 11/20/2014 and its use in the screening process, CDC has recognized that a few changes are necessary to make the form more useful from a follow-up standpoint and easier for the respondents to complete the process. These changes are as follows:
        i. Renamed “Departure date” as “Departure date from affected country”
        ii. Renamed “1st email address” and “2nd email address” as “Email address” and “Alternate email address”
        iii. Renamed “1st telephone number” and “2nd telephone number” as “Telephone number” and “Alternate telephone number”. Added a check box for number provided to indicate whether it is a mobile phone.
        iv. Reversed the order of “Home address” and “Address(es) for next 21 days”.
        v. Added two addresses (for next 21 days)
        vi. Added dates fields, e.g. Dates at address: [date] to [date] for 21 day period.

vii. After “Gave tear sheet”, added “(if CARE Kit not available)”.
viii. In the disposition section of the form, “Referred to CDC” has been changed to “Referred to Tertiary” for increase clarity in record keeping and communication between DHS and CDC.
ix. Revised the instructions to DHS on visual observation for signs of illness to further clarify that this is an action to be taken by DHS and not a question to be asked of the traveler.

c. Since the approval of the Ebola Entry Screening Risk Assessment Form on 11/20/2014 and its use in the screening process, CDC has recognized that a few changes are necessary to make the form more sensitive to risk and easier to administer. These changes are mainly concerned with the instructions so that individuals who meet certain risk thresholds are assisted according to the most updated version of the CDC’s revised Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure. The changes, in detail, are as follows:
    i. A revised title, which is now the Ebola Entry Screening Risk Assessment Form.
    ii. A clarification of the instructions on how to complete the form correctly. This information is intended for the CDC official conducting the assessment and constitutes no burden to the individual being screened.
    iii. Instructions for consulting with CDC headquarters (CDC Ebola Consultant) have been removed, because these instructions have been included in the general Quarantine Station Guidance.
    iv. Instructions for documentation have been made more explicit to ensure a more complete record of the assessment. A separate “definitions” section has been created. “Blood” has been included in list of body fluids in the definition.
    v. Clinical section/symptoms questions have been moved to the beginning of the form so that Medical Officer can make a more informed decision about personal protective equipment use. Similarly, instructions for completing clinical section of the assessment have been moved to top of the instructions section for improved use by the assessors.
    vi. A qualifying statement about the use of fever reducing medication *within the last 12 hours* has been added to limit questions to this time period thus minimizing the response burden of this question.
    vii. In question one, CDC has clarified several points, including asking about “other potential exposures” (besides contact) and stating that the question includes situations while wearing personal protective equipment (PPE). CDC additionally added: *Note to interviewer: As applicable, ask about activities such as cleaning/disinfecting contaminated areas or spraying in HCF doffing areas (i.e. before PPE removal) or of dead bodies/body bag*. This is to better ascertain potential exposures. This is being included based on common interactions with individuals who relay this useful information to CDC without being specifically prompted to do so

in order not to miss individuals who do not volunteer the information without prompting.

viii. In question two, CDC has added phlebotomist to the description of patient care, to better identify these individuals who might not consider themselves as having taken care of patients.

ix. In question three, CDC has added: *Note to interviewer: Please clarify context; for travelers that report visiting Ebola treatment units (ETUs) this question refers only to areas of the ETU where PPE is typically required, such as direct patient care areas*. This is to assist CDC is assessing the level of exposure risk and to minimize the response burden to people who entered a facility designated as an ETU but in a capacity that did not put them at risk for exposure to Ebola patients, e.g. administrators. In the documentation (check boxes), "nonclinical activities" has been added to "observer" to capture people who did not provide patient care but who entered into a patient care area in an occupational capacity rather than as an observer.

x. In question number four, CDC added a field for the name of lab where an individual may have worked. Assessors were previously asked to find out the name of the lab; the field is added for improved documentation. Obtaining the name of the lab minimizes the response burden as individuals who worked in labs that CDC has inspected and determined that appropriate biosafety precautions are routinely followed do not require additional questioning about lab-related activities.

xi. In question number four, the instructions have been changed to include an option for a "Some Risk" assessment.

xii. Question five has been altered to include a simpler, more overarching question "Were you around dead bodies or did you attend a funeral?" This should limit the additional time to ask the more detailed exposure questions to only those people who were in this situation.

xiii. Documentation for question six has been clarified to require recording of time living in the household of a person with Ebola to only the period that the person was symptomatic/infectious.

xiv. Question number seven has been re-worded in an attempt to more accurately discern if any exposures have occurred in locations other than in an ETU or a household, which would have been discovered in answering either question three or six. This question is less redundant and more sensitive to potential unprotected exposures.

xv. A new question eight was added to ask explicitly about PPE breaches if PPE was worn in situations where there was a potential exposure to Ebola (as determined through questions one and three-five). This question should function as a sub-part to questions one and three-five, so should not add any additional burden to respondents.

xvi. Several changes have been made to improve documentation and notation during the assessment. These include:
    1. New space to provide more detailed description of any symptoms
    2. More space for detailed narrative information to describe the assessment
    3. A section for outlining a justification for the traveler disposition has also been added
    4. The positioning of spaces for free text transcription are moved so that they are more likely to be used by assessment staff.

xvii. The rest of the changes are simple wording changes to improve ease of use and understanding

d. Through experience at the ports of entry where screening is being conducted and discussions with our port partners, CDC has determined that the French and Arabic versions of the health declaration and risk assessment would be more efficiently used as aides for translation, and not stand alone versions. Currently, the interviews and assessments are carried out by English-speaking DHS officers and CDC medical officers with assistance from translators. CDC is now seeking approval to remove the English instructions from the forms, and keep the French and Arabic questions and definitions as a guide for translation, with the English translations appearing to the side. The actual answers and narrative derived from the interviews and assessments will be written on the English versions of the forms. No change to burden is requested, and the French and Arabic translation guides will remain accounted for in the burden tables in Sections 12a and 12b.

2. The incorporation of a telephonic, automated survey administered through the Interactive Voice Response (IVR) phone system, referred to as the CARE Hotline, which will ask travelers if they have developed a fever or any other symptoms potentially indicative of Ebola exposure (OMB Control No 0920-1034). This system would be used as a tool to assist public health authorities in maintaining contact with returning travelers to ensure that signs and symptoms of disease are reported as soon as possible. The additional burden requested for the use of the IVR system is 71,400 hours.

No revisions are requested to the Air Travel, Maritime Conveyance or Land Travel Illness and Death Investigation forms or burden associated with these information collections. The current burden associated with these forms is 314 hours.

The total additional burden requested for this revision is 105,571 respondents and 85,063 burden hours. The estimated total burden for 0920-0821 is 109,429 respondents and 85,382 burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC and CPB may report aggregate totals of number of people screened and number of positives publicly, as appropriate. Similarly, aggregate numbers of illness or death investigations may be reported.

Currently, CDC has no plans for tabulation or publication of any IVR related data, and no project time schedule. The IVR tool is currently not being used, but several states have taken steps, independent of CDC, to begin testing modified versions of the IVR, based on the free and open source IT infrastructure provided by private sector stakeholders. CDC is providing consultations to States for these programs, but is not funding or taking substantive control in any way.

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

Display of the expiration date is appropriate. No exemption is 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 Code of Federal Regulations part 70
Attachment A3 – 42 Code of Federal Regulations part 71
Attachment B – 60 day Federal Register Notice
Attachment B1 – Public Comment to Federal Register
Attachment C – Air Travel Illness or Death Investigation Form
Attachment D – Maritime Conveyance Illness or Death Investigation Form
Attachment E – Land Travel Illness or Death Investigation Form
Attachment F1a – United States Traveler Health Declaration - English
Attachment F1b – United States Traveler Health Declaration – electronic portal
Attachment F1c – United States Traveler Health Declaration – fillable PDF
Attachment F2 – United States Traveler Health Declaration – French Translation Guide
Attachment F3 – United States Traveler Health Declaration – Arabic Translation Guide
Attachment G1 – Ebola Entry Screening Risk Assessment Form – English
Attachment G2 - Ebola Entry Screening Risk Assessment French Translation Guide
Attachment G3 - Ebola Entry Screening Risk Assessment Arabic Translation Guide
Attachment H – IVR Script - English
Attachment I – IVR Script - French
Attachment J – Human Subjects Non-Research Determination
Attachment K – IVR Script – Arabic (English version) provided by translation services