Data Collection for Evaluation of Education, Communication, and Training (ECT) Activities for the Division of Global Migration and Quarantine (0920-0932)

Evaluating the Effectiveness of Ebola CARE Plus Program

Generic Information Collection Request

April 2, 2015

Statement A

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Goal of the study: The purpose of this assessment is to assess travelers' knowledge, attitudes, beliefs, and behaviors related to Ebola active monitoring and reporting requirements in a way that considers (1) factors that affect traveler experience and compliance, (2) cultural competence of educational materials; and (3) program implementation over time (process evaluation).

Intended Use: The information collected in this assessment will be used to help refine the Ebola CARE+ program and understand the effects of a program intended to enhance the traveler entry screening experience and increase initial uptake and participation in active monitoring until completion of the full 21-day monitoring period.

Methods: Android tablets pre-programmed with survey questions will be used to conduct the brief surveys of travelers in airports and a computer-assisted telephone interview (CATI) system will be used to conduct telephone surveys with travelers at two different points in time in their period for monitoring and reporting, one survey at the beginning. Online survey is an option for the cultural competency assessment of Ebola health education materials. In person interviews will also be done.

Subpopulation: Travelers from countries with widespread Ebola outbreaks.

Quantitative data will be analyzed using SPSS software. Descriptive statistics will be calculated for the entire sample. Dependent samples t-tests, Chi-square, and binary logistic regression will be used to examine relationships between independent and dependent variables at baseline and follow-up and to measure change between time points. To determine statistical significance, alpha will be set at the traditional level of 0.05. Qualitative data will be transcribed by the contractor. The text responses will be uploaded to NVivo, ATLAS.ti, or MAXQDA and analyzed using thematic analysis.

Part A. Justification

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) National Center for Emerging and Zoonotic Infections Diseases (NCEZID) Division of Global Migration and Quarantine (DGMQ) requests approval to conduct an assessment of the Check and Report Ebola (CARE) Plus (CARE+) Program First, we will conduct surveys with a convenience sample of travelers (i.e., a systematic sample of travelers stratified by arrival times and airport) who speak English or French and are 18 years or older, coming into the United States (U.S.) at two of the five designated entry airports from countries with widespread Ebola outbreaks: John F. Kennedy (JFK) and Dulles International Airport (IAD) over four months (April-July, 2015.) – we estimate 1200 people. Once all interviews have been conducted the evaluation team will make a monthly request of data from up to 50 health departments who are conducting active monitoring programs of travelers in their jurisdictions. The request for information will be about aspects of active monitoring that the CARE+ program was intended to influence. Information from health departments will validate "self-reported" responses from travelers. Finally, a cultural competency assessment will be conducted with 30 already-identified consultants from affected countries to assess and apply a cultural competence instrument.

CDC's Division of Global Migration and Quarantine (DGMQ) is at the forefront of the U.S. response to the recent Ebola outbreak in West Africa working in close collaboration with other federal and state agencies. A core component of DGMQ's contribution to the response is the development and deployment of clear and effective risk communication messages and resources as they relate to travelers to the U.S. who arrive from a country with an Ebola outbreak. More specifically, DGMQ plays a role in encouraging travelers' participation in active monitoring of symptoms for the 21 days after their arrival in the United States. The goal is twofold: 1) prevent spread of Ebola and; 2) identify people potentially infected with Ebola as early as possible so that appropriate treatment and control measures can be taken.

In October 2014, CDC began the Check and Report Ebola (CARE) program, which involved the distribution of CARE kits to all travelers at five U.S. airports (New York City John F. Kennedy, Newark Liberty, Washington Dulles, Chicago O'Hare, and Atlanta Hartsfield-Jackson) who have recently been in countries with widespread Ebola transmission or cases in urban areas with uncertain control measures. The CARE Kit contains: Guidance on how to check and report possible Ebola symptoms for 21 days, description of possible Ebola symptoms, digital thermometer with instructions, 21-Day symptom log, and information on who to call if they develop symptoms of Ebola. An evaluation of the CARE program was implemented (OMB Gen IC No. 0920-0932) in December 2014 to assess how the CARE program enhanced traveler

knowledge of Ebola, awareness of active monitoring, intention to participate in active monitoring, and initiation and retention in active monitoring. On November 16, 2014, CDC began the CARE+ program to enhance the existing CARE program infrastructure and overcome early program challenges that states were experiencing in terms of active monitoring for 100% of travelers.

The CARE+ program, which aims to improve U.S.-based Ebola entry screening and active monitoring at five U.S. airport, added trained health educators and social workers (called CARE Ambassadors) reviewing the CARE kit with all travelers along with providing all adult and unaccompanied minors with a low-cost, pre-paid cell phone with at least 21 days of voice and text service so that they could use to report their temperature and Ebola symptoms to a health department. The CARE cell phone numbers are provided to the health department at the travelers' destination, along with other contact information collected during the U.S. Customs and Border Protection enhanced entry screening process. The PLUS (+) represents a substantial investment of resources.

The objectives of the CARE+ program were to increase travelers' knowledge of Ebola symptoms, awareness of active monitoring requirements, intentions to participate, knowledge of how to seek medical care safely, trust in the US public health system, and to remove barriers to participation in active monitoring. The ultimate goal is to improve travelers' initiation into and retention in active monitoring.

This assessment of the CARE+ program will use many of the questions used in the assessment of the Ebola Care program that was completed in December 2014 (OMB Gen IC No 0920-0932.) However, more close-ended questions are proposed in the assessment of the CARE + program with response options that came from the content analysis of open-ended questions that were asked in the CARE program evaluation in December 2014. Newly proposed questions have not been pilot tested but are grounded in social science literature in their respective domains (e.g., social influence, trust). The contractor who will perform this work has a long history of constructing orally-administered surveys both by in-person encounters and phone. The contractor has estimated that each of the instruments can be completed within the proposed time.

This request is for a one-time data collection related to a newly established enhanced entry screening effort and associated educational program that have been put in place due to the unprecedented outbreak of Ebola virus disease in some West African countries. Specifically, CDC needs this assessment to ensure that the CARE+ program effectively educates, equips, and encourages mobile populations who may be at increased public health risk to fulfill Ebola

monitoring and reporting requirements. On-going evaluation is an important part of this program because it can reveal reasons why expected actions of program staff and travelers occur, or do not occur, and help identify alternate or supplemental strategies that can be used with them to support delivery of the program as intended in a way that results in the program's intended effects. Interviews with current travelers can help articulate motivations for and against complying with the recommendations to monitor for and report Ebola symptoms. Implementing changes based on results from this assessment is expected to facilitate program improvement and ensure the most efficient allocation of resources as the epidemic is contained and stopped.

A.2. Purpose and Use of the Information Collection

The purpose of this assessment is to assess travelers' knowledge, attitudes, beliefs, and behaviors related to Ebola active monitoring and reporting requirements in a way that considers (1) factors that affect traveler experience and compliance (see previous lists of concepts); (2) cultural competence of educational materials; and (3) program implementation over time (process evaluation). The information collected in this assessment will be used to help refine the Ebola CARE+ program. Additionally, this information will be used to understand the effects of a program intended to enhance the traveler entry screening experience and increase initial uptake and participation in active monitoring until completion of the full 21-day monitoring period. A core component of CDC's Ebola response is the development and deployment of clear and effective risk communication to assist travelers to and from West Africa with participation in daily active monitoring and early reporting of symptoms until 21 days after their departure from the affected country.

Program evaluation activities are an essential data collection for program refinement as well as the CARE+ program's influence on traveler compliance with requirements. Although results will have limited generalizability, conducting this assessment is and will provide critical information about traveler knowledge of Ebola, awareness of active monitoring, intention to participate in active monitoring, and initiation and retention in active monitoring and the factors that help or hinder traveler retention in active monitoring. The results of this evaluation should provide information that can be used to enhance and revise the existing program as well as offer lesson learned in order to inform future programs that involve education and active monitoring of travelers for the control of infectious diseases.

A.3. Use of Improved Information Technology and Burden Reduction

This information request is in compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Two technologies will be used to improve data collection and to reduce burden on participants: (1) Android tablets pre-programmed with survey questions will be used to conduct the brief surveys of travelers in airports and (2) a computer-assisted telephone interview (CATI) system will be used to conduct telephone surveys with travelers at two different points in time in their period for monitoring and reporting, one survey at the beginning (3-5 days after their airport survey) and one survey near the end (2 days before the end of their reporting period). Online survey is an option for the cultural competency assessment of Ebola health education materials.

A.4. Efforts to Identify Duplication and Use of Similar Information

The current Ebola epidemic and resulting airport screening activities are unprecedented. As such, previous data collection has not been done on any federal government endeavor with a scope of this kind. It is not expected that any of the information collected under this proposed generic clearance to assess the enhanced entry screening effort is duplicate or is already in the possession of the federal government. In December 2014 a baseline evaluation of the Ebola CARE program, the precursor of the Ebola CARE+ program (which added CARE Ambassadors in airports and the distribution of cell phones) was completed (OMB Gen IC NO. 0920-0932.) The findings of that small and time-limited evaluation have informed the design and instruments for this evaluation. The information collected through this assessment will be used to ensure that the CARE+ program effectively educates, equips, and encourages mobile populations who may be at increased public health risk to fulfill Ebola monitoring and reporting requirements. On-going evaluation is an important part of this program because it can reveal reasons why expected actions of program staff and travelers occur, or do not occur, and help identify alternate or supplemental strategies that can be used with them to support delivery of the program as intended in a way that results in the program's intended effects. Orally administered surveys with current travelers can help articulate motivations for and against complying with the recommendations to monitor for and report Ebola symptoms. Implementing changes based on results from this assessment is expected to facilitate program improvement and ensure the most efficient allocation of resources as the epidemic is contained and stopped. Finally, this information will be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs of this sort.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be impacted in the data collection.

A.6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection related to a newly established and recently enhanced screening effort that is a result of an unprecedented disease outbreak. Specifically,

without this information DGMQ's ability to effectively communicate messages in a culturally competent manner to mobile populations who may be at increased public health risk may be compromised. Assessment is important in the health communication process because it can reveal why specific activities occur, or do not occur, as planned. In particular, results can be gained through this assessment that can facilitate program improvement and ensure best allocation of resources. Surveys with current travelers can help articulate motivations for and against complying with the recommendations to monitor and report Ebola symptoms.

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

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

A. This data collection is being conducted using the Generic Information Collection mechanism of The Data Collection for Evaluation of Education, Communication, and Training (ECT) Activities for DGMQ– OMB No. 0920-0932. A 60-day Federal Register Notice was published in the Federal Register on August 10, 2011, Vol. 76, No. 154; pp. 49487-88 (Attachment G). The 30-day FRN was published on December 7, 2011 (76 FR 76415). One non-substantive comment was received, and CDC's standard response was sent to address the comment.

B. CDC staff across the agency was consulted to obtain their views on availability of data, frequency of collection, clarity of instructions and record keeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported. Staff at Research Triangle Institute (RTI), the contractor hired to perform this evaluation, were consulted in the design and development of this assessment.

A.9. Explanation of Any Payment or Gift to Respondents.

CDC and contractors will not provide payments or gifts to respondents.

A.10. Assurance of Confidentiality Provided to Respondents

<u>Overview of the Data collection System</u>

This is a mixed-method assessment consisting of multiple data collection instruments:

1. In-person Survey of Traveler Intercepted at the Airport (Attachment A)

2. Telephone Survey within 3-5 days of the airport interview (Attachment B)
3. Telephone Survey 2 days before the traveler's end date for monitoring and reporting (Attachment C)
4. Data request to health departments (Attachment D)
5. Tool for assessing cultural competence (Attachment E)of the CARE Kit (Attachment F)

Traveler data (1-3, above) will be collected in two ways at three points in time—one in-person survey at the airport and two phone surveys at the beginning and near the end of the traveler's monitoring and reporting period. Data will be collected in-person from about 1200 travelers coming into two of the designated airports for Ebola screening over the course of four months using a survey (see Attachment A) that is pre-programmed in to an Android tablet. This survey will take approximately 10 minutes. Travelers who consent to phone follow-up surveys will be contacted for a second survey within 3-5 days of their airport interview (see Attachment B) which will take approximately 10 minutes and again for a third survey within 2 days of their end date for monitoring and reporting to health departments (see Attachment C). The third phone survey will take approximately 5 minutes. Computer-assisted telephone interviewing (CATI) systems will be used by the contractor to conduct both sets of phone surveys. This sample of travelers will allow a robust view of the knowledge, beliefs, and behaviors of those who are undergoing screening and complying with monitoring and reporting requirements over time.

Many of the questions were used in the baseline assessment of the Ebola Care program that was completed in December 2014 (OMB Gen IC No. 0920-0932.) More close-ended questions are proposed with response options that came from the content analysis of open-ended questions that were asked in the baseline evaluation. Newly proposed questions have been pilot tested and are grounded in social science literature in their respective domains (e.g., social influence, trust). The contractor who will perform this work has a long history of constructing orally-administered surveys both by in-person encounters and by phone. The contractor has estimated that each of the instruments can be completed within the proposed time. Feedback from the baseline assessment was also used to ensure tools were culturally appropriate and to estimate burden hours.

After all surveyed travelers have completed their monitoring and reporting period, the evaluation team will request information from health departments on a monthly basis about aspects of active monitoring that the CARE+ program was intended to influence (see Attachment D). The evaluation team will provide health departments with the list of CARE ID numbers of participants and ask the health departments for data described above on a monthly basis.

Cultural competence data will be collected from 30 consultants from Ebola-affected countries who are on the prepared list of CDC volunteers for consultation. These individuals will review

CDC's Ebola CARE Kit (Attachment F) using the cultural competency assessment tool (Attachment E), which we estimate to take 30 minutes. The participant will have the option to conduct their review using one of three formats depending on their preference: (1) pen and paper survey; (2) on-line survey; or (3) phone interview. Below is a brief description the five data collection instruments that are included in this request.

Description of the Information to be collected

The two follow-up surveys of travelers will be collected by trained interviewers at the contractors survey research facility using computer-assisted telephone interviewing (CATI) technology that is programmed with the survey instruments for each of the surveys (Attachment B and C, respectively). The evaluation team will provide health departments with the list of CARE ID numbers of participants and ask the health departments for information about aspects of active monitoring that the CARE+ program was intended to influence (Attachment D). The team will request this information on a monthly basis for the four month period of this project (April- July 2015). An attempt will be made to obtain this information on all interviewed travelers but health departments are not required to provide this information. Consultants from Ebola-affected counties who are on the prepared list of CDC volunteers for consultation will be invited to use it to review CDC's Ebola CARE Kit (Attachment F) using the cultural competency assessment tool (Attachment E.) These individuals will have the option to conduct their review using one of three formats depending on their preference: (1) pen and paper survey; (2) on-line survey; or (3) phone interview. Below is a brief description the five data collection instruments that are included in this request.

In-person Survey of Traveler Intercepted at the Airport

This in-person survey will take approximately 10 minutes and will occur at the airport after travelers have had an encounter with a CARE Ambassador (see Attachment A). Information will be collected by trained interviewers at two U.S. airports conducting airport entry screening for Ebola (John F. Kennedy and Washington Dulles) using these survey questions which will be pre-programmed in an Android tablet. Although most of the questions are scaled, several are followed up by an open-ended question. At the conclusion of the survey, travelers will be asked if they are willing to participate in a telephone survey in 3 to 5 days. If they agree, they will be asked for their name and contact information (phone number).

Telephone Survey within 3-5 days of the airport interview

This telephone survey will take approximately 10 minutes and will occur within 3-5 days of the traveler's airport interview (see Attachment B). Computer-assisted telephone interviewing (CATI) systems will be used by the contractor to conduct this survey. At the conclusion of the

survey, travelers will be asked if they are willing to participate in a telephone survey near the end of the monitoring and reporting period. If they agree, the interviewer will confirm their name and contact information (phone number).

Telephone Survey 2 days before the traveler's end date for monitoring and reporting

Travelers who consent to phone follow-up surveys will be contacted for this third survey which will occur within 2 days of their end date for monitoring and reporting to health departments (see Attachment C). This phone survey will take approximately 5 minutes and will employ the use of a computer-assisted telephone interviewing (CATI) system.

Data request to health departments

After all surveyed travelers have completed their monitoring and reporting period, the evaluation team will request information from health departments about aspects of active monitoring that the CARE Plus program was intended to influence (see Attachment D). The evaluation team will provide health departments with the list of CARE ID numbers of participants and ask the health departments for data on a monthly basis over the four months of this project. An attempt will be made to obtain this information on all interviewed travelers but health departments are not required to provide this information. The evaluation team is requesting eight data points from health departments that the CARE+ program was intended to influence

Tool for assessing cultural competence of health education materials

Up to 30 consultants who are from Ebola-affected countries and who have indicated an interest in being consulted by CDC staff will be contacted to participate in the assessment of materials for cultural competency. On December 5, 2014, CDC staff participated in the West African Diaspora Ebola Summit where the Ebola outbreak and response efforts were discussed. At the gathering, CDC had an exhibit booth that had a sign-up sheet for receiving partnership e-newsletters. On that sign-up sheet there was a question with a check box that asked summit participants if they would like to be contacted by CDC to help on future partnership efforts. CDC contacted all individuals who said yes to see if they would like to be consulted from time to time on messaging to specific audiences. CDC's Joint Information Command (JIC) outreach team maintains this list and has engaged this group several times over the course of the Ebola response via email, telephone conference calls, and interactive webinars. Individuals from the list will be invited to use it to review CDC's Ebola CARE Kit (Attachment F) using the cultural competency assessment tool (Attachment E), which we estimate to take 30 minutes. The participant will have the option to conduct their review using one of three formats depending on their preference: (1) pen and paper survey; (2) on-line survey; or (3) phone interview. The first 26 questions use a four point Likert-scale for response items from strongly agree to strongly

disagree followed by one open ended question at the end. Insights will be used to refine the instrument.

Description of How the Information will be shared and for What Purposes

The information collected through this assessment will be used to help refine interventions that are designed to enhance the travelers' experience of entry screening experience and increase travelers' initial uptake and participation in active monitoring for the full 21-day period. Finally, this information will be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs of this sort.

The information collected will include the traveler's name, contact information (phone number), and a CARE ID number, a unique identification number provided to them in the CARE Kit which can be linked back with traveler identifiers and contact information in DGMQ's secure database of all screened travelers. The assessment team will assign a unique participant number that will be used to connect data from the three surveys and the data from the health department so that personally identifiable information including the CARE ID number can be removed before data analysis begins. The Computer Assisted Telephone Interview (CATI) system will store name and contact information for each traveler from the first survey until the last survey is completed. Once all survey contacts are completed, names and phone numbers will be deleted. Only members of the assessment team (staff who are conducting telephone follow-up surveys) will have access to contact information. The evaluation team will provide a list of CARE ID numbers to request information from health departments about aspects of active monitoring that the CARE+ program was intended to influence. Once this information is collected and connected to survey data, all personally identifiable information (including the CARE ID number) will be removed and the link between traveler participants and DGMQ's database will be severed.

Final reports, manuscripts, and presentations will contain no information regarding identities of the participants. All collected data (including numeric codes) and audio recordings (from audio capture tool on the Android tablet) will be destroyed three years after the data collection is complete. Audio recordings will be deleted and paper files shredded.

Impact the Proposed Collection will have on the Respondent's Privacy

Prior to participating in the assessment at the airport and via telephone, prospective respondents will receive verbal information informing them of CDC's assessment project, their rights as participants, and contacts for more information about the project. Prior to the beginning of the assessment, a staff member will also address any questions the participants have about the

project. Participants must provide verbal consent at the time of each interview before any information will be collected. Participant consent for obtaining information from health departments will not be obtained since it could affect their responses to survey questions, their interactions with health departments, and their participation in active monitoring.

The assessment has no foreseeable risks other than the very low risk of breach of security. Travelers are not required to participate. The choice to participate is completely voluntary. Participants have the right to withdraw at any time for any reason. The immigration status, entry into the United States, or legal standing of the traveler will not be affected by the choice to participate or not participate or any information provided. Traveler participation will also not affect the entry screening process or post-arrival monitoring. None of the information being collected would reasonably place subjects at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputations. It is important to note that all of these individuals will be considered to be at low or some risk of Ebola, but will not be part of the assessment group if they are symptomatic. Thus, there are no threats to the security of Ebola cases or suspected Ebola cases that could potentially be compromised. The data collected will be retained for three years, though participant identifiers will be removed after a state has verified completion of monitoring and reporting requirements, and then all data will be destroyed.

Whether Individuals are informed that providing the Information is Voluntary or Mandatory

Participation in the assessment is voluntary. Verbal consent will be obtained prior to interview. Participants will be informed they are free to skip questions they do not wish to answer, respond "I don't know," or end the interview at any time for any reason. Once informed of this information, participant's agreement to participate in the interview will be their consent to participate in the assessment. Interviews will only be conducted with those who agree to participate. After the traveler has completed their monitoring and reporting period, the evaluation team will request information from health departments about aspects of active monitoring that the CARE+ program was intended to influence. Because this data request will come after completion of active monitoring there will be no potential ramifications for the traveler, the health department, or their relationship/interaction during the monitoring and reporting period.

Participant consent for obtaining information from health departments will not be obtained since it could affect their responses to survey questions, their interactions with health departments, and their participation in active monitoring. This data collection is an evaluation of a public health program and is not intended to obtain generalizable knowledge; therefore a nonresearch determination was made by CDC's Institutional Review Board (see Attachment H)

Prior to participating in the information collection at the airport and via telephone, prospective respondents will receive verbal information informing them of the CDC assessment project, their rights as participants, risks and benefits in participating, and contacts for more information about the project as demonstrated in the script used in all surveys (Attachments A, B, and C) as well as the consultants assessing the cultural competency assessment tool.

Participation in the surveys and assessment is voluntary. Participants will be informed they are free to skip questions they do not wish to answer, respond "I don't know," or end the interview at any time for any reason. Prior to the beginning of the information collection, a staff member will also address any questions the participants have about the project. Participants must provide verbal consent at the time of each interview before any information will be collected. Surveys will only be conducted with those who agree to participate.

The immigration status, guarantee of entry into the United States, or legal standing of the traveler will not be affected by the choice to participate or not participate. None of the information being collected would reasonably place subjects at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputations. It is important to note that all of these individuals will be considered to be at low or some risk of Ebola, but will not be part of the assessment group if they are symptomatic. Thus, there are no threats to the security of Ebola cases or suspected Ebola cases that could potentially be compromised.

The data request to health departments is also voluntary. The written information request (see Attachment D) includes the following text:

Your response to this data collection request is completely voluntary. Whether your organization chooses to participate and any information you provide will not impact your organization's relationship with CDC. The evaluation is only intended to capture the impact of the CARE+ program on travelers' participation in monitoring as described above, and will not assess health departments' performance in conducting monitoring. The evaluation, including traveler interviews and this information collection, has been approved by CDC as a program evaluation that does not represent human subjects research. The CDC evaluation team is willing to answer any questions that you may have about this evaluation project. The CDC point of contact is Christine Prue (cep9@cdc.gov) and she can be reached at (404) 639-2273.

Opportunities to Consent, and Share Submission of Information

Participation in the assessment is voluntary. Participants must provide verbal consent at the time of each survey before any information will be collected. Surveys with travelers, interviews with

consultants, and data requests from health departments will only be conducted with those who agree to participate.

Information Secured

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

System of Records

No system of records is being created for this information collection. 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.

IRB Approval

This data collection was reviewed by the Scientific Regulations Advisor for the EOC Ebola Response and determined to be "public health non-research" (Attachment H).

A.11. Justification for Sensitive Questions

The information collected from travelers will include the traveler's name, CARE ID, and phone number. This information will be requested during the first survey (Attachment A), and is critical for following up with the two telephone surveys (Attachment B and C) and connecting survey information to information requested from health departments (Attachment D.) No other sensitive questions will be asked. To minimize the possibility of distress, participants will be informed that the survey is voluntary, and they are free to skip questions they do not wish to answer, respond "I don't know," or end the survey at any time for any reason. No sensitive questions will be asked during the cultural competency assessment (Attachment E).

A.12. Estimates of Annualized Burden Hours and Costs

The estimate for survey burden hours is based on the burden hours from interviews conducted in the assessment of the CARE program in December 2014 as well as pilot-testing of the revised airport, and telephone instruments. Each of these revised instruments was tested 3 times. Revised instruments have more close-ended questions with response options derived from the qualitative analysis of traveler responses to open-ended questions asked in the CARE program assessment interviews. In addition, questions were added to measure knowledge, beliefs, and behaviors that that the CARE+ program was intended to influence. The contractor pilot-tested the three brief surveys of travelers without the use of Android tablets or the CATI system in order to assess whether the surveys could be administered within the proposed time frames. The times recorded for the three pilot tests of each survey instrument were as follows:

- In-airport surveys were completed in 10, 12, and 13 minutes
- Telephone surveys within 3-5 days of airport interview were completed in 10, 13, and 15 minutes.
- Telephone surveys 2 days before reporting end date were completed in 4, 6, and 7 minutes

Because the instruments were new to the pilot-tester and because none of the planned technologies were used in the pilot test, the contractor and CDC believe that current estimates for survey administration are sound.

The estimate for burden hours for the monthly data request from health departments is based on similar assessments, specifically experience implementing the 21-day active monitoring and reporting their findings to CDC. Using the March 4, 2015 report from the Global Migration Task Force, the evaluation team reviewed data about the number of travelers being monitored by each state to calculate a range and average number of travelers being monitored on a monthly basis. Thirty states monitored fewer than 10 travelers, eight states monitored between 11-30 travelers, eight states monitored between 31-100 travelers, and four states monitored over 100 travelers. The range was between 1- 229, the median was 26, and the mode was 7. We estimated the number of these travelers that would be coming through the airports included in this data collection (Dulles and JFK), which is 70% of all travelers, and consulted with epidemiologists to get their input on how long it would take to complete the form for that number of travelers each month. For the purposes of estimating burden hours, 240 minutes will be used.

The estimate for burden hours for the cultural competency assessment is based on similar assessments conducted by the contractor. For the purposes of estimating burden hours, 30 minutes will be used for the time it would take consultants to use the cultural competency assessment tool to read the Ebola CARE kit materials and respond to the 26 Likert-scale questions currently in the tool.

To summarize, the evaluation team believes the average length of time to complete each of the data collections proposed in this request are as follows:

- In-person Survey of Traveler Intercepted at the Airport - 10 minutes
- Telephone Survey within 3-5 days of the airport survey – 10 minutes
- Telephone Survey 2 days before the traveler's end date for monitoring and reporting – 5 minutes
- Data request to health departments – 240 minutes
- Cultural competency assessment tool to assess Ebola materials – 30 minutes

Table A.12.a: Estimated Annualized Burden Hours to Respondents

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Burden Hours
Traveler	In-Person Survey of Traveler	1200	1	10/60	200
Traveler	Telephone Survey Within 3-5 Days	960	1	10/60	160
Traveler	Telephone Survey 2 Days Before Reporting End Date	768	1	5/60	64
Health Department	Monthly Health Department Data Request	50	4	240/60	800
Consultants who are from Ebola-affected countries and who have indicated an interest in being consulted by CDC staff	Cultural Competency Assessment Tool	30	1	30/60	15
					1239

B. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for the general public's mean hourly wages [7, http://www.bls.gov/oes/current/oes_nat.htm#00-0000]. Based on DOL data, an average hourly wage of $22.33 is estimated for 1200 respondents using the In Person Survey of Traveler (Attachment A), 960 respondents using the Telephone Survey Within 3-5 Days (Attachment B), 780 respondents using the Telephone Survey 2 Days Before Reporting End Date (Attachment C), the mean hourly wage for epidemiologists working in state government I $30.86 and was used for up to 50 respondents for the monthly health department data request (Attachment D, and the 30 respondents using the Cultural Competency Assessment (Attachment E). Table A.12.b shows estimated burden and cost information.

We expect 75% of travelers to participate in airport interviews (n=1200) and then approximately, 80% to participate in first telephone survey (n=960), and that 80% of those individuals will participate in the second telephone survey (n=768.) In other words, between the airport survey and each of the telephone surveys we expect some travelers to decline and some that consent to participate but who are not reached within the five attempts that we plan for surveying them.

Table A. 12.b Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Traveler	In-Person Survey of Traveler	200	$22.33	$4,466.00
Traveler	Telephone Survey Within 3-5 Days	160	$22.33	$3,572.80
Traveler	Telephone Survey 2 Days Before Reporting End Date	64	$22.33	$1,429.12
Health Department	Monthly Health Department Data Request	800	$30.86	24,688.00
Consultants who are from Ebola-affected countries and who have indicated an interest in being consulted by CDC staff	Cultural Competency Tool	15	$22.33	$334.95
		1239		$34,490.87

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

There will be no costs to the participants other than their time to participate in the surveys (one in-person and two by telephone), the health departments to respond to the data requests, and in the review of materials for the cultural competency by consultants.

A.14. Annualized Cost to the Government

There are no equipment costs. The only cost to the federal government would be the travel and salary of the staff supporting the design (protocol and instrument development as well as IRB and OMB approvals), implementation (data collection), and analysis and reporting. The estimated cost to the federal government rates were obtained from the Office of Personnel Management's website (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2014/general-

schedule/) using Atlanta, Georgia as an example location. Actual salaries may vary by the location and step for each participating employee. Table A-14 describes how this cost estimate was calculated.

Table A.14-A: Annualized Cost to the Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Associate Director for Behavioral Science, NCEZID (GS 15)	480	75.52	$36,249.60
Associate Director for Training, Education, and Communication, NCEZID (GS 14) Primary in assessment design, data analysis, and outputs. Support in data collection	240	$49.03	$11,767.20
Behavioral Scientist, NCHHSTP (03 LT) Primary in assessment design, data analysis, and outputs. Support in data collection	240	$37.01	$8,882.40
Behavioral Scientist, NCEZID (GS12) Primary Support in data collection. Support in assessment design, data analysis, and outputs	240	$39.56	$9,494.40
Evaluation Fellow, NCEZID (GS 11)	240	$29.32	$5,277.60
Estimated Total Cost of Information Collection			$71,671.20

This is a 12 month project, with an annualized cost to the government of $1,388,115. Of the total annual cost, 95% is contractor costs (primarily data collection) [$1,316,444], and 5% is federal employee costs (oversight, data management and analysis) [$71,671.20].

A.15. Explanation for Program Changes or Adjustments

This is a new data collection for the Data Collection for ECT Activities for the DGMQ generic package.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A summary of this timeline is provided below:

Project Time Schedule	**Days after Approval**
Edit data collection instruments	Completed
Develop instruments , data collection protocols, instructions, and analysis plan	Completed
Finalize data collection instruments	Completed
Prepare IRB package	Completed
Submit IRB package	Completed
Prepare OMB package	In process
Submit OMB package	In process
OMB approval	By March 31, 2015
Data Collection	April 1, 2015
Data Analysis	Data analysis will begin the week data collection occurs, and continue throughout the data collection process
Complete field work	July 31, 2015
Development of manuscripts, presentations and submission for publication	120-356 days after OMB approval

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

The display of the OMB expiration date is not inappropriate. No exemption is being requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

ATTACHMENTS

A. In-person Survey of Traveler Intercepted at the Airport
B. Telephone Survey within 3-5 days of the airport interview
C. Telephone Survey 2 days before the traveler's end date for monitoring and reporting
D. Data request to health departments
E. Tool for assessing cultural competence of health education materials
F. Ebola CARE Kit
G. 60 Day Notice – 0920-0932
H. IRB Letter of Determination