

**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 Program

Generic Information Collection Request

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Statement A

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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 Infectious Diseases (NCEZID) Division of Global Migration and Quarantine (DGMQ) requests approval to conduct an assessment of the Check and Report Ebola (CARE) Program with all of, or about 143, travelers coming who speak English and are 18 years or older, coming into the United States (U.S.) at three of the five designated entry airports (Atlanta Hartsfield-Jackson, Newark Liberty, Chicago O'Hare) from countries with widespread Ebola outbreaks over the period of one week. Interviews will be conducted in English because it is the primary language of the interviewers. Proficiency will be assessed through non-verbal communications (e.g., facial expressions that show confusion or express that something is not understood). Current Ebola screening procedures as well as customs in-processing is done in English. We do not have an estimate of this constraint on non-response bias. This one time 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 the Division of Global Migration and Quarantine: – OMB No. 0920-0932.

CDC's 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 the response is the development and deployment of clear and effective risk communication resources to assist travelers from West Africa with participation in daily active monitoring and early reporting of symptoms for 21 days after their arrival in the United States. The goal of this effort is twofold: 1) to prevent the spread of Ebola and; 2) to identify people infected with and affected by Ebola as early as possible so that appropriate treatment and control measures can be taken.

CDC has developed materials, the Check and Report Ebola (CARE) Program, for travelers to review upon arrival to the United States (during entry screening) given to travelers by Customs Border Protection (CBP) at each of the five airports approved for flights from affected countries in West Africa (New York City John F. Kennedy, Newark Liberty, Washington Dulles, Chicago O'Hare, and Atlanta Hartsfield-Jackson). CARE Program includes materials (Attachment F) that inform travelers of Ebola symptoms and tools to use for monitoring, like a thermometer, Ebola symptom card and log, an Ebola Health Advisory information sheet about who to call if symptoms develop, instructions on how to monitor temperature, and phone numbers for all state and local health departments. In an effort to assure the usefulness of the items and with the desire to improve them as necessary, CDC will assess the utility of developed messages and materials

developed for the CARE program and assess their effect on traveler knowledge, beliefs, and behaviors.

A.2. Purpose and Use of the Information Collection

The purpose of this information collection is to assess traveler knowledge of Ebola, awareness of active monitoring, intention to participate in active monitoring, and initiation and retention in active monitoring. The information collected through this assessment will be used to help refine communication materials related to Ebola and entry screening. Additionally, this information will be used to develop tools and interventions to supplement entry screening practices, enhance the travelers' experience of entry screening, 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.

Program evaluation activities are an essential data collection for program refinement. 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.

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.

Because this work is unprecedented, a mix of quantitative and qualitative questions will be used during both points of data collection: 1) in-person interview (Attachment A) and 2) during the telephone interview (Attachment C). The quantitative questions will provide the ability to detect a measurable difference between the first and second interviews. The qualitative, open-ended questions will allow participants to use their own words and stories to describe and illustrate their experiences. Interviews will be audio recorded so that the interviewer can conduct the interview as efficiently as possible without the burden of taking notes, which allows for more error than recording and requires more time from the interviewee. Because many travelers may not have access to computer or internet technology, and travelers may have low-literacy levels, and/or limited English literacy levels, written surveys and computer-based data collection will not be used.

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 is duplicate or is already in the possession of the federal government. The information collected through this assessment will be used to help refine communication materials related to Ebola and entry screening. Additionally, this information will be used to develop tools and interventions to supplement entry screening practices, enhance the travelers' experience of entry screening, 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.

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

No small businesses will be involved in this 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 screening effort that is a result of an unprecedented disease outbreak. The current Ebola crisis underscores what global migration and public health experts have asserted for some time: infectious diseases can move around the world in a matter of hours or days if a sick person travels from one part of the world to another. Specifically, without this information DGMQ's ability to effectively communicate messages 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. Interviews 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 B). 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 outside the agency were not 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

Overview of the Data collection System

This data collection involves two assessments at two time points: a) An initial intercept interview at the airport using the Intercept Interview Guide (Attachment A) and b) a follow-up interview conducted over the phone using the Telephone Interview Guide (Attachment C). The data collection instruments are designed to assess traveler knowledge of Ebola, awareness of active monitoring, intention to participate in active monitoring, and initiation and retention in active monitoring. In addition, the instruments will provide insight into traveler comprehension of Check and Report Ebola (CARE) Kit messages and traveler perception of CARE Kit materials. This information will be used to develop tools and interventions to supplement entry screening practices, enhance the travelers' experience of entry screening, and increase travelers' initial uptake and participation in active monitoring for the full 21-day period. Additionally, this information will be used to develop presentations, reports, and manuscripts.

The data collection period will last approximately 7 days. One hundred and forty-three respondents will be invited to participate in the interview. It is expected that approximately 128 respondents will be interviewed initially using the Intercept Interview Guide (Attachment A) and 90 are expected in the follow-up assessment using the Telephone Interview Guide (Attachment C). Data will be collected at 2 time points. First, brief (10 minute) interviews will be conducted in-person with all English speaking travelers leaving the Customs Border Protection secondary Ebola screening area (see Intercept Interview of Traveler interview guide, Attachment A). The proposed number of travelers will allow a reasonably robust view of the knowledge, beliefs, and behaviors of those who are undergoing screening.

The second data collection will include those who agree to a second interview, which will be determined immediately after the initial interview. This data collection process will take place by phone 3 to 5 days after travelers received the CARE Kit during the airport screening process. The interview will assess traveler knowledge of Ebola, awareness of active monitoring, intention

to participate in active monitoring, and ask about their initiation and retention in active monitoring. Data will be collected using the Telephone Interview Guide (see Attachment C). We anticipate that this interview will take approximately 15 minutes.

Early questions were pilot tested with 9 travelers at John F. Kennedy Airport in New York. Travelers were selected using a convenience sampling strategy and asked sample questions about their experiences. The time required to ask these questions and quality of responses based on questions posed were used to revise the data collection instruments and determine the composition of the final interview documents. Feedback from the pilot test was also used to ensure tools were culturally appropriate and to estimate burden hours.

Description of the Information to be collected

Information will be collected by CDC staff at three U.S. airports conducting airport entry screening for Ebola (Atlanta Hartsfield-Jackson, Newark Liberty, and Chicago O'Hare). The information collection will include an in-person interview Intercept Interview of Traveler (Attachment A) and a Telephone Interview Guide (Attachment C) 3 to 5 days after the traveler is given the CARE Kit.

In the Intercept Interview of Traveler Guide, travelers are asked 13 key questions:

1. Did you get a CARE Kit?
2. How clear was the purpose of Ebola screening?
3. Have you opened the CARE Kit yet?
4. How serious of a health concern is Ebola to you?
5. How would you know whether you had Ebola or not?
6. In your opinion, how likely do you think it is that you will get sick with Ebola?
7. Based on what you've heard so far, how long do you need to do health checks for Ebola?
8. Over the next few weeks, how often should you take your temperature?
9. How confident are you that you can check yourself for the next few weeks for symptoms of Ebola?
10. How likely is it that you will report temperature and symptoms to the health department every day for the next few weeks?
11. If you have a temperature of 100.4 degrees Fahrenheit or 38 degrees Celsius, how likely would you be to seek medical care?
12. How likely is it that you will use the resources given to you today?
13. Can I call you on the phone within the next week to ask you a few more questions about your experience coming to the U.S.?

Although most of these questions are scaled, several are followed up by an open-ended question to better assess the travelers knowledge of Ebola, awareness of active monitoring, and intention to participate in active monitoring.

At the conclusion of the Intercept Interview, travelers will be asked if they are willing to participate in a telephone interview in 3 to 5 days. If they agree, they will be asked for their name and contact information (phone number).

The telephone interview guide is also composed of 13 questions. In this interview guide questions are focused on key self-monitoring and reporting behaviors in the previous day to assess intention and retention of the travelers using the CARE Kit.

1. Have you opened your CARE Kit? (If no, skip to 2)
2. In your opinion, how likely do you think it is that you will get sick with Ebola?
3. How serious of a health concern is Ebola to you?
4. Did you check your temperature twice yesterday?
5. Did you report your temperature and symptoms to the health department yesterday?
6. Based on what you've heard so far, how long do you need to do health checks for Ebola?
7. Over the next few weeks, how often should you take your temperature?
8. If you had a temperature of 100.4 F or 38.0 C, how likely would you be to seek medical care?
9. How confident are you that you can check yourself for Ebola for the next few weeks?
10. How likely is it that you will report your temperature and symptoms to the health department every day for the next few weeks?
11. What challenges might make it hard to report your health checks to the health department every day?
12. Was there any information in the CARE Kit that was unclear or confusing to you?
13. What suggestions do you have for helping us get important information to travelers who may come in the future?

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

The project team will maintain a master list of participants in a Microsoft Excel file, which indicates the name, phone number, and a project assigned tracking number (e.g., Airport identifier, date, and interview number). All contact information will be stored separately from notes and recordings. Only members of the assessment team will have access to contact information and separate files containing field notes and interview information. Final reports, manuscripts, and presentations will contain no information regarding identities of the participants

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

Stringent safeguards are in place to ensure a respondent's information is kept secure, including authorized users, physical safeguards, and procedural safeguards. The information collected will include the traveler's name and phone number. All collected data and audio recordings will be destroyed within 3 months after the data collection is complete. Audio recordings will be deleted and paper files shredded.

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

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, as demonstrated below in the script used in both interview guides (Attachment A; Attachment C)

Great! Thank you for your willingness to share your opinions with me about your experience today. Your opinions will help us improve the process. I have just a few questions that will take less than 10 minutes so you so you can continue your journey.

Before I begin I want to go over a couple of items:

- *This interview is voluntary. You can decline to answer any question.*
- *There are no right or wrong answers. I am interested in your opinion. If you don't understand the question, feel free to let me know and I can ask it another way. This is not a test, so feel free to say you don't know or don't have an opinion to offer and "I don't know" is a perfectly acceptable response to any question I ask you.*
- *The information you provide today will be kept secure. I will ask for your permission to call you in a few days which would require me to ask for a name and phone number. You do not need to decide on whether you want to participate in a follow-up interview right now. It's important to know that the questions I'm about to ask you will NOT be linked directly back to you individually and will only be reported at the group level.*
- *With your permission, I would like to record our conversation. I do this simply to make sure that I capture all of the information that you share and so I can listen to what you have to say and not worry about taking notes. The recording helps me in writing my report and is used for that purpose only. Is it okay for me to record our conversation?*
- *Do you have any questions before we begin?*

Participation in the 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. Interviews 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 (Please 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).

Opportunities to Consent, and Share Submission of Information

Participation in the assessment is voluntary. Participants must provide verbal consent at the time of each interview before any information will be collected. Interviews will only be conducted with those who agree to participate.

This information will be used to develop presentations, reports, and manuscripts.

Information Secured

A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations, which are located in a secure area of the airport. 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” (Attachments D & E).

A.11. Justification for Sensitive Questions

The information collected will include the traveler’s name and phone number. This information will be requested during the first interview, Intercept Interview Guide (Attachment A), and is critical for following up with the second interview using the Telephone Interview Guide (Attachment C). No other sensitive questions will be asked. To minimize the possibility of distress, participants will be informed that the interview is voluntary, and 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.

A.12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on the pilot testing of early questions with 9 travelers at John F. Kennedy Airport in New York. Travelers were selected using a convenience sampling strategy and asked sample questions about their experiences. The time required to ask these questions and quality of responses based on questions posed were used to revise the data collection instruments and determine the composition of the final interview documents.

Feedback from the pilot test was also used to ensure tools were culturally appropriate and to estimate burden hours. Pilot testing of the questions indicated that the average length of time needed to complete the Intercept Interview Guide of Traveler (Attachment A), including time for reviewing instructions, will be approximately 10 minutes. For the purposes of estimating burden hours, 10 minutes will be used. Again, pilot testing of the questions indicated that the average length of time needed to complete the Telephone Interview Guide (Attachment C), including time for reviewing instructions, will be approximately 15 minutes. For the purposes of estimating burden hours, 15 minutes will be used.

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

Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Burden Hours
Intercept Interview of Traveler	128	1	10/60	21
Telephone Interview Guide	90	1	15/60	23
				44

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 128 respondents using the Intercept Interview Guide (Attachment A), and 90 respondents using the Telephone Interview Guide (Attachment C). Table A.12.b shows estimated burden and cost information.

Table A. 12.b Estimated Annualized Cost to Respondents

Form Name	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Intercept Interview of Traveler	10/60	21	\$22.33	\$468.93
Telephone Interview Guide	15/60	23	\$22.33	\$513.59
		44		\$982.52

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 in-person interview and the phone interview.

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 CDC 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 Training, Education, and Communication, NCEZID (GS 14) Primary in assessment design, data analysis, and outputs. Support in data collection	50	\$49.03	\$2,451.50
Behavioral Scientist, NCHHSTP (03 LT) Primary in assessment design, data analysis, and outputs. Support in data collection	150	\$37.01	\$5,551.50
Behavioral Scientist, NCEZID (GS12) Primary Support in data collection. Support in assessment design, data analysis, and outputs	150	\$39.56	\$5,934.00
Associate Director for Behavioral Science (GS14) Primary in assessment design, data analysis, and outputs. Support in data collection	150	\$74.77	\$11,215.50
Training Specialist, NCEZID (Contractor) Primary in assessment design data analysis, and outputs. Support in data collection	150	\$37.55	\$5,632.50
Senior Training Specialist, NCEZID (Contractor) Primary in assessment design data analysis, and outputs. Support in data collection	150	\$38.50	\$5,775.00
Estimated Total Cost of Information Collection			\$36,560.00

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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:

<u>Project Time Schedule</u>	<u>Days after Approval</u>
Edit interview guides	Completed
Develop interview guide protocol, instructions, and analysis plan	Completed
Pilot test interview guides	Completed
Prepare IRB package	Completed
Submit IRB package	Completed
Submit OMB package	Completed
Prepare OMB package	In process
Submit OMB package	In process
OMB approval	TBD
Data Collection	2-3 days after OMB approval
Data Analysis	Data analysis will begin the week data collection occurs, and continue throughout the data collection process
Complete field work	14 days after OMB approval
Improvement of education and communication materials	30 days after OMB approval
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

Assessment of Travelers and the Ebola CARE Program
Supporting Statement A

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. Intercept Interview Guide
- B. 60 Day Notice – 0920-0932
- C. Telephone Interview Guide
- D. IRB Letter of Determination
- E. Determination of Applicability of Human Subjects Regulation
- F. Ebola Care Kit