**Information Collection for Evaluation of Education, Communication, and Training (ECT) Activities for the Division of Global Migration and Quarantine**

**Evaluating the Effectiveness of Quick Response Codes in Educating Panel Physicians**

**Generic Information Collection Request**

**OMB No. 0920-0932**

**June 11, 2013**

**Statement A**

**Program Official/Project Officer**

Amy McMillen

OMB Specialist

Office of the Director

National Center for Emerging and Zoonotic Infectious Diseases

1600 Clifton Road, NE, MS C12

Atlanta, Georgia 30333

Phone: 404-639-1045

Fax Number: 404-639-7090

Email: AUH1@cdc.gov

TABLE OF CONTENTS

[**PART A. JUSTIFICATION**](#_Toc299967992) 2

 [1. Circumstances Making the Collection of Information Necessary](#_Toc299967993) 2

 [2. Purpose and Use of Information Collection](#_Toc299967994) 5

 [3. Use of Improved Information Technology and Burden Reduction](#_Toc299967995) 8

 [4. Efforts to Identify Duplication and Use of Similar Information](#_Toc299967996) 8

 [5. Impact on Small Businesses or Other Small Entities](#_Toc299967997) 8

 [6. Consequences of Collecting the Information Less Frequently](#_Toc299967998) 9

 [7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5](#_Toc299967999) 9

 [8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency](#_Toc299968000) 10

 [9. Explanation of Any Payment or Gift to Respondents](#_Toc299968001) 10

 [10. Assurance of Confidentiality Provided to Respondents](#_Toc299968002) 10

 [11. Justification for Sensitive Questions](#_Toc299968003) 11

 [12. Estimates of Annualized Burden Hours and Costs](#_Toc299968004) 12

 [Table 12.A and B: Estimated Annualized Burden Hours and Costs to Respondents](#_Toc299968005) 12

 [13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers](#_Toc299968007) 13

 [14. Annualized Cost to the Government](#_Toc299968008) 13

 [Table 14: Estimated Annualized Cost to the Federal Government](#_Toc299968009) 14

 [15. Explanation for Program Changes or Adjustments](#_Toc299968010) 14

 [16. Plans for Tabulation and Publication and Project Time Schedule](#_Toc299968011) 15-15

 [17. Reason(s) Display of OMB Expiration Date is Inappropriate](#_Toc299968012) 15

 [18. Exceptions to Certification for Paperwork Reduction Act Submissions](#_Toc299968013) 15

[**REFERENCES**](#_Toc299968014) 16

[**ATTACHMENTS**](#_Toc299968015) 16

# PART A. JUSTIFICATION

## 1. Circumstances Making the Collection of Information Necessary

### Background

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), Immigrant, Refugee, and Migrant Health Branch (IRMH), requests approval to conduct evaluation research about the effectiveness of Quick Response (QR) codes for informing international panel physicians about U.S. medical screening policies for U.S.-bound immigrants and refugees. 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.

The information collection for which approval is sought is in accordance with DGMQ’s mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. This mission is supported by delegated legal authorities.

The Secretary of Health and Human Services also has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. § 1182(a)(1)(A)) and Section 325 of the Public Health Service Act. These regulations are codified in 42 CFR Part 34, which establish requirements that determine whether aliens can be admitted into the U.S.

To achieve DGMQ’s mission, the Immigrant, Refugee and Migrant Health branch (IRMH) works with domestic and international programs to improve the health of U.S.-bound immigrants and refugees to protect the U.S. public by preventing the importation of infectious disease. These goals are accomplished through IRMH’s oversight of medical exams required for all U.S. - bound immigrants and refugees who seek permanent residence in the U.S. IRMH is responsible for assisting and training the international panel physicians with the implementation of medical exam *Technical Instructions* (TI). Technical Instructions are detailed requirements and national policies regarding the medical screening and treatment of all U.S.-bound immigrants and refugees. Most panel physicians currently refer to print copies of the Technical Instructions as well as laminated reference guides to verify the medical screening requirements for immigrants and refugees. The hard-copy reference guides are synthesized versions of the complete Technical Instructions, and thus, do not contain in-depth information that might be needed to administer medical exams. More detailed information and complete versions of the Technical Instructions are available on DGMQ’s website.

Introducing Quick Response (QR) codes—which are two-dimensional barcodes that store thousands of alphanumeric characters of information and data--on the laminated reference guides and other DGMQ resources will allow panel physicians to immediately access the detailed Technical Instructions provided on CDC’s websites. Furthermore, QR codes can be designed to link users to specific sections of text on a webpage. This minimizes the time users spend searching for information. The online tuberculosis (TB) Technical Instructions, for example, is a lengthy document that contains in-depth information about TB testing and treatment procedures (among other things). A panel physician may only be interested in verifying U.S. TB classification standards. The physician could scan the QR code on the TB Technical Instructions fact sheet or laminated reference guide and be immediately connected to the section on the webpage that discusses U.S. TB classifications. In short, panel physicians can use their mobile devices while conducting medical screenings in the field to access up-to-date and detailed information regarding medical requirements for U.S.-bound immigrants and refugees. The sample QR coded Panel Physician tools are included as attachments:

* Attachment C(1) Panel Physician Tool TB TI
* Attachment C(2) Panel Physician Tool Length of Validity Prior to Travel
* Attachment C(3) Panel Physician Tool Vaccination Requirements
* Attachment C(4) Panel Physician Tool Mental Disorders and Substance Abuse
* Attachment C(5) Panel Physician Tool Contact List
* Attachment C(6) Panel Physician Tool Medical Examination Forms
* Attachment C(7) Physician Panel Tool Vaccination Worksheets

Data collection is needed to evaluate if QR codes are an appropriate mechanism for linking panel physicians to U.S. immigrant and refugee medical screening guidelines. The evaluation will inform DGMQ staff about how often online resources are used by panel physicians. Based on the results, we will be able to determine if the availability of QR codes on our printed health education materials increases panel physician use of our online resources. Regardless of the outcome, DGMQ staff will be better informed about appropriate and effective ways to share important medical guidelines and requirements with panel physicians and their staff.

**1.1 Privacy Impact Assessment**

Overview of Data Collection System

This is a mixed-method, randomized intervention consisting of three data collection instruments: a) pre-knowledge survey, b) semi-structured questionnaire, and c) in-depth interviews (See Attachments A(1), A(2), and A(3) for the data collection instruments). The data collection instruments are designed to assess the effectiveness and feasibility of QR codes as a mechanism to link panel physicians to Technical Instructions and other resources needed for conducting medical screenings and to assess the quality and appearance of the information provided on the online Panel Physician Portal. Data collection methods will be conducted online and in-person. The pre-knowledge survey and semi-structured questionnaire are web-based surveys. Both tools were pilot tested by 3 DGMQ internal staff members. Feedback was used to refine questions as needed, to ensure accurate administration and skip patterns, and to establish the estimated time required to complete the questionnaire. The in-depth interview guide was also pilot tested by 3 DGMQ internal staff members. Feedback from the pilot test was used to adjust the interview questions to ensure the questions were culturally appropriate.

In 2007, CDC updated the tuberculosis Technical Instructions to use more precise tests to improve TB detection rates before refugees and immigrants come to the United States and to improve the health of refugees and immigrants through earlier diagnosis and updated treatment methods. The 2007 Technical Instruction updates make testing more precise by requiring cultures and drug susceptibility testing for refugee and immigrant applicants thought to have TB. To date, 56 of the 151 panel site jurisdictions have fully implemented the updated 2007 Culture and Directly Observed Therapy TB Technical Instructions (CDOT TB TIs). The 95 jurisdictions that have yet to implement the CDOT TB Technical Instructions have a deadline of October 1, 2013. Given that the October 1, 2013 deadline is less than a year away, we decided to select the jurisdictions that have yet to implement the CDOT TB Technical Instructions as our study sample. The three data collection instruments will be administered to 95 international panel physicians whose sites have yet to implement the new CDOT TB Technical Instructions. All panel physicians are certified medical physicians appointed by the U.S. consular section in their respective country. The data collection instruments are described below:

1. A pre-knowledge aptitude web-based survey will be administered to 95 panel physicians. The survey will consist of closed and open-ended questions. The purpose of the survey is to collect demographic information and to gauge familiarity with QR codes. The survey will be administered using MS Interview software and will take no longer than 10 minutes to complete. The research team will be notified when participants complete the survey. (See Attachment A(1)— Screenshot Pre-Knowledge Aptitude Survey).
2. After the pre-knowledge aptitude survey is complete, the 95 participants will be randomly distributed into two groups- the exposed group (s=48) and the non-exposed group (s=47). The participants in the exposed group will be sent new educational materials loaded with QR codes. The study participants in the non-exposed group will also be sent the new educational materials, but without the QR codes. After a period of 6 weeks, a semi-structured questionnaire will be administered to participants in both the exposed group and non-exposed group. The questionnaires--which will be a compilation of open-ended, close-ended, and Likert scale questions-- will be administered online using MS Interview software. Participants will receive an email with a link, which will take them to the questionnaire. The questionnaire will take 15-20 minutes to complete. After completing the questionnaire, the participants will click ‘submit.’ Upon submission, the research team will be notified that the questionnaire has been completed. Participants will have three-weeks to complete the questionnaire. The research team will send a reminder email one-week before the questionnaire opens and before it closes. (See Attachment A(2)—Screenshot Semi-Structured Questionnaire).
3. Interviews will be conducted with 20 key informants. Key informants will include panel physicians and panel site staff from panel site jurisdictions in the exposed group. Because the in-depth interviews will be conducted in-person during FY 2013 quality assessment site visits, the jurisdictions that will be able to participate in the in-depth interviews are already pre-determined. Interviews will be recorded (upon consent) using an audio voice recorder and will last no longer than 60 minutes. The purpose of the in-depth interview is 1) to understand panel physicians’ experience with QR codes for exposed participants, 2) to identify and address specific challenges associated with QR code use for exposed participants, 3) to identify the advantages of using QR codes to access Technical Instructions and the Panel Physician Portal for exposed participants, 4) to determine what types of medical content and information is most useful to panel physicians, and 5) to determine which tool is most effective for linking panel physicians and their staff to Technical Instructions and medical screening requirements. Panel physicians will be informed about the option to participate in the interview before the site visit occurs. A written consent letter will be provided onsite before the interview takes place. (See Attachment A(3)—In-Depth Interview Guide).

Items of Information to be Collected

The information collected does involve individually identifiable information of consulate appointed panel physicians. The individual identifiable information includes: name, email, panel site address, and work phone number. The information will be used for identification purposes only. Because IRMH’s mission is to provide technical assistance to panel physicians and to conduct panel site quality assessment visits, we already have access to panel physician identifiable information. Additionally, the consular sections in each country have the contact information of each panel physician which is available to the general public upon request. Thus, no new identifiable information is being collected and the study is unlikely to have any effect on the respondent’s privacy.

Panel physicians who agree to participate in the evaluation will receive an informed consent letter via email. The informed consent letter will include details about the evaluation, confidentiality procedures, and participation procedures and requirements. Participants will be asked to review and sign the letter to indicate consent. Each participant is required to keep a copy of the letter for his/her records. A copy of the signed consent letter must also be returned via email or fax to a member of the research team. The consent forms will be stored in locked and secured file cabinets at DGMQ headquarters in Atlanta, as well as in a scanned electronic format within password-secured computers.

After the consent forms have been received by the research team, they will assign the participating panel physicians a unique numeric identification code. From this point forward, the numeric code will be used on all documents instead of the panel physician’s name. The research team will have a master list in Microsoft Excel, which indicates the name and numeric code of each participant. All contact information will be stored separately from notes and recordings. Only members of the research team will have access to contact information.

Several audience variables will be assessed under the auspices of this generic OMB clearance. These include: knowledge, opinions, practices, behaviors, skills, self-efficacy, and information needs and sources. Insights gained from evaluation research will assist in the development, refinement, implementation, and evaluation of health education and communication activities.

## 2. Purpose and Use of Information Collection

The purpose of the Quick Response (QR) code project is to provide panel physicians’ immediate, more direct access to current U.S. requirements regarding medical screening and treatment requirements for U.S- bound immigrants and refugees. The addition of QR codes to the TB, vaccine, mental health, and sexually transmitted infection Technical Instruction reference guides will enable panel physicians to immediately access in-depth and up-to-date screening and treatment requirements online. The goal of this evaluation is 1) to determine if QR codes are a feasible and appropriate mechanism for linking panel physicians to Technical Instructions and medical screening information; 2) to determine if the information provided on the Technical Instructions and panel physician website is adequate for the panel physicians; and 3) to identify at what points during the medical screening process panel site staff could benefit from further technical guidance from the CDC.

In sum, panel physicians can use their mobile devices while conducting medical screenings in the field to access up-to-date and detailed information regarding medical requirements for U.S.-bound immigrants and refugees. By utilizing QR codes on vaccination, TB, mental health, and sexually transmitted infection reference guides and fact sheets, we hope that panel physicians will be better informed about DGMQ’s medical requirements, and as a result, more immigrants and refugees will be diagnosed and treated properly.

On completion of the evaluation, a manuscript will be produced, findings will be summarized and presented to DGMQ staff, an academic article will be produced and published in an agreed-upon journal, and findings will also be presented at an agreed-upon conference.

Privacy Impact Assessment Information

1. The information collected does involve individually identifiable information of consulate appointed panel physicians and the National Center for Emerging and Zoonotic Infectious Diseases has determined that the Privacy Act does apply.
2. On Monday November 24, 1986, CDC published a notice of a new system of records under the Privacy Act of 1974 that enables CDC officials to maintain training records and access the impact of the agency's training programs on the knowledge, attitudes and practices of clinicians and other health care personnel, in order to develop improved training curricula and programs for disease prevention and control for such health care personnel.. The data will become part of CDC Privacy Act System of Records 09-20-0161, “Records of Health Professionals in Disease Prevention and Control Training Programs”. Disclosure may be made to CDC contractors in the conduct of training surveys and studies covered by this system notice and in the preparation of scientific reports, in order to accomplish the stated purposes of the system. The recipients will be required to maintain Privacy Act safeguards with respect to such records. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when: (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

Access is granted to only a limited number of personnel, i.e., CDC Project Officer, interviewers 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 security includes locked cabinets in locked rooms, 24-hour guard service in buildings, personnel screening of visitors, electronic anti-intrusion devices in operation at the Federal Records Center, fire extinguishers, overhead sprinkler system and card-access control equipment in the computer room, computer terminals and automated records located in secured areas. Procedural safeguards include protection for computerized records both on the mainframe and the CIO 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 backup procedures and Vault Management System for secure off-site storage is available for backup tapes. To avoid inadvertent data disclosure, “degaussing” is performed to ensure that all data are removed from Privacy Act computer tapes and/or other magnetic media. Additional safeguards may be built into the program by the system analyst as warranted by the sensitivity of the data.

CDC and contractor employee 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.

1. Prior to participating in the information collection, prospective respondents will receive information such as the sponsorship of the evaluation project, their rights as participants, risks and benefits in participating, and contacts for more information about the evaluation project. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the evaluation project.

Participants will be informed that the in-depth interviews may be recorded and transcribed, and that multimedia recordings will be destroyed after completion of each report on findings. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner.

1. After the respondents have provided consent, they will be assigned a unique numeric identification code. From this point forward, the numeric code will be used on all documents instead of the panel physician’s name. The research team will have a master list in Microsoft Excel, which indicates the name and numeric code of each participant. All contact information will be stored separately from notes and recordings. Only members of the research team will have access to contact information. Final reports, manuscripts, and presentations will contain no information regarding identities of the participants. All collected data (including numeric codes) and audio recordings will be destroyed three years after the evaluation is complete. Audio recordings will be deleted and paper files shredded.

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

DGMQ staff will employ electronic technology to collect and process data in order to reduce respondent burden and aid in data processing and reporting efficiency. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Data collection will be conducted using the most current modes. Data collection will involve IT methods. Computer-assisted methods including web-based surveys and questionnaire will be employed to reach the intended audience. In cases when respondents do not have access to electronic means of communication, a paper-based data collection will be implemented on a limited basis.

In-depth interviews will be conducted in-person during FY 2013 Quality Assessment panel site visits.

In all information collections, the number of questions posed will be held to the minimum required in order to elicit the necessary data.

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

Because DGMQ’s public heath mission is supported by regulatory responsibilities, as outlined in Section A1, it is not expected that any of the information collected under this proposed generic clearance is duplicative or is already in the possession of the federal government. The proposed evaluation will allow DGMQ to significantly improve its ability to develop, refine and evaluate communication, education, and training activities. The results and final products from these activities may be used by multiple government and non-profit agencies.

QR codes are a new example of an innovative technological tool that quickly links audiences to vast amounts of information. QR codes were created in 1994 by a subsidiary of Toyota Group in Tokyo. The major difference between QR codes and barcodes is the amount of information that can be stored. QR codes are able to store 100 times more information than barcodes (Millan, 2012). These data can be retrieved simply by scanning the QR codes with a smartphone or camera phone. Today, most mobile phones are equipped with scanners. For individuals who have mobile devices that are not already equipped with scanners, free scanner software can be downloaded on the Internet. While QR codes have emerged in the consumer industry as an advertising tool, they have yet to expand to other fields such as health, medicine, and education. Health informatics and technology literature was reviewed using PubMed and Web of Science. Results indicate that there is little, if any, research concerning the use of QR codes in the public health field (1).

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

No small businesses will be involved in this data collection.

## 6. Consequences of Collecting the Information Less Frequently

If this information is not collected, DGMQ’s ability to effectively communicate messages to medical professionals responsible for treating mobile populations who may be at increased public health risk will be compromised. According to the CDC’s Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide (2), evaluation is critical for engaging in scientifically sound communication, training, and educational efforts. Communications evaluation, often encompassing concept, message, and materials testing activities, is essential in pre-testing materials and tools to evaluate a wide variety of dimensions that include, but are not limited to, appeal, saliency, clarity, cultural appropriateness, and readability/understandability. If a concept and/or a message is not tested, then resources could be expended without evidence that the activity is appropriate or effective.

Evaluation is equally important because it provides accountability to stakeholders for DGMQ’s activities by demonstrating the effectiveness and the impact of the communication, training, and educational activities. Evaluation can also help to improve the effectiveness and efficiency of existing programs, and support the most effective distribution of resources. For example, the evaluation of QR code utility can potentially impact CDC’s global immunization initiatives by helping to strengthen global immunization rates in vulnerable and mobile populations. QR codes can provide quick access to important, current immunization information for panel physicians while conducting medical examinations. CDC programs can use QR codes to link medical professionals and the general public to pertinent health information.

This request is for a one time data collection. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

1. 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. 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.
2. Consultation

CDC personnel voted on 10 agency wide projects and our proposal was chosen to receive the funding. In addition, the following experts have been consulted on the need for data collection with the audiences, and for the purposes, described in this clearance package:

|  |  |  |  |
| --- | --- | --- | --- |
| **Individuals** | **Title** | **Role** | **Contact Information** |
| Dr. Angel Contreras, MD | International Panel Physician’s Association President | Consulted on the need for data collection, approved necessity of project | abcontreras@codetel.net.do |
| Mike Dolce | Department of State, Visa Specialist | Consulted on the purpose of the project | dolcemr@state.gov  |
| Gaby Benenson, MPH | Senior Health Education Specialist | Provided feedback on entire OMB package and data collection materials | Gkb6@cdc.gov |
| Stefanie Erskine, MPH | Communication Specialist | Reviewed data collection instruments and provided feedback on the structure of the questionnaires | Soa5@cdc.gov |
| Chris Hurst, MPH | Policy Contractor | Reviewed OMB package | Ije7@cdc.gov |
| Clive Brown, MBBS | Medical Epidemiologist | Reviewed study design and data collection methods | Cmb8@cdc.gov |
| Emad Yanni, PhD | Senior Service Fellow | Provided guidance on randomized method design and sampling procedures | Dyn8@cdc.gov |

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

DGMQ will not provide remuneration or incentives to participants

## 10. Assurance of Confidentiality Provided to Respondents

DGMQ and contractors will follow procedures for ensuring and maintaining privacy during all stages of data collection. Respondents will be recruited using the established databases of international panel physicians.

Respondents will be informed that information collected may be recorded and transcribed, and that any multimedia recordings will be destroyed after completion of each report on findings. DGMQ staff, in conjunction with the contractor, will collect and evaluate the research data.

All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner.

### IRB Approval

The CDC Human Research Subject Officer has determined that the QR code evaluation is exempt under 45 CFR 46.101(b)(2). The determination is valid for three years through 2/25/2016. (See Attachment B--IRB Determination).

## 11. Justification for Sensitive Questions

No information will be collected that are of a personal or sensitive nature.

To minimize psychological distress, the principal investigator will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time. In addition, a subject matter expert from DGMQ or delegated organization will be present during the information collection to answer questions from participants at the end of the information collection activity.

## 12. Estimates of Annualized Burden Hours and Costs

A. The survey and questionnaire, and in-depth interview guide, for each information collection activity will be submitted for OMB review. The average burden for each respondent depending on the specific data collection will range from 12-60 minutes. The estimated burden to respondents is summarized in Table 12.A below.

The estimate for burden hours is based on a pilot test of the data collection instruments by 3 health communication specialists. In the pilot test, the average time to complete the pre-knowledge aptitude survey, including time for reviewing instructions and completing the survey, was approximately 10 minutes. Based on these results, the estimated time range for actual respondents to complete the demographic survey is 10-12 minutes. For the purposes of estimating burden hours, the upper limit of this range is used. We estimate that 95 respondents will respond to this collection for a total of 19 hours.

The average time to complete the semi-structured questionnaire, including time for reviewing instructions and completing the questionnaire, was approximately 15 minutes. Based on these results, the estimated time range for actual respondents to complete the questionnaire is 15-20 minutes. For the purposes of estimating burden hours, the upper limit of this range is used. Two groups will respond to the Semi-Structured Questionnaire, an Exposed group and a Not Exposed group. We anticipate a total of 16 burden hours for each group.

The average time to complete the in-depth interview was 45 minutes per informant. Based on these results, the estimated time range for actual respondents to complete the interview is 45-60 minutes. For the purposes of estimating burden hours, the upper limit of this range is used. We anticipate 20 respondents for the In-Depth Interview, for a total of 20 burden hours.

Information will be collected over a 6 month time period. There are no costs to respondents except their time to participate in the research activities. The total annualized burden, as indicated in Table 12.A, is 71 hours.

**Table 12.A: Estimated Annualized Burden to Respondents**

| **Type of Respondents** | **Form Name** | **Number of Respondents** | **Number of Responses per Respondent** | **Average Burden per Response (in hours)** | **Total Burden Hours** |
| --- | --- | --- | --- | --- | --- |
| International Panel Physicians | Pre-Knowledge Aptitude Survey | 95 | 1 | 12/60 | 19 |
| International Panel Physicians | Exposed Group Semi-Structured Questionnaire | 48 | 1 | 20/60 | 16 |
| International Panel Physicians | Not Exposed Group Semi-Structured Questionnaire | 47 | 1 | 20/60 | 16 |
| International Panel Physicians and other medical staff at panel sites | In-Depth Interview Guide | 20 | 1 | 1 | 20 |
| **TOTAL** |  **71** |

B. All of the respondents will be international panel physicians. Table 12.B presents the calculations for cost of respondents’ time using one category of mean hourly wages for a physician in the U.S. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website (http://www.bls.gov/cps/minwage2010.htm), specifically originating from the 2009 National Compensation Survey. Based on DOL data, an average hourly wage of $88.78 is estimated for all 95 respondents. Table A.12-B shows estimated burden and cost information. The total estimated annualized respondent cost is $6,319.

**Table 12.B: Estimated Annualized Burden Hours**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondents’ Costs** |
| International Panel Physicians | Pre-Knowledge Aptitude Survey | 19 |  $89 | $1691 |
| International Panel Physicians | Exposed Group Semi-Structured Questionnaire | 16 | $89 | $1424 |
| International Panel Physicians | Non-Exposed Group Semi-Structured Questionnaire | 16 | $89 | $1424 |
| International Panel Physicians (TBD other medical staff at panel sites) | In-Depth Interview Guide | 20 | $89 | $1780 |
| **TOTAL** | **--** | **71** | **$89** | **$6,319** |

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

 There will be no direct costs to the respondents other than their time to participate in the survey questionnaire, and in-depth interviews.

**14. Annualized Cost to the Government**

The annualized cost to the Government is composed of personnel costs: 30% FTE of 1 GS-13 employee, 10% of 1 contractor at GS-11 level, and 100% of 1 contractor at GS-11 level. The average hourly rate was obtained from the Office of Personnel Management’s website (http://www.opm.gov/oca/09tables/html). The hourly rate for a GS-13 in metro Atlanta is $40.11 per hour, which is about $83,500 per year. The contractor will be of similar experience and skill, and so the hourly salary level will be comparable. The contractor was hired with grant money from the Innovation Fund which DGMQ received specifically for this project. The average cost for transcription services and travel is estimated at $10,000.

There are no costs to the Government other than the time of the employees involved in the data collection and analysis process.

**Table 14:** **Estimated Annualized Cost to the Federal Government**

|  |  |  |
| --- | --- | --- |
| **Contract and Personnel**  | **Role** | **Average Cost** |
| Federal employee costs, per information collection (30% FTE of one GS-13 at $83,500/year) | Consultation with PI on OMB package preparation, supervisory role on design of data collection instruments, participate in data collection and analysis |  $25,050 |
| Contractor employee costs per information collection (100% contractor of one GS-11 equivalent at$56,000/year) | PI, design IRB and OMB project package, design data collection tools, work with web team to ensure survey instruments are functioning properly online, conduct data collection and analysis, write final manuscript for publication,  | $56,000 |
| Contractor employee costs per information collection (10% contactor of one GS-11 equivalent to $60,000) | Participate in data collection | $6,000 |
| Estimate transcription costs, travel expenses |  | $10,000 |
| **Total Costs** |  | **$97,050** |

## 15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

On completion of data collection and analysis, the following reports and presentations will be produced:

An informative and summative manuscript will be produced for DGMQ staff.

Findings will be summarized and presented to DGMQ staff.

An academic article will be produced and published in an agreed-upon journal.

* Findings will also be presented at an agreed-upon conference.
* Depending on the outcomes, the evaluation findings will be used to scale-up the QR code project across CDC divisions through Innovation Fund reporting, presentations, and other communication avenues at the agency.

**Table 16: Project Schedule**

| **Activity** | **Time Table** |
| --- | --- |
| Develop protocol, data collection tools, IRB and OMB application, identify participants, develop any other materials, submit materials for clearance | Prior and during OMB clearance period |
| Send participants invitation letter to participate in the study; send consent letters to participants who agree to take part in the study | 1weeks after OMB approval |
| Send materials and detailed instruction letter to participants | 2 weeks after OMB approval |
| Data collection | 2-6 months after OMB approval |
| Data analysis (will be conducted throughout data collection period) | 3-7 months after OMB approval |
| Development of the final manuscript, presentations, and submission for publication | 8 months after OMB approval |

## The deadline for the international panel sites to implement the new CDOT TB Technical Instructions is October 1, 2013. In order to provide the panel physician’s with materials that may help the implementation process, we would like to complete this project before the October 1st, 2013 deadline. Based on the results of this study, we can adapt our educational and communication materials to better meet the needs of the panel physicians and help them meet the October 1st implementation deadline.

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

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

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

There are no exceptions to the certification.

REFERENCES

(1) Millan, M. (2012 July 2-8). QR codes have become ubiquitous--just as they're falling out of favor with advertisers. *Bloomberg Businessweek*, pp. 28-30.

(2) Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide, 2011, available at: http://www.cdc.gov/eval/guide/

ATTACHMENTS
Note: Attachments are included as separate files as instructed.

Attachment A(1)\_ Screenshot Pre-Knowledge Aptitude Survey

Attachment A(2) Screenshot Semi-Structured Questionnaire

Attachment A(3) In-Depth Interview Guide

Attachment B IRB Determination

Attachment C(1) Panel Physician Tool TB TI

Attachment C(2) Panel Physician Tool Length of Validity Prior to Travel

Attachment C(3) Panel Physician Tool Vaccination Requirements

Attachment C(4) Panel Physician Tool Mental Disorders and Substance Abuse

Attachment C(5) Panel Physician Tool Contact List

Attachment C(6) Panel Physician Tool Medical Examination Forms

Attachment C(7) Physician Panel Tool Vaccination Worksheets