Qualitative Information Collection
on emerging diseases among the foreign-born in the United States

Request for OMB Approval of a Generic Clearance for Data Collection

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Statement A

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Qualitative Information Collection on emerging diseases among the foreign-born in the United States

Request for OMB Approval of a "Generic Clearance" Data Collection

This is a request for a new generic information collection. CDC is requesting a three year approval to collect data.

PART A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests approval of a new "generic clearance" to facilitate the implementation of qualitative data collection projects that will allow us to better understand the knowledge, beliefs, attitudes and practices related to communicable and other emerging diseases among foreign-born individuals in limited, targeted geographic areas of the United States, e.g. neighborhoods, cities, and counties. Foreign-born individuals include temporary and permanent immigrants, international visitors, and refugees settled in the United States.

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 United States. This mission is supported by delegated legal authorities

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries or possessions into the United States and from one state or possession into any other state or possession. These regulations are codified in 42 Code of Federal Regulations (CFR) Parts 70 and 71.

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)) (Attachment C) and Section 325 of the Public Health Service Act (Attachment D). These regulations are codified in 42 CFR Part 34, which establish requirements that determine whether aliens can be admitted into the United States.

Foreign-born populations pose risks for introduction of communicable and emerging diseases into and/or within the United States and are vulnerable to higher morbidity and mortality because

international disease exposures, language, legal and cultural barriers and limited access to preventive care and health information once settled in the United States.

This qualitative data collection is needed by DGMQ because foreign-born individuals are considered hard-to-reach populations and are often missed by routine information collection systems in the United States [1-3]. As a consequence, limited information is available about the health status [4], knowledge, attitudes, health beliefs [5-7] and practices related to communicable diseases and other emerging health issues (e.g., tuberculosis, influenza, viral hepatitis, rickettsial and parasitic diseases) amongst foreign-born populations in the United States [8]. Foreign-born populations are very diverse in terms of countries of origin, socio-demographic, cultural and linguistic characteristics and geographic destinations in the U.S. Data is especially limited at the local level.

This generic OMB clearance will allow DGMQ to more timely collect critical qualitative information, not available otherwise, on knowledge, attitudes, health beliefs and practices related emerging health issues amongst high risk foreign-born populations in the United States. This information is needed by DGMQ for planning and implementation of disease prevention and control strategies targeting emerging diseases among high-risk foreign-born communities in specific and limited geographic areas in the United States where high numbers of those populations live.

Privacy Impact Assessment Information

Overview of Data Collection System

Information collections will consist of **focus group discussions** and **key informant interviews** with community leaders and members of the target populations and individuals working in organizations serving those communities. Each proposed information collection will submit the tools used for data collection in the request provided to OMB. To enhance participation and ensure cultural and linguistic appropriateness of data collection DGMQ will, as appropriate, seek collaboration with target community representatives and local organizations.

For focus groups, respondents will only provide their first name during the discussion as part of the introductory activity to allow respondents to feel more comfortable. Respondents will be told they can utilize a pseudonym if they prefer. DGMQ staff or a contractor will remove any first names that were used during the focus groups from the summary notes and any transcripts and a random numerical identifier will be assigned to the participants immediately after focus groups take place. For both focus groups and key informant interviews, no personally identifiable information will be filed or retrievable. No additional individually identifiable information will be collected.

Focus groups

DGMQ staff or a contractor will work with community based organizations to recruit participants by advertising the focus groups to the target population who utilize their services.

A screening tool will be used in order to ensure appropriate recruitment (Attachment E: Participant Screener). As many as 300 respondents in total may take part in one of the 30 focus groups with 10 persons each per year for which we are requesting approval.

A moderator will lead the discussions, using a discussion guide comprised of key topics and probing questions (Attachments F). All reasonable attempts will be made to conduct the focus groups in the native language of the participants. If that is not possible, an interpreter will be present to ensure the moderator's words are appropriately communicated to discussion participants and that the words of the participants are also appropriately captured. The discussions will be audio-recorded and transcripts will be prepared from these recordings. Notes will also be taken during the discussions to ensure that records of the focus groups exist in the case of audio equipment malfunction.

Analysis will begin after the focus group discussion has been transcribed. Results will be aggregated in a final summary report in which comments and results will not be linked to individual participants to uphold anonymity. All information collected will be destroyed after three years.

Key informant interviews

Participants will be recruited among target community leaders and individuals working in organizations serving those communities and are familiar with community members' knowledge, practices, and beliefs about communicable diseases. Community members will also be recruited to participate in key informant interviews as experts on this subject matter. DGMQ local partners will be consulted to identify potential participants and participants will be contacted directly by DGMQ to set up the interviews. All interviews will be conducted with the use of interview guides (Attachment G)

Most data collection will take place in person or by phone. When appropriate for the target population, web-based focus groups and interviews may be also used.

Items of Information to be Collected

Items of information to be collected include:

- Knowledge, beliefs and practices related to communicable and emerging diseases, including beliefs about the causes and modes of transmission for diseases, effective treatments and prevention strategies
- Terminology used by the community to refer to diseases, sign and symptoms and health-related behaviors
- Information about community members' access to health care and trusted sources of health information

Examples of the data collection, topics and specific target populations that are **within the scope** of this Generic includes:

1. Focus groups with Chinese-born residents in Los Angeles and San Francisco to assess their knowledge, practices and trusted sources of health information related to pandemic flu.

2. Focus groups with Somali refugees being served by three social service organizations in St. Louis and Cook counties, Minnesota. Information collected to learn about their beliefs and knowledge about hepatitis B prevention and treatment.

3. To gain more depth of understanding about Somali beliefs and knowledge of hepatitis B, key informant interviews are conducted with Somali community religious and political leaders and learn what language the community uses to describe disease prevention and treatment.

A.2. Purpose and Use of Information Collection

Privacy Impact Assessment Information

DGMQ and contractors will follow procedures for assuring and maintaining privacy during all stages of data collection. All information collected will not be shared outside of the data collection team. Any individually identifiable information will be removed, and data will be aggregated in a final summary report.

All information provided by respondents will be maintained in password protected folders on secure servers and destroyed after three years 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. Participants in focus groups and interviews will also be informed that the information collected may be recorded and transcribed, and that multimedia recordings will be destroyed after completion of each report of the findings. Information collected through focus groups will be aggregated so that no comments can be linked directly to the respondents to protect their anonymity. Respondents will only provide their first name during the discussion as part of the introductory activity to allow respondents to feel more comfortable. Respondents will be told they can utilize a pseudonym if they prefer. DGMQ will remove any first names that were used during the focus groups from the summary notes and any transcripts and a random numerical identifier will be assigned to the participants immediately after focus groups take place. No personally identifiable information will be filed or retrievable.
The proposed data collection will have little or no effect on the respondent's privacy.

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

The nature of this proposed activity requires direct interaction between respondents and project staff. Additionally, given the potential language barriers posed by the linguistic isolation and

limited English proficiency of some target communities, administering the data collection instruments in person will reduce the likelihood of confusion and misunderstanding on the part of the respondents, the moderator and note taker. CDC generally makes all reasonable attempts to incorporate web-based and other burden reducing information collection technologies, as they apply. The number of questions posed will be kept to the minimum required in order to elicit the necessary data. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. Each proposed information collection will submit the tools used for data collection, including focus group and interview guides, in the statement provided to OMB.

A.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 or other organizations that work with foreign-born individuals in the United States. In addition, as indicated above, there is limited information about knowledge, attitudes, beliefs and practices related to communicable and emerging diseases in reference to foreign-born populations [1-3]. These hard-to-reach populations are missed by our routine national health information systems because of language and cultural barriers, distrust of government, legal migration status, small population size, and recent arrival to the U.S, among other factors. Relevant information is especially lacking at the local level. In any case, to avoid duplicative efforts in data collection, DGMQ actively pursues coordination and collaboration with other federal, state and local agencies and organizations working on the disease topics and populations of interest.

Prior to each proposed information collection, DGMQ staff will also search the literature to ensure that the information of interest has not already been collected. DGMQ will make all reasonable efforts to ensure that the information collection does not overlap with other data collection on immigrant health, such as those authorized under OMB control numbers 1405-0113 Medical Examination for Immigrant or Refugee Applicant, 0920-0006 Application for Waiver of Inadmissibility Under Immigration and Nationality Act, 1615-0029 Application For Waiver U S Department of Homeland Security United States Citizenship and Immigration Services, and 1615-0033 Medical Examination of Alien Seeking Adjustment of Status.

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

No small businesses will be involved in these information collections.

A.6. Consequences of Collecting the Information Less Frequently

There is limited information on knowledge, attitudes, beliefs and practices related to communicable and other emerging diseases at the local level and for high-risk foreign-born

populations. Foreign-born populations are often missed by routine information collections [1-3]. These populations are highly mobile and hard-to-reach, which increases the risk of disease transmission within these migrant groups and across the broader communities in which they live and work. This also increases the likelihood that foreign-born groups continue to suffer from increased morbidity and mortality. The countries of origin, socio-demographic and cultural characteristics, health risks and geographic destinations in the U.S of those migrant populations is becoming increasingly diverse and also changes over time. Thus there is a significant need for more frequent information collection on communicable and other emerging diseases, at the local level, among certain foreign-born sub-groups. All individual projects under this Generic will be a **one-time data collection** involving a specific combination of public health topic of concern, geographic area, and targeted group(s) of foreign born**.** Prior to expiration of the Generic, the subsequent GenICs will target different foreign-born populations and geographic locations.

The information collections proposed under this new generic clearance are needed for DGMQ to better identify and respond to communicable and emerging diseases risks at the local level and in a timely manner, in order to reduce risks of disease transmission and address health disparities among the foreign born. Less frequent data collection limits DGMQ's availability to protect local communities against communicable diseases and emerging health risks associated with population mobility.

There are no legal obstacles to reducing the burden.

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

Various data collection activities may be conducted under the auspices of this request. Each activity is anticipated to be a one-time collection. The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

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

A.8a. A 60-day Federal Register notice was published in the Federal Register on Tuesday, September 4, 2012, Vol. 77, No. 171 (Attachment B). CDC received one non-substantive comment.

A.8.b Consultation

The following agencies and organizations outside of CDC have been consulted on the need for data collection with the audiences, and for the purposes, described in this generic clearance package:

- In consultation with The Association of Refugee Health Coordinators, the need for clear, culturally and linguistically appropriate information for refugees on infectious diseases was identified in 2009. This organization also recognized the need to gather information from refugees to help develop these communication materials.

  Jennifer Cochran, Former Chair
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- In consultation with the International Society for Travel Medicine, the need for public health-related information for international travelers was identified.

  David Freedman, Board Member
  Phone: 205.934.1630

- In consultation with the Health Initiative of the Americas, the need for information regarding the health status, risk factors for disease and other health outcomes among foreign-born and migrant populations.

  Xochitl Castañeda, Director
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- In consultation with a demography professor at San Diego State University, the need for information regarding the health status, health beliefs, risk factors for disease and other health outcomes among foreign-born and other hard to reach migrant populations in the United States.

  Enrico Marcelli, Associate Professor, Department of Sociology
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A.9. Explanation of Any Payment or Gift to Respondents

DGMQ will not directly provide an incentive to respondents. Respondents will receive the incentives through a community organization contracted to recruit participants.

A cash stipend or other non-monetary incentive (e.g., a transportation or food token, phone cards, gift cards) may be offered to the focus group participants as a token of appreciation for a respondent's time and interest in the project and to reimburse for expenses such as transportation and childcare costs may be given to focus group participants. Amounts and justifications will be determined on an individual project basis. This information will be included in the submission provided to OMB for each information collection to be conducted by DGMQ. No incentives will be provided to key informants.

The Need for Incentives

Incorporating modest incentives (e.g., between $20 and $40) to aid in recruitment for focus groups is standard practice among commercial market researchers and public health researchers. Non-monetary incentives (e.g., transportation token, assistance with child care) or, in limited occasions, cash incentives may be offered to the participants as a token of appreciation for a respondent's time and interest in the project. For each generic ICR intended for a population and location where CDC staff or contractors have expert knowledge, CDC will evaluate whether or not, based on professional expertise, existing research, communication with local partners, or other factors, incentives are appropriate or needed to increase participation rates. The default position will be that no incentives are provided. Any rationale for using direct incentives in a generic ICR will be accompanied by scientific evidence supporting their use.

The level of incentive payment will be determined after consulting with community representatives, community-based organizations and trained focus group moderators who have worked with similar populations in the past. CDC will attempt, though participation with local partners and location of focus group facilities, to limit inconveniences associated with travel. This will hopefully decrease the need for higher incentives.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by CIO who determined that the Privacy Act does not apply. No individually identifiable information will be collected in any of the generic information requests submitted to OMB for approval.

Each proposed information collection will submit an application to determine whether or not IRB approval is necessary. The application will outline procedures for obtaining consent from the respondents. However, prior to participating in the information collection, prospective respondents will receive information such as the purpose and sponsorship of the project, their rights as participants, risks and benefits in participating, and contacts for more information about the project. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project.

Focus groups
Respondents will only provide their first name during the focus group discussions as part of the introductory activity to allow respondents to feel more comfortable. Respondents will be told they can utilize a pseudonym if they prefer. DGMQ will remove any first names that were used during the focus groups from the summary notes and any transcripts and a random numerical identifier will be assigned to the participants immediately after focus groups take place. No personally identifiable information will be filed or retrievable. No additional individually identifiable information is being collected during the focus groups.

Key informant interviews

No personally identifiable information will be collected during key informant interviews. Respondents will be advised of the nature of the information collection activity, the length of time it will require, and that participation is purely voluntary. Respondents will be assured that no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human participants.

For both focus groups and key informant interviews:

1. Individuals responding to this request are doing so voluntarily. Participants who do not wish to be recorded will be thanked for attending, and told that the audio recording is necessary, so they are free to leave if they do not want to participate.

2. Prior to participation in the information collection, the moderator will inform each participant that the session is being audio-recorded. The Participant Information Sheet (Attachment H) will be distributed to participants at the beginning of the session, which may include the following: details regarding the nature of the information collection activity, the length of time it will require, sponsorship of the project, their rights as participants, risks and benefits in participating, and contacts for more information about the project. Respondents will be advised that participation is purely voluntary. Moderators will orally communicate information provided in the written description aloud to the group and, if needed, an experienced interpreter will be available during this time to ensure that all information is accurately communicated to participants. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project. Informed consent will be secured orally in the group setting after participants have had the opportunity to be fully briefed about the discussion. Consent will be obtained orally to avoid drawing attention to any participants who may be illiterate or unable to provide their signature.

3. All data will be stored in secured electronic files at CDC's and/or a contractor's office and will be accessible only to staff directly involved in the project. All members of the project will be required to sign a statement pledging their personal commitment to guard the security of data. Data files will be retained for a period of no more than three years and then destroyed. After the three years, the documents and multimedia recordings will be deleted. Online data collections will conform totally to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987] and will be required to have comprehensive, written plans to maintain security. This plan will include having all personnel who will have access to individual identifiers sign data security agreements. They will also be trained in the meaning of data security, particularly as it relates to handling requests for information from respondents, and in providing assurance to respondents about the protection of their responses.

4. No system of records is being created under the Privacy Act. This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and determined that the Privacy Act does

not apply. Individuals responding to this request will not provide any personal identifying information.

A.11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, some respondents may find thinking about and discussing a disease unpleasant, or a portion of respondents could consider questions about race, ethnicity, or other demographic characteristics to be sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some respondents may feel uncomfortable answering particular questions about their individual experiences, level of disease awareness, believes and/or adopted preventative behaviors (or lack thereof) associated with various diseases. However, such questions are necessary for the purposes of a targeted CDC activity and thus to the information collection. To minimize psychological distress, the interviewer or focus group moderator 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. Each individual information collection will provide justification for the inclusion of any questions that may be of a sensitive nature.

A.12. Estimates of Annualized Burden Hours and Costs

A. We estimate the total number of focus groups per year to be no more than 30. Each focus group will contain between eight and 10 participants. For the purposes of Table A.12-A, an estimate of 10 participants per focus group was used. Therefore, 300 respondents will participate in focus groups per year. Focus groups will take no more than 2 hours each, for a total of 600 burden hours. Standard recruitment procedures estimate that twice the number of respondents needed must be screened in order to yield the desired number of respondents. Therefore, 600 respondents will complete the screening form, which will take no more than 10 minutes, resulting in 100 burden hours.
B. We estimate the total number of key informant interviews per year to be 125, and contacted directly by DGMQ staff to participate in an interview. Key interviews will take no more than one hour each, for a total of 125 burden hours.

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

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Foreign-born from specific country of birth in the United States	Screeners for focus groups (assuming 2 screenings for each recruited participant in focus groups) (300X2 = 600)	600	1	10/60	100
Foreign-born from specific country of birth in the United States	Focus Groups (Approximately 30 focus groups/year and 10 participants per focus group)	300	1	2	600
Foreign-born community leaders and staff from organizations serving those communities	Key informant interviews (Approximately 125 interviews/year)	125	1	1	125
TOTAL					825

Information will be collected over a three year time period. There are no costs to respondents except their time to participate in the research activities. The total annualized burden to respondents is 825 hours.

A. Table A.12-B presents the calculations for cost of respondents' time using the general public's mean hourly wages. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website, specifically originating from the 2011 National Occupational Employment and Wage Estimates for the United States. The total estimated annualized respondent cost (including the screening form) is $17,936.

The total respondent costs are summarized in Table A.12-B below.

Table A.12-B: Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Foreign-born from specific country of birth in the United States	Screeners for focus groups	100	$21.74	$2,174
Foreign-born from specific country of birth in the United States	Focus Groups (Approximately 30 focus groups/year)	600	$21.74	$ 13,044
Foreign-born from specific country of birth in the United States	Key informant interviews (Approximately 125 interviews/year)	125	$21.74	$2,718
TOTAL				$17,936

*Public wages from http://www.bls.gov/oes/current/oes_nat.htm#00-0000

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

There are no costs to respondents other than their time.

A.14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is $256,000. This figure encompasses 50% FTE of two GS-13 employees and information collection contract costs. The average hourly rate was obtained from the Office of Personnel Management's website (http://www.opm.gov/oca/09tables/html/atl_h.asp). The hourly rate for a GS-13 in the San Diego area is $42.65 per hour, which is about $89,000 per year. The contractual cost for an information collection (e.g. the development of a screener and instrument, participant recruitment, incentive payments, facility rental (when applicable), transcriptions, translation services and final reports) is estimated at $167,000. This total annual cost of information collection assumes an average cost of $5,000 per focus group and a total of $17,000 for key informant interviews (Please see Table A.14-A for details).

Table A.14-A: Estimated Annualized Cost to the Government per Activity and Total

Estimated Annualized Cost to the Government	
Cost Category	Estimated Annualized Cost
Federal employee costs for information collection (50% FTE of two GS-13 at $89,000/year)	$89,000
Contractual costs for an information collection: a) Focus groups (e.g. facility rental, moderator, participant recruitment, translations, transcriptions and final reports) b) Key informant interviews (e.g., interviewer, participant recruitment, translations, transcriptions and final reports)	(30 focus groups @$5,000) (125 interviews, total $17,000)
Total cost of information collections/year	$256,000

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request.

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

Project Time Schedule

In some cases, the results of information collection will not be published; instead, the information will be used to inform activities across DGMQ. In other cases, results will be presented at professional conferences and in peer-reviewed journals. Project timelines will vary, depending on the program requirements and the activity itself. The project timeline will be dependent on the nature of the data collection and will be provided in each individual information collection. However, we estimate most projects will be up to one year long.

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

The display of the OMB expiration date is not inappropriate.

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

Not applicable. No certification exemption is being sought.

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ATTACHMENTS

A. Legislative Authority: Section 361 of the Public Health Service (PHS) Act (42 USC 264). These regulations are codified in 42 Code of Federal Regulations (CFR) Parts 70 and 71.

B. 60-Day Federal Register Notice

C. Legislative Authority: Section 212(a)(1)(A) of the Immigration and Nationality Act

D. Legislative Authority: Section 325 of the Public Health Service Act.

E. Participant Screener

F. Example of a Focus Group Guide

G. Example of an Interview Guide

H. Participant Information Sheet