Mixed-methods 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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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 data collection projects that will allow us to better understand the risk factors, attitudes and practices related to communicable and other emerging diseases among foreign-born individuals in specific geographic areas of the United States. 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 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], health beliefs [5-7], practices and risk factors for 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]. Data is especially limited at the local level. The countries of origin, socio-demographic and cultural characteristics, health risks and geographic destinations in the U.S of foreign-born populations are becoming increasingly diverse and also change over time.

This generic OMB clearance will allow DGMQ to more timely collect critical information, not available otherwise, for planning and implementation of disease prevention and control strategies targeting communicable and other 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 small, **probability-based surveys** (Attachment E) targeting specific foreign-born sub-populations (e.g., Mexican-born) within limited and defined geographic areas (e.g., cities, census tracts) either where they congregate in the United States and/or DGMQ will engage with groups conducting ongoing projects, and will partner with local governmental and non-governmental organizations.

For target communities concentrated in specific census tracts or neighborhoods in a geographic area of interest (e.g., a city), area-based (household), probability surveys will be conducted. For more dispersed populations, survey participants will be recruited in two ways a) randomly from lists of members of organizations serving the target community in a geographic area, or b) recruited at locations or events where the target community tends to congregate at certain times of the day/week/year. A screening tool will be developed to assist in determining eligibility for participation (Attachment F).

To complement the quantitative (probability-based) surveys, DGMQ will also conduct a limited number of **focus group discussions** with leaders and members of the target populations and individuals in organizations serving those communities (Attachment G). This information will provide richer context to the small, probability-based surveys and will also help in interpreting its meaning. Mixed-methods approaches such as the one proposed here have been recommended for data collection with multicultural, vulnerable and hard-to-reach populations, as the ones we are targeting for this generic. 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.

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

Items of Information to be Collected

Data collection will be limited to information needed by DGMQ to design and implement public health interventions to address communicable and other emerging diseases among high-risk foreign-born populations in specific geographic areas in the United States. Items of information to be collected include:

- Socio-demographics (e.g., age, gender, occupation, education)

- Language(s) spoken
- Travel history
- Self-report of signs or symptoms of a communicable or other emerging disease, such as tuberculosis, sexually transmitted diseases, influenza, and mental health issues
- Self-report history of having been diagnosed in the past, by a health care provider, with a communicable or other emerging disease
- Knowledge, beliefs and practices related to communicable and emerging diseases
- Access to health care and health information

Self-reports of signs or symptoms and of having been diagnosed with a disease within a specific time period will be used to estimate prevalence of communicable or other emerging diseases in the target population.

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

1. A household survey of Chinese-born residents in census tracts in Los Angeles and San Francisco with a high percentage (e.g., >30%) of Chinese residents. Data could be collected to assess their knowledge, practices and trusted sources of health information related to pandemic flu. Focus groups on the same topics to be conducted with members of the Chinese community in the same geographic areas.

2. A phone survey to assess self-reported lifetime diagnosis of Hepatitis B, beliefs and knowledge about hepatitis B prevention and treatment among Somali refugees being served by three social service organizations in St. Louis and Cook counties, Minnesota. Focus groups on the same topics to be conducted with members of the target population.

3. An in-person survey of Iraqis attending a cultural fair at the Iraqi Community Center in El Cajon, San Diego County, CA. Information is collected on self-reported influenza disease in the previous 12 months, use of antibiotics to treat influenza and knowledge about transmission prevention strategies. Focus groups on the same topics could also be conducted with members of the target population to better understand cultural beliefs and practices related to influenza.

This OMB Generic **will not** be used to obtain generalizable national-level information about the foreign born and communicable and emerging diseases. Neither will this OMB Generic be used for data collection during public health emergency situations.

A.2. Purpose and Use of Information Collection

Privacy Impact Assessment Information

The purpose of the new generic clearance is to facilitate the implementation of information collection projects to allow DGMQ, in collaboration with local partner organizations, to better address communicable and other emerging diseases among specific foreign-born populations in limited geographic areas of the United States. This generic OMB clearance is needed for DGMQ to better fulfill its regulatory authority and public health mission. Insights gained from information collections will assist in the planning, implementation and improvement of disease prevention and control activities in order to reduce communicable and emerging disease risks and burden in specific geographic areas of the United States.

No personally identifiable information will be collected under this generic information collection. The proposed data collection will have little or no effect on the respondent's privacy.

DGMQ and contractors will follow procedures for assuring and maintaining privacy during all stages of data collection. Respondents will be recruited through various community-based organizations and other groups/methods including but not limited to: Census Bureau data, state and local health departments, on-site recruitment at various points of interest such as border crossings and ports of entry, and cultural- and faith-based organizations.

Each proposed information collection will submit an IRB application to determine whether or not 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.

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. Participants in focus groups 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. DGMQ staff and contractors will collect and analyze the information.

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

Whenever possible, DGMQ staff will employ electronic technology (e.g., computer-assisted personal and phone surveys, web-based surveys, web-based focus groups) to collect and process data 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. Each proposed information collection will submit the tools used for data collection, including questionnaires, focus group guides and screenshots of web-based surveys, in the statement provided to OMB. The number of questions posed will be held to the minimum required in all information collections in order to elicit the necessary data.

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 communicable and emerging diseases in reference to foreign-born populations [1-3]. These hard-to-reach populations are missed by routine national health information systems because of language 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. 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 and available data sources to ensure that the information of interest has not already been collected or is in the process of being 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 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 information about 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.

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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
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- 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.

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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.

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

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. Incentives have been recommended for data collection among foreign-born individuals [9]. Several surveys in the United States targeting foreign-born populations have reported the usefulness of incentives for data collection. For example, the New Immigrant Survey, which targets foreign-born individuals admitted to the U.S for permanent residence, has used monetary incentives from $5 up to $100 to increase the participation rate [10]. The National Latino and Asian American Survey, which targeted minority populations in the United States, including foreign-born minorities, provided a $50 incentive for participating in the household survey [11].

If, due to lack of local area knowledge or experience, CDC decides to subcontract survey or focus group execution to a local organization with knowledge of the population, CDC will pay this organization a certain amount for recruitment purposes. CDC will allow the local organization to determine the most effective method for recruitment, which may include small cash or other incentives for the time spent responding to questions or engaging in discussions. If it is determined that incentives would appreciably increase participation in the specified population, project leads will consult with the contractors for approval of recruitment methods. To account for differences in local culture and socioeconomic factors, DGMQ investigators will set the level and type of incentives so they do not have the effect of coercing individuals to participate.

CDC will attempt, though participation with local partners and location of survey/focus group facilities, to limit inconveniences associated with travel. This will hopefully decrease the need for higher incentives.

A.10. Assurance of Confidentiality Provided to Respondents

DGMQ and contractors will follow procedures for securing and maintaining the security of respondents' information during all stages of data collection. Respondents will be recruited through various community-based organizations and other groups/methods including but not limited to: Census Bureau data, state and local health departments, on-site recruitment at various points of interest such as border crossings and ports of entry, and culturally- and faith-based organizations.

Respondents will be informed that responses may be recorded and transcribed, and that any multimedia recordings will be destroyed after completion of each report of the findings. DGMQ staff, in conjunction with the contractor, will collect and analyze 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. An application to determine whether or not IRB review is needed will be submitted for each proposed information collection, which will outline their procedure for participant consent.

Privacy Impact Assessment Information

1. 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.

2. Each investigator proposing to complete an information collection will submit an application to determine whether an IRB review and approval is needed, which will outline the procedures for obtaining participant consent. 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 (Attachment H). Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project.

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, demographic characteristics, or behaviors 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, and/or adopted preventative behaviors (or lack thereof) associated with various diseases. Such questions, if asked, would be necessary for the purposes of a targeted CDC activity and thus to the information collection. To minimize psychological distress, the survey administrator, focus group moderator, or data collection instrument instructions 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. The information collection instruments for each information collection activity will be submitted for OMB review. The average burden for each respondent depending on the specific information collection and mix of methodologies will range from 10-60 minutes.

   Similarly, potential respondents may be screened for interest and eligibility using a customizable screening form. Screening forms for each information collection will be submitted for OMB review. Based on experience recruiting participants, it is estimated that twice the number of respondents needed must be screened in order to yield the desired number of respondents.

   We estimate the total number of information collections per year to be no more than 10. Each information collection will consist of at least one survey in one or more limited

geographic locations targeting community members of specific country(ies) of birth. Several focus groups with different members of the target population will also be conducted. The estimated burden to respondents is summarized in Table A.12-A below. The estimated total number of respondents for all information collections has been calculated based on the following assumptions: a) twice the number of respondents needed must be screened in order to yield the desired number of respondents; b) 10 surveys with an average sample size of 600 participants (total = 6,000 participants) c) 30 focus groups with 10 participants each (total = 300 participants)

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 in the United States	Screeners for Surveys and Focus Groups (assuming 2 screenings for each recruited participant in surveys and focus groups) (6,000 + 300) x 2 = 12,600	12,600	1	10/60	2,100
Foreign-born from specific country of birth in the United States	Surveys (Approximately 10 surveys/year and 600 participants per survey)	6,000	1	45/60	4,500
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	1.5	450
TOTAL					7,050

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 7,050 hours.

B. 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 $153,267.

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 in the United States	Screeners for Surveys and Focus Groups	2,100	$21.74	$ 45,654
Foreign-born from specific country of birth in the United States	Surveys (Approximately 10 surveys/year)	4,500	$21.74	$97,830
Foreign-born from specific country of birth in the United States	Focus Groups (Approximately 30 focus groups/year)	450	$21.74	$ 9,783
TOTAL				$153,267

*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 $889,900. 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 $800,000. This total annual cost of information collection assumes an average cost of $5,000 per focus group and, $15,000 per survey.(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) Surveys (e.g., questionnaire adaptation and translation, survey administrator training, field work, data analysis, final report) b) Focus groups (e.g. facility rental, moderator/interviewer, participant recruitment, translations, transcriptions and final reports)	(10 surveys @$65,000) = $650,000 (30 focus groups @$5,000) $150,000
Total cost of information collections/year	$889,000

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. Example of a Survey

F. Example of a Screener

G. Example of a Focus Group Guide

H. Participant Information Sheet