Qualitative Information Collection on Emerging Diseases Among the Foreign-Born in the United States

Request for OMB approval of an Extension Information Collection
(OMB Control No. 0920-0987)

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Supporting Statement A

Contact:
Nancy Khalil, J.D.
MS H16-5
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30329-4027
Phone: (770) 488-2070
Email: kuj2@cdc.gov
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- The goal of the generic information collection is to enhance the ability to determine knowledge, attitudes, health beliefs and practices related to communicable diseases and other emerging health issues amongst high risk foreign-born populations in the United States.
- Intended use of the resulting data is to improve the planning and implementation of disease prevention and control strategies targeting communicable diseases and other emerging health issues among high-risk foreign-born communities in specific and limited geographic areas in the United States where high numbers of those populations live.
- Methods used to conduct the information collections include focus groups and key informant interviews.
- The respondent sub-population is foreign-born individuals living within the United States.
- Data will be analyzed depending on the method and purpose of collection. For example, qualitative analysis software such as NVivo, AtlasTi, MaxQDA to look at trends in terminology, themes in responses, or content elicited during information collected. Thematic analysis might be conducted using Excel.

This is a request for a renewal of a 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 an extension of a 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 diseases and other emerging health issues 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 A1)** 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 **(Attachment A2)** and 71 **(Attachment A3)**. 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 A4)** and Section 325 of the Public Health Service Act **(Attachment A5)**. These regulations are codified in 42 CFR Part 34 **(Attachment A6)**, which establish requirements that determine whether aliens can be admitted into the United States. Finally, CDC is authorized to collect these data under the Public Health Service Act (42 USC 241), Section 301 **(Attachment A7)**.

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, parasitic diseases, lead poisoning, and mental health) 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.

A.2. Purpose and Use of Information Collection

This generic clearance will allow DGMQ to more timely collect critical qualitative information, not available otherwise, on knowledge, attitudes, health beliefs and practices related to communicable diseases and other emerging health issues amongst high risk foreign-born populations in the United States. This information is needed and will be used 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.

Since the extension granted in 2016, DGMQ was limited in its ability to conduct information collections using this generic due to numerous emergency responses. Several staff and significant Division resources were dedicated to follow-up actions to the Ebola outbreak in West

Africa, and then the subsequent Zika outbreak. Preserving approval of this generic information collection will be useful in the event that more targeted projects focusing on foreign-born populations in the United States are needed to better inform timely public health interventions.

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

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 for individual sub-populations (e.g., Central-Americans or Dominicans) and at the local level (most CDC assessments are done at the national 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. Specifically, DGMQ actively participates in key national, regional and state working groups focused on relevant populations and health issues (e.g., Latino health, health disparities, language access, refugee health, farmworker health immigrant health). During public health emergencies when CDC's coordinated EOC response organization is staffed and operating, DGMQ participates in CDC's overall response, which allows us to monitor and coordinate relevant qualitative information collection activities being planned or conducted by other CIOs, federal agencies and state and local stakeholders. CDC's scientific clearance process has enabled greater coordination within the agency and with other federal partners who are working to combat the spread of the Zika virus. Partnerships include collaboration with the Puerto Rico health authorities and multiple U.S. state health departments, Office for Refugee Resettlement, and many communities along the U.S.- Mexico Border.

Additionally, while a number of KAPs data collection activities were conducted during the Zika epidemic, most have been focused on Puerto Rico or on the general US or traveling population. Very limited information is available about Spanish speakers or US residents from Zika affected

countries. This information collection tool will provide an expedited process to approach these types of populations in the event of a different public health event.

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 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 August 8, 2019 Vol. 84, No. 153, pages 38988 - 38989 **(Attachment B).** CDC received two non-substantive comments (**Attachment B1, B2**), and the standard response was sent.

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
  Phone: 617.983.6596
  E-mail: jennifer.cochran@state.ma.us

- 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
  Phone: 510.643.4088
  E-mail: Xochitl.Castaneda@berkeley.edu

- 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

Phone: 617.642.9361
E-mail: Enrico.Marcelli@sdsu.edu

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

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. Type, amount and justification for the use of incentives 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. In general, incentives will be less than $40 for in-person interviews or focus groups of 90 minutes or longer.

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 type and level of incentive 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by the Information Collection Review Office (ICRO) Desk Officer who determined that the Privacy Act may apply depending on information collections submitted under this generic. CDC does not anticipate collecting or storing PII for purposes outside of ensuring that individuals who are screened for participation in focus groups or key informant interviews can be identified correctly when they arrive. In the past, CDC has stated that participants are free to use a pseudonym if they would like to have a greater degree of assurance about privacy, and this is a practice that will be considered for future projects. No PII will be collected during the focus groups or key informant interviews.

CDC does not anticipate that it will store PII collected during these projects in a manner that is searchable by that PII and so does not anticipate creating new systems of records. In the event that PII is stored in a searchable manner, the following systems of records will be used depending on the project:

- Privacy Act System Notice 09-20-0160: Records of Subjects in Health Promotion and Education Studies
- Privacy Act System Notice 09-20-0136: Epidemiologic Studies and Surveillance of Disease Problems

The proposed information collections 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 the projects. Information collected will not be shared outside of the project teams. Any individually identifiable information will be removed, and de-identified data will be aggregated in a final summary report.

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

Focus groups

No additional individually identifiable information is being collected during the 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. An example of a focus group discussion guide is included as attachment C.

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. . An example of an interview guide is included as attachment D.

For both focus groups and key informant interviews:

- 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.

- 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 E) 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.

- 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.

- No system of records is being created under the Privacy Act.

A.11. Institutional Review Board (IRB) and 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.

IRB 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.

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 15. 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, 150 respondents will participate in focus groups per year. Focus groups will take no more than 2 hours each, for a total of 300 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, 300 respondents will complete the screening form (Attachment F), which will take no more than 10 minutes, resulting in 50 burden hours.
B. We estimate the total number of key informant interviews per year to be 100, 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 100 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) (150X2 = 300)	300	1	10/60	50
Foreign-born from specific country of birth in the United States	Focus Groups (Approximately 15 focus groups/year and 10 participants per focus group)	150	1	2	300
Foreign-born community leaders and staff from organizations serving those communities	Key informant interviews (Approximately 100 interviews/year)	100	1	1	100
TOTAL					450

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 450 hours. CDC DGMQ was limited in the number of information collections it could perform with foreign born populations in the United States during the previous three years due to a combination several factors: emergency responses that prevented key Unit staff from focusing on carrying on these types of GenIC's, a lack of specific project funding, and a transition of key Unit leadership to another office. These factors have subsided, and with the current Zika outbreak and improved communicating regarding the availability of this generic information collection to select CDC staff, CDC believes that conducting information collections under the burden described above is feasible.

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 2018 National Occupational Employment and Wage Estimates for the United States. The total estimated annualized respondent cost (including the screening form) is $11,241

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	50	$24.98	$1,249
Foreign-born from specific country of birth in the United States	Focus Groups (Approximately 30 focus groups/year)	300	$24.98	$7,494
Foreign-born from specific country of birth in the United States	Key informant interviews (Approximately 125 interviews/year)	100	$24.98	$2,498
TOTAL				$11,241

*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 $263,914. This figure encompasses Two FTE GS-13 employees and information collection contract costs. The average yearly salary was obtained from the Office of Personnel Management's website (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2019/general-schedule/). Because the projects are anticipated to be administered by staff in San Diego and Atlanta depending on the topic of the project, an average of the personnel costs is used. The annual salary for a GS-13 in the Atlanta area is $93,282 per year, and for San Diego is $98,773. This averages to $96,028.

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, with 15 focus groups) and a total of $8,500 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 (Two GS-13 at $90,207/year)	$180,414
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)	(15 focus groups @$5,000 each) (100 interviews, total $8,500)
Total cost of information collections/year	$263,914

A.15. Explanation for Program Changes or Adjustments

The burden has been reduced slightly as CDC DGMQ was limited in the number of information collections it could perform with foreign born populations in the United States during the previous three years due to a combination several factors: emergency responses that prevented key Unit staff from focusing on carrying on these types of GenIC's, a lack of specific project funding, and a transition of key Unit leadership to another office.

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.

REFERENCES

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8. Painter, T., *Connecting The Dots: When the Risks of HIV/STD Infection Appear High But the Burden of Infection Is Not Known—The Case of Male Latino Migrants in the Southern United States.* AIDS and Behavior, 2008. **12**(2): p. 213-226.

ATTACHMENTS

Attachment A1: Section 361 of the Public Health Service (PHS) Act (42 USC 264).
Attachment A2: 42 CFR 70
Attachment A3: 42 CFR 71
Attachment A4: Section 212(a)(1)(A) of the Immigration and Nationality Act
Attachment A5: Section 325 of the Public Health Service Act.
Attachment A6: 42 CFR part 34
Attachment A7: Section 301 of the Public Health Service Act (42 USC 241)
Attachment B: 60-Day Federal Register Notice
Attachment B1: Public comment
Attachment B2: Public comment
Attachment C: Example of a Focus Group Discussion Guide
Attachment D: Example of an Interview Guide
Attachment E: Participant Information Sheet
Attachment F: Participant Screener