**Mixed-methods Information Collection on emerging diseases among the foreign-born in the United States**

**Request for OMB Approval of a “Generic Clearance” Data Collection**

**Statement B**

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

**PART B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS**

**B.1. Respondent Universe and Sampling Methods**

The respondent universe consists of foreign-born individuals in specific geographic areas (e.g., neighborhoods, cities, counties) in the United States. Foreign-born individuals include temporary and permanent immigrants, international travelers, and refugees settled in the United States. Each information collection will only target individuals from a specific country(ies) of birth (e.g., Mexican-born) and within defined geographic areas (e.g., city of San Diego CA or DeKalb County GA).

For small, **probability-based sample surveys** potential participants for each data collection will be selected using the simplest sampling methodology possible depending on the availability of a sampling frame and the characteristics of the specific target foreign-born population for that data collection:

1. For data collection of foreign-born communities concentrated in certain neighborhoods in a given geographic area of interest (e.g., a city): U.S Census Bureau data will be used to identify census tracts (or census block groups) with a high proportion of target residents (e.g., >30%). A limited number (at least 30) of those census tracts will be randomly selected. The sampling frame will consist of a listing of addresses from the selected census tracts. Households will be randomly selected from the list of addresses. Participants will be randomly selected among residents of selected households who belong to the target population.
2. For a target, foreign-born populations more dispersed geographically, the sampling frame will most frequently be a contact list of members of organizations serving the target communities. Participants will be randomly selected form those lists. For example, a phone survey of Somali refugees among Somalis being served by three community-based organizations in St. Louis and Cook counties, Minnesota. When no sampling frame list is available, participants may be recruited using a probabilistic snowball sampling approach with multiple entry points into the target community, or they may recruited at locations or events where target community members tend to congregate at certain times of the day/week/year (e.g., at ethnic stores, places of worship or employment. In this situation, systematic random sample will be used to select participants. For example, systematic random screening and information collection of Iraqis arriving to an Iraqi cultural festival in San Diego County, California.

Power calculations will be conducted for each data collection to determine appropriate sample sizes based on the specific health indicators of interest and desired precision of the data collection. DGMQ will conduct non-response bias analysis on each quantitative collection and transparently report the limitations of the generalizability of each collection to the users of the information.

**For focus groups,** purposive non-probability sampling will be used to identify and recruit participants in accordance with the specific target population (e.g., country of birth, age, gender, ethnic group, language ability, education level) and purpose of the project. Participants’ recruitment will take place through collaboration with community-based organizations and other groups/methods including but not limited to: state and local health departments, on-site recruitment at various points of interest such as international ports of entry and ethnic events, and culturally- and faith-based organizations. Eligibility criteria will be established for all focus group participants, and potential participants will be screened using a standard screening form. As many as 300 respondents are anticipated to take part in focus groups or large group discussions each year.

Each proposed activity will submit an application for IRB review and approval, which will outline their procedure for participant selection and consent.

**B.2. Procedures for the Collection of Information**

*Probability-based sample surveys*

In community surveys, information will be collected through in-person interactions at the household or other location where the target population can be sampled. When telephone surveys or electronic, web-based surveys are appropriate, investigators will do so. (See Attachment E for a Sample Survey) As many as 6,000 respondents in total may take part in one of the 10 surveys per year for which we are requesting approval.

Potential survey participants will be screened for appropriate demographic or other characteristics as indicated by the project purpose. Each proposed information collection request will include submitting an application for IRB review to determine whether IRB approval is needed. The application will outline the procedure for participant selection and consent.

*Focus groups*

Focus group discussions will occur under the direction of a trained moderator and with the assistance of an interpreter, as needed. The verbal discussion that ensues will be partly directed by the moderator and partly by the comments of other participants (See Attachment G for a Sample Focus Group Discussion Guide). These discussions may take place in-person, through web-interface or by telephone. 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.

Each proposed project will submit culturally and linguistically appropriate tools for data collection, (including questionnaires, screenshots of web-based surveys and focus group guides) in the statement provided to OMB. As many as 300 respondents in total may take part in one of the 30 focus groups per year for which we are requesting approval.

*Estimation procedures*

All survey analysis will be conducted under the advice of a statistician/data analyst as needed, and may involve generating descriptive statistics and performing regression analysis. Linking collected data to existing data sources by non-personal identifiers (e.g., state, county, city name) may be used to increase the overall utility of a proposed data collection. When required, the planned sample strategies will also permit sub-analyses that may include analyzing knowledge, attitude, and belief disparities among different sub-populations. Corrections will be made for over/under sampling, non-response, non-standard distributions, or any other unanticipated sampling or measurement error that may skew or bias the information collection and analyses.

*Degree of accuracy needed for the purpose described in the justification*

The use of simple but scientifically sound sampling methods and power calculations will ensure that DGMQ collects data with enough accuracy to inform the Division about communicable and other emerging disease issues among certain foreign-born populations in specific geographic areas in order to effectively design and implement programs and services. Collaboration with local community-based organizations and leaders will help ensure that data collection activities are conducted in a culturally and linguistically appropriate manner, and will also enhance participation from community members, which will reduce non-response bias. Complementary qualitative data collected through focus groups will provide DGMQ with additional contextual information to properly interpret survey results and better understand attitudes, beliefs and practices related to communicable and other emerging disease issues among foreign-born communities.

*Unusual problems requiring specialized sampling procedures*

Unusual problems requiring specialized sampling are expected to be rare and will be disclosed in individual requests under this generic clearance.

*Any use of periodic (less frequent than annual) data collection cycles to reduce burden*

Use of periodic data collection cycles, e.g. once over the approval term of the generic, for specific target sub-populations (e.g., Mexican-born) and geographic locations is likely for most information collections as part of this generic clearance. The periodicity of data collection will be described in each proposed project. Justification and description for more frequent data collection will be provided if it applies to the proposed project.

**B.3. Methods to Maximize Response Rates and Deal with Non-response**

The following are the examples of the procedures that have proven effective in previous studies and will be used when possible to obtain an adequate response rate:

* Informing respondents of what the project is asking, why it is being asked, who will see the results, and how the results will be used, as well as discussing how respondents will benefit from the results and how the findings will be put into action.
* Using bilingual and bicultural information collection personnel and focus group moderators and culturally and linguistically appropriate data collection instruments and procedures.
* A token of appreciation for a respondent’s time and interest may be given to research participants.
* Addressing data security and anonymity with respondents.
* Minimizing the time needed for participation in the project.
* Informing respondents how much time the project will take so that they know what to expect.
* Utilizing deadlines, reminders, and follow-ups to remind respondents and encourage participation.
* Providing easy access to research instruments, regardless of method being utilized. When appropriate for the audience being studied, research instruments will be designed to be easily accessed by electronic means, from a link in an e-mail or on a website.
* Potential respondents will be informed about the importance of these projects and encouraged to participate through a variety of methods, including announcements from community organizations and letters of support from key individuals.
* When appropriate, a dedicated toll-free number and e-mail account will be established at CDC or a contractor’s office to allow potential respondents to confirm a research activity’s legitimacy, ask questions, and voice concerns.
* For telephone surveys, outgoing calls that result in no answer, a busy signal, or an answering machine will be automatically rescheduled for subsequent attempts.
* A phone or in-person interview will be arranged in case of non-response to initial web-based distribution of questionnaires.
* Over-sampling if necessary to address potential for non-response.
* Collaborating to collect information with community-based, faith-based, and culturally-based organizations that serve the target populations.
* Obtaining support for information collections from trusted community leaders from the target populations.

**B.4. Test of Procedures or Methods to be Undertaken**

DGMQ will implement strategies, e.g. pilot testing, key informant interviews, to ensure that all information collection instruments and tools are linguistically and culturally appropriate for the populations targeted in each proposed project. The importance of utilizing culturally and linguistically appropriate instruments and procedures is well-documented in the literature and is an important aspect of designing and implementing DGMQ’s activities and programs [[1-5](#_ENREF_1)]. The strategies used will be disclosed in each individual submission under this generic clearance.

1. *Probability-based sample surveys*

As appropriate, DGMQ will use validated standard questions from existent national health surveys. To test newly developed survey instruments and to ensure that they are culturally and linguistically appropriate when translated into other languages, DGMQ will implement several procedures that may be include [[6](#_ENREF_6)]:

* Developing protocols, scenarios, and question probes--follow-up questions used to gain more information about respondents' strategies for answering questions.
* Concurrent think-aloud interview--respondents think aloud while answering questions and responses are probed extensively.
* Retrospective think-aloud interview--respondents answer all questions first, then are asked how they arrived at their answers.
* Sorting and ranking tasks--respondents sort lists or similar items into groups that go together and rank the items according to a specified scale.
* Confidence ratings--respondents relate the degree of confidence they have in the accuracy of their answers.
* Memory cues-focus group moderator reads terms which are intended as aids to recall.
* Response latency--measurement of the elapsed time between the presentation of the question and the respondent’s answer.
* Paraphrasing--respondents repeat the questions in their own words.
* Translation and back-translation of survey instruments
* Collaboration with community representatives in developing survey instruments

1. *Focus Groups*

The use of previously validated focus group guides and information collection instruments will be encouraged, as appropriate. If previously validated instruments are not available or appropriate for a proposed project, then the instruments and methods of data collection will be pilot tested before information collection is implemented. Lessons from the pilot test will be identified, and changes will be incorporated into the instrument and method, as necessary. All pre-tests will involve no more than nine individuals unless OMB clearance is sought for more than nine participants.

**B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The following individuals, including contractors, who may be chosen to pre-test information collection instruments and tools and conduct information collections, will be available to provide advice about the design of statistical and sampling procedures undertaken as part of these data collection activities:

* Clive Brown, MBBS, Associate Director for Science, Division of Global Migration and Quarantine
* Nicole Cohen, MD, Associate Chief for Science, Quarantine and Border Health Services Branch, Division of Global Migration and Quarantine
* Christine Prue, PhD, Health Communication Specialist, Office of the Director, National Center for Emerging and Zoonotic Infectious Diseases
* Margaret Coleman, PhD, Economist, Office of the Director, Division of Global Migration and Quarantine
* Jianrong Shi, Statistician, Office of the Director, Division of Global Migration and Quarantine
* Mark Sotir, PhD, MPH, Lead, Surveillance and Epidemiology Team, Traveler’s Health Branch, Division of Global Migration and Quarantine
* Hongjiang Gao, PhD, Statistician, Office of the Director, Division of Global Migration and Quarantine

DGMQ will determine if additional consultation is required and will report any consultants, as well as any individuals collecting and/or analyzing the data in the individual packages.

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