Request for Sub-collection under the Generic ICR: Formative Research and Tool Development
OMB #0920-0840 Expires 10/31/2021

Health Communication Message Testing on Tuberculosis— Centers for Disease Control and Prevention, Division of Tuberculosis Elimination

Supporting Statement Part A

February 8, 2019

Supported by:

Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

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EXHIBITS

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- The purpose of the CDC DTBE Message Testing with Non-U.S.-Born Individuals Considered at High Risk for Tuberculosis project is to explore participants' reactions to messages related to testing for and treating latent tuberculosis infection (LTBI).
- The intended use of this data is to gain:
    - A better understanding of the variances in knowledge, attitudes, beliefs, and misconceptions around LTBI across audience segments and geographic locations, as well as the motivators and barriers to getting tested and treated.
    - Insights into LTBI terms (language, wording) and messages (facts, information, concepts) that are clear, effective, and motivating as well as the best received tone(s) for those messages.
    - Knowledge of audience-trusted health information sources, audience-seeking healthcare behavior (including where they obtain healthcare services), audience-preferred communication channels, and audience-preferred information material formats.
    - To use the above to ultimately develop and disseminate resources (e.g., print materials, educational materials, radio/television PSAs, online tools) tailored to and aimed at educating a broad population at high risk for tuberculosis through CDC tuberculosis resources and through a national health promotion communications campaign.
    - To use the above to develop oral presentations and publications aimed at communicating key findings to relevant stakeholders and leaders in the field—at the national level.
    - To use the above, in conjunction with other information, to enhance LTBI surveillance strategies to monitor changes in disease epidemiology.
- The method that will be used for data collection is focus groups.
- The subpopulation to be studied are up to 135 individuals, including:
    - 27 individuals who were born in Mexico;
    - 27 individuals who were born in the Philippines;
    - 27 individuals who were born in India;
    - 18 individuals who were born in Guatemala;
    - 18 individuals who were born in China and

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Division of Tuberculosis Elimination (DTBE) is requesting approval for a new data collection titled, "Health

Communication Message Testing on Tuberculosis—Centers for Disease Control and Prevention, Division of Tuberculosis Elimination," under the OMB approved Generic Clearance titled "Formative Research and Tool Development" (OMB #0920-0840 exp. 10/31/2021). This new request falls under the larger generic clearance umbrella as it is a form of formative research that is being used to inform the NCHHSTP DTBE's future communication efforts. Conducting this data collection activity will add to CDC's knowledge of the most effective way to write Latent Tuberculosis Infection (LTBI) messages/information.

CDC's DTBE is the division responsible for preventing, controlling, and, ultimately, eliminating TB in the U.S.—a critical and multifaceted task that is vital to our nation's health. Key strategies for reaching elimination status include educating high-risk populations about LTBI and the progression to TB disease; encouraging LTBI testing; getting those who do test positive for LTBI into treatment; and ensuring they adhere to their treatment. In the past, the CDC focused on finding and treating active TB cases. The focus now is prevention by testing for LTBI.

As is the case with any public health crisis, high-risk—and often, not yet served—populations are key to prevention and elimination strategies. Recognizing that non-U.S.-born individuals represent approximately 70 percent of all TB cases in the U.S., it is critical that a major focal point of CDC DTBE's prevention and elimination efforts be on these high-risk groups.

It is at this juncture that CDC's DTBE contracted IQ Solutions, Inc. to implement a qualitative project to help solidify key messages that resonate with members of these target audiences.

The system that the project team will use to collect data are 15 in-person focus groups conducted in 5 geographic locations. Our qualitative research will use volunteer participants in groups and use standardized methods for: exploratory and formative research; and concept, material, and product development and testing.

Short-term qualitative research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate interventions. Research activities—including facilitator guide question domains—will provide information on how target audience members respond to questions and ways in which question response bias and error can be

reduced. Ultimately, the results of these research activities will be used to inform many aspects of a national health promotion communications campaign, intended to reach a broad audience. No personally identifiable information will be collected.

In health communications, target audience members or representatives provide information for delivering clear and influential health messages. Provisional versions of messages—which include key terminology—must be tested with members of target audiences.[1,2,3,4] The results from the focus groups will be used to inform the development of tools and resources (e.g., print ads, educational materials, radio/television PSAs, provider toolkits) for the general public and for practitioners and community leaders who serve populations at high risk for tuberculosis. Resources will be developed according to what the research will reveal, and will be tailored to and aimed at educating populations at high risk for tuberculosis through CDC resources and a national communications campaign. Further, for stakeholders in particular research results will be shared widely via oral presentations and publications. Lastly, results of the qualitative focus groups will also be used in conjunction with other information to enhance or develop the most appropriate and successful surveillance strategies to monitor changes in disease epidemiology.

This request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

This data collection activity will conclude by September 15, 2019 and will be managed by CDC DTBE's contractor IQ Solutions, Inc.

2. Purpose and Use of Information Collection

CDC's DTBE seeks to conduct message testing with individuals who were born in the top six countries of origin that contribute to the U.S.'s current TB rates to explore participants' reactions to

[1] Schmid KL, Rivers SE, Latimer AE, Salovey P. Targeting or tailoring? Maximizing resources to create effective communications. Mark Health Serv. 2008;28(1):32-37.
[2] Randolph W, Viswanath K. Lessons learned from public health mass media campaigns: marketing health in a crowded media world. Annu Rev Public Health. 2004;25:419-37.
[3] Brown KM, Lindenberger JH, Bryant CA. Using pretesting to ensure your messages and materials are on strategy. Health Promot Pract. 2008 Apr;9(2):116-22.
[4] Lapka C, Jupka K, Wray RJ, Jacobsen. Applying cognitive response testing in message development and pre-testing. Health Educ Res. 2008 Jun;23(3):467-76.

terms and messages related to testing for and treating LTBI **(Attachment 3)**.

Formative research is an integral part of the operations research and surveillance activities at NCHHSTP because they are dependent upon the target audience members (general public, health professionals) to obtain the data needed to monitor changes in disease epidemiology and design more effective and efficient interventions. CDC will process the results from the research activities presented in this document into CDC resources and a national communications campaign in a timely manner.

Data for this project will be collected through focus groups. This methodology was chosen based on the exploratory nature of this project's purpose. The data collection instruments are included with this submission (**Attachment 1a-b)**. A moderator's guide will be used to guide all focus group discussions **(Attachment 1a).** One component of this discussion—as detailed in the moderator's guide—includes sharing with participants a brief educational PowerPoint on TB and LTBI **(Attachment 4)** prior to testing the terms and messages **(Attachment 3).** A professional recruitment vendor will be used to recruit focus group participants. There will be a brief screening process to see if interested individuals qualify **(Attachment 1b).**

Qualitative methodologies, including focus groups, provide rich, in-depth information that is useful in understanding what and how target audience members think, feel, and behave, and why they do so. Although this project's focus group findings will provide valuable insights, limitations in this methodology must be considered when reviewing the findings. This qualitative methodology (focus groups) does not allow for generalizability of the findings to the population universe of interest as we will not be recruiting participants randomly and the sample size is relatively small. Nonetheless, the sample size is sufficiently large to observe similar themes repeated across focus groups. In addition, there may be biases to the data collected—for example, because of self-selection (e.g., individuals who choose to participate in a focus group may be different in some important ways compared to individuals who decline to participate in a focus group) and/or social desirability (e.g., when participants report answers they think will please the project team or sponsor).

Data collected will be used to better understand: knowledge, attitudes, and intended behaviors related to LTBI and LTBI

treatment among individuals representing populations at high risk for tuberculosis; ways to word messages/statements that will grab the attention of and be effective with target populations; and trusted health information sources, preferred health information formats, and healthcare seeking behavior of target populations. Key variables to be explored are described in Exhibit A2.1.

Exhibit A2.1: Items of Information to be Collected

Variables to be explored	Data collection tool and citation	Project Related Procedures	Target Population
General knowledge of diseases and tuberculosis/LTBI; reactions to messages categorized by message themes; trusted information sources and preferred health communication channels and formats; healthcare seeking behaviors	Attachment 1a. Moderator's Guide	In-person focus groups	Individuals born in Mexico, Guatemala, China, Vietnam, the Philippines, or India
Country of birth; age; gender; years in the United States; level of education; race/ethnicity; total household income; health insurance type; source of medical care; perception that provider respects one's culture; comfort speaking and reading English	Attachment 1b. Recruitment Screener	Telephone	Individuals born in Mexico, Guatemala, China, Vietnam, the Philippines, or India

IQ Solutions, Inc. will report the findings in summary form in the form of a narrative document and PowerPoint presentation. The project team may present the findings in the aggregate at professional conferences and in articles to be submitted in peer reviewed scientific journals. The purpose of sharing this information is to share lessons learned and best practices with practitioners and community leaders who serve populations at high risk for tuberculosis, with the ultimate goal of controlling the spread of tuberculosis in the United States.

All participants' privacy will be protected as we will not collect any individually identifiable information.

3. Use of Improved Information Technology and Burden Reduction

Focus groups for this project will be held in person instead of virtually. It is critical for these focus groups to be held in person given the purpose of the project, which is to test highly detailed, information-rich, and sometimes complex messages.

Focus group participants will be asked to carefully review each message, available to them in writing/hard-copy, and to mark-up the messages in response to questions posed by the moderator.

Assessing body language and facial expressions will also be part of the data gathering and observation process.

All focus groups will be audio-recorded so that transcripts can be made available for data analysis. Focus groups will also be live video streamed for project staff to view remotely (the live video streaming will be terminated immediately at the end of each focus group discussion). Live video streaming will save the government money as only critical project staff (1 moderator and 1 note-taker) have to travel—all other project staff will not incur travel costs (e.g., flight, hotel).

4. Efforts to Identify Duplication and Use of Similar Information

The focus groups will collect key information that CDC believes is not captured elsewhere. CDC believes no other data collection effort has been conducted, or has been planned to collect similar information, on CDC DTBE target populations. CDC conducted a review of similar studies prior to the issuance of the contract and determined that this project is collecting unique information from CDC DTBE target populations. This project requires the collection of new, primary/original data.

5. Impact on Small Businesses or Other Small Entities

This data collection effort does not involve any small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The proposed project involves a one-time data collection, with approximately 6 weeks of data collection in five geographic locations.

There are no legal obstacles to reducing burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

The 60 Day Federal Register notice was published for the Generic Collection on Monday, April 23, 2018, Vol. 83, No. 78, pp. 17663.

9. Explanation of any Payment or Gift to Respondents

To encourage participant participation and to convey appreciation to participants for contributing to this important project, participants who participate in a focus group will receive a $40 token of appreciation.

Numerous studies have shown that tokens of appreciation can significantly increase response rates and the use of modest tokens of appreciation is expected to enhance response rates without biasing responses [5,6,7]. Offering tokens of appreciation is considered necessary to recruit minorities and historically underrepresented groups into data collection efforts. Timely tokens of appreciation have been shown to improve participation rates among minority groups, as a tangible recognition of the participants' time and effort[8].

Participants will receive the token of appreciation regardless of whether they skip any questions during the focus group discussions.

The use of a token of appreciation for participation in this project is appropriate because the project seeks to conduct focus

[5] Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association.*
[6] Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15,* 231–250.
[7] Göritz, Anja S. (2006). Incentives in web studies: Methodological issues and a review. *International Journal of Internet Science, 1(1),* 58-70.
[8] Yancey, A. K., Ortega, A. N., & Kumanyika, S. K. (2006). Effective recruitment and retention of minority research participants. *Annual Review of Public Health, 27,* 1-28.

groups with not-yet-served and highly selective populations. We anticipate that higher participation rates will lead to a more accurate representation of the underlying populations of interest.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC NCHHSTP Information System Security Officer (ISSO), have assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the overall information collection. The project will not collect PII (email addresses and telephone numbers) for participants.

We will inform focus group participants that their responses will be kept private to the extent permitted by the law. All participants who participate in a focus group will be informed that the information collected will not be attributable directly to any individual participant and will only be discussed among members of the evaluation team.

Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Project team members who will play a role in data collection and analysis have been trained in proper procedures for data handling. We will be prepared to describe these procedures in full detail and to answer any related questions raised by participants at the beginning of each focus group discussion.

During the focus group discussions, we will maintain participant privacy by using first names only (no last names). The project team—both the CDC and the contractor (IQ Solutions)—will never see individual participants' full names or other personally identifiable information.

For purposes of recruiting, the project team will work with a professional recruitment vendor to recruit participants to take part in the focus groups. This professional recruitment vendor builds and manages its own database of thousands of potential focus group participants--each of whom has voluntarily opted-in to be part of the vendor's database (each of these database individuals has thus agreed to being reached for upcoming projects of potential interest). Although the professional recruitment vendor collects personally identifiable information such as first and last names, telephone numbers, and email addresses so that they can conduct outreach and reminders, the project team (CDC and IQ Solutions) will never see any of the

vendor's personally identifiable information. Project team members who will be physically present at a focus group will receive focus group participant grids stripped of all personally identifiable information. None of the data collection questions, moreover, needs focus group participant personally identifiable information to be satisfactorily addressed during the data analysis stage of the project.

In conjunction with the data policy, members of contractor project staff are required to:

- Comply with procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the Project Manager, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the Project Manager and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-project team personnel.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The CDC determined that CDC’s role in this project does not constitute engagement in research and thus CDC human subject review action is not required (**Attachment 2a-b**).

Sensitive Questions

Some of the focus group questions may induce negative thoughts, and participants may feel uncomfortable sharing reservations or criticisms they might have. Participants will be assured that the information they provide is voluntary and will be treated as private. We will inform all participants at the start of each focus group discussion that they may skip any focus group question that makes them uncomfortable or stop focus group participation at any time for any reason, without penalty.

12. Estimates of Annualized Burden Hours and Costs

We predict that 6,750 potential participants will need to be screened in order to reach our target of 135 total participants.

The screening process is anticipated to take 8 minutes (8/60 hours) per participant for a total of 877.50 burden hours (Participant Recruitment Screener, **Attachment 1b**).[9]

Focus group participation per participant will take 90 minutes (1.50 hours) per participant (for a total of 202.50 burden hours (1.50*135 total participants).

The total number of burden hours is 1,080.00.

Exhibit A12.1: Estimated Annual Burden Hours

Type of Participant	Form Name	No. of Participants	No. of Responses Per Participant	Average Burden Per Response (in Hours)	Total Burden Hours
Individual born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Screener Attachment 1b	6,750	1	8/60	877.50
Individual born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Moderator's Guide Attachment 1a	135	1	1.50	202.50
Total					1,080.00

12B. Estimated Annual Burden Costs

[9] We will work with a professional recruitment vendor to recruit participants.

The total costs to the participants are described in Exhibit A12.2. The total estimated cost of the burden to participants is approximately $29,764.80.

Estimates for the average hourly wage for participants are based on Bureau of Labor Statistics data accessed in February 2019 providing national wage estimates (https://www.bls.gov/news.release/empsit.t19.htm). This cost represents the average hourly earnings of all employees on private, non-farm payrolls ($27.56, January 2019).

Exhibit A12.2: Estimated Annual Burden Costs

Type of Participant	Form Name	Total Burden Hours	Hourly Wage Rate	Total Participant Costs
Individual born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Screener Attachment 1b	877.50	$27.56	$24,183.90
Individual born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Moderator's Guide Attachment 1a	202.50	$27.56	$5,580.90
Total				**$29,764.80**

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

There are no costs to participants for participating in this survey other than their time.

14. Annualized Cost to Federal Government

Cost will be incurred by the government in personnel time for overseeing the project, as well as travel costs to attend a select few focus groups. CDC time and effort for overseeing the

contractor's assistance with data collection and answering questions posed by the contractor and funded agencies are estimated at 20% for the Contracting Officer's Representative and 1.5% for a GS-13 level contracting officer. The average annual cost to the federal government for oversight and project management, as well as travel, is $38,500 (**Table A14-1**).

The contractor's costs are based on the current annual funding level for carrying out the data collection activities. This estimate includes the cost of data collection, analysis and reporting, recruitment, and the cost of the tokens of appreciation.

The estimated cost to carry out the data collection activities annually for this project is $**253,463**.

Exhibit A14.1: Annual Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, COR (2, 0.20 FTE)	$22,000
	CDC, Contracting Officer (GS-13, 0.015 FTE)	$1,500
	Travel	$15,000
	Subtotal, Direct Costs	**$38,500**
Cooperative Agreement or Contract Costs	Contract Cost	$214,963
	Subtotal, Contract Costs	**$214,963**
	TOTAL COST TO THE GOVERNMENT	**$253,463**

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request under Generic Clearance titled “Formative Research and Tool Development” (OMB #0920-0840 exp. 10/31/2021).

16. Plans for Tabulation and Publication and Project Time Schedule

Our aim is to disseminate the results of the research activities widely to partners and stakeholders in the form of oral presentations as well as through publications. Findings will be reported in summary form in the form of a narrative document and PowerPoint presentation. The project team may present the findings in the aggregate at professional conferences and in articles to be submitted in peer reviewed scientific journals. The purpose of sharing this information is to share lessons learned and best practices with practitioners and community leaders who serve populations at high risk for tuberculosis, with the ultimate goal of controlling the spread of tuberculosis in the United States. Tabulation will include descriptive characteristics of project participants as reported in the Participant Recruitment Screener **(Attachment 1b)**.

The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Health Communication Message Testing on Tuberculosis Project Time Schedule

Activity	Time Schedule
Protocol development, data collection tools	3-4 months before OMB submission
Pilot test data collection (2 virtual focus groups with 8 total participants)	2-3 months before OMB submission
Pilot test data analysis finalized and pilot test report submitted	2-3 months before OMB submission
Full data collection (15 focus groups with up to 135 total participants)	1-3 months after OMB approval
Analysis plan implemented for qualitative data	3-4 months after OMB approval
Summary report written and submitted	5-6 months after OMB approval

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

We do not seek approval to eliminate the expiration date.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.