Request for Collection under the Generic ICR:
Health Message Testing System (HMTS)
OMB #0920-0572 Expires 08/31/2021

Health Communications Testing for Latent Tuberculosis Infections Campaign– Centers for Disease Control and Prevention, Division of Tuberculosis Elimination

Supporting Statement Part A

May 11, 2020 draft

Supported by:

Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

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- The primary goal for this message testing project is to explore and understand influences, barriers, and facilitators for testing and treating latent tuberculosis infection (LTBI) in order to develop a communications campaign.
- Project objectives for the public health program activities are as follows:

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 Generic Information Collection (genIC) titled, "**Health Communications Testing for Latent Tuberculosis Infections Campaign—Centers for Disease Control and Prevention, Division of Tuberculosis Elimination**," under the OMB approved Generic Clearance titled "**Health Message Testing System (HMTS)" (OMB #0920-0572 exp. 8/31/2021)**. This formative data collection request is being submitted under the HMTS genIC for testing messages for salience, clarity, appeal, and persuasiveness before CDC disseminates the information to the public.

This formative information collection will inform NCHHSTP DTBE's future public service campaign efforts targeted to consumers at high-risk for LTBI and the providers who serve them. This information collection activity is essential because it will provide CDC with effective messages for communicating about this disease and infection to motivate at-risk consumers to get preventive screening and, if infected, treatment, and to motivate healthcare providers to encourage testing and early detection.

The United States reported 9,025 tuberculosis (TB) cases during 2018. Although TB cases continue to decline, the annual percentage decrease in case count and incidence rate from 2017 to 2018 is the smallest year-to-year decrease observed since 1993. Over two-thirds of total cases of TB disease in the U.S. occurred among non-U.S.-born persons. The most common countries of birth among non-U.S.-born TB patients include Mexico, the Philippines, India, Vietnam, Guatemala, and China.

More than 80% of U.S. TB cases are now believed to be associated with longstanding untreated LTBI. Expanding targeted testing and treatment of LTBI is key to eliminating TB disease in the U.S. CDC has contracted with the Weber Shandwick team to develop and implement a communications campaign under the CDC's Office of the Associate Director (OADC) Blanket Purchase Agreement (BPA).

In order to develop an effective communications campaign that educates individuals at high risk for LTBI and the healthcare providers who serve them, CDC DTBE seeks to conduct formative message testing with Filipino, Indian, Vietnamese, Chinese, Mexican, and Guatemalan consumers and healthcare providers that

serve these audiences, to gain an understanding of issue awareness, knowledge, attitudes, beliefs, and misconceptions about LTBI. Message testing will be conducted in areas where target audiences live in highest population density. They will be conducted in Spanish for Mexican and Guatemalan audiences, in Mandarin for Chinese audiences, in Vietnamese for Vietnamese audiences, and in English for Indian and Filipino audiences. (Subject matter experts have advised to conduct message testing among Indian and Filipino audiences in English. However, moderators for these audiences will have the capability to speak Hindi and Tagalog if needed.)

The approach that the project team will use to collect data is qualitative, consisting of 16 virtual focus groups and 12 virtual interviews conducted in three geographic locations.

No personally identifiable information will be collected.

This request is authorized by Section 301 of the Public Health Service Act (41 U.S.C. 241).

This data collection activity will conclude by September 29, 2020 and will be managed by CDC DTBE's contractor Weber Shandwick.

2. Purposes 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 and the providers that serve them to explore participants' reactions to messages related to testing for and treating LTBI.

Data for this project will be collected through virtual focus groups and in-depth interviews (IDIs). This methodology was chosen based on the formative nature of this work, the value of eliciting information about our audiences' mindsets in their own words (open-ended questions), to reveal their thinking—including barriers, both real and perceived, and motivators.

Qualitative methodologies, including focus groups and interviews, 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.

Qualitative methodologies do not allow for statistical generalizability of the findings to the population universe.

Nonetheless, the sample size is sufficiently large to observe patterns and similar themes repeated across focus groups and interviews.

The screening questionnaires, consent forms, data collection instruments, and test materials, and virtual handouts are included with this submission (**Attachments 1-4**). A professional recruitment (vendor) will be used to recruit focus group and interview participants. We will administer a brief screening questionnaire to determine if individuals qualify based on established criteria **(Attachments 1a-b).** All participants who qualify will be provided a Consent Form to read and sign prior to data collection activities (**Attachments 2a-c**). Moderator and Interviewer Guides will be used to guide all focus group discussions and interviews **(Attachments 3a-c).**

Data collected among individuals representing populations at high risk for TB will be used to better understand awareness, knowledge, attitudes, behaviors, and practices related to TB; barriers to TB testing and treatment; and, motivators to TB testing and treatment. This information will inform strategies to improve draft messages and language choices. Furthermore, we will learn about trusted health information sources and preferred health information formats of target populations.

Data collected among health care providers serving populations at high risk for TB will be used to better understand their TB knowledge, awareness of TB testing guidelines, and protocols for TB testing and/or treatment. This information will inform draft messaging.

Key variables and areas of exploration are described in **Exhibit A2.1**.

Exhibit A2.1: Items of Information to be Collected

Target Population	Key Variables and Areas of Exploration	Data Collection Tool and Citation	Project Related Procedures
Consumers: Individuals born in Mexico, Guatemala, China,	General healthcare behaviors and practices, general knowledge, awareness and beliefs of tuberculosis/LTBI; barriers related to the	Attachment 3a: Moderator Guide	Virtual In-person focus groups

Target Population	Key Variables and Areas of Exploration	Data Collection Tool and Citation	Project Related Procedures
Vietnam, the Philippines, India	fear and stigma of testing; barriers related to seeking out healthcare services (including public charge concerns); barriers related to treatment; trusted information and communication sources preferences; reactions to messages.		
Healthcare providers: physicians, nurses, PAs or nurse practitioners	Knowledge and awareness of testing and screening guidelines, the IGRA blood test and treatment for LTBI (specifically shorter regimens) Protocols for testing for LTBI and TB, reasons for testing, factors involved in decision to test If protocols do not exist, probe on intentions, likelihood of testing and treating patients in their practice Experience with helping target audiences navigate barriers related to TB testing and treatment, including fear and stigma, barriers to seeking healthcare services, , and how they seek to overcome these barriers and make testing and treatment easier for these audiences Forms of patient education	Attachments 3b-c: Moderator Guide and Interviewer Guide	Virtual focus groups and in-person interviews

Target Population	Key Variables and Areas of Exploration	Data Collection Tool and Citation	Project Related Procedures
	materials (in English and in-language) that are used in their practice Reactions to messages		
Consumers: Individuals born in Mexico, Guatemala, China, Vietnam, the Philippines, 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;	Attachment 1a: Recruitment Screener	Telephone
Healthcare providers: physicians, nurses, PAs or nurse practitioners	Role within practice; prescribing authority; populations served within practice; number of patients served; type of communication services and language practice offers	Attachment 1b: Recruitment Screener	Telephone

The Weber Shandwick Team will report the findings in the form of a narrative document and PowerPoint presentation.

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 virtually instead of in-person.
Data collection activities will be conducted using the Civicom platform, an adobe-based online platform with telephone for voice. Civicom is web-based, meaning that it does not download anything to a person's personal computer (participants and viewers need only have an internet connection and the latest version of Adobe on their computers). Civicom allows for virtual focus groups with webcams to be conducted seamlessly, drawing upon all of the benefits of in-person focus groups without the limitation of geography. Respondents will be able to see and hear each other, and interact in real-time. A potential drawback of web-enabled focus groups is that the added technology sometimes creates added technology complications. To mitigate this potential, we have a technician present at each of the focus groups to help us with feedback on

phones, internet, and webcam problems for respondents, viewers, and the moderator, should they arise.

External webcams are mailed to any respondents who do not have camera-enabled computers or a webcam. All respondents will be encouraged to check their technology to make sure it works in the days leading up to the focus group, ensuring that they are able to both log-on to the virtual platform, as well as turn their cameras on and feel comfortable with the process. It also serves as an additional reminder and helps to boost show rates of the focus groups. Respondents will also be called by a technician 15 minutes prior to the start time of their scheduled group in order to make sure all technology is working properly prior to starting.

Once all participants are on the line, the technician connects them to the moderator and remains logged on and on the phone for the duration of the group. Both respondents and the moderator use their own telephones to talk during the focus groups. Should anything go wrong with their internet connection, conversation can continue seamlessly while the technician works to troubleshoot.

Focus group participants will be asked to carefully review each message, which will be presented to them as a virtual handout, and respond to questions posed by the moderator.

All focus groups and in-depth interviews will be audio-recorded and transcribed for analysis. Focus groups conducted in non-English languages will be simultaneously translated/interpreted for observers to follow along in real-time.

4. Efforts to Identify Duplication and Use of Similar Information

The focus groups will collect essential information that is not available from other sources. CDC conducted a review of similar studies and determined that this project is collecting unique information from CDC DTBE target populations. CDC is not aware of any effort to collect similar information from among CDC DTBE target populations.

Additionally, Weber Shandwick conducted a literature review during this contract to understand any implications for this project. It was determined that there is not sufficient data on this topic from among target consumer audiences or the healthcare providers who serve them for campaign development.

Thus, this project requires primary data collection.

5. Impact on Small Businesses or Other Small Entities

This information collection does not involve burden to 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 eight weeks of data collection in three geographic locations.

This information collection will provide the primary qualitative data needed to understand any identified barriers and to effectively communicate with target audiences so CDC can motivate audiences in education and outreach to get preventive screening and treatment if needed.

If this data is not collected, CDC will be lacking an in-depth contextual understanding of factors that may affect the success of its messaging and communications campaign.

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

This request fully complies with the regulation 5 CFR 1320.5. and there are no special circumstances.

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

8a. Federal Register Notice

A 60-day Federal Register Notice was published in the *Federal Register* on Thursday, May 10, 2018 Vol. 83, No. 91, Page(s) 21776 - 21778. One non-substantive comment received.

8b. Outside Consultation

In addition to review by **Joan Mangan**, PhD, CDC behavioral scientist within the Division of Tuberculosis Elimination, and their research and communications contractors Weber Shandwick, KRC Research, GC Global, Brunet Garcia and IW Group, Inc., the following were consulted for the development of this study (see Table below). There were no unresolved issues associated with the consultation process.

INSERT NAME **TITLE** **AFFILIATION** **ADDRESS** **CONTACT INFORMATION**	**INSERT NAME** **TITLE** **AFFILIATION** **ADDRESS** **CONTACT INFORMATION**
Carol Sue Hany **Head of Research and Data Science** **Qualtrics** **carolh@qualtrics.com** **1-802-258-0518**	**Michelle Dixon Johns** **Health Education Specialist** **Office of Smoking and Health** **CDC** **Mqd3@cdc.gov** **770-488-5289**

9. Explanations 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 or interview will receive a $75 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 [1,2,3]. 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[4].

[1] 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.*
[2] Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15*, 231–250.
[3] Göritz, Anja S. (2006). Incentives in web studies: Methodological issues and a review. *International Journal of Internet Science, 1(1)*, 58-70.
[4] 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.

Participants will receive the token of appreciation regardless of whether they skip any questions during the focus group discussions or interviews. Additionally, if participants arrive virtually for the focus group, but are excused due to including only seven participants, they will also be given the incentive.

The use of a token of appreciation for participation in this project is appropriate because the project seeks to conduct focus groups and interviews with not-yet-served and highly selective populations and healthcare providers. We anticipate that higher participation rates will lead to a more accurate representation of the underlying populations of interest.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has determined that the Privacy Act does not apply to data collections conducted according to the procedures described in this application. The project will not collect PII (e.g., email addresses and telephone numbers) from participants.

10.1 Privacy Impact Assessment Information

All participants who participate in a focus group or interview 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. Their responses will be kept private to the extent permitted by the law.

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 and interview.

During the focus group discussions and interviews, we will maintain participant privacy by using first names only. The project team—both the CDC and the contractor (Weber Shandwick)—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 and interviews. This professional recruitment vendor builds and manages its own database of thousands of potential focus group and interview 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 Weber Shandwick) will not see any of the vendor's personally identifiable information. Project team members who will be observing focus groups and/or interviews will receive participant grids stripped of all personally identifiable information. None of the data collection questions, moreover, needs 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 5a**).

Sensitive Questions

Some of the focus group or interview 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 and interview that they may skip any question that makes them uncomfortable.

12. Estimates of Annualized Burden Hours and Costs

We predict that 1,240 potential participants will need to be screened in order to reach our target of 124 total participants. We expect to screen 1,080 consumers, and we expect about 8% to be eligible to participate in the data collection, which yields a final sample size of 84. For healthcare providers, expect to screen 160 (120 for nurses and 40 for physicians), and we expect 25% to be eligible to participate in the data collection, which yields a sample size of 40. Of the total participants, 84 are consumers participating in focus groups, 28 are healthcare providers (nurses, nurse practitioners, physician assistants) participating in focus groups and 12 are healthcare providers (physicians) participating in in-person, in-depth interviews.

The screening process is anticipated to take 8 minutes (8/60 hours) per participant for a total of 165.33 burden hours (Participant Recruitment Screeners, **Attachments 1a-b**.[5]

The time to review the consent form is anticipated to take 5 minutes (5/60 hours) per participant for a total 10.33 burden hours (Participant Consent Forms, **Attachments 2a-c**).

Focus group participation per participant will take 90 minutes (1.5 hours) per participant for a total of 168 burden hours (1.5*112 total participants). Interview participation per participant will take 60 minutes (1.0 hours) per participant for a total of 12.0 burden hours (1.0*12 total participants).

The total number of burden hours is 355.66.

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

Exhibit 12A: Estimated Annualized Burden Hours

Type of Participant	Form Name	No. of Participants	No. of Responses Per Participant	Average Burden Per Response (in Hours)	Total Burden Hours
Individuals born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Screener Attachment 1a	1,080	1	8/60	144.00
Healthcare providers (nurses, nurse practitioners, physician assistants)	Screener Attachment 1b	120	1	8/60	16.00
Healthcare providers (physicians)	Screener Attachment 1c	40	1	8/60	5.33
Individuals born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Consent Form Attachment 2a	84	1	5/60	7
Healthcare providers (nurses, nurse practitioners, physician assistants)	Consent Form Attachment 2b	28	1	5/60	2.33
Healthcare providers (physicians)	Consent Form Attachment 2c	12	1	5/60	1

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	Moderator's Guide Attachment 3a	84	1	1.5	126.00
Healthcare providers (nurses, nurse practitioners, physician assistants)	Moderator's Guide Attachment 3b	28	1	1.5	42.00
Healthcare providers (physicians)	Moderator's Guide Attachment 3c	12	1	1.00	12.00
Total					355.66

12a. Estimated Annual Burden Costs

The total costs to the participants are described in Exhibit A12.2. The total estimated cost of the burden to participants is approximately $6,768.78, which represents the total burden hours multiplied by the three (consumers, physicians, and nurses) below.

- Estimates for the average hourly wage for consumer participants are based on Bureau of Labor Statistics data accessed in January 2020 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 ($28.32, December 2019).

- Estimates for the average hourly wage for healthcare provider participants are based on Bureau of Labor Statistics data accessed in January 2020 providing national wage estimates

(https://www.bls.gov/news.release/ocwage.t01.htm). For physicians, the mean hourly wage for “family and general practitioners,” the best available analogue for this study’s primary care physician audience, is $101.82.

The mean hourly wage for physician assistants is $52.13., $36.30 for registered nurses and $52.90 for nurse practitioners (May, 2018). Because an equal number of respondents from all nurse types will participate in this study, and because we anticipate no differences in their rate of qualification, we have used the average of these three hourly wages ($47.11) below.

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 1a	144.00	$28.32 ($3.78 for 8 min: 8/60)	$544.32
Healthcare providers (nurses, nurse practitioners, physician assistants)	Screener Attachment 1b	16.00	$47.11 ($6.28 for 8 min (8/60)	$100.48
Healthcare providers (physicians)	Screener Attachment 1b	5.33	$101.82($13.58 for 8 min (8/60)	$72.38
Individuals born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Consent Form Attachment 2a	7	$28.32 ($2.36 for 5 min: 5/60)	$16.52
Healthcare providers (nurses, nurse practitioners, physician assistants)	Consent Form Attachment 2b	2.33	$47.11 ($6.28 for 5 min (5/60)	$14.63
Healthcare providers (physicians)	Consent Form Attachment 2c	1	$101.82($8.49 for 5 min (5/60)	$8.49

Exhibit A12.2: Estimated Annual Burden Costs				
Individual born in Mexico, Guatemala, China, Vietnam, the Philippines, or India	Moderator's Guide Attachment 3a	126.0	$28.32	$3,568.32
Healthcare providers (nurses, nurse practitioners, physician assistants)	Moderator's Guide Attachment 3b	42.0	$47.11	$1,978.62
Healthcare providers (physicians)	Moderator's Guide Attachment 3c	12.0	$101.82	$1,221.84
Total				**$6,7868.78**

13. Estimates of Other Annualized Respondent Capital and Maintenance Costs

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. Estimates of Annualized Cost to Federal Government

Cost will be incurred by the government in personnel time for overseeing the project 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 is $2,500 (**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 $724,434.70.

Exhibit A14.1: Annual (One-Time) Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, COR (2, 0.25 FTE)	$25,000
	CDC, Contracting Officer (GS-13, 0.01 FTE)	$2,500
	Subtotal, Direct Costs	**$34,100**
Cooperative Agreement or Contract Costs	Contract Cost	$ 696,934.70
	Subtotal, Contract Costs	**$696,934.70**
	TOTAL COST TO THE GOVERNMENT	**$724,434.70**

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR). There are no program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

Findings will be reported in summary form in a narrative document and PowerPoint presentation. The report will include aggregated demographic and descriptive characteristics of project

participants collected as part of the Participant Recruitment Screeners **(Attachments 1a-b).**

The project timeline is detailed in **Exhibit A16.1.**

Exhibit A16.1: Project Time Schedule

Activity	Time Schedule
Protocol development, data collection tools	3-4 months before OMB submission
Data collection (16 focus groups and 12 interviews with up to 156 total participants)	1-2 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.