



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

Print Date: 1/6/21

Title: Health Communications Testing for Latent Tuberculosis Infection Campaign

Project Id: 0900f3eb81c5a88a

Accession #: NCHHSTP-CT-12/16/20-5a88a

Project Contact: Parmer_John E. (bkz8)

Organization: NCHHSTP/DTBE/CEBSB/CT

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 09/29/2020

Estimated Completion Date: 09/29/2021

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-0840

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Other - Public health program activity	12/18/20	Dodson_Janella R. (jhd7) CIO HSC
PRA:			

PRA Applies		12/30/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator
ICRO: Returned with No Decision		12/30/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 12/31/2020

Determination Start Date: 12/16/20

Description:

The most common countries of birth among non-U.S.-born persons with TB include Mexico, the Philippines, India, Vietnam, and China. More than 80% of U.S. TB cases are now believed to be associated with longstanding untreated latent TB infection (LTBI). Expanding targeted testing and treatment of LTBI is key to eliminating TB disease in the U.S. CDC has funded Weber Shandwick to develop and implement a communication 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 TB and the healthcare providers who serve them, CDC DTBE seeks to conduct public health program activities for testing draft campaign concepts and materials with consumers and healthcare providers. These activities will be based on formative work conducted in 2020 (project ID: 0900f3eb81a93d31). Concept and material testing activities will be conducted with individuals born in Vietnam (in-language) and individuals born in The Philippines (in English), as well as the nurse practitioners, physician assistants, and physicians who serve them. These public health program activities will result in a better understanding of which concepts are clearest, most informative, and most effective at driving LTBI testing and treatment outcomes. The creative materials will then be used as part of a communications campaign with the same goals.

IMS/CIO/Epi-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

CDC's DTBE seeks to conduct public health program activities for concept and material testing with individuals who were born in two of the top six countries of origin that contribute to the U.S.'s current TB rates—a critical target audience group that is considered at high risk for TB disease - and the healthcare professionals (primary care physicians, nurse practitioners, and physician assistants) that serve them. The primary goal for these public health program activities is to pilot test storyboards, posters, fact sheets, and concept names and descriptions in order to develop a communication campaign to reach these audiences.

Objective:	Project objectives for the public health program activities are as follows: # Understand healthcare behaviors and practices (context for reactions to creative materials) # Understand levels of awareness, knowledge, attitudes, beliefs, practices, and cultural influences related to TB and LTBI among consumer audiences at risk, and their healthcare providers (context for reactions to creative materials) # Understand healthcare providers# experience serving target audiences as it relates to barriers to testing and treatment of TB and LTBI, and how providers overcome those barriers # Understand healthcare providers# most commonly used educational materials related to TB and LTBI that are provided to patients # Evaluate reactions to creative materials, including extent to which materials capture attention, feel relevant to intended populations, are useful, are clear, motivate audiences to learn more, and motivate audiences to test
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Asian, Healthcare Provider
Tags/Keywords:	Latent Tuberculosis, Tuberculosis, Focus Groups, Interview
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Focus Group; Individual Interviews (Qualitative)
Methods:	DTBE has funded Weber Shandwick to conduct 6 virtual consumer focus groups with non-U.S.-born individuals considered at high risk for TB. The Vietnamese focus groups will be conducted in Vietnamese and the Filipino focus groups in English. Weber Shandwick will also conduct 4 virtual interviews among nurse practitioners and physician assistants and 8 virtual interviews with primary care physicians. CDC is sponsoring, but not conducting data collection. Weber Shandwick will conduct all virtual focus groups and interviews with participants who live in Seattle and Los Angeles. Consumers participating in the focus groups will have immigrated from: the Philippines and Vietnam. CDC is sponsoring, but not conducting data collection. Weber Shandwick will conduct all virtual focus groups and interviews in Seattle and Los Angeles. Consumers participating in the focus groups will have immigrated from either the Philippines or Vietnam. Weber Shandwick will conduct three focus groups, 4 physician interviews and 2 nurse interviews in Seattle and the same number in Los Angeles. The cities selected were based on 2019 TB case rate data, the latest population data, locations which would provide a geographically diverse sample, as well as markets that have ethnic or in-language media outlets for each of our target consumer populations. The metropolitan areas of Seattle and Los Angeles are areas where TB case rate exceeds the national average of 2.7 cases per 100,000 population and represents metropolitan areas with some of the highest rates of TB within the U.S. Additionally, individuals born in the top countries of origin for TB are well-represented among the populations of these cities. Focus groups will be comprised of no more than seven participants each, and each discussion will last approximately 90 minutes. The interviews will last approximately 60 minutes. For each group, three consumer campaign concepts will be tested. For the provider interviews, 4 provider-specific materials will be tested as well as a brief conversation about the consumer campaign concepts.
Collection of Info, Data or Biospecimen:	
Expected Use of Findings/Results:	The findings from these activities will inform strategy, concepts, creative, and materials for a national education campaign on latent TB infection to reach audiences who are at risk and their healthcare providers with the goal of encouraging LTBI testing and treatment.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Contract	Latent Tuberculosis Infection Educational Campaigns and Communication Support	75D301-19F-05695	2020	3

HSC Review

HSC Attributes

Other - Public health program activity Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule	No Selection
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Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
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Children capable of providing assent	No Selection
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Parental permission	No Selection
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Consent process shown in an understandable language

Reading level has been estimated	No Selection
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Comprehension tool is provided	No Selection
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Short form is provided	No Selection
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Translation planned or performed	No Selection
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Certified translation / translator	No Selection
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Translation and back-translation to/from target language(s)	No Selection
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Other method	No Selection
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Clinical Trial

Involves human participants	No Selection
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Assigned to an intervention	No Selection
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Evaluate the effect of the intervention	No Selection
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Evaluation of a health related biomedical or behavioral outcome	No Selection
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Registerable clinical trial	No Selection
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Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
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Human genetic testing is planned now or in the future	No Selection
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Involves long-term storage of identifiable biological specimens	No Selection
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Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Institutions yet to be added

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
John Parmer	12/21/2021		12/17/2022		Program Lead	bkz8@cdc.gov	404-639-4598	Communications Team

Data

DMP

Proposed Data Collection Start Date: 3/1/21

Proposed Data Collection End Date: 4/1/21

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - focus group and individual interview data

Public Access Justification: All focus groups and interviews will be held virtually, using a web-enabled platform. Weber Shandwick will audio and video-record each focus group discussion and interview. The raw data collected by Weber Shandwick will be reflected in transcripts of up to 21 hours of focus group session and individual interview activity. CDC does not have plans to make available these raw data, however these data will be used to develop public campaign materials that will be made publicly available.

How Access Will Be Provided for Data: Not applicable given the description above.

Plans for Archival and Long Term Preservation:

Raw data from this data collection effort will never become part of a system of records containing permanent identifiers that can be used for retrieval. CDC has no direct contact with participants and no identifiers will be available.

Spatiality

Country	State/Province	County/Region
United States	California	Los Angeles
United States	Washington	King

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									



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