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

Print Date: 7/17/20

Title:	Data Collection Through Web Based Surveys for Evaluating Act Against AIDS Social Marketing Campaign Phases Targeting Consumers Development of Messages for the Lets Stop HIV Together National Campaign
Project Id:	0900f3eb81b3307c
Accession #:	NCHHSTP-RET-4/27/20-3307c
Project Contact:	Erskine_Stefanie (soa5)
Organization:	NCHHSTP/DHAP/TICB/RET
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	06/29/2020
Estimated Completion Date:	06/29/2021
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-0920

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Program Evaluation Other - Social Marketing Campaign	7/14/20	Dodson_Janella R. (jhd7) CIO HSC

PRA: **PRA Applies**		7/16/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator
ICRO: **Returned with No Decision**		7/16/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	06/22/2020
Determination Start Date:	06/08/20
Description:	This project determination request is to get approval of this non-research project, which CDC is sponsoring and will get PRA approval. In support of the Ending the HIV Epidemic initiative, CDC will design, implement, and evaluate concepts, messages, and taglines for a social marketing campaign to prevent new HIV transmission by promoting proven interventions including condoms, pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP). The concepts, messages and taglines need to be tested and verified to ensure their acceptability and effectiveness among populations of all ages, genders, races and ethnicities, and sexual orientations. These formative activities support the development of new and continuing social marketing resources as part of the Let's Stop HIV Together campaign.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The goal is to evaluate the acceptability and potential effectiveness of proposed concepts, messages, and taglines for a component of the Let#s Stop HIV Together campaign focused on HIV prevention that promotes proven, effective prevention strategies, such as PrEP and TasP, among audiences# ages 18 to 64 years old in the United States.
Objective:	The main objectives are to examine receptivity to messages and perceived credibility among populations exposed to Let#s Stop HIV Together messages; differences in attitudes, beliefs, and knowledge about HIV among those who report exposure and do not report exposure to Let#s Stop HIV Together phases and messages; intentions related to HIV prevention; and behaviors among those who report and do not report exposure to the various Let#s Stop HIV Together messages.
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, White, Female, Male, Transgender, Adult 18-24 years
Tags/Keywords:	Formative Evaluation, consumers, HIV prevention, Social Marketing, Message Testing, Materials Testing, Concept Testing

CDC's Role:	Other
Method Categories:	Convenience Sample; Individual Interview (Quantitative); Needs Assessment; Survey
Methods:	Evaluation data will be conducted via 30-minute closed-ended, online surveys. Potential participants will be recruited through online survey panel vendors, external partners (e.g., community-based organizations, membership organizations), and the Internet. Individuals selected from panels vendors contacted by email and asked to complete an eligibility survey. They will be screened for eligibility using a standardized screening form. If eligible, individuals will be invited to participate and will be shown a consent form prior to the start of the survey. Those who do not consent will receive a message thanking them for their time and will exit the website. Those who consent to participation will be immediately directed to the survey screener. Those who are eligible, based on the inclusion criteria, will then be directed to the survey. Those who are not eligible will receive a message thanking them for their time and will exit the website. The consent, screener, and survey will be online and accessible on personal computers or devices with internet access. Repeat submissions will be prohibited by the survey vendor.
Collection of Info, Data or Biospecimen:	We will employ non-probability purposive sampling to recruit participants from cities across the United States. The samples for the surveys will consist of participants selected from a combination of sources, including (1) online survey vendors with proprietary panel lists, (2) external partners (e.g., community-based or membership organizations), and (3) the Internet. Inclusion criteria will depend on the specific project phase being evaluated and the target population for the messaging. The informed consent process and screener will be combined. Participants who consent will complete the screener, and if eligible, they will be linked to the online survey. Participants will be offered a token of appreciation of $20-$40 cash or cash equivalent for taking part in a survey; higher amounts will be offered for data collections involving specific audiences known to be difficult to reach (e.g., MSM, PLWH). By providing monetary incentives, we can improve coverage of specialized respondents, rare groups, or minority populations, including MSM, transgender men and women, African Americans, and Hispanics. Including these respondents is important to this study to improve the generalizability of findings and ensure that the campaign materials reflect the information needs and perspectives of those at highest risk for HIV. The web-based surveys will be self-administered and accessible any time of day for a designated period. All data collection materials are at an 8th grade reading level or below due to sample eligibility criteria and CDC requirements. Each respondent can complete the survey only once.
Expected Use of Findings/Results:	The data obtained will be used to inform CDC, policy makers, prevention practitioners, and researchers about audience receptivity and the potential effects of campaign concepts, messages, and taglines. While this is an ongoing communication effort, this data collection will support the development of new concepts and messaging for diverse audiences.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers?	No
Is an assurance of confidentiality in place or planned?	No
Is a certificate of confidentiality in place or planned?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Contract	PN-0128 and PN-1826 Research and Evaluation of HIVAIDS Prevention Communication Science Programs for General Education, Testing including Transgender, Prevention and Care Efforts, and Partnership Initiatives	200-2015-F-88167	2015	5

HSC Review

HSC Attributes

Program Evaluation Yes

Other - Social Marketing Campaign 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 waviers

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

Requested documents of informed consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

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

Clinical Trial

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

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection

Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
RTI					200-2015-F-88167

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
Euna August	12/20/2022		11/09/2019		Principal Investigator	wvj3@cdc.gov	404-639-8297	TECHNICAL INFORMATION AND COMMUNICATIONS BRANCH
Jennifer Uhrig	02/21/2023				Co-Investigator	uhrig@rti.org	919-316-3311	RTI
Pamela Williams	02/21/2023				Co-Investigator	pamwilliams@rti.org	919-316-3936	RTI
Stefanie Erskine	02/21/2023				Co-Investigator	soa5@cdc.gov	404-639-4530	RESEARCH & EVALUATION TEAM

Data

DMP

Proposed Data Collection Start Date: 5/11/20

Proposed Data Collection End Date: 5/10/23

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Data is intended to improve and guide a CDC program.

Public Access Justification: Aggregated and translated data will be shared with the public through publications, presentations, and through finalized campaign assets.

How Access Will Be Provided for Data: RTI, CDC's evaluation contractor, maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a #need-to-know# basis only. The online vendor panels take the following security measures to ensure separation between participants# identity and their survey data. First, the survey instrument does not contain PII. The only way a survey is identified is with a digital identification number. Second, although the invitation method (i.e., e-mail, mail, or direct mail) will inherently have PII information included, this will not be combined with survey responses so the responses from the survey cannot be linked to the PII. Third, screener data will be considered part of the survey data. The vendors will provide the results of the screener questions for all panelists, regardless of whether they qualify for the study. However, they will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. Fourth, the vendors will retain study records for the duration of the study. Upon final delivery of data files to RTI and completion of the project, the vendors will destroy all study records, including data files, upon request. The vendors will not be able to supply or access this information for any reason, even at the request of RTI, once destroyed. Finally, data coming directly from the survey engine are stored in a proprietary database. Although these data are not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to RTI by the vendors will be sent via encrypted files. CDC will not be provided with PII.

Plans for Archival and Long Term Preservation:

Spatiality

Country	State/Province	County/Region
United States		

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...