



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-15-0840]; [Docket No. CDC-2015-0046]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed extension of the "Formative Research and Tool Development" information collection. Project activities are designed to allow CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) to conduct formative research information collection activities used to inform many aspects of

surveillance, communications, health promotion, and research project development for NCHHSTP's four priority diseases (HIV/AIDS), sexually transmitted diseases/infections (STD/STI), viral hepatitis, tuberculosis elimination (TB), and school and adolescent health (DASH).

**DATES:** Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0046 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.Regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed

collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

#### Proposed Project

Formative Research and Tool Development- Extension – National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

The Centers for Disease Control and Prevention's, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests approval for an extension and a three-year approval for its generic information collection plan entitled "Formative Research and Tool Development". Project activities are designed to allow CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) to conduct formative research information collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development for NCHHSTP's four priority diseases (HIV/AIDS), sexually transmitted diseases/infections (STD/STI), viral hepatitis, tuberculosis elimination (TB), and school and adolescent health (DASH).

Formative research is the basis for developing effective strategies including communication channels, for influencing behavior change. It helps researchers identify and understand the characteristics—interests, behaviors and needs—of target populations that influence their decisions and actions. Formative research is also integral in developing programs as well as improving existing and ongoing programs. NCHHSTP formative research helps develop new or adapting programs that deal with the complexity of behaviors, social context, cultural

identities, and health care that underlie the epidemiology of HIV/AIDS, viral hepatitis, STDs, and TB in the U.S, as well as school and adolescent health.

CDC conducts formative research to develop public-sensitive communication messages and user friendly tools prior to developing or recommending interventions, or care. Sometimes these studies are entirely behavioral but most often they are cycles of interviews and focus groups designed to inform the development of a product.

Products from these formative research studies will be used for prevention of HIV/AIDS, Sexually Transmitted Infections (STI), viral Hepatitis, and Tuberculosis. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC's health communication takes place within campaigns that have fairly lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This request includes studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced.

This request also includes collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to identify needs.

Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: 1) Structured and qualitative interviewing for surveillance, research, interventions and material development, 2) cognitive interviewing for development of specific data collection

instruments, 3) methodological research 4) usability testing of technology-based instruments and materials, 5) field testing of new methodologies and materials, 6) investigation of mental models for health decision-making, to inform health communication messages, and 7) organizational needs assessments to support development of capacity. Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements.

In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project.

Participation of respondents is voluntary. Also, there is no cost to participants other than their time.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hrs.)
General public and health care providers	Screeners	97,440	1	10/60	16,240
General public and health care providers	Consent Forms	48,720	1	5/60	4,060
General public and	Individual interview	7,920	1	1	7,920

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hrs.)
health care providers					
General public and health care providers	Group interview	4,800	1	2	9,600
General public and health care providers	Survey of Individual	36,000	1	30/60	18,000
<b>Total</b>		194,880			55,820

**Leroy A. Richardson,**  
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