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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[30Day-18-0840]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Formative Research and Tool Development" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 23, 2018 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Formative Research and Tool Development (OMB Control No. 0920-0840, Expiration 1/31/2019) - 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, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests approval for an extension and a three year approval for the previously approved Generic Clearance, "Formative Research and Tool Development". This information collection request is designed to allow 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 and the Division of 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 integral in developing programs, as well as improving existing and ongoing programs. Formative research also looks at the community in which a public health intervention is being or will be implemented, and helps the project staff understand the interests, attributes and needs of different populations and persons in that community. Formative research is research that occurs before a program is designed and implemented, or while a program is being conducted. NCHHSTP formative research is necessary for developing new programs 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 for 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 identified 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. The total burden hours for this collection is 46,516.

Participation of respondents is voluntary. There is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response
General public	Screeners	56840	1	10/60
Health care providers	Screeners	24360	1	10/60
General public	Consent Forms	28420	1	5/60
Health care providers	Consent Forms	12180	1	5/60
General public	Individual Interview	4620	1	1
Health care providers	Individual Interview	1980	1	1
General public	Focus Group Interview	2800	1	2
Health care providers	Focus Group Interview	1200	1	2
General public	Survey of Individual	21000	1	30/60
Health care providers	Survey of Individual	9000	1	30/60

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