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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0840]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Formative Research and Tool Development—(OMB # 0920-0840, Exp. 1/31/2013) - Revision — 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 request approval for a revision and a 3 year approval for the previously approved Formative Research and Tool Development. This information collection request has been revised to include one additional type of formative research information collection activity, additional detail regarding the previously approved categories of formative research, and instrument testing for data collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development for NCHHSTP's 4 priority diseases (HIV/AIDS, sexually transmitted diseases/infections (STD/STI), viral hepatitis, and tuberculosis elimination. 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.

Formative research is an integral part of developing 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.

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 assessment 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. The total estimated burden is 55820 hours.

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
General public and health care providers	Screener	97440	1	10/60

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response
General public and health care providers	Consent Forms	48720	1	5/60
General public and health care providers	Individual interview	7920	1	1
General public and health care providers	Group interview	4800	1	2
General public and health care providers	Survey of Individual	36000	1	30/60

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