NCCCP and NSBT grantee program implementation, and achievement of CDC priorities and goals.

CDC will use findings from the assessment to inform development of future TTA efforts that utilize the core elements across the two models to more effectively and efficiently support NCCCP's partner organizations.

CDC seeks a two-year approval to collect the required information. Participation is voluntary and respondents will not receive incentives for participation. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| DP13–1314 and DP13–1315 Awardee Organizations. | Worksheet for Identifying Case Study Interviewees. | 10 | 1 | 60/60 | 10 |
| DP13–1314 Program Directors/Managers. | Case Study Interview Guide for DP13–1314 Program Managers. | 16 | 1 | 90/60 | 24 |
| | Case Study Follow-Up Interview Guide for DP13–1314 Program Managers. | 16 | 1 | 60/60 | 16 |
| DP13–1315 Program Directors/Managers. | Case Study Interview Guide for DP1–1315 Program Managers. | 4 | 1 | 90/60 | 6 |
| | Case Study Follow-Up Interview Guide for DP1–1315 Program Managers. | 4 | 1 | 60/60 | 4 |
| DP13–1314 Evaluators | Case Study Interview Guide for DP1–1314 Evaluators. | 16 | 1 | 60/60 | 16 |
| DP13–1315 Evaluators | Case Study Interview Guide for DP1–1315 Evaluators. | 4 | 1 | 60/60 | 4 |
| DP13–1314 Partners | Case Study Interview Guide for DP1–1314 Partners. | 32 | 1 | 60/60 | 32 |
| DP13–1315 Partners | Case Study Interview Guide for DP1–1315 Partners. | 8 | 1 | 60/60 | 8 |
| NCCCP and NSBT Program Directors, Staff, Partners, and Coalition Members. | Survey | 1560 | 1 | 15/60 | 390 |
| NCCCP and NSBT Program Directors, Staff, Partners, and Coalition Members. | TTA Recipient Interview Guide | 10 | 1 | 30/60 | 5 |
| Total | | | | | 515 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30 Day–17–16AVC]**

### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

CDC/ATSDR Formative Research and Tool Development—New — Office of the Director, Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Centers for Disease Control and Prevention requests approval for a new generic information collection plan entitled *CDC/ATSDR Formative Research and Tool Development.* This

information collection plan is designed to allow CDC to conduct formative research information collection activities for developing new tools and methodologies to support agency research, surveillance, program evaluation, communications, health promotion, and research project development. It helps researchers identify and understand the characteristics 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 looks at the community in which a public health intervention is planned 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 occurs before a program is designed and implemented, or while a program is being conducted.

CDC conducts formative research to develop public-sensitive and effective communication messages and data collection tools. To develop scientifically valid and appropriate methods, interventions, and instruments, cycles of interviews and focus groups are designed to inform the development of a product.

Products from these formative research studies will be used for prevention of illness and disease. 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 process.

This request may include 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 may include the 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 the identified needs.

Overall, these development activities are intended to provide information that will increase the success of 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. There is no cost to participants other than their time. Annual estimated burden is 18,750 hours.

| 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. | Screener | 5,000 | 1 | 15/60 | 1,250 |
| | Interview | 5,000 | 1 | 1 | 5,000 |
| | Focus Group Interview | 5,000 | 1 | 2 | 10,000 |
| | Survey | 5,000 | 1 | 30/60 | 2,500 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3180–N4]**

### Food and Drug Administration

**[Docket No. FDA–2010–N–0308]**

### Program for Parallel Review of Medical Devices

**AGENCY:** Food and Drug Administration; Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) (the Agencies) are informing the public that the Parallel Review of medical devices pilot program will be fully implemented and extended indefinitely. The Agencies are soliciting nominations from manufacturers of innovative medical devices to participate in the ''Program for Parallel Review of Medical Devices.'' The Parallel Review program is a collaborative effort that is intended to reduce the time between FDA marketing approval or FDA's granting of a de novo request and Medicare coverage decisions through CMS's National Coverage Determination (NCD)