

analyzed to determine the agents, sources, modes of transmission, or risk factors so that effective prevention and control measures can be implemented. During an unanticipated outbreak or event, immediate action by CDC is necessary to minimize or prevent public harm. The legal justification for EEIs are found in the Public Health Service Act (42 U.S.C. Sec. 301 [241]) (a).

Successful investigations are dependent on rapid and flexible data collection that evolves during the investigation and is customized to the unique circumstances of each outbreak or event. Data collection elements will be those necessary to identify the agents, sources, mode of transmission, or risk factors. Examples of potential

data collection methods include telephone or face-to-face interview; email, web or other type of electronic questionnaire; paper-and-pencil questionnaire; focus groups; medical record review; laboratory record review; collection of clinical samples; and environmental assessment. Respondents will vary depending on the nature of the outbreak or event; examples of potential respondents include health care professionals, patients, laboratorians, and the general public. Participation in EEIs is voluntary and there are no anticipated costs to respondents other than their time. CDC will use the information gathered during EEIs to rapidly identify and effectively

implement measures to minimize or prevent public harm.

CDC projects 60 EEIs in response to outbreaks or events characterized by undetermined agents, undetermined sources, undetermined transmission, or undetermined risk factors annually. The projected average number of respondents is 200 per EEI, for a total of 12,000 respondents. CDC estimates the average burden per response is 0.5 hours and each respondent will be asked to respond once. Therefore, the total estimated annual burden hours are 6,000. These estimates are based on the reported burden for EEIs that have been performed during the previous two years. OMB approval is requested for three years.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Emergency Epidemic Investigation Participants.	Emergency Epidemic Investigation Data Collection Instruments.	12,000	1	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-1154]

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 CDC/ATSDR 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 August 23, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments 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

CDC/ATSDR Formative Research and Tool Development—(OMB Control No. 0920-1154, Exp. 1/31/2020)—Extension—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests approval for an extension of a generic clearance for CDC/ATSDR Formative Research and Tool Development. This information collection request is designed to allow CDC to conduct formative research information collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development at CDC. 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 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 occurs before a program is designed and implemented, or while a program is being conducted.

At CDC, formative research is necessary for developing new programs or adapting programs that deal with the complexity of behavior, social context, cultural identity, and health care that underlie the epidemiology of diseases and conditions 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 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 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. There is no cost to participants other than their time. The total estimated annual burden is 20,000 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response
General public and health care providers	Screeners	10,000	1	15/60
	Interview	5,000	1	1
	Focus Group Interview	5,000	1	2
	Survey	5,000	1	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-379, CMS-10242, CMS-1771, CMS-10180 and CMS-R-199]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to

comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and