

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 an intervention is being or planning to be implemented and helps the project staff understand the interests, attributes and needs of different populations and persons in their 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 formation of a product. 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. Products from the proposed studies will be used for sustainable projects for HIV/AIDS, Sexually Transmitted Infections (STI), viral Hepatitis, and Tuberculosis prevention that are presented as evidence to disease specific National Advisory Committees, in order to support revisions to existing prevention and intervention methods, and provide new recommendations which cannot be developed without formative research.

This request includes studies investigating the utility and acceptability of proposed 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. Overall, these development activities are intended to provide information that will increase the success of the surveillance or research project 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) Focus group and individual interviews; (2) Cognitive interviews for development and testing of specific data

collection instruments; (3) Component testing of instruments developed from qualitative research or communication methods; (4) testing of behavioral interventions; (5) public acceptance of intervention and prevention methods; (6) utilizing computer-assisted instruments (including web-based technology). The implementors may be health jurisdictions, non-governmental organizations including academia, for-profit contractors, private health care facilities, pharmacies, or a combination of these agencies.

Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer-assisted development activities) are selected purposely 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 purposely or systematically from within an ongoing surveillance or research project. Participants may be offered cash or gift certificates as tokens of appreciation for participating.

CDC estimates that the public will participate in 10 different information collection activities, each lasting between 6–12 months. Participation of respondents is always voluntary and there is no cost to the respondents other than their time. The estimated annual burden hours requested is 46,516 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General public and health care providers .....	Screener .....	81,200	1	10/60
General public and health care providers .....	Consent Forms .....	40,600	1	5/60
General public and health care providers .....	Individual interview .....	6,600	1	1
General public and health care providers .....	Group interview .....	4,000	1	2
General public and health care providers .....	Individual Survey .....	30,000	1	30/60

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**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60–Day–09–0741]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and

Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

*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; and (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. Written comments should be received within 60 days of this notice.

**Proposed Project**

The Study to Explore Early Development, [OMB# 0920-0741 Exp. 6/30/2010]—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, correlates, and causes of autism and related disabilities. Under the provisions of this act, CDC funded 5 Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) including the California

Department of Health and Human Services, Colorado Department of Public Health and Environment, Johns Hopkins University, the University of Pennsylvania, and the University of North Carolina at Chapel Hill. CDC National Center on Birth Defects and Developmental Disabilities participates as the 6th CADDRE site. The SEED multi-site, collaborative project is an epidemiological investigation of possible causes for the autism spectrum disorders.

Study participants are to be selected from children born in and residing in the following six areas: Atlanta metropolitan area, San Francisco Bay area, Denver metropolitan area, Baltimore metropolitan area, Philadelphia metropolitan area, and Central North Carolina. Children with autism spectrum disorders are compared to children with other developmental problems, referred to as the neurodevelopmentally impaired group (NIC), as well as children who do not have developmental problems, referred to as the subcohort.

Data collection methods consist of the following: (1) Medical record review of

the child participant; (2) medical record review of the biological mother of the child participant; (3) packets sent to the participants with self-administered questionnaires and a buccal swab kit; (4) a telephone interview focusing on pregnancy-related events and early life history (biological mother and/or primary caregiver interview); (5) a child development evaluation (more comprehensive for case participants than for the control group participants); (6) parent child development interview (for case participants only) administered over the telephone or in-person; (7) a physical exam of the child participant; (8) biological sampling of the child participant (blood and hair); and, (9) biological sampling of the biological parents of the child participant (blood only). Minor changes to some of the self administered questionnaires and the telephone interview include clarification of instructions to the respondent and clarifying specific questions to make the instruments easier to complete and further improve data quality.

There is no cost to respondents other than their time.

**ESTIMATE OF ANNUALIZED BURDEN HOURS**

Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
1. Initial Contact by Mail .....	9,252	1	10/60	1,542
2. Invitation Telephone Contact .....	3,886	1	20/60	1,295
3. Self-administered Questionnaires and buccal sample .....	1,749	1	3	5,247
4. Caregiver Interview by telephone .....	1,434	1	1.5	2,151
5. Child Clinic Visit (Child Development Evaluation, physical exam, and biosamples) .....	1,329			
Case .....	443	1	2	886
NIC .....	443	1	2	886
Subcohort .....	443	1	2	886
6. Parent Child Development Interview (Case participants only) .....	414	1	3	1,242
7. Parent biosamples .....	1,242	1	15/60	311
<b>Total</b> .....				<b>14,446</b>

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**Maryam I. Daneshvar,**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Customer Satisfaction Survey**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60-day advance opportunity for public

comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

*Proposed Collection: Title:* 0917-NEW, "Indian Health Service Customer Satisfaction Survey." *Type of Information Collection Request:* Three-year approval of this new information collection, 0917-NEW, "Indian Health Service Customer Satisfaction Survey." *Form(s):* Tribal Homeowner Survey, Tribal Partner Survey, Annual Operator Operation and Maintenance (O&M)