



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development

Submission for OMB review; comment request

New proposed collection, Neuropsychosocial Formative Research Methodological Studies for the National Children's Study

SUMMARY: Under the provisions of Section (3507(a)(1)(D)) of the Paperwork Reduction Act of 1995, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on May 2, 2011, pages 24497-24498, and allowed 60 days for public comment. Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. The written comments were identical and questioned the cost and utility of the study. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* Neuropsychosocial Formative Research Methodological Studies for the National Children's Study (NCS). *Type of Information Request:* NEW. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Public Law 106-310) states:

- (a) **PURPOSE.**—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.
- (b) **IN GENERAL.**—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate

Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

- (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
 - (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.
- (c) REQUIREMENT.—The study under subsection (b) shall—
- (1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children’s well-being;
 - (2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and
 - (3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children’s Health Act of 2000, the results of formative research will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of tools to assess language, behavior, and neurodevelopment, psychosocial stress, and health literacy and thereby inform data collection methodologies for the National Children’s Study (NCS) Vanguard (Pilot) and Main Studies. With this information collection request, the NCS seeks to obtain OMB’s generic clearance to conduct formative research featuring neuropsychosocial measures.

The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard (Pilot) Study and Main Study neuropsychosocial measures in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study.

Frequency of Response: Annual [As needed on an on-going and concurrent basis].

Affected Public: Members of the public, researchers, practitioners, and other health professionals. *Type of Respondents:* Women of child-bearing age / potential NCS participants, infants, children, fathers, legal guardians, health care facilities and professionals, hospital administrators and staff, pediatric professional organizations and practitioners, educational professionals, public health organizations, community leaders, members, and organizations, and cultural and faith-based centers, and . These include

both persons enrolled in the NCS Vanguard Study and their peers who are not participating in the NCS Vanguard Study. *Annual reporting burden:* See Table 1. The annualized cost to respondents is estimated at: \$742,000 (based on approximately \$10 per hour for NCS participants and members of the NCS target population (non-NCS participants), \$101 per hour for health providers (OB/GYNs), and \$20 per hour for social service providers). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Physical measurement and examinations	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants)	4,000	1	1	4,000
Child Developmental Measures (cognitive)	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants)	4,000	1	1	4,000
Computer-based reaction time testing	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants)	4,000	1	1	4,000
Small, focused survey and instrument design and administration	NCS participants	4,000	2	1	8,000
	Members of NCS target population (not NCS participants)	4,000	2	1	8,000
	Health Care Providers	1,000	1	1	1,000
	Social Service Providers	1,000	1	1	1,000
	Community Stakeholders	2,000	1	1	2,000
Focus groups	NCS participants	2,000	1	1	2,000
	Members of NCS target population (not NCS participants)	2,000	1	1	2,000
	Health Care Providers	1,000	1	1	1,000
	Social Service Providers	1,000	1	1	1,000
	Community	2,000	1	1	2,000

Table 1. Estimated Annual Reporting Burden Summary, Neuropsychosocial Measures					
Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
	Stakeholders				
Cognitive interviews	NCS participants	500	1	2	1,000
	Members of NCS target population (not NCS participants)	500	1	2	1,000
Total		45,000			54,000 hrs

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by E-mail to OIRA_submission@omb.eop.gov, or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Jamelle E. Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call a non-toll free number (301) 496-1877 or E-mail your request, including your address to banksj@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: March 21, 2012

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National Institute of Child Health and Human Development

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