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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: April 20, 2011.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2011-10186 Filed 4-26-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Revision to Proposed Collection; Comment Request; Formative Research Methodology Studies for the National Children's Study

SUMMARY: 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 National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Formative Research and Pilot Methodology Studies for the National Children's Study (NCS).

Type of Information Collection Request: RENEWAL of OMB Clearance 0925-0590, Expiration June 30, 2011.

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, the results of formative research and pilot tests will be used to maximize the efficiency of NCS procedures, materials, and methods for outreach, engagement of stakeholders, recruitment and retention of Study subjects, and to ensure scientifically robust data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to renew its OMB generic clearance to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider feedback information collection surrounding outreach, engagement, recruitment, consent and questionnaire design, and retention activities. Under separate notice, the NCS also requests OMB generic clearance for formative research featuring environmental, neurodevelopmental, and study logistic information collection. These separate and distinct generic clearances will facilitate the efficiency of submission and review of these projects as required by the OMB Office of Information and Regulatory Affairs.

Background

The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health and development. The Study defines "environment" broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. Findings from the Study will be made available as the research progresses, making potential benefits known to the public

as soon as possible. The National Children's Study is led by a consortium of Federal partners: The U.S.

Department of Health and Human Services (including the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

The results from formative research and pilot tests proposed will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study recruitment, retention, study visit measures and study logistics 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.

With this submission, the NCS seeks to renew its OMB generic clearance to conduct survey and instrument design and administration, focus groups, cognitive interviews, and health and social service provider feedback information collection surrounding outreach, engagement, recruitment, consent and questionnaire design, and retention activities. Under separate notice, the NCS also requests OMB generic clearance for formative research featuring environmental, neurodevelopmental, and study logistic information collection. These separate and distinct generic clearances will facilitate the efficiency of submission and review of these projects as required by the OMB Office of Information and Regulatory Affairs.

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, fathers, community leaders, members, and organizations, health care facilities and professionals, public health, environmental, social and

cognitive science professional organizations and practitioners, hospital administrators, cultural and faith-based centers, and schools and child care organizations. 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: \$300,000 (based on \$10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY

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
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 and Social Service Providers	2,000	1	1	2,000
	Community Stakeholders	2,000	1	1	2,000
Focus groups	NCS participants	2,000	1	2	2,000
	Members of NCS target population (not NCS participants).	2,000	1	2	2,000
	Health and Social Service Providers	2,000	1	2	2,000
	Community Stakeholders	2,000	1	2	2,000
Cognitive interviews	NCS participants	500	1	2	1,000
	Members of NCS target population (not NCS participants).	500	1	2	1,000
Total	21,000	30,000 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 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Sarah L. Glavin, Deputy Director, 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 non-toll free number (301) 496-1877 or E-mail your request, including your address to glavins@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: April 20, 2011.
Sarah L. Glavin,
Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Biospecimen and Physical Measures Formative Research Methodology Studies for the National Children's Study

SUMMARY: 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 National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of

Management and Budget (OMB) for review and approval.

Proposed Collection:
Title: Biospecimen and Physical Measures Formative Research Methodology Studies for the National Children's Study (NCS)
Type of Information Collection Request: Generic Clearance
Need and Use of Information Collection: The Children's Health Act of 2000 (Pub. L. 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—