

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 21, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Environmental Science 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: Environmental Science 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—

(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 will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of environmental sample collection procedures and technology, storage procedures, accompanying questionnaires, and assays, and thereby inform data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain an OMB generic clearance to collect environmental samples from homes and child care settings, and conduct accompanying short surveys related to the physical and chemical environment.

The NCS has obtained an 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, recruitment and retention (0925–0590; requesting renewal). Under separate notice, the NCS is also requesting an OMB generic clearance to conduct formative research featuring biospecimen and physical measures, 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.

In this request, the NCS is requesting a generic clearance from OMB for formative research activities relating to the collection, storage, management, and assay of environmental samples and accompanying questionnaires. 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 and Main Study environmental sample and information collection 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.

The NCS has obtained generic clearance for formative research activities pertaining to outreach, recruitment and retention (0925–0590). Under separate notice, the NCS also requests an OMB generic clearance for formative research featuring biospecimen and physical measures, neurodevelopmental measures, and study logistic information collection. These separate and distinct generic clearances are requested to 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, public health

and environmental science professional organizations and practitioners, 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: \$780,000 (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, ENVIRONMENTAL SCIENCE

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
Home Air	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
Home Water	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
Home Dust	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
School and Child Care Facility Air ...	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
School and Child Care Facility Water	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants).	4,000	1	1	4,000
School and Child Care Facility Dust	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 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	1	2,000
	Members of NCS target population (not NCS participants).	2,000	1	1	2,000
	Health and Social Service Providers.	2,000	1	1	2,000
	Community Stakeholders.	2,000	1	1	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	69,000	78,000 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 Communication, National Institute of Child Health and Human Development.

[FR Doc. 2011-10191 Filed 4-26-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Study Logistic 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: Study Logistics 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—

(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 will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of new and existing study measures, participant communication techniques, and technologies being utilized, and thereby inform data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain an OMB generic clearance to conduct formative research relating to instrument design and modality with a view to reduce item and unit non-response to Study instruments while preserving scientific quality.

The NCS has obtained an 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, recruitment and retention (0925-0590; requesting renewal). Under separate notice, the NCS is also requesting an OMB generic clearance to conduct formative research featuring biospecimen and physical measures, environmental, and neurodevelopmental and psycho-social information collection. These separate and distinct generic clearances are requested to 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.

In this request, NCS is requesting approval from OMB for formative research activities relating to instrument design and modality with a view to reduce item and unit non-response to Study instruments while preserving scientific quality. 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 and Main Study instrument design and modality in a manner that minimizes public information collection burden compared to burden anticipated if these instruments were incorporated directly into either the NCS Vanguard or Main Study.

The NCS has obtained generic clearance for formative research activities pertaining to outreach, recruitment and retention (0925-0590). Under separate notice, the NCS also requests an OMB generic clearance for formative research featuring biospecimen and physical measures, environmental samples, and