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. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23609–23611, and allowed 60 days for public comment. One written comment was received. The comment questioned the cost and utility of the study and federally funded biomedical research in general. The purpose of this notice is to allow an additional 30 days for public comment.

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—

(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 tests will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of biospecimen and physical measurement collection procedures, accompanying questionnaires, storage and information management processes, and assay procedures, thereby informing data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB's generic clearance to conduct formative research featuring biospecimen and physical measurement collections.

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 biospecimen collection procedures and physical measurements 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, infants, children, fathers, health care facilities and professionals, public health professional organizations and practitioners, and hospital administrators.

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: $600,000 (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, BIOLOGICAL AND PHYSICAL 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
Blood:					
Adult	NCS participants	4,000	1	0.5	2,000
	Members of NCS target population (not NCS participants).	4,000	1	0.5	2,000
Infant/Child	NCS participants	2,000	1	0.5	1,000
	Members of NCS target population (not NCS participants).	2,000	1	0.5	1,000
Urine:					
Adult	NCS participants	4,000	1	0.25	1,000
	Members of NCS target population (not NCS participants).	4,000	1	0.25	1,000
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Hair:					

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, BIOLOGICAL AND PHYSICAL MEASURES—Continued

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
Adult	NCS participants	4,000	1	0.25	1,000
	Members of NCS target population (not NCS participants).	4,000	1	0.25	1,000
Nails:					
Adult	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Cervical Fluid:					
Women	NCS participants	4,000	1	0.5	2,000
	Members of NCS target population (not NCS participants).	4,000	1	0.5	2,000
Breast Milk:					
Women	NCS participants	4,000	1	0.5	2,000
	Members of NCS target population (not NCS participants).	4,000	1	0.5	2,000
Cord Blood:					
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Meconium:					
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Placenta:					
Infant	NCS participants	4,000	1	0.25	1,000
	Members of NCS target population (not NCS participants).	4,000	1	0.25	1,000
Length:					
Infant	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Height:					
Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Weight:					
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Head Circumference:					
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Middle Upper Arm Circumference:					
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
Ulnar Length:					
Infant/Child	NCS participants	2,000	1	0.25	500
	Members of NCS target population (not NCS participants).	2,000	1	0.25	500
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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, BIOLOGICAL AND PHYSICAL MEASURES—Continued

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
	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	.....	113,000	.....	.....	60,000

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 30 days of the date of this publication.

Dated: June 21, 2011.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2011–16299 Filed 6–28–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Endogenous Insulin Secretion Preservation.

Date: July 27, 2011.

Time: 8:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *ls38z@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 23, 2011

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–16298 Filed 6–28–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals,