heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information required on Form FDA–356h have been approved under OMB control number 0910–0338; and the collections of information required on Form FDA–3397 have been approved under OMB control number 0910–0297.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–22373 Filed 8–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request New proposed collection, Biospecimen and Physical Measures Formative Research Methodology 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 April 27, 2011, pages 23609–23611, 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: Biospecimen and Physical Measures Formative Research Methodology 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 (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

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
	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:					
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	1000
	Members of NCS target population (not NCS participants).	4,000	1	0.25	1000
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
	Health and Social Service Providers	2,000	1	1	2,000

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
	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 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: August 25, 2011.

Jamelle E. Banks,

Public Health Analyst, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2011–22456 Filed 8–31–11; 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 Meetings

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 meetings.

The meetings 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; NIDDK Ancillary Studies to Major Ongoing Clinical Studies: DCCT/EDIC.

Date: September 30, 2011.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Seeding.

Date: October 5, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: D.G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Novel Therapies for NIDDM P01.

Date: October 14, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: D.G. Patel, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition.

Date: October 18, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115.

Contact Person: Thomas A. Tatham, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–3993. *tathamt@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes,