The Agencies have decided to continue the program as currently designed for an additional period of 2 years from the date of publication of this notice.

DATES: This notice is effective December 18, 2013.

FOR FURTHER INFORMATION CONTACT: John Burke, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5460, Silver Spring, MD 20993–0002, 301–796–5738, *John.Burke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 11, 2011 (76 FR 62808), the Agencies announced the procedures and guiding principles for the Parallel Review Pilot Program and solicited nominations for the pilot. To date, there has been significant interest in the pilot and the Agencies are currently working through the parallel review process with the approved pilot program participants. We believe that interest in the pilot has also facilitated mutually informative discussions between additional sponsors and the Agencies.

In the October 11, 2011 (76 FR 62808), Parallel Review Pilot Program notice, the Agencies stated their intent to accept requests for a 2-year period, followed by an announcement in the **Federal Register** as to the future of the pilot. The Agencies have decided to continue the program as currently designed for an additional 2 years from the date of publication of this notice.

Once a representative group of participants have completed the pilot process the Agencies will formally evaluate the program for best practices and will announce any future revisions and/or enhancements in a future **Federal Register** notice.

Dated: December 5, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 6, 2013.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

[FR Doc. 2013–29822 Filed 12–17–13; 8:45 am]

BILLING CODE 4120–01–M; 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Children's Study, Vanguard (Pilot) Study; Submission for OMB Review; 30-Day Comment Request

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 Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 23, 2013, page 52548 and allowed 60-days for public comment. Two public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Eunice Kennedy Shriver, National Institute of Child Health and Human Development (NICHD), 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.

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 the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

Comment 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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496–7898 or Email your request, including your address to *glavins@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The National Children's Study, Vanguard (Pilot) Study, 0925–0593, Expiration 8/31/2014—Revision, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this request is to continue data collection activities for the NCS Vanguard Study and receive a renewal of the Vanguard Study clearance. The NCS also proposes the initiation of a new enrollment cohort, the addition of new Study visits, revisions to existing Study visits, and the initiation of methodological substudies. The NCS Vanguard Study is a prospective, longitudinal pilot study of child health and development that will inform the design of the Main Study of the National Children's Study.

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. 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 (NCS) has several components, including a pilot or Vanguard Study, and a Main Study to collect exposure and outcome data.

The NCS Vanguard Study continues to follow the children and families enrolled in the Vanguard Study, conducting Study visits in participants' homes and over the telephone. Data Collection visits may include the administration of questionnaires, neurodevelopmental assessments, physical measures, and the collection of biospecimens and environmental measures. The Vanguard Study has yielded valuable data and field experience related to participant recruitment, the conduct of Study assessments, and operational requirements associated with NCS infrastructure and field efforts. The purpose of the proposed data collection is to obtain further operational and performance data on processes and administration Study visit measures.

Research Questions: The primary research goal is to systematically pilot additional study visit measures and collections for scientific robustness, burden to participants and study infrastructure, and cost for use in the Vanguard (Pilot) Study and to inform the Main Study. A secondary goal is to increase enrollment in the Vanguard Study through the identification of subsequent pregnancies among enrolled women.

Methods: The NCS Vanguard Study data collection schedule currently

includes pre-pregnancy, pregnancy, and birth periods, as well as post-natal collection points at defined intervals between 3 and 30 months. This request extends the collection of data about the children in the Vanguard cohort through 60 months of age, with home visits scheduled for children 36, 48, and 60 months of age. Two intervening remote (phone or internet) survey data collections are proposed as well. We propose to add or modify the selected measures below to address analytic goals of assessing feasibility, acceptability, and cost of specific study visit measures.

Enrollment of Sibling Birth Cohort: We will enroll approximately 1,000 sibling births identified among currently enrolled women. Following new pregnancies will allow us to pilot the collection of biospecimens, environmental samples, and standardized neurodevelopmental assessments on sufficient numbers of participants to understand what activities are feasible in specific settings, participants' willingness to complete requested measures, and whether measures are useful and scalable. Participants will be administered the same protocol as approved for the NCS Vanguard Study by the Office of Information and Regulatory Affairs within the Office of Management and Budget, including the collection of environmental samples, biospecimens and physical measurements during pre-pregnancy and pre- and post-natal visits. Those who report that they are trying to conceive will be initially administered the protocols approved for preconception data collection. Others who self-report a pregnancy at a later time will receive pregnancy visit instrumentation and collections.

Supplemental Information Collections

Core Questionnaire: We propose a revised core questionnaire containing key variables and designed to collect core data at every study visit contact from the time that the enrolled child is 6 months of age to the time the child is 5 years of age.

Age-Specific Modular Questionnaires: At each Study visit, participants will be administered brief questionnaire modules that include measures relevant to the specific age of the enrolled child.

Biospecimen Collections: Microbiome swabs will be collected from the biological mother at birth from the vagina, mouth, and rectum and at 6, 24, and 48- month visits from the nasal cavity, mouth, and rectum. Microbiome swabs will also be collected from NCS children from the nasal cavity, mouth, and rectum at 6, 24, and 48-month visits. Shed deciduous teeth will be collected from NCS children beginning at age five. Instructions on retrieval and shipment and to postage-paid shipping materials will be provided to participants.

Environmental Sample Collection: Noise measurements will be taken at the homes of randomly-selected enrolled participants. With their consent, their homes will be equipped with a noise meter and measured for noise levels at various time intervals, and data collectors will ask questions about the source and frequency of noise they encounter at home.

Physical Measures: BIA, or bioelectrical impedance analysis, is a non-invasive method for estimation of body composition including Body Mass Index. BIA will be measured on a small subsample of approximately 200 NCS children. For comparison, conventional skinfold measurements using previously approved and implemented protocols will be collected. Physical activity in children will be measured with accelerometers at three data collection points with a subsample of approximately 600 NCS enrolled children. Participants will be asked to wear the Actigraph GT3X-plus physical activity monitor on their wrist for a 7-day period. Pulmonary function will be measured at age five through spirometry, a simple, non-invasive method.

NIH Toolbox Measures: The NIH Toolbox (*www.nihtoolbox.org*) is a series of short assessments designed to measure emotional, cognitive, sensory, and motor function in children as young as age three.

Assessing Participant Experience: NCS participants will be asked to complete self-administered questionnaires designed to assess feelings towards the NCS and motivation to be engaged in research. Through the use of these instruments, the NCS aims to maintain positive relationships with participants and allow them to provide useful feedback about the Study, its procedures and perceived value to them, their families, and communities.

Retrospective Pregnancy Questionnaire: Women who joined the NCS after the birth of the enrolled child will be asked to complete a Retrospective Pregnancy Questionnaire designed to collect prenatal medical information.

OMB approval is requested for 3 years. The additional annualized cost to respondents over the 3 year data collection period is estimated at an annualized cost of $633,541 (based on $10 per hour). The total estimated annualized burden hours are 63,354 hours (see Table 1).

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR VANGUARD (PILOT) STUDY RESPONDENTS, STUDY VISITS THROUGH 60 MONTHS OF AGE OF THE CHILD

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hrs)	Estimated total annual burden hours
Pregnancy Screening Activities:					
Pregnancy Screener Sibling Birth Cohort SAQ *(9M to 60M)*.	Biological Mother	1,122	10	3/60	561
Retrospective Pregnancy Interview *(Birth, 3M, 6M)*.	Biological Mother	422	1	47/60	331
Continuous Activities:					
Participant Verification & Tracing (PVT) Interview *(PV1 to 60M)*.	Pregnant Woman, Father/Father Figure, Biological Mother, Primary Caregiver, Secondary Residence Caregiver.	877	15	7/60	1,535
Validation Interview *(Pre-Pregnancy to 60M)*.	Pregnant Woman, Father/Father Figure, Biological Mother, Primary Caregiver, Secondary Residence Caregiver.	850	1	2/60	28

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR VANGUARD (PILOT) STUDY RESPONDENTS, STUDY VISITS THROUGH 60 MONTHS OF AGE OF THE CHILD—Continued

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hrs)	Estimated total annual burden hours
Participant Information Update—Incentive Substudy *(24M to 60M)*.	Primary Caregiver	1,364	1	5/60	114
Event Driven Activities:					
Pregnancy Loss, Stillbirth, & Neonatal Death Interview *(PV1, PV2, Birth)*.	Pregnant Woman, Biological Mother	13	1	17/60	4
Parent-Caregiver Death Interview *(3M to 60M)*.	Proxy	3	1	3/60	0.17
Child Death Interview *(3M to 60M)*.	Primary Caregiver	4	1	3/60	0.22
Non-Interview Respondent Interview *(Pre-Pregnancy to 60M)*.	Pre-Pregnant Woman, Pregnant Woman, Father/Father Figure, Biological Mother, Primary Caregiver.	603	1	5/60	50
Secondary Residence Interview *(36M, 48M, 60M)*.	Secondary Residence Caregiver	221	1	13/60	48
Preconception Activities:					
Pre-Pregnancy Interview	Pre-Pregnant Woman	445	1	21/60	156
Adult-Focused Biospecimen Collection—Blood & Urine.	Pre-Pregnant Woman	356	1	26/60	154
Pregnancy Probability Group Follow-up.	Pre-Pregnant Woman	445	1	15/60	111
Pre-Natal Activities:					
Pregnancy Visit 1 Interview	Pregnant Woman	333	1	50/60	278
Pregnancy Visit 2 Interview	Pregnant Woman	333	1	18/60	100
Adult-Focused Biospecimen Collection—Blood & Urine *(PV1, PV2)*.	Pregnant Woman	267	2	26/60	231
Environmental Sample Collection—Vacuum Bag Dust *(PV1)*.	Primary Caregiver	283	1	3/60	14
Father Pre-Natal Interview *(PV1 or PV2)*.	Father/Father Figure	317	1	32/60	169
Pregnancy Health Care Log *(PV1 or PV2)*.	Biological Mother	333	1	5/60	28
Birth Activities:					
Birth Interview	Biological Mother	317	1	15/60	79
Adult-Focused Biospecimen Collection—Blood, Urine, Cord Blood, Breast Milk, Placenta, & Microbiome Swab.	Biological Mother	253	1	85/60	358
Child-Focused Biospecimen Collection—Infant Blood Spot.	Child	253	1	3/60	13
Post-Natal Activities:					
Infant & Child Health Care Log *(Birth to 60M)*.	Primary Caregiver	2,067	1	5/60	172
3-Month Interview	Primary Caregiver	475	1	37/60	293
	Biological Mother	475	1	2/60	16
Adult-Focused Biospecimen Collection—Breast Milk, Blood, Urine, Saliva, & Microbiome Swab *(3M, 6M, 12M, 24M, 36M, 48M, 60M)*.	Primary Caregiver	832	14	40/60	7,811
6-Month Interview	Primary Caregiver	475	1	32/60	253
Core Questionnaire—Child, Adult, & Household *(6M to 60M, except 9M)*.	Primary Caregiver	1,107	9	34/60	5,646
Child-Focused Biospecimen Collection—Urine, Blood, Saliva, Microbiome Swab, & Teeth *(6M, 12M, 24M, 36M, 48M, 60M)*.	Primary Caregiver	886	14	44/60	9,027
9-Month Interview	Primary Caregiver	554	1	3/60	28
Father Post-Natal Interview *(9M or 18M)*.	Father/Father Figure	558	1	14/60	130
12-Month Interview	Primary Caregiver	554	1	34/60	314

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR VANGUARD (PILOT) STUDY RESPONDENTS, STUDY VISITS THROUGH 60 MONTHS OF AGE OF THE CHILD—Continued

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hrs)	Estimated total annual burden hours
Child-Focused Physical Measures—Anthropometry, Blood Pressure, Vision Screening, Lung Function, & Motor Skills *(6M, 12M, 24M, 36M, 48M, 60M)*.	Child	1,217	2	9/60	365
	Primary Caregiver	935	13	41/60	8,375
Environmental Sample Collection—Vacuum Bag Dust, Indoor and Outdoor Visual Observations, & Dust Wipes *(12M, 36M, 48M, 60M)*.	Primary Caregiver	1,085	13	8/60	1,775
18-Month Interview	Primary Caregiver	562	1	40/60	375
24-Month Interview	Primary Caregiver	1,046	1	26/60	453
30-Month Interview	Primary Caregiver	1,286	1	50/60	1,072
36-Month Interview	Primary Caregiver	1,711	1	61/60	1,740
	Child	1,711	1	22/60	627
42-Month Interview	Primary Caregiver	1,364	1	32/60	728
	Biological Mother, Biological Father	1,364	1	15/60	341
48-Month Interview	Primary Caregiver	1,380	1	89/60	2,047\
54-Month Interview	Primary Caregiver	1,431	1	23/60	549
60-Month Interview	Primary Caregiver	1,332	1	46/60	1,021
	Child	1,332	1	22/60	488
Subsample Studies:					
Noise *(36M, 60M)*	Primary Caregiver	200	2	17/60	113
Bioelectrical Impedance Analysis (BIA) *(48M, 60M)*.	Primary Caregiver	67	2	7/60	16
Physical Activity (Accelerometer) *(36M, 48M, 60M)*.	Primary Caregiver	200	3	43/60	430
Total Vanguard (Pilot) Study					48,567
Total Formative Research ..					2,835

Dated: December 6, 2013.

Sarah L. Glavin,

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

[FR Doc. 2013–30091 Filed 12–17–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Low-Dose CT Imaging (UO1).

Date: February 26, 2014.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, DEM II, Suite 951, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3398, *hayesj@mail.nih.gov.*

Dated: December 12, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–30012 Filed 12–17–13; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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