20852, Telephone: (301) 443–5204, Fax: (301) 443–9602, E-Mail: *Andrew.Diggs@ihs.gov.*

3. Questions on systems matters may be directed to:

Mr. Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 443–9602, E-Mail: *Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Date: August 16, 2013.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2013–20535 Filed 8–22–13; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Children's Study, Vanguard (Pilot) Study Proposed Collection; 60-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) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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 to be 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.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. 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.

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.

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 includes pre-pregnancy, pregnancy, and birth periods, as well as post-natal collection points at defined intervals between 3 and 60 months. 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 NCS children from the nasal cavity, inside of the elbow, and rectum at two time points. 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. We propose to provide $10 per shed deciduous tooth collected and shipped.

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. Once the monitor has been returned, a check for $25 will be mailed to the participant as a token of appreciation for their time. 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).

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
Screening Activities:					
Pregnancy Status Screener (Sibling Birth Cohort) (9M to 60M).	Biological Mother	1,072	10	3/60	536
Retrospective Pregnancy Screener (Birth or 3M or 6M).	Biological Mother	422	1	39/60	274
Continuous Activities:					
Participant Verification, Scheduling, & Tracing Interview (PVST) (PV1 to 60M).	Biological Mother, Primary Caregiver, Secondary Caregiver, Adult Caregiver-Identified Father.	843	15	9/60	1,898
Parent-Caregiver Death Questionnaire (3M to 60M).	Secondary Caregiver	3	1	2/60	0.17
Child Death Questionnaire (3M to 60M)	Primary Caregiver	4	1	3/60	0.22
Participant Information Update SAQ—Incentive Substudy (24M to 60M).	Primary Caregiver, Secondary Caregiver.	1,292	7	3/60	754
Validation Questionnaire (Pre-Pregnancy to 60M).	Primary Caregiver, Secondary Caregiver.	818	16	5/60	436
Non-Interview Respondent (NIR) SAQ (Pre-Pregnancy to 60M).	Biological Mother, Primary Caregiver, Secondary Caregiver, Adult Caregiver-Identified Father.	998	1	5/60	83
Preconception Activities:					
Pre-Pregnancy Interview	Biological Mother	440	1	40/60	293
Adult-Focused Biospecimen Collection—Blood & Urine.	Biological Mother, Primary Caregiver, Secondary Caregiver.	352	1	24/60	141
Pregnancy Probability Group Follow-up	Biological Mother	440	1	15/60	110

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
Prenatal Activities:					
Pregnancy Visit 1 Interview	Biological Mother, Primary Caregiver, Secondary Caregiver.	333	1	38/60	211
Pregnancy Visit 2 Interview	Biological Mother	333	1	16/60	89
Adult-Focused Biospecimen Collection—Blood & Urine (PV1, PV2).	Biological Mother, Primary Caregiver, Secondary Caregiver.	267	2	24/60	213
Environmental Sample Collection—Vacuum Bag Dust (PV1).	Primary Caregiver, Secondary Caregiver.	283	1	3/60	14
Father Pre-Natal Interview (PV1 or PV2).	Adult-Caregiver Identified Father.	317	1	29/60	153
Pregnancy Health Care Log (PV1 or PV2).	Biological Mother	333	1	5/60	28
Pregnancy Loss, Stillbirth, & Neonatal Death Interview.	Biological Mother	13	1	35/60	8
Birth-Related Activities:					
Birth Interview	Primary Caregiver, Secondary Caregiver.	317	1	15/60	79
Pregnancy Loss, Stillbirth, & Neonatal Death Interview.	Biological Mother	13	1	35/60	7
Adult-Focused Biospecimen Collection—Blood, Urine, Cord Blood, Breast Milk, & Placenta.	Biological Mother, Primary Caregiver, Secondary Caregiver.	253	1	34/60	144
	Child	253	1	3/60	13
Child-Focused Biospecimen Collection—Infant Blood Spot & Microbiome Swab.	Primary Caregiver, Secondary Caregiver.	253	1	20/60	84
Postnatal Activities:					
Infant Child Health Care Log (Birth to 60M).	Primary Caregiver, Secondary Caregiver.	2,050	1	5/60	171
3-Month Interview	Biological Mother, Primary Caregiver, Secondary Caregiver.	475	1	39/60	309
Adult-Focused Biospecimen Collection—Breast Milk, Blood, Urine, & Saliva (3M, 6M, 12M, 36M, 60M).	Biological Mother, Primary Caregiver, Secondary Caregiver.	807	11	43/60	6,364
6-Month Interview	Primary Caregiver, Secondary Caregiver.	475	1	38/60	301
Core Questionnaire—Child, Adult Caregiver, & Household (6M to 60M, except 9M).	Primary Caregiver, Secondary Caregiver.	1,064	10	30/60	5,320
Child-Focused Biospecimen Collection—Urine, Blood, Saliva, Microbiome Swab & Teeth (6M, 12M, 36M, 48M, 60M).	Biological Mother, Primary Caregiver, Secondary Caregiver.	900	12	67/60	12,064
9-Month Interview	Primary Caregiver, Secondary Caregiver.	554	1	5/60	46
Father/Father Figure Post-Natal Questionnaire (9M or 18M).	Adult-Caregiver Identified Father.	558	1	17/60	158
12-Month Interview	Primary Caregiver, Secondary Caregiver.	554	1	45/60	416
Child-Focused Physical Measures—Anthropometry, Blood Pressure, Vision Screening, Lung Function, & Motor Skills (6M, 12M, 24M, 36M, 48M, 60M).	Primary Caregiver, Secondary Caregiver.	952	15	63/60	14,989
Environmental Sample Collection—Vacuum Bag Dust, Indoor and Outdoor Visual Observations, & Dust Wipes (12M, 36M, 48M, 60M).	Primary Caregiver, Secondary Caregiver.	1,046	14	15/60	3,660
18-Month Interview	Primary Caregiver, Secondary Caregiver.	562	1	47/60	440
24-Month Interview	Primary Caregiver, Secondary Caregiver.	1,046	1	30/60	523
30-Month Interview	Primary Caregiver, Secondary Caregiver.	1,009	1	59/60	992

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
36-Month Interview	Primary Caregiver, Secondary Caregiver.	1,434	1	94/60	2,247
42-Month Interview	Primary Caregiver, Secondary Caregiver.	1,325	1	47/60	1,038
48-Month Interview	Primary Caregiver, Secondary Caregiver.	1,380	1	103/60	2,369
54-Month Interview	Primary Caregiver, Secondary Caregiver.	1,431	1	23/60	549
60-Month Interview	Primary Caregiver, Secondary Caregiver.	1,421	1	103/60	2,439
Subsample Studies:					
Noise (36M, 60M)	Primary Caregiver, Secondary Caregiver.	200	2	17/60	113
Bioelectrical Impedance Analysis (BIA) (48M, 60M).	Primary Caregiver, Secondary Caregiver.	67	2	5/60	11
Physical Activity (Accelerometer) (36M, 48M, 60M).	Primary Caregiver, Secondary Caregiver.	200	3	43/60	430
Total Vanguard (Pilot) Study					60,519
Total Formative Research		2,835			2,835
Grand Total Vanguard (Pilot) Study		29,166			63,354

Dated: August 14, 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. 2013–20549 Filed 8–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

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

The meeting 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 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 Advisory Mental Health Council.

Date: September 19, 2013.

Open: 8:30 a.m. to 2:00 p.m.

Agenda: Presentation of NIMH Director's report and discussion of NIMH program and policy issues.

Place: National Institutes of Health (NIH), Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Closed: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room C/D/E, Rockville, MD 20852.

Contact Person: Jane A. Steinberg, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–5047.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 16, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–20560 Filed 8–22–13; 8:45 am]

BILLING CODE 4140–01–P