



[BILLING CODE 4140-01-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
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

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 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-Focused Biospecimen Collection - Infant Blood Spot & Microbiome Swab	Child	253	1	3/60	13
	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
36-Month Interview	Primary Caregiver, Secondary Caregiver	1,434	1	94/60	2,247

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
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

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