Those interested in more information should refer to the PhUSE Web site at *http://www.phuse.eu/ssc4p.aspxweb.*

The conference will make available an exhibition hall. The exhibitor price for this conference is $3,500.

Dated: January 24, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1887 Filed 1–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Revision to Proposed Collection; Comment Request; National Institute of Child Health and Human Development; the National Children's Study, Vanguard (Pilot) 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.

Proposed Collection

Title: The National Children's Study, Vanguard (Pilot) Study.

Type of Information Collection Request: Revision.

Need and Use of Information Collection: The purpose of the proposed methodological study is to continue the Vanguard phase of the National Children's Study with updated instruments and additional biospecimen collections and physical measures and to evaluate the feasibility, acceptability, and cost of a different sampling strategy for enrollment of pregnant women. This study is one component of a larger group of studies being conducted during the Vanguard Phase of the National Children's Study (NCS), a prospective, national longitudinal study of child health and development. In combination, these studies will be used to 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 sample frame for the NCS Vanguard and Main Study was initially based on a national probability sample using geography as the basis and selecting about100 of the about 3000 counties in the United States as the basis for Primary Sampling Units. Within the Primary Sampling Units, smaller geographic segments were selected as Secondary Sampling Units in an attempt to normalize live birth rates per area sampled. Women who resided at the time of enrollment within a designated Secondary Sampling Unit and were either pregnant or between 18 and 49 were eligible for enrollment. The initial recruitment technique within the selected geographic areas was household contact by field workers going door to door.

The Vanguard Study was launched in January 2009, and by summer 2009, field experience suggested that the household contact recruitment strategy was not feasible with available resources. Thus, in 2010 new recruitment strategies were launched to evaluate options. By late 2011, the NCS had sufficient data to evaluate operational aspects of various recruitment strategies. Preliminary analyses suggested that a provider based recruitment strategy was the most efficient, but due to constrictions of the geographic sampling frame, the potential of the strategy was limited. Specifically, many women had to be screened at a particular provider to locate the relatively few who resided in a designated segment. Anticipating this limitation, the NCS Program Office developed and discussed with the NCS Advisory Committee a different sampling frame, using provider location. This new sampling strategy is termed Provider Based Sampling (PBS). Information from this data collection is critical to determine the plausibility of a provider based sampling frame as an option for some parts of the NCS Main Study.

Research Questions

Two research goals will be accomplished by this information collection. The first goal is to systematically pilot additional study visit measures and collections whose scientific robustness, burden to participants and study infrastructure, and cost for use in the Vanguard (Pilot) Study and to inform the Main Study. The second goal is to test the feasibility, acceptability, and cost of Provider Based Sampling using three locations.

Methods

We will continue with the current data collection schedule which include pre-pregnancy, pregnancy, and birth periods, as well as postnatal data collection points at 3, 6, 9, 12, 18, and 24 months of age. 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.

Supplemental Information and Biospecimen Collections

Core Questionnaire: We propose to pilot use of a 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.

30-Month Data Collection Module: We propose piloting the approach of use of a core instrument plus an age specific module with the 30 month visit.

Validation Questions for 18, 24 and 30 month: We propose addition of brief, telephone-based questions that would be fielded to a random sample of each interviewer's cases after completion of the 18-Month, 24-Month, and 30-Month interviews to monitor interviewer performance and identify occurrences of data falsification.

Nonrespondent Questionnaire will collect information on why a participant chose to not enroll or withdraw from the NCS. This information may be used to revise our approaches to recruitment and will help the Study frame other systematic analyses of nonresponse bias.

Physical Measures: The addition of 6 month and 12 month infant measures of child anthropometry and blood pressure may provide critical pieces of information for future research on the causes of obesity, diabetes, premature puberty and a host of other health outcomes.

Revised Father Questionnaire: The NCS seeks to incorporate behavioral, emotional, educational and contextual consequences to enable a complete assessment of psychosocial influences on children's well-being. The Revised Father Questionnaire now includes measures addressing key social/personal resources and fathers' capacity, desire and attitudes towards engaging with mothers and children.

Revised 24 Month Interview: The Modified Checklist for Autism in toddlers (M–CHAT™) is a validated brief screening measure for identification of Autism and will be added to the 24 month interview.

Breast Milk Collection 1 and 3 months: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

Infant Urine Collection at 6 and 12 months: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

Infant Blood and Saliva Collection at 12 months: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

Provider Based Sampling

We will compile, at three Vanguard Study locations, a list of prenatal providers serving women who reside in the Primary Sampling Unit. Providers will be asked to complete a brief questionnaire about their practice and their patient demographics. For this pilot, a woman will be eligible for recruitment if she resides in the Primary Sampling Unit and is seeing a provider for her first prenatal visit.

Recruitment of participants at the selected provider offices will follow the protocol and procedures developed for the Provider-Based Sample Recruitment Substudy, as previously approved by the Office of Information and Regulatory Affairs within the Office of Management and Budget. Potential participants will be screened on age eligibility, residence in the sampled Primary Sampling Unit, and status of an initial prenatal visit. In some locations, medical records may be prescreened to identify participants meeting these eligibility criteria.

Frequency of Response: See above descriptions.

Affected Public: Healthcare Providers, Age-eligible women, Pregnant women, Fathers, and their children.

Annual Reporting Burden: See Table 1. The additional annualized cost to respondents over the 3 year data collection period is estimated at annualized cost of $1,966,069 (based on $10 per hour). This is calculated as estimating 415,894 respondent contacts at an estimated average of 0.47 hours per contact, for a total estimated annual respondent burden as 196,607 hours. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR RECRUITMENT SUBSTUDY RESPONDENTS, PRENATAL TO 30 MONTHS, PHASE 2

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
Pregnancy Screener (PB, EH, TT–HI)	Age-Eligible Women	68,538	1	0.42	28,558
Provider Based Sampling Eligibility Screener (PBS).	Age-Eligible Women	9,375	1	0.25	2,344
Healthcare Provider Questionnaire (PB)	Healthcare Providers	600	1	0.17	100
Provider Based Sampling Frame Questionnaire (PBS).	Healthcare Providers	1,225	1	0.17	204
Household Enumeration Instrument (EH)	HH Reporters	120,000	1	0.33	40,000
Low-intensity Invitation to High-intensity Script (TT–HI).	Age-Eligible Women	15,840	1	0.25	3,960
Pregnancy Screener (TT–LI, TT–HI)	Age-Eligible Women	48,000	1	0.35	16,800
Low-Intensity Consent Script (TT–LI)	Age-Eligible Women	28,800	1	0.33	9,600
Nonrespondent Questionnaire (PB, EH, TT–HI, TT–LI, PBS).	Pregnant Women, Non-Pregnant Women, Mothers or Fathers.	3,000	1	0.08	250
Preconception Activities:					
Non-pregnant Women's Informed Consent (PB, EH, TT–HI).	Age-Eligible Women	1,825	1	0.50	913
Pre-Pregnancy Interview (PB, EH, TT–HI)	Age-Eligible Women	1,095	1	0.75	821
Biological and Environmental Sample Collection—Preconception (PB, EH, TT–HI).	Age-Eligible Women	986	1	0.25	246
Pregnancy Probability Group Follow Up Script (PB, EH, TT–HI, TT–LI).	Age-Eligible Women	11,152	6	0.10	6,691
Low-intensity Questionnaire (Non-Pregnant) (TT–LI).	Age-Eligible Women	10,057	1	0.50	5,029
Validation Script (PB, EH, TT–HI, TT–LI, PBS).	Age-Eligible Women	3,805	1	0.08	304
Pregnancy Activities:					
Pregnant Women's Informed Consent Form (PB, EH, TT–HI, PBS).	Pregnant Women	12,967	1	0.50	6,484
Low-intensity Questionnaire (Found Pregnant) (TT–LI).	Pregnant Women	518	1	0.50	259
Pregnancy Visit 1 Interview (PB, EH, TT–HI, PBS).	Pregnant Women	6,310	1	1.00	6,310
Biological and Environmental Sample Collection—Pregnancy (PB, EH, TT–HI, PBS).	Pregnant Women	10,363	1	0.25	2,591
Pregnancy Visit 2 Interview (PB, EH, TT–HI, PBS).	Pregnant Women	6,190	1	0.75	4,643
Pregnancy Health Care Log (PB, EH, TT–HI, PBS).	Pregnant Women	5,048	1	0.33	1,683
Father Informed Consent Form (PB, EH, TT–HI, PBS).	Alternate Caregiver	5,048	1	0.50	2,524
Father Interview (PB, EH, TT–HI, PBS)	Alternate Caregiver	3,029	1	0.25	757

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR RECRUITMENT SUBSTUDY RESPONDENTS, PRENATAL TO 30 MONTHS, PHASE 2—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
Birth-Related Activities:					
Birth Visit Interview (PB, EH, TT–HI, PBS)	Mother/Baby	3,422	1	0.40	1,369
Low-intensity Questionnaire (Birth-focus) (TT–LI).	Mother/Baby	1,296	1	0.50	648
Postnatal Activities:					
Infant Feeding Log (PB, EH, TT–HI, PBS)	Mother/Baby	3,319	1	0.33	1,106
Low-intensity Questionnaire (Child-focus) (TT–LI).	Mother/Baby	1,147	4	0.50	2,295
Biological Sample Collection—Mother/Baby (PB, EH, TT–HI, PBS).	Mother/Baby	11,635	1	1.50	17,452
3-Month Interview (PB, EH, TT–HI, PBS)	Mother/Baby	3,298	1	0.33	1,099
Core Questionnaire (PB, EH, TT–HI, TT–LI, PBS).	Mother/Child	2,911	6	0.30	5,240
6-Month Visit Interview (PB, EH, TT–HI, PBS).	Mother/Baby	3,199	1	0.50	1,599
Physical Measures (6-Month, 12-Month, 24-Month).	Baby/Child	2,677	3	0.50	4,016
9-Month Interview (PB, EH, TT–HI, PBS)	Mother/Baby	3,103	1	0.17	517
12-Month Visit Interview (PB, EH, TT–HI, PBS).	Mother/Baby	3,010	1	0.50	1,505
18-Month Interview (PB, EH, TT–HI, PBS)	Mother/Child	2,859	1	0.50	1,430
24-Month Interview (PB, EH, TT–HI, PBS)	Mother/Child	2,716	1	0.75	2,037
30-Month Visit Interview (PB, EH, TT–HI, TT–LI, PBS).	Mother/Child	2,580	1	0.92	2,365
Formative Research:					
Formative—Developmental					14,542
Grand Total, Alternate Recruitment Substudy.		415,894			182,065
Total, Formative Research					14,542
Grand Total		415,894			196,607

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 Jamelle E. Banks, Project Clearance Liaison, 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 Email 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 60 days of the date of this publication.

Dated: January 19, 2012.

Jamelle E. Banks,

Project Clearance Liaison, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2012–1934 Filed 1–27–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; 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: Vascular and Hematology Integrated Review Group, Hemostasis and Thrombosis Study Section.

Date: February 22, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Bukhtiar H Shah, Ph.D., DVM, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 435–1233, *shahb@csr.nih.gov.*