Recordkeeping	Number of record keepers	Hours per year	Total burden hours
Recordkeeping			
Non-alternative Facilities (124.510(a))	33	50	1,650.00
Unrestricted Availability (124.510(b))	30	50	1,500.00
Subtotal Recordkeeping Burden			3,150.00

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 20, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–10031 Filed 4–25–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development Submission for OMB Review; Comment Request; Provider-Based Sampling Feasibility Study for the Vanguard (Pilot) Study and Data Collection Updates for the National Children's Study (NICHD)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the 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 January 30, 2012, pages 4569–4571, and allowed 60 days for public comment. No written comments were received. 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: Provider-Based Sampling Feasibility Study for the Vanguard (Pilot) Study and Data Collection Updates for the National Children's Study (NICHD).

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 about 100 of the about 3,000 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 the summer of 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 Federal 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. One goal is to test the feasibility of Provider-Based Sampling using three study locations. Another goal is to systematically pilot additional study visit measures and collections to assess the scientific robustness, burden to participants and study infrastructure, and cost for use in the Vanguard (Pilot) Study and to inform the design of the Main Study.

Methods

Provider Based Sampling

We will compile a list of prenatal providers serving women who reside within the Primary Sampling Unit at three study locations. 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 largely follow the protocol and procedures developed for the Provider-Based 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 pregnancy status at the initial prenatal visit. In some locations, medical records may be pre-screened to identify participants meeting these eligibility criteria.

Supplemental Information and Biospecimen Collections

We will continue data collection with 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.

Core Questionnaire: We propose to pilot 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 an age-specific module alongside of the Core Questionnaire with the 30-Month Interview.

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: We 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, 12, and 24-Month infant measures of child anthropometry and/or 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: We seek 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.

Additional Instrument at the 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-Month Visits: Additional collections are needed to determine the feasibility, acceptability and cost of collection.

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

Frequency of Response: See above descriptions.

Affected Public: Healthcare providers, pregnant women, fathers, and their children. The additional annualized cost to respondents over the three-year data collection period is estimated at annualized cost of $229,804. This is calculated as estimating 31,082 respondent contacts at an estimated average of 0.73 hours per contact, for a total estimated annual respondent burden as 22,791 hours. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours	Estimated total annual respondent cost
Screening Activities						
Provider Based Sampling Eligibility Screener (PBS)	Pregnant Women	3,125	1	20/60	1,042	$10,417
Provider Based Sampling Frame Questionnaire (PBS)	Healthcare Providers	50	1	25/60	21	2,104
Continuous Activities						
Nonrespondent Questionnaire (PB, EH, TT–HI, TT–LI, PBS)	Pregnant Women, Mothers or Fathers	480	1	5/60	40	400
Validation Interview—up to 30 Months (PB, EH, TT–HI, TT–LI, PBS).	Respondents	1,268	1	5/60	106	$1,057
Participant Verification (PB, EH, TT–HI, TT–LI, PBS).	Pregnant Women, Mothers or Fathers.	2,320	1	5/60	193	1,933
Tracing Interview (PB, EH, TT–HI, TT–LI, PBS).	Respondents	1,167	13	10/60	2,528	25,281
Pregnancy Activities						
Low-intensity Questionnaire (Found Pregnant) (TT–LI).	Pregnant Women	173	1	15/60	43	432

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours	Estimated total annual respondent cost
Pregnancy Visit 1 Interview (PB, EH, TT–HI, PBS).	Pregnant Women	2,018	1	35/60	1,177	11,774
Pregnancy Visit 2 Interview (PB, EH, TT–HI, PBS).	Pregnant Women	1,817	1	25/60	757	7,569
Biological and Environmental Sample Collection—Prenatal (PB, EH, TT–HI).	Pregnant Women	1,456	2	60/60	2,913	29,127
Pregnancy Health Care Log (PB, EH, TT–HI, PBS).	Pregnant Women	1,615	1	20/60	538	5,382
Father Interview (PB, EH, TT–HI)	Alternate Caregiver.	818	1	35/60	477	4,770
Birth-Related Activities						
Birth Visit Interview (PB, EH, TT–HI, PBS).	Mother/Baby	1,141	1	20/60	380	3,802
Low-intensity Questionnaire (Birth-focus) (TT–LI).	Mother/Baby	432	1	15/60	108	1,080
Postnatal Activities						
Infant Feeding Log (PB, EH, TT–HI, PBS).	Mother/Baby	1,106	1	20/60	369	3,688
Biological Sample Collection—Mother/Baby (PB, EH, TT–HI).	Mother/Baby	761	4	22.5/60	1,141	11,411
3-Month Interview (PB, EH, TT–HI, TT–LI, PBS).	Mother/Baby	1,518	1	20/60	506	5,061
6-Month Interview (PB, EH, TT–HI, PBS).	Mother/Baby	1,066	1	30/60	533	5,331
Physical Measures—Child Anthropometry (6-,12-, 24-Month) (PB, EH, TT–HI).	Baby/Child	701	3	20/60	701	7,014
Physical Measures—Child Blood Pressure (12-, 24-Month) (PB, EH, TT–HI).	Baby/Child	675	2	10/60	225	2,250
9-Month Interview (PB, EH, TT–HI, TT–LI, PBS).	Mother/Baby	1,428	1	10/60	238	2,381
12-Month Interview (PB, EH, TT–HI, PBS).	Mother/Baby	1,003	1	50/60	836	8,360
18-Month Interview (PB, EH, TT–HI, TT–LI, PBS).	Mother/Child	1,316	1	30/60	658	6,582
24-Month Interview (PB, EH, TT–HI, TT–LI, PBS).	Mother/Child	1,251	1	35/60	729	7,295
Core Questionnaire (PB, EH, TT–HI, TT–LI, PBS).	Mother/Child	1,188	1	30/60	594	5,940
30-Month Visit Interview (PB, EH, TT–HI, TT–LI, PBS).	Mother/Child	1,188	1	55/60	1,089	10,890
Total, Vanguard (Pilot) Study	.....	31,082	.....	.....	17,943	181,331
Total, Formative Research	.....	.....	.....	.....	4,847	48,473
Grand Total	.....	31,082	.....	.....	22,791	229,804

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 Email 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 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 30 days of the date of this publication.

Dated: April 16, 2012.

Jamelle E. Banks,

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

[FR Doc. 2012–10113 Filed 4–25–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications.

Date: May 16, 2012.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Maja Maric, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, Room 3266, Bethesda, MD 20892–7616, 301–451–2634, *maja.maric@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 19, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10089 Filed 4–25–12; 8:45 am]

BILLING CODE 4140–01–P

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: Center for Scientific Review Special Emphasis Panel RFA–RM–11–016 Regional Comprehensive Metabolomics Resource Cores.

Date: May 15–16, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: James J Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–806–8065, *lijames@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR12–010 Smoking and Tobacco Revision Applications: Social Sciences and Population Studies.

Date: May 21–22, 2012.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Social Sciences and Population Studies: Second Panel.

Date: May 21–22, 2012.

Time: 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Myocardial Metabolism, Ischemia and Heart Failure.

Date: May 22, 2012.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435–1195, *Chengy5@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 19, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10088 Filed 4–25–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Risk, Prevention and Health Behavior.

Date: May 9–10, 2012.

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