717–757–2888, FAX: 717–650–3650, or e-mail: *afdo@afdo.org.*

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following:

- Globalization, Imports, and Supplier Controls,
- Medical Product Theft and Criminal Investigations,
- Proposed Changes to the 510(K) Review Process,
- Health Fraud,
- Streamlining the FDA Enforcement Process,
- The Future of Medical Products Regulation,
- Medical Devices in Canada,
- The Freedom of Information Act,
- Medical Product Complaint Investigations,
- Writing Corrective and Preventive Actions Procedures and Documents to Reflect Compliance Initiatives, and
- Top Ten FDA–483 Objectionable Observations.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

Dated: February 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2458 Filed 2–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Revision to Proposed Collection; Comment Request; The National Children's Study (NCS), Vanguard (Pilot) Study

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 November 15, 2010, pages 69680–69681, and allowed 60 days for public comment. One comment was received. The comment questioned the value and utility of the proposed data collection, stating that this type of research is not needed. 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: Pilot Study for the National Children's Study *Type of Information Collection Request:* Revision. *Affected entities:* Households and individuals. *Types of respondents:* People potentially affected by this action are pregnant women, women age 18–49 years of age, their husbands or partners, and their children who live in selected areas within National Children's Study sites. Health care professionals, community leaders, and child care personnel are also potentially affected.

Frequency of Response: On occasion. See burden table for estimated number of annual responses for each respondent.

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 (NCS) to evaluate the feasibility, acceptability, and cost of recruitment strategies and study design elements for a prospective, national longitudinal study of child health and development. In combination, the sub-studies encompassed by the Vanguard Phase will be used to inform the design of the Main Study of the National Children's Study.

We propose to continue data collection among the 37 Vanguard Study locations up to and including the visit planned to take place when the sample children have reached 24 months of age. This would align study visits approved for the initial 7 Vanguard Study locations (which extend past the birth visit to include a 3-, 6-, 9-, 12-, 18- and 24-month visit) with the study visits approved for the 30 additional Vanguard Study locations (which were initially proposed and approved up to and including the birth visit). Extending the data collection of the 30 additional Vanguard Study locations to 24 months of age would support rigorous, empirical evaluation of participant retention as it may relate to recruitment strategy. A strong understanding of how to encourage retention of study participants, particularly during the infancy and early childhood years, will be essential to planning the Main Study. Additionally, continuing data collection post-birth among the alternate recruitment strategy study locations allows us to generate additional data to inform the development of study visit procedures, both for future Vanguard Study efforts and the Main Study.

We also propose reintroduction of a limited set of study visit measures to all 37 of the Vanguard Study locations engaged in data collection. Recall that extensive measures, including biospecimens, were previously approved for use in the initial 7 Vanguard Study locations. When the additional 30 locations were added, we streamlined data collection to allow focus on improving recruitment rates. Now that we have the training for those new locations (and retraining for the initial locations) completed, it is an opportune time to reintroduce selected measures that have the benefit of field experience. That field experience has been used to improve their scientific robustness, burden, and cost. These improved measures now require field testing to best inform their suitability for the Main Study. Specifically, we would like to reincorporate a father interview; maternal blood and urine collection; infant cord blood collection; home tap water and dust collection; a pregnancy health care log; and an infant and child health care log. In addition to supporting further testing of refined items, including these measures in the Recruitment Substudy would result in a data collection scope more closely mirroring the anticipated scope of the Main Study, thereby allowing better gauge of data collection scope and

resources and the relationship with retention and study logistics over time.

We will evaluate the feasibility (technical performance), acceptability (respondent tolerance and impact on study infrastructure), and cost (operations, time, and effort) of each recruitment and retention strategy using pre-determined measures. We will compare these findings and use them as a basis to inform the strategies, or combinations of strategies, that might be used in the Main Study of the NCS. Further details pertaining to the NCS background and planning can be found at: *http://www.nationalchildrensstudy.gov.*

Burden statement: The additional public burden for this study will vary depending on the method of recruitment. The table below provides the annualized average burden per person over the two-year data collection period for all three alternate recruitment strategies.

The additional annualized cost to respondents over the two-year data collection period for the 30 locations engaged in the alternate recruitment strategies to extend data collection from birth to age 2 is estimated at $82,000 (based on $10 per hour) and the differential time estimates in Table A.2.e, below. To reintroduce the proposed measures into the 30 locations engaged in the alternate recruitment strategies, the annualized cost to respondents over the same period is estimated at an additional $79,000 (based on $10 per hour) and the differential time estimates in Table A.2.e, below. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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Table A.2.a Estimated Additional Hour Burden and Cost for the Recruitment Substudy Respondents, Postnatal to Age 2, PROVIDER-BASED

Strategy	Activity	Type of Respondent	Number of Respondents	Responses per Respondent	Hours per Response	Annual Hour Burden	Annual Respondent Cost
Provider-Based	**Screening Activities**						
	Address Lookup Tool	Age-Eligible Women	7,500	1	0.10	750	$7,500
	Pregnancy Screener (Provider Based)	Age-Eligible Women	1,500	1	0.40	600	$6,000
	Healthcare Provider Questionnaire	Healthcare Providers	600	1	0.16	96	$960
	Preconception Activities						
	Non-pregnant Women's Informed Consent	Age-Eligible Women	205	1	0.50	103	$1,025
	Pre-Pregnancy Interview	Age-Eligible Women	123	1	0.75	92	$923
	Pre-Pregnancy Blood and Urine Collection	Age-Eligible Women	111	1	0.25	28	$277
	Pregnancy Probability Group Script	Age-Eligible Women	123	6	0.10	74	$738
	Validation Script	Age-Eligible Women	225	1	0.08	19	$188
	Pregnancy Activities						
	Pregnant Women's Informed Consent Form	Pregnant Women	1,295	1	0.50	648	$6,475
	Pregnancy Visit 1 Interview	Pregnant Women	572	1	1.00	572	$5,720
	Pregnancy Visit 1 Blood and Urine Collection	Pregnant Women	415	1	0.25	104	$1,038
	Pregnancy Visit 2 Interview	Pregnant Women	572	1	0.75	429	$4,290
	Pregnancy Visit 2 Blood and Urine Collection	Pregnant Women	515	1	0.25	129	$1,287
	Pregnancy Health Care Log	Pregnant Women	458	1	0.33	153	$1,525
	Father Informed Consent Form	Alternate Caregiver	458	1	0.50	229	$2,288
	Father Interview	Alternate Caregiver	275	1	0.25	69	$686
	Birth-Related Activities						
	Birth Visit Interview	Mother/Baby	299	1	0.40	120	$1,196
	Total, Prenatal and Birth Activities		***15,244***			***4,212***	***$42,115***
	Postnatal Activities						
	Infant/Child Health Care Log	Mother/Baby	290	1	0.33	96	$957
	3-Month Phone Call	Mother/Baby	290	1	0.33	96	$957
	6-Month Visit Interview	Mother/Baby	281	1	0.50	141	$1,407
	9-Month Phone Call	Mother/Baby	273	1	0.17	46	$464
	12-Month Visit Interview	Mother/Baby	265	1	0.50	132	$1,324
	18-Month Maternal Phone Call	Mother/Baby	251	1	0.50	126	$1,257
	24-Month Maternal Phone Call	Mother/Baby	239	1	0.50	119	$1,194
	Total, Postnatal to 24-Month		***1,889***			***756***	***$7,560***
	Total, Provider-Based		**17,134**			**4,968**	**$49,675**

Table A.2.b Estimated Additional Hour Burden and Cost for the Recruitment Substudy Respondents, Postnatal to Age 2, ENHANCED HOUSEHOLD

Strategy	Activity	Type of Respondent	Number of Respondents	Responses per Respondent	Hours per Response	Annual Hour Burden	Annual Respondent Cost
Enhanced Household	**Screening Activities**						
	Household Enumeration Instrument	HH Reporters	120,000	1	0.33	39,600	$396,000
	Pregnancy Screener (Enhanced Household)	Age-Eligible Women	51,198	1	0.42	21,503	$215,032
	Preconception Activities						
	Non-pregnant Women's Informed Consent	Age-Eligible Women	352	1	0.50	176	$1,758
	Pre-Pregnancy Interview	Age-Eligible Women	211	1	0.75	158	$1,583
	Pre-Pregnancy Blood and Urine Collection	Age-Eligible Women	190	1	0.25	47	$475
	Pregnancy Probability Group Script	Age-Eligible Women	211	6	0.10	127	$1,266
	Validation Script	Age-Eligible Women	388	1	0.08	31	$311
	Pregnancy Activities						
	Pregnant Women's Informed Consent Form	Pregnant Women	2,236	1	0.50	1,118	$11,180
	Pregnancy Visit 1 Interview	Pregnant Women	986	1	1.00	986	$9,860
	Pregnancy Visit 1 Blood and Urine Collection	Pregnant Women	716	1	0.25	179	$1,791
	Pregnancy Visit 2 Interview	Pregnant Women	986	1	0.75	740	$7,395
	Pregnancy Visit 2 Blood and Urine Collection	Pregnant Women	887	1	0.25	222	$2,219
	Pregnancy Health Care Log	Pregnant Women	789	1	0.33	263	$2,629
	Father Informed Consent Form	Alternate Caregiver	789	1	0.50	394	$3,944
	Father Interview	Alternate Caregiver	473	1	0.25	118	$1,183
	Birth-Related Activities						
	Birth Visit Interview	Mother/Baby	516	1	0.40	206	$2,064
	Total, Prenatal and Birth Activities		***180,928***			***65,869***	***$658,689***
	Postnatal Activities						
	Infant/Child Health Care Log	Mother/Baby	501	1	0.33	165	$1,652
	3-Month Phone Call	Mother/Baby	501	1	0.33	165	$1,652
	6-Month Visit Interview	Mother/Baby	486	1	0.50	243	$2,428
	9-Month Phone Call	Mother/Baby	471	1	0.17	80	$801
	12-Month Visit Interview	Mother/Baby	457	1	0.50	228	$2,284
	18-Month Maternal Phone Call	Mother/Baby	434	1	0.50	217	$2,170
	24-Month Maternal Phone Call	Mother/Baby	412	1	0.50	206	$2,061
	Total, Postnatal to 24-Month		***3,261***			***1,305***	***$13,047***
	Total, Enhanced Household		**184,189**			**67,174**	**$671,736**

Table A.2.c Estimated Additional Hour Burden and Cost for the Recruitment Substudy Respondents, Postnatal to Age 2, TWO TIER HIGH INTENSITY

Strategy	Activity	Type of Respondent	Number of Respondents	Responses per Respondent	Hours per Response	Annual Hour Burden	Annual Respondent Cost
Two-Tier (High)	**Screening Activities**						
	Invitation from Low- to High-intensity Script	Age-Eligible Women	15,840	1	0.25	3,960	$39,600
	Pregnancy Screener	Age-Eligible Women	15,840	1	0.42	6,653	$66,528
	Preconception Activities						
	Non-pregnant Women's Informed Consent	Age-Eligible Women	1,268	1	0.50	634	$6,342
	Pre-Pregnancy Interview	Age-Eligible Women	761	1	0.75	571	$5,708
	Pre-Pregnancy Blood and Urine Collection	Age-Eligible Women	685	1	0.25	171	$1,712
	Pregnancy Probability Group Script	Age-Eligible Women	761	6	0.10	457	$4,566
	Validation Script	Age-Eligible Women	1,426	1	0.08	114	$1,141
	Pregnancy Activities						
	Pregnant Women's Informed Consent Form	Pregnant Women	8,236	1	0.50	4,118	$41,180
	Pregnancy Visit 1 Interview	Pregnant Women	3,552	1	1.00	3,552	$35,520
	Pregnancy Visit 1 Blood and Urine Collection	Pregnant Women	2,580	1	0.25	645	$6,451
	Pregnancy Visit 2 Interview	Pregnant Women	3,552	1	0.75	2,664	$26,640
	Pregnancy Visit 2 Blood and Urine Collection	Pregnant Women	3,197	1	0.25	799	$7,992
	Pregnancy Health Care Log	Pregnant Women	2,842	1	0.33	947	$9,472
	Father Informed Consent Form	Alternate Caregiver	2,842	1	0.50	1,421	$14,208
	Father Interview	Alternate Caregiver	1,705	1	0.25	426	$4,262
	Birth-Related Activities						
	Birth Visit Interview	Mother/Baby	1,857	1	0.40	743	$7,428
	Total, Prenatal and Birth Activities		2,842	1	0.50	1,421	$14,208
	Postnatal Activities						
	Infant/Child Health Care Log	Mother/Baby	1,801	1	0.33	594	$5,944
	3-Month Phone Call	Mother/Baby	1,801	1	0.33	594	$5,944
	6-Month Visit Interview	Mother/Baby	1,747	1	0.50	874	$8,736
	9-Month Phone Call	Mother/Baby	1,695	1	0.17	288	$2,881
	12-Month Visit Interview	Mother/Baby	1,644	1	0.50	822	$8,220
	18-Month Maternal Phone Call	Mother/Baby	1,562	1	0.50	781	$7,809
	24-Month Maternal Phone Call	Mother/Baby	1,484	1	0.50	742	$7,418
	Total, Postnatal to 24-Month Activities		***11,734***			***4,695***	***$46,949***
	Total, Two-Tier (High)		**14,007**			**5,832**	**$58,316**

Table A.2.d Estimated Additional Hour Burden and Cost for the Recruitment Substudy Respondents, Postnatal to Age 2, TWO TIER LOW INTENSITY

Strategy	Activity	Type of Respondent	Number of Respondents	Responses per Respondent	Hours per Response	Annual Hour Burden	Annual Respondent Cost
Two-Tier (Low)	**Screening Activities**						
	Pregnancy Screener (TT-LI, TT-HI)	Age-Eligible Women	48,000	1	0.35	16,800	$168,000
	Low-Intensity Consent Script	Age-Eligible Women	28,800	1	0.33	9,504	$95,040
	Preconception and Pregnancy Activities						
	Low-intensity Questionnaire (Non-Pregnant)	Age-Eligible Women	10,057	1	0.50	5,029	$50,285
	Pregnancy Probability Group Script	Age-Eligible Women	10,057	6	0.10	6,034	$60,342
	Low-intensity Questionnaire (Pregnant)	Pregnant Women	518	1	0.50	259	$2,590
	Father Low Intensity Informed Consent Form	Alternate Caregiver	1,451	1	0.33	484	$4,837
	Father Low Intensity Interview	Alternate Caregiver	871	1	0.17	145	$1,451
	Validation Script	Age-Eligible Women	1,586	1	0.08	127	$1,269
	Birth-Related Activities						
	Low-intensity Questionnaire (Birth-focus)	Mother/Baby	1,296	1	0.50	648	$6,480
	Total, Prenatal and Birth Activities		***102,636***			***39,029***	***$390,295***
	Postnatal Activities						
	Low-intensity Questionnaire (Child-focus)	Mother/Baby	1,147	4	0.50	2,295	$22,947
	Total, Postnatal to 24-Month Activities		***1,147***			***2,295***	***$22,947***
	Total, Two-Tier (Low)		**103,784**			**41,324**	**$413,241**

Table A.2.e Estimated Additional Hour Burden and Cost for the Recruitment Substudy Respondents, Postnatal to Age 2, COMBINED TOTAL

Activity	Number of Respondents	Annual Hour Burden	Annual Respondent Cost
Total, Prenatal and Birth, Recruitment Substudy	301,082	110,247	**$1,10247**
Total, Postnatal to 24-Months, Recruitment Substudy*	15,440	8,195	**$81,954**
Total, Reintroduction of Selected Measures, Prenatal and Postnatal	24,839	7,828	**$78,277**

* Infant health care log hours are represented in the tally of hours for the reintroduction of selected measures.

BILLING CODE 4140–01–C

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 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.

FOR FURTHER INFORMATION CONTACT: 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, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jamelle E. Banks, M.P.H., National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call non-toll free number (301) 443–7210, or e-mail 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: January 28, 2011.

Jamelle E. Banks,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011–2539 Filed 2–3–11; 8:45 am]

BILLING CODE 4140–01–P