displays a currently valid OMB control number.

Proposed Collection: Title: STAR METRICS.

Science and Technology for America's Reinvestment: Measuring the Effects of Research on Innovation, Competitiveness and Science. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The aim of STAR METRICS is twofold. The initial goal of STAR METRICS is to provide mechanisms that will allow participating universities and Federal agencies with a reliable and consistent means to account for the number of scientists and staff that are on research institution payrolls, supported by Federal funds. In subsequent generations of the program, it is hoped that STAR METRICS will allow for measurement of science impact on economic outcomes (such as job creation), on knowledge generation (such as citations and patents) as well as on social and health outcomes.

Frequency of Response: Quarterly.

Affected Public: Universities.

Type of Respondents: University administrators.

Estimated Number of Respondents: 100.

Estimated Number of Responses per Respondent: 4.

Average Burden Hours per Response: Reduced by 156; and

Estimated Total Annual Burden Hours Requested: Reduced by 15,600.

The annualized cost to respondents is estimated to be reduced by $780,000. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

A.12—1 ESTIMATES OF NET HOUR BURDEN REDUCTION

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Stage 1: Immediate	100	1	72	+7200
Stage 1: Expected Reduction in Current burden (assuming 100 universities and at median)	100	4	40	−16000
Net reduction in burden	100	4		−8800
Stage 1: Future	100	4	1.0	+400
Stage 2: Expected Reduction in Current burden (assuming 100 universities and at median)	100	4	40	−16000
Net reduction in burden	100	4		−15600

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.

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 the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, 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: Dr. Stefano Bertuzzi, MSC 0166, Building 1 Room 218, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–496–9286 or E-mail your request, including your address to: *Stefano.bertuzzi@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: June 2, 2010.

Laverne Stringfield,

Executive Officer, Office of the Director, National Institutes of Health.

[FR Doc. 2010–13736 Filed 6–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Revision to Proposed Collection; Comment Request; the National Children's Study (NCS), Vanguard (Pilot) Study, Recruitment Substudy Phase 1

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 March 22, 2010, pages 14165–14168, 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 evaluate the feasibility, acceptability, and cost of three separate recruitment strategies for enrollment of women into a prospective, national longitudinal study of child health and development. This Recruitment Substudy is a component of the Vanguard Phase of the National Children's Study (NCS). In combination, the studies in the Vanguard Phase will be used to inform the design of the Main Study of the National Children's Study.

This data collection will evaluate the feasibility, acceptability and cost of three separate recruitment strategies for enrollment of women into the NCS. Up to 30 additional sites will be added to the NCS Vanguard Cohort, as reflected in the burden table, in order to ensure an adequate cohort size. These additional sites will be chosen from among those already identified for the Main Study of the NCS. Across these additional sites, three alternate recruitment strategies will be assessed:

- An enhanced household enumeration strategy that builds on the lessons learned in the existing Vanguard Study by enhancing enumeration techniques and employing a more streamlined recruitment process;
- A provider based recruitment strategy that relies on health care providers for assistance in participant identification and recruitment; and
- A two-tiered recruitment strategy that relies on larger secondary sampling units to increase the number of geographically-eligible women in a given area, and allows for both higher-intensity and lower-intensity forms of data collection.

The feasibility (technical performance), acceptability (respondent tolerance and impact on study infrastructure), and cost (operations, time, and effort) of each of these three strategies will be evaluated using pre-determined measures. The findings will be assessed and used 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 statemen*t: The public burden for this study will vary depending on the eligibility and pregnancy status of potential participants at the time of household screening and the method of recruitment. The table below provides an annualized average burden per person for each stage of the Recruitment Substudy.

TABLE 1—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1

[July 2010 to December 2010]

Recruitment strategy/activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
Provider-based: 10 Study Locations—Projected for Stage 1 (July 2010–December 2010)					
Screening Activities					
Address Look-Up	Age-Eligible Women	7,500	1	0.1	750
Pregnancy Screening	Age-Eligible Women	1,500	1	0.42	630
Preconception Activities					
Pre-Pregnancy Interview	Age-Eligible Women	123	1	0.75	92
PPG Follow Up Script	Age-Eligible Women	123	6	0.1	74
Pregnancy Activities					
Women's Informed Consent Form	Pregnant Women	1,500	1	0.67	1,005
First Pregnancy Interview	Pregnant Women	572	1	1	572
Second Pregnancy Interview	Pregnant Women	572	1	0.75	429
Birth-Related Activities					
Birth Visit Interview	Mother/Baby	299	1	0.4	120
Total—Stage 1		12,188			3,671
Enhanced Household: 10 Study Locations—Projected for Stage 1 (July 2010–December 2010)					
Screening Activities					
Household Enumeration Script	HH reporters	120,000	1	0.33	39,600
Pregnancy Screening	Age-Eligible Women	51,198	1	0.42	21,503
Neighbor Report	Neighbors	12,000	1	0.05	600
Preconception Activities					
Pre-Pregnancy Interview	Age-Eligible Women	211	1	0.75	158
PPG Follow Up Script	Age-Eligible Women	211	6	0.1	127
Pregnancy Activities					
Women's Informed Consent Form	Pregnant Women	2,586	1	0.67	1,733
First Pregnancy Interview	Pregnant Women	986	1	1	986
Second Pregnancy Interview	Pregnant Women	986	1	0.75	740
Birth-Related Activities					
Birth Visit Interview	Mother/Baby	516	1	0.4	206
Total—Stage 1		188,695			65,653
Two Tier (Low): 10 Study Locations Across Both Tiers—Projected for Stage 1 (July 2010–December 2010)					
Screening Activities					
Low-intensity CATI Preg. Screener	Age-Eligible Women	48,000	1	0.35	16,800
Low Intensity Consent Script	Age-Eligible Women	28,800	1	0.33	9,504
Preconception Activities					

TABLE 1—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1—Continued

[July 2010 to December 2010]

Recruitment strategy/activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
Low-intensity CATI Questionnaire	Age-Eligible Women	10,057	1	0.5	5,028
PPG Follow Up Script	Age-Eligible Women	10,057	6	0.1	6,034
Pregnancy Activities					
Low-intensity CATI Questionnaire	Pregnant Women	518	1	0.5	259
Birth-Related Activities					
Low-intensity CATI Questionnaire	Mother/Baby	166	1	0.5	83
Total—Stage 1		97,598			37,709
Two Tier (High): 10 Study Locations Across Both Tiers—Projected for Stage 1 (July 2010–December 2010)					
Screening Activities					
Pregnancy Screening	Age-Eligible Women	15,840	1	0.42	6,653
Preconception Activities					
Pre-Pregnancy Interview	Age-Eligible Women	761	1	0.75	571
PPG Follow Up Script	Age-Eligible Women	761	6	0.1	456
Pregnancy Activities					
Women's Informed Consent Form	Pregnant Women	9,504	1	0.67	6,368
First Pregnancy Interview	Pregnant Women	3,552	1	1	3,552
Second Pregnancy Interview	Pregnant Women	3,552	1	0.75	2,664
Birth-Related Activities					
Birth Visit Interview	Mother/Baby	1,857	1	0.4	743
Total—Stage 1		35,826			21,006
Grand Total, Recruitment Substudy.		334,308			176,876

The estimated annualized cost to respondents is $1,782,053 based on the differential hourly rate estimates in the above table. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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: Sarah L. Glavin, Ph.D., 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 e-mail your request, including your address to *glavins@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: June 2, 2010.

Sarah L. Glavin,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–13705 Filed 6–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0250]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for premarket approval of medical devices.

DATES: Submit either electronic or written comments on the collection of information by August 9, 2010.