[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request:

Child Health Disparities Substudy for the National Children's 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 March 16, 2012, pages 15780-15782 (Volume 77, Number 52) of the Federal Register 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: Child Health Disparities Substudy for the National Children's Study (NCS). Type of Information Collection Request: NEW. Need and Use of Information Collection: The Children's Health Act of 2000 (Public Law 106-310) states:

> (a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.
> (b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—
> (1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
> (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.
> (c) REQUIREMENT.—The study under subsection (b) shall—
> (1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;
> (2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and
> (3) consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the Child Health Disparities Substudy will validate measures needed for studying health disparities and selected biomarkers. Utilizing cognitive interview techniques and components of standardized questionnaires, responses will be used to assess and validate measures of health literacy, discrimination, parenting self-efficacy, and health care accessibility. Acceptability and feasibility of saliva collection from a subsample of women and young children will also be evaluated. The incorporation of saliva measurements will increase

understanding of biological responses to environmental factors and how these may be correlated with health disparities within this population.

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. By studying children through their different phases of growth and development, researchers will be better able to understand the role these factors have on health and disease. 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 is led by a consortium of federal partners: the U.S. Department of Health and Human Services (including the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention), and the U.S. Environmental Protection Agency.

To conduct the detailed preparation needed for a study of this size and complexity, the NCS was designed to include a preliminary pilot study known as the Vanguard Study. The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study procedures, and outcome assessments that are to be used in the NCS Main Study. The Vanguard Study begins prior to the NCS Main Study and will run in parallel with the Main Study. At every phase of the NCS, the multiple methodological studies conducted during the Vanguard phase will inform the implementation and analysis plan for the Main Study.

In this information collection request, the NCS requests approval from OMB to perform a multi-center substudy called the Child Health Disparity Substudy. This substudy aims to validate measures needed for studying health disparities and selected biomarkers. Developing optimum measures for studying health disparities is of particular interest to the NCS because studies have shown that health literacy, discrimination, parenting self-efficacy, health care (access, utilization, and quality) contribute to health disparities. Additionally, aspects of the social environment such as social isolation, lack of control and contingency and social support, violence, discrimination, challenging and changing social relationships, and restricted access to health care are thought to interact with biological processes. Variation in these processes has been associated with negative emotional states, cognitive deficits, problem behavior, and a variety of metabolic and immune-related processes. Alone, or particularly in combination with other commonly collected measures of social forces and family relationships, salivary analytes have the potential to advance our understanding of maternal and child health and development. This project will make its contribution to the NCS Main Study and to the health disparities field as a whole by constructing a validated set of questionnaire measures and biomarker analyses that can be used among pregnant women and mothers of young children for the purpose of investigating disparities.

Frequency of Response*:* One-time data collection conducted in multiple phases

Affected Public: Pregnant women, mothers with young children, and their children

Type of Respondents: Pregnant women, mothers with young children, and their children who are not geographically eligible to enroll in the NCS Vanguard Study

Annual reporting burden: See Table 1. The annualized cost to respondents is estimated at $25,000 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Table 1. Estimated Annual Reporting Burden and Cost Summary, Child Health Disparities Substudy

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 for Cognitive Interview	Mothers of children ages 0-5	Members of NCS target population (not NCS participants)	100	1	5/ 60	8	$83
Screening for Primary Data Collection	Women	Members of NCS target population (not NCS participants)	2,000	1	5 / 60	167	$1,667
Screening for Saliva Collection	Women	Members of NCS target population (not NCS participants)	600	1	5/60	50	$500
Cognitive Interview	Mothers of children ages 0-5	Members of NCS target population (not NCS participants)	60	1	75 / 60	75	$750
Primary Data Collection	Pregnant Women / Mothers of children ages 0-5	Members of NCS target population (not NCS participants)	600	2	65 / 60	1,300	$13,000
	Mothers of children ages 0-5		600	1	65/ 60	650	$6,500
Saliva Collection	Pregnant Women / Mothers of children	Members of NCS target population (not NCS	200	2	15 / 60	100	$1,000

Table 1. Estimated Annual Reporting Burden and Cost Summary, Child Health Disparities Substudy							
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**
	ages 0-5						
	Additional mothers of children ages 0-5		200	1	15 / 60	50	$500
	Children ages 0-5	participants)	400	1	15 / 60	100	$1,000*
Total			**4,760**			**2,500**	**$25,000**

* The allotted hourly wage rate accounts for the mother's time associated with the data collection activity.

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.

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 E-mail 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 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: June 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. 2012-16028 Filed 06/28/2012 at 8:45 am; Publication Date: 06/29/2012]