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, 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 data collection 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 substudies encompassed by the Vanguard phase 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, and biological factors 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 includes 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 strategies, study logistics, and study visit measures that are to be used in the design of 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.

The Vanguard Study is conducted through study locations across the United States. Seven of these locations began recruitment in the winter and spring of 2009, and an additional 30 locations will begin recruiting in late 2010. These 30 sites were added to the Vanguard Study to evaluate the feasibility, acceptability and cost of three separate recruitment strategies for enrollment of pregnant women into the NCS; additional study locations were established to yield greater precision in statistical analyses. The original seven sites used a household enumeration and screening strategy to identify eligible women for recruitment into the study. The 30 sites that entered the study in 2010 are recruiting pregnant women as participants using three methods: (a) A provider-based recruitment method, where women are recruited via their health care providers; (b) an enhanced household enumeration method; and (c) a two-tiered recruitment procedure where women are offered participation in a lower-intensity data collection and then may be able to convert to a higher-intensity data collection. These sites have been collecting data relating to the pre-pregnancy, pregnancy, and birth periods. The original seven Vanguard sites have been collecting data relating to the pre-pregnancy, pregnancy, and birth periods, as well as postnatal data collection points at 3-, 6-, 9- and 12-months of age.

Methods

We propose to continue data collection during this phase of the Vanguard Study among the 37 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 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.

Frequency of Response: See above descriptions.

Affected Public: Pregnant women and their children.

The additional annualized cost to respondents over the two-year data collection period for all three recruitment strategies combined is estimated at annualized respondent cost of $*75,000* (based on $10 per hour). This is calculated as estimating 15,000 respondents across all three recruitment strategies, contacted once per visit, at an estimated average of .5 hours per response, for a total estimated annual respondent burden as 7,500 hours. 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 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 Dr. Sarah L. Glavin, Deputy Director, 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 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 60 days of the date of this publication.

Dated: November 5, 2010.

Sarah L. Glavin,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; California Health Interview Survey Cancer Control Module (CHIS–CCM) 2011 (NCI)

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 Cancer Institute (NCI), 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: California Health Interview Survey Cancer Control Module (CHIS–CCM) 2010. *Type of Information Collection Request: Revision. Need and Use of Information Collection:* The NCI has sponsored five Cancer Control Modules in the California Health Interview Survey (CHIS), and will be sponsoring a sixth to be administered in 2011. CHIS is a telephone survey that collects population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the State. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults, in 2005 to 43,020 adults, and in 2007 to 48,150 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2011 is planned for continual administration to 48,150 adults and 3,316 adolescent Californians. This study will allow NCI to examine patterns and trends in cancer screening and follow-up, as well as to study other cancer-related topics such as tobacco control, diet, physical activity, obesity, and human papillomavirus. Additionally, CHIS is designed to be comparable to the National Health Interview Survey (NHIS) data in order to conduct comparative analyses. CHIS provides enhanced estimates for cancer risk factors and screening among racial/ethnic minority populations. *Frequency of Response:* Once. *Affected public:* Individuals. *Types of Respondents:* U.S. adults and adolescents (persons 12 years of age and older). The total annual burden hours requested are 2,177 (see Table 1). There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response—minutes/hours	Annual hour burden
Adults	Adult Pilot	50	1	8/60 (0.133)	6.67
	Adult Survey	16,000	1	8/60 (0.133)	2,133.33
Adolescents	Adolescent Pilot	6	1	2/60 (0.033)	0.20
	Adolescent Survey	1,100	1	2/60 (0.033)	36.67
Total		17,156			2,176.87

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 proposed 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: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nancy Breen, PhD, Project Officer, National Cancer Institute, EPN 4094, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20852–7344, or call non-toll