U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Centers for Disease Control and Prevention
U.S. ENVIRONMENTAL PROTECTION AGENCY

THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT

DATE: April 20, 2011

TO: Dr. Margo Schwab, Dr. Julie Wise
Office of Management and Budget
Office of Information and Regulatory Affairs

FROM: Dr. Jennifer Park

THROUGH: Dr. Steven Hirschfeld

SUBJECT: Request for Non-Substantive Change to National Children's Study, Vanguard (Pilot) Study (OMB Control #0925-0593, Expiration July 31, 2013) – Inclusion of Formative Research Projects: LOIX-QUEX-01-B, LOI2-INF-17, LOI3-ENV-01-D

CC: Dr. Sarah Glavin, Ms. Jamelle Banks, Ms. Seleda Perryman, Ms. Mikia Currie

---

We request non-substantive change to the National Children's Study (NCS) Vanguard (Pilot) Study protocol approved as revised by the Office of Information and Regulatory Affairs (OIRA) on April 13, 2011.

We request that three formative research projects, LOIX-QUEX-01-B ("Evaluation of Household Inventory Questionnaire to Increase Response Rate and Efficiency"), LOI2-INF-17 ("Feasibility and Acceptability of Alternate Methods of Postnatal 3- and 9-Month Phone Interview Data Collection"), and LOI3-ENV-01-D ("Evaluating methods for dust collection to quantify exposure to semivolatile organic compounds (SVOCs)"), be approved under the NCS Vanguard (Pilot) Study (OMB Control #0925-0593, Expiration Date: July 31, 2013).

The above-mentioned formative research projects align with the current scope of work for the NCS Vanguard Study. Recall the NCS Vanguard Study is designed to assess the feasibility (technical performance and reliability), acceptability (impact on study participants and study infrastructure), and cost (level of effort, personnel, resources, and money) of recruitment, study visit measures, and study logistics to inform the NCS Main Study. Additionally, these formative research projects would be implemented with NCS participants, and do not feature aspects that would interfere with the comparison of recruitment and retention strategies described in the Alternate Recruitment Substudy of the NCS Vanguard Study.

The purpose, mode(s) of data collection, and rationale for inclusion in the NCS Vanguard Study for the formative research projects mentioned above are noted in Table 1.

Table 1. Candidate Projects for Non-Substantive Change to the NCS Vanguard Study (OMB Collection # 0925-0593, Expiration Date 7/31/2013)					
Project ID Number	Project Title	Purpose	Proposed Additional Information Collection	Rationale for Inclusion in Vanguard Study	Respondent Burden Hours
LOIX-QUEX-01-B	Evaluation of Household Inventory Questionnaire (HIQ) to Increase Response Rate and Efficiency	To evaluate demographic composition of response rates by utilizing a household inventory questionnaire as a supplement to the Pregnancy Screener	Phone or direct mail administration of HIQ	The data collected will inform the questionnaire and mode design for instruments to be used during the NCS Main Study.	0
LOI2-INF-17	Feasibility and Acceptability of Alternate Methods of Postnatal 3- and 9-Month Phone Interview Data Collection	To examine the feasibility (completion rates), acceptability, staff time and cost-effectiveness of three modes of data collection for the postnatal 3-month and 9-phone interviews already approved by OMB/OIRA)	Current NCS participants will be randomly assigned (a) telephone (b) a secure, web-based data collection, or (c) a mailed survey. Then, participants will be asked to complete a short questionnaire regarding their preferred mode of response.	The project tests the feasibility, acceptability, and cost of 3 modes of survey administration, which will inform the design of the NCS Main Study.	20
LOI3-ENV-01-D	Evaluating methods for dust collection to quantify exposure to semivolatile organic compounds (SVOCs)	To evaluate exposure data, as detected in the household environment, reported by the participant, and stored in participant biomarkers for quality, and redundancy in measurement	Adding an air sampling device at Pregnancy Visit 1.	The project evaluates the feasibility, acceptability and cost of two methods for dust sampling with an aim to reduce overall burden in the NCS Main Study.	19

1. LOIX-QUEX-01-B: Evaluation of Household Inventory Questionnaire to Increase Response Rate and Efficiency

The NCS formative research project, LOIX-QUEX-01-B, aims to improve evaluation of response rates among the Two-Tier study locations by utilizing a Household Inventory Questionnaire (HIQ) as a supplement to the Pregnancy Screener (latter approved by OMB/OIRA on April 13, 2011). The HIQ will provide demographic information of persons who are eligible but decline to enroll in the Study, thus assisting in nonresponse bias estimation.

The original NCS enumeration procedure, conducted by in-person field staff, was comprehensive, though resource-intensive, in terms of staff and time. By using the HIQ, the NCS will be able to estimate the usefulness of this approach in identifying age-eligible women living in eligible households throughout the selected samples within secondary sampling units. The data collected will inform the questionnaire and mode design for instruments pertaining to screening activities to be used during the NCS Main Study.

For this project, all 10 Study Centers participating in the Two-Tier Recruitment Strategy would administer the Household Inventory Questionnaire to a random selection of 50% of their geographically eligible households(N=24,000) in phone or by direct mail (N=24,000 respondents X 0.13 hours per response = 3,200 hours). Among those receiving the HIQ, those who respond (expected response rate: 60%) will receive the Pregnancy Screener (N=24,000 respondents X 60% expected response rate X 0.35 hours per response = 5,040 hours). Because of this split-sample design, we will not request additional burden hours for this activity (8,240 expected versus 8,400 approved).

IRB Approval for participating Study Centers: Yes
Total Requested Participant Burden: 0 hours

2.LOI2-INF-17: Feasibility and Acceptability of Alternate Methods of Postnatal 3-and 9-Month Phone Interview Data Collection

The NCS formative research project, LOI2-INF-17, proposes to administer the 3- and 9-month instruments as direct mail and web, in addition to phone (the latter only was previously approved by OMB/OIRA on April 13, 2011), to current NCS participants who are willing and have the necessary technical skills to participate in all three data collection modes. To facilitate recruitment for this project, NCS participants will be pre-screened for computer competence and access prior to the survey administration, and asked if they are willing to participate. Participants will be randomly assigned to receive a telephone, web-based, or self-administered mail survey.

In addition to the mode variation for the already OMB-approved 3- and 9-month instruments, the NCS would like to administer the Participant Internet Usage and Contact Preference Survey to a total of 240 respondents, resulting in 20 hours of additional burden hours (240 respondents X 0.08 hours/respondent = 20 hours). The Participant Internet Usage and Contact Preference Survey results will be used to evaluate the participant acceptability of these information collection modes with a view to informing the modalities to be offered in the Main Study.

IRB Approval for participating Study Centers: Yes
Total Requested Participant Burden: 20 hours

3.LOI3-ENV-01-D: Evaluating Methods for Dust Collection to Quantify Exposure to Semivolatile Organic Compounds (SVOCs)

The NCS formative research project, LOI3-ENV-01-D, proposes to evaluate exposure data as detected in the household environment, reported by the participant, and stored in participant biomarkers for quality and redundancy in measurement. The purpose of the project is to generate operational data to determine the most appropriate and efficient conditions for collection, processing, storage, and analysis of dust, air, and urine samples from the homes of study participants. In addition to the biological and environmental samples already approved to be collected at the Pregnancy Visit 1 per the NCS Vanguard Study Phase II protocol (approved by OMB/OIRA on April 13, 2011), LOI3-ENV-01-D proposes adding an air sampling device to be placed in the home for 30 days at Pregnancy Visit 1 for a subset of NCS participants at up to 10 Study Centers. The characteristics and placement of the proposed air monitoring device were described in the Initial Vanguard Study protocol (approved by OMB/OIRA on September 22, 2008).

The additional data collection described above represents a minimal amount of additional burden (55 respondents X 0.35 additional burden hours/ respondent = 19 hours). The project will test the feasibility and acceptability of two methods for dust collection, and will apply efficiencies ascertained from the data to reduce overall burden to the participant in the NCS Main Study.

IRB Approval for participating Study Centers: Pending OMB approval (submitted to IRBs of record)
Total Requested Participant Burden: 19 hours

Table 2. Respondent Burden Table for Candidate Projects (OMB Collection # 0925-0593, Expiration Date 7/31/2013)

Formative Research Project Number	Type of Respondent	Number of Respondents	Responses per Respondent	Hours per Response	Hour Burden
LOIX-QUEX-01-B	Household	24,000	1	0.13	0 *
	Age-Eligible Women	14,400	1	0.35	
LOI2-INF-17	Mother / Baby	240	1	0.08	20
LOI3-ENV-01-D	Household	55	1	0.35	19

**See above description on planned variation for LOIX-QUEX-01-B, resulting in no additional burden.*

For your consideration, please see the associated instruments for each project that are supplemental to the approved Vanguard Study Phase II submission.

Attachments (2):

1. Household Inventory Questionnaire – LOIX-QUEX-01-B
2. Participant Internet Usage and Contact Preference Survey - LOI2-INF-17