Note to File – Description of Formative Research Projects

*** Future change requests will lay out protocol for each formative research project. ***

The following description pertains to formative research projects (excerpted from Supporting Statement A):

NCS Recruitment Substudy: Supplemental Measures to Evaluate Selected, Coordinated Formative Research Protocols

A fourth research goal of the Recruitment Substudy is to examine the feasibility, acceptability and cost of a series of formative research protocols within a subset of Vanguard Study participants and their peers with the aim of informing the NCS Main Study.

For example, some extensive measures, including biospecimens, were previously approved for use in the initial 7 Vanguard Study locations. As described above, when first launched the additional 30 study locations in the Recruitment Substudy used streamlined data collection instruments to allow focus on improving recruitment rates. Subsequently, we would reintroduce selected measures that have been revised to improve their scientific robustness, burden, and cost. However, unlike the study visit assessments described under, "*NCS Recruitment Substudy: Supplemental Measures to Evaluate Selected Study Visit Assessments*," at the time of the current submission the exact protocol revisions we intend to use, and the subset of participants we would engage, have not been fully determined. Therefore, we intend to submit these particular proposals in the future as requests for non-substantive change.

Other examples of planned coordinated formative research protocols include data collection from persons not enrolled in the NCS Vanguard Study as a means of testing items for relevant populations efficiently in advance of the NCS Main Study. For example, smaller, in-depth data collection would be requested from children demographically similar to, but older than Vanguard Study children to test age-specific items, persons demographically, but not geographically, eligible to participate in the Vanguard Study to test recruitment messaging, and hospital and other service providers whose opinions could inform information collection practices for the NCS Main Study. At this time, the exact protocol revisions we intend to test, and the size and specific subpopulations to be recruited have not been fully determined. Therefore, we intend to submit these particular proposals in the future as requests for non-substantive change.

The NCS Main Study will benefit from many focused formative research projects. Therefore, we intend to use the current clearance in conjunction with generic clearance already obtained on behalf of the NCS.

IC#: 30

# of Hours Approved for Formative Research: 14,542

Formative Research Project #	Formative Research Project Name	Type of Respondent	Number of Respondents	Responses per Respondent	Hours per Response	Burden Hours
LOIX-QUEX-01-B[1]	Evaluation of Household Inventory Questionnaire to Increase Response Rate and Efficiency	Household	24,000	1	0.13	0 *
		Age-Eligible Women	14,400	1	0.35	
LOI2-INF-17[1]	Feasibility and Acceptability of Alternate Methods of Postnatal 3-and 9-Month Phone Interview Data Collection	Mother / Baby	240	1	0.08	20
LOI3-ENV-01-D[1]	Evaluating Methods for Dust Collection to Quantify Exposure to Semivolatile Organic Compounds (SVOCs)	Household	55	1	0.35	19
LOI2-BIO-18[2,3]	Placenta Studies: Cell Collection, Banking, and Morphology Assessment	Mother (Child)	617	1	0.25	154
LOI3-PHYS-02[2]	Evaluation of Ulnar Length Measurement	Mother / Infant / Child	1,500	2	0.33	1,000
LOI3-PHYS-01[2]	Lung Function Among Children 1-8 Years	Mother / Child	450	3	0.33	450
LOI2-QUEX-14[2]	Improving Dietary Assessment in Pregnant Women and Children	Mother / Child	150	5	0.85	638
LOI3-BIO-02; LOI3-BIO-05[4]	Prospective Analysis of Environmental Chemicals in Breast Milk	Mother	180	5	1.00	900
LOI2-PHYS-15[4]	Visit Assessment Tool to Address Birth Defects and Dysmorphology	Infant / Child	300	1	0.75	225

TOTAL REMAINING HOURS 11,136

* LOIX-QUEX-01-B uses a split-sample design. The study was approved for 8,400 burden hours on 4/13/11. The expected burden for this activity is 8,240 hours. Therefore, additional burden hours are not being requested.

[1] These formative research projects (LOIX-QUEX-01-B, LOI2-INF-17, LOI3-ENV-01-D) were submitted as a request for nonsubstantive change to the NCS Vanguard (Pilot) Study protocol on April 20, 2011 and approved by OIRA on June 1, 2011.

[2] These formative research projects (LOI2-BIO-18, LOI3-PHYS-01, LOI3-PHYS-02, LOI2-QUEX-14) were submitted as a request for nonsubstantive change to the NCS Vanguard (Pilot) Study protocol on June 21, 2011.

[3] There are no data collection instruments associated with this project (LOI2-BIO-18). Also, there is no burden associated with hospital staff, as they are paid for their services.

[4] These formative research projects (LOI3-BIO-02; LOI3-BIO-05, LOI2-PHYS-15) were submitted as a request for nonsubstantive change to the NCS Vanguard (Pilot) Study protocol on September 9, 2011. Two formative research projects, LOI2-QUEX-13 and LOI3-QUEX-01, have since been removed from this collection, per instruction from OIRA. One formative research project, LOI2-QUEX-5, requires more information and will be re-submitted at a later date.