Formative Research and Pilot Methodology Studies for the National Children's Study (NICHD)

Supporting Statement and Attachment
OMB Submission – 30 January, 2008

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REQUEST FOR OMB CLEARANCE

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A. Justification

A.1 Need for the data collections

Patterns of children's health and illness have changed dramatically over the past 100 years (Arias 2004). While infectious diseases were the principal threat during the first half of the last century, today the major conditions that affect children stem from a complex array of environmental and genetic determinants. Some have termed this the "new pediatric morbidity". These conditions include premature births (Ananth et al., 2005), asthma (CDC Surveillance of Asthma, 1998), injuries (Centers for Disease Control and Prevention, Injury Center), neurodevelopmental disorders such as learning disabilities, dyslexia, mental retardation (Centers for Disease Control and Prevention, 2005a), attention deficit/hyperactivity disorder (Centers for Disease Control and Prevention, 2005), autism (Centers for Disease Control and Prevention, 2007), obesity (National Center for Health Statistics, 2006), type 2 diabetes (Centers for Disease Control and Prevention, 2005b), birth defects (Centers for Disease Control and Prevention, 2007), and cardiac defects (Centers for Disease Control and Prevention, 1998). Addressing the causes and contributors to these and other chronic conditions is now the major task of public health practitioners and pediatric researchers and constitutes the frontier that must be crossed in order to protect and improve the health of children in developed countries. If the causes of any of these diseases were to be discovered, billions of dollars could potentially be saved if viable intervention approaches were made available.

Examining the role of the environment on the health of children is critical to understanding the causes of these health conditions. A study that investigates the effects of both the natural and the built environment; components of the environment, such as biological, chemical, physical, and social factors; and aspects of the child's immediate environment, including family and cultural influences, behaviors, and geographic aspects is necessary to preventing and/or curing chronic health conditions. Finally, the genetic makeup of the child and family would allow for analysis of the gene-environment interactions.

In 2000, the President's Task Force on Health Risks and Safety Risks to Children concluded that a study to define the actual risks associated with broad environmental exposures is an essential first step in addressing these questions. Following this recommendation, the U.S. Congress passed the Children's Health Act of 2000 (PL 106-310), which directs the National Institute of Child Health and Human Development (NICHD) to conduct a national longitudinal study of environmental influences (including physical, chemical, biological and psychosocial influences) on children's health and development. The scientific rationale for this program of research has evolved as the National Children's Study (NCS).

The National Children's Study is designed as a multi-center longitudinal study that will enroll and follow a nationally representative sample of approximately 100,000 children born in the U.S. In the first stage of sampling, 105 locations were randomly selected from all U.S. counties. Of these, 7 locations have been selected as the Vanguard locations which are currently working with the NICHD Program Office and the Coordinating Center on Study protocols and procedures. Contracts for 15-20 additional Study Centers will be awarded in September 2007.

We are requesting approval for programmatic clearance of pilot and formative research to be used in the development of instruments, materials, and procedures for the NCS. This will include community outreach materials, medical provider and participant materials, questionnaires and measures, use of technology such

as Interactive Voice Recognition (IVR), and other aspects related to data collection. Activities will include small focused surveys to test data collection items and methods on a specific or targeted population, validation of questionnaires for targeted populations, focus groups within NCS communities to test forms and procedures, cognitive interviews to test data items, and the use of materials on targeted populations such as medical providers and hospitals, and materials translated into other languages. These activities will be conducted over the life of the Study to develop procedures and materials for each stage of data collection.

A.2 Purpose and use of this formative research and pilot testing

The results of these pilot tests will be used to maximize the efficiency of survey procedures, materials, and methods for community outreach, engagement of the medical community, for recruiting and retaining study subjects prospectively across study visits and to ensure that data collection methodologies are efficient and valid for all potential participants. Without this information, NCS will be hampered in its efforts to effectively publicize the NCS, gain public and professional support, and effectively recruit and retain respondents and collect data over the life of the Study.

A.3. Use of automated data collection and burden reduction

The focus of these data collections is the improvement of data collection methodologies for the NCS, including the use of automated data collection (e.g., IVR) and other procedures designed to decrease participant burden and improve data accuracy.

A.4 Identification of duplication

Attention has been paid to the extant literature on isolated facets of individual data collection (e.g., comparisons of different methods of questionnaire administration), as well as the experience of other large Federal studies (e.g., National Health and Nutrition Examination Survey, National Health Interview Survey, Early Childhood Longitudinal Study-Birth Cohort). However, the breadth and depth of data collection proposed for the NCS combined with the population-based enrollment of women during and before pregnancy pose circumstances unique to the NCS.

A.5 Impact on small businesses

The potential impact of these data collections on small businesses will be limited to a small number of medical providers, hospitals, and perhaps community organizations asked to provide structured comment on potential NCS materials. Where requested, the study will reimburse providers for any expenses incurred as part of filling requests for information.

A.6 Consequences of not collecting the information

These data collections are designed to decrease participant burden and improve data collection for the NCS, a crucial requirement given the mandated scope of the Study. Without these small studies, data collection for the NCS is likely to be less efficient than it could be.

A.7 Special circumstances relating to guidelines of 5 CRF 1320.5

There are no special circumstances that would cause this information collection to be conducted in a manner inconsistent with 5 CFR 1320.5.

A.8 Comments in response to the Federal Register Notice and efforts to consult outside agency

The 60-day Federal Register Notice regarding the NCS is published on pages 65047 through 65048 of Volume 72, Number 222 of the Federal Register on November 19, 2007.

Comment #1 (abridged) – "…THERE IS ENDLESS PAPER COLLECTION BY NIH AND THEY NEVER SPEND THE TIME IN THE LAB FINDING AN ANSWER TO ANY DISEASE AT ALL.

INSTEAD DEVOTE THIS TIME AND MONEY TO GETTING AT THE ANSWER TO WHY ONE OUT OF 60 CHILDREN IN NJ IS BEING BORN AUTISTIC AT THE PRESENT TIME.

SOMETHING IS DESPERATELY WRONG. WE HAVE A STUDY GROUP ALL READY FOR INVESTIGATION. LETS GET TO THE BOTTOM OF SOMETHING RATHER THAN THIS ENDLESS PAPER COLLECTION BY NIH WITH NO ACTION AND NO ADVANCEMENT FOR HEALTH ISSUING FROM NIH."

A.8.1 Efforts to consult outside agency

Several committees and many individuals have been consulted on the NCS methodology, sampling and hypotheses, as well as specific instruments and samples to be collected, for the National Children's Study. The Study committees are described below.

National Children's Study Federal Advisory Committee—The National Children's Study Federal Advisory Committee (NCS-FAC), constituted under the Federal Advisory Committee Act, provides advice and recommendations to the Director of the National Children's Study, the Director of the National Institute of Child Health and Human Development, and the Interagency Coordinating Committee regarding critical aspects of the Study. Members of the FAC include representatives from academia, industry, health care practice, and other professions. Early in the planning phase of the NCS, 22 Working Groups were convened under the auspices of the NCS-FAC, to enable the Study to receive input from literally hundreds of non-Federal scientists and other professionals.

Interagency Coordinating Committee—The Interagency Coordinating Committee (ICC) organizes and directs operations of the Study. This committee is made up of staff from two federal agencies: the U.S. Department of Health and Human Services (DHHS) and the U.S. Environmental Protection Agency (EPA). Within DHHS, staff is contributed from the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). CDC contributes staff from the National Center on Birth Defects and Developmental Disabilities and the National Center for Health Statistics; NIH contributes staff from the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences. EPA contributes staff from the National Center for Environmental Research, the National Health and Environmental Effects Research Laboratory, the Office of Children's Health Protection, and the National Exposure Research Laboratory.

Steering Committee—The National Children's Study Steering Committee consists of members from each of the Vanguard Centers; the NCS Program Office, the Coordinating Center, the ICC, and invited community representatives. This list will be expanded as additional Study Centers are added to represent additional study

locations. Various working teams within the Steering Committee have convened and provided input into the study protocol and procedures (e.g, Sampling Team, Outreach and Engagement Team).

A.9 Explanation of payment or gifts to respondents

In order to maximize cooperation, many research studies, particularly those involving medical procedures, offer compensation for participants. For example, the National Health and Nutrition Examination Survey (NHANES) has offered their participants compensation since the 1970's. Participants in NCS pilot studies, especially focus groups and cognitive interviews, will receive monetary compensation for their time and any expenses incurred (e.g., transportation costs). The amount of compensation will be determined by the amount of time required of the participant for the particular test, as well as the type of activities that will be required. Compensation amounts will be addressed specifically in IRB submissions for each pilot.

A.10 Assurance of confidentiality for respondents

For each pilot test, confidentiality procedures will be developed and submitted to the relevant IRB's. Since some tests will be done by the Study Centers, and others will be performed by the Coordinating Center, different sets of IRB's will be involved, depending on the specific pilot test. Study participants will be assured that the data collected will be safeguarded closely and that actions will be taken to protect confidentiality. Participants in cognitive testing or focused surveys will be provided with the appropriate informed consent documents to sign (as approved by the relevant IRB's). Westat, the NCS Coordinating Center, has clear policies and procedures regarding assurance of confidentiality and a pledge that all employees must sign. In addition, Westat provides all safeguards mandated by NICHD. IRB approval will be sought from relevant IRB's for individual pilot tests.

A.11 Justification for sensitive questions

The NCS will be collecting information on sensitive topics such as pregnancy status, reproductive and medical histories, and recreational drug use. Some of these items may be included in one or more of the pilot tests to ensure that they meet the needs of respondents in assuring them that the data collected will be kept confidential, and that the data items are sensitive to the needs of the participants.

A.12 Estimates of hour burden including annualized hourly costs

The costs to respondents will vary depending on the type of data collection (e.g. focus group vs. cognitive interview), the length of the data collection and the participant's role (e.g. healthcare providers, such as doctors, will be compensated at a higher rate). The 2005 median income in the Vanguard Center states ranged from $41,000 per year up to $59,000. Compensation for participants is usually based on median hourly income for their areas of residence. Exhibit 1 presents the estimated hour and annual cost response burden for respondents.

Exhibit 1. Estimated Hour and Annual Cost Response Burden

Data collection activity	Total number of respondents	Responses per respondent	Hours per response	Annual burden hours	Cost per hour	Annual burden cost
Small focused surveys	1,250	1	1.5	1,875	$10	$18,750
Focus groups with potential participants	350	1	3.0	1,050	$10	$10,500
Focus groups with health care professionals	350	1	3.0	1,050	$50	$52,500
Focus groups with community leaders	350	1	3.0	1,050	$10	$10,500
Medical provider feedback on materials through informal in-person contacts	700	1	.5	350	$50	$17,500
Cognitive interviews	150	1	3.0	450	$10	$4,500
Total	3,150			5,825		$114,250

A.13 Estimate of other total annual cost burden to respondents or record keepers

Participants in these formative or methods development studies will be reimbursed for any expenses resulting from their participation in such studies. This may include transportation costs to and from focus groups or cognitive interview sites, and babysitting or elder care expenses. Medical providers, hospitals, and day care centers participating in such studies will be reimbursed at their usual and customary rates. There are no other known costs to study participants.

A.14 Estimate of annualized cost to Federal Government

The estimated cost to the Federal Government of these pilot and formative studies is $500,000 per year over the three year period.

A.15 Explanation of program changes or adjustments

Not applicable, as this is a new data collection request.

A.16 Timeline for publication plans

The proposed data collections are small scale pilot studies and focus groups intended to increase data collection efficiency for the NCS and do not have a planned publication schedule. The studies will take place over the three year period specified in this submission.

A.17 Display of expiration date of OMB approval

The NCS is not seeking an exemption from displaying the expiration date of OMB approval.

A.18 Exception for Item 19, “Certification for Paperwork Reduction Act Submissions.” of OMB Form 83-I

NCS is not requesting exceptions from OMB Form 83-I.