REQUEST FOR OMB CLEARANCE
Information Collection Request
Child Health Disparities Substudy for the National Children's Study (NCS)
Phase I: Cognitive Interview Testing of Constructs Needed for Disparities Measurement

Part A only

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The President's Task Force on Health Risks and Safety Risks to Children recommended in 1999 that a large study to define the actual risks associated with broad environmental exposures is the critical first step in addressing the potential risk factors that may affect the health and development of children in the United States (US). Following the recommendation of the task force, Congress passed the Children's Health Act of 2000 (Public Law 106-310) which authorized the National Institute of Child Health and Human Development (NICHD) to conduct a national longitudinal study of environmental influences on children's health and development. These environmental influences include physical, chemical, biological, and psychosocial aspects.

As stated, by law, the Children's Health Act of 2000 (Sec. 1004) states that the Director of the NICHD shall establish a consortium of representatives from appropriate Federal agencies to plan, develop, and implement a prospective cohort study, from birth to adulthood to fulfill two main purposes justifying the collection of information:

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."
2. "Investigate basic mechanisms of development disorders and environmental factors, both risk and protective, that influence health and development that influence health and developmental processes. "

Required, by law, under the Children's Health Act of 2000 (Sec. 1004), the national longitudinal study, termed the National Children's Study [NCS], outlines three research imperatives justifying the collection of information:

1. "Incorporate behavioral, emotional, education, 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 population for children, which may include the consideration of prenatal exposures."
3. "Consider health disparities among children which may include the consideration of prenatal exposures."

The NIH developed a systematic approach to fulfilling the NCS mission. The NCS is an integrated system of activities that include a NCS Vanguard (Pilot) Study for operations and methods development and an NCS Main Study to collect data on exposure and response The NCS Vanguard (Pilot) Study (OMB #0925-0593), was submitted to OIRA/OMB on and renewed recently by the Office of Information and Regulatory Affairs within the Office of Management and Budget with an expiration date of 8/31/2014.

The purpose of the Vanguard Study is to assess the feasibility, acceptability, and cost of the recruitment strategy, study logistics and operations, and study visit assessments that will be used in the second component, the NCS Main Study. 'Feasibility' assessment refers to technical performance and reliability. 'Acceptability' refers to the impact on the study participants and overall study infrastructure. 'Cost' refers to the level of effort, personnel, resources, and money involved in a study development and implementation.

The NCS Main Study, currently in the concept phase, will run in parallel with the NCS Vanguard (Pilot) Study. Additional substudies and formative research projects will inform future NCS design and activities. For more detailed information regarding the NCS Vanguard (Pilot) Study, please see the National Children's Study: An Evolving Concept - Concept of Operations.

Purpose of this Submission

With this information collection request (ICR), the NCS seeks approval from OIRA/OMB to perform the first phase of a two-phased project called the Child Health Disparities Substudy. The first phase is to develop a cognitive interview tool to test content validity in assessing health literacy, discrimination, and stress and education level in mothers of small children across diverse populations. Following the analysis of qualitative data gained from Phase I cognitive interviews, Phase II, to be submitted in a subsequent ICR, will continue data collection on health disparity measures and saliva collection using the tool informed by the Phase I cognitive interviewing phase.

While discrimination and health literacy are increasingly recognized as important factors that lead to health disparities not only in adults but potentially leading to disparate health and developmental outcomes in the offspring, these measures had not been included in the NCS Vanguard Study to date. Including valid measures of discrimination experiences and health literacy that work across varied racial and ethnic groups as well as across ranges of socioeconomic and educational attainment is critical to conducting health disparities research with Main Study data. Thus, it is paramount that we test the validity of these measures among diverse subpopulations (race/ethnic, socioeconomic, and educational status) before the Main Study data collection is implemented, particularly among mothers of young children which have not been well-reported in the scientific literature.

Health disparities are inequitable and potentially avoidable differences in health and health care. Developing optimum measures of measuring health disparities is of particular interest because studies have shown that health literacy, discrimination, stress and low socioeconomic status contribute to health disparities in children and adults. Knowledge of factors that contribute to health disparities is needed to investigate and understand mechanisms that produce disparities in pregnancy outcomes, child health and development outcomes and potentially adult health.

Reports by the Institute of Medicine have highlighted health disparities and health literacy as crucial indicators of health quality and level of access to health care, and as such, are critical issues to be addressed[1] . Limited health literacy is known to be associated with high health care costs and negative

[1] *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare, IOM, National Academies Press, 2003*

health outcomes. Since 2004, there has been a greater focus on understanding the state of child health disparities as compared to adults[2]. Specifically, many studies have found that parental health literacy may contribute significantly to child health outcomes. In addition to health literacy as a specific focus, research has demonstrated the ongoing contribution of racial discrimination to health disparities in the United States. However, the longitudinal impacts of racial discrimination on observed child health disparities have received little study except in demonstrations of added risk for lower birth weight infants among minority women who perceived racism. A recent literature review by Pachter and Coll[3] has confirmed that there are a limited number of studies evaluating the relationship between racial discrimination and child health, and that most of the work has been limited to African American youth populations, with little research on the impact of health outcomes of younger children. Studies have not yet sought to establish a standardized, validated method for measuring health disparities, health literacy, and feelings of racial discrimination in parents with young children. The measures and procedures developed by this substudy will be nonproprietary and available to all.

The primary goal of Phase 1 of this substudy will be to assess content validity of measures of health literacy, discrimination, stress and education level in in mothers of small children across diverse populations (African American, English and Spanish-speaking Latinos, and Asians) using cognitive interviewing and a process of adaptation, translation and back translation by Dela Cruz et al.[4] Phase I aims to contribute to the NCS Main Study and to the health disparities field as a whole by assessing, potentially revising, and translating to Spanish a validated set of questionnaire measures that can be used in mothers of small children across diverse racial and ethnic backgrounds, for the purpose of investigating disparities. Based on cognitive testing, if certain measures are found to generate response error or misinterpretation, these measures would not be recommended for the NCS Main Study. It is anticipated that some measures may not be valid in certain racial or ethnic groups. If certain wording changes reduce response error and misinterpretation, a process of adaptation and, if in Spanish, translation and back translation, then further testing would be pursued as described by Dela Cruz et al.

Three measures that are appropriate for families who may not speak English, have low health literacy, and are from diverse backgrounds to be used in the cognitive interviewing are listed below. A detailed description of these instruments is found in B.2.

- Newest Vital Sign™ (health literacy test)

[2] *How Far Have We Come in Reducing Health Disparities? Progress Since 2000* - Workshop Summary, IOM, National Academies Press, Released: September 12, 2012.
http://www.iom.edu/Reports/2012/How-Far-Have-We-Come-in-Reducing-Health-Disparities.aspx

[3] Pachter LM, Coll CG. *Racism and child health: a review of the literature and future directions*. J Dev Behav Pediatr. 2009 Jun;30(3):255-63.

[4] Dela Cruz FA, Padilla GV, Agustin EO. Adapting a measure of acculturation for cross-cultural research. J Transcultural Nursing, 2000;11:191-198.

- Krieger Experiences of Discrimination
- Williams Everyday Measure of Discrimination

A.2 Purpose and Use of the Information Collection

Phase I of the Child Health Disparities Substudy will aim to validate measures of health disparities, specifically health literacy, discrimination, stress and education level in mothers of small children across diverse populations. Measures of discrimination have mainly been tested in African American populations with limited testing in Latinos or Asians. There has been limited content validity testing of the Newest Vital Sign™, a nutritional label used as a quick screening test for health literacy; and it has been primarily used with Caucasians and African Americans. In addition, there has been limited content validity testing of the Spanish translations of these measures. Cognitive testing will assist in assessing content validity in diverse populations.

Using methods of cognitive testing, content validity will be assessed. Cognitive testing investigates how well questions perform when asked of respondents: if respondents understand the question correctly and if they can provide accurate answers. It assesses whether survey questions successfully capture the intent of the question, and is understood by the respondent. The interview is designed to elicit respondents' thought processes when answering the tested question. Data from cognitive interviews are qualitative, and the analysis may identify potential sources of response error and various interpretations of the question across groups of people. This type of analysis is especially useful when examining the comparability of measures between racial ethnic groups, countries or social classes.

Phase I begins with a cognitive interview in a convenience sample of 5-20 women with children ages 0-5 from each of the 5 collaborating sites (N=60). In order to enroll 60 mothers with children ages 0-5 in the cognitive interview, we anticipate that 100 women may need to be screened. The participants will be screened using the Cognitive Interview Screener to determine eligibility. The cognitive interview involves (1) a recorded conversation, (2) a short test about nutrition and food labels: to see how people understand health information [The Newest Vital Sign™], (3) questions regarding unfair treatment and discrimination that the mother has experienced [Krieger], (4) questions about stressful situations that the mother has experienced [Williams], (5) questions about demographic background and (6) questions about the administration of personal interviews for data collection.

Participants will be recruited from pediatric clinics, WIC (Women, Infant and Children supplemental food sites), child care sites and other public sites using flyers at five NCS collaborative sites: John Hopkins University (JHU), University of California, Los Angeles (UCLA), University of Miami, University of Hawaii and University of California, Irvine (UCI). In addition to racial/ethnic diversity the study team will also sample for socio-economic diversity with education level serving as a proxy measure. See Table A1 for more details.

Table A1. Child Health Disparities Substudy Recruitment Distribution

Site	Education Level	English Speaking	Spanish Speaking

UCLA 15 participants	Low (High School or Less)	3 AAPI 1 Latina Central American 1 Latina Mexican	2 Latina Central American 2 Latina Mexican
	High (Above High School/ GED)	2 AAPI 1 Latina Central American 1 Latina Mexican	1 Latina Central American 1 Latina Mexican
JHU 10 participants	Low (High School or Less)	3 African American 2 African/Caribbean or 1st Generation	
	High (Above High School/ GED)	3 African American 2 African/Caribbean or 1st Generation	
University of Miami 20 participants	Low (High School or Less)	3 African American 3 Latina Caribbean 3 non-Latina Caribbean	3 Latina Caribbean
	High (Above High School/ GED)	2 African American 2 Latina Caribbean 2 non-Latina Caribbean	2 Latina Caribbean
UCI 10 participants	Low (High School or Less)	1 AAPI	4 Latina Mexican
	High (Above High School/ GED)	4 AAPI	1 Latina Mexican
University of Hawaii 5 participants	Low (High School or Less)	3 AAPI	
	High (Above High School/ GED)	2 AAPI	
Total 60 participants		44 participants	16 participants

AAPI: Asian American Pacific Islander

A.3 Use of Information Technology and Burden Reduction

The Child Health Disparities Substudy Phase I is designed to validate measures needed for studying health disparities. To achieve this, the cognitive interviews will include digital recording and other procedures designed to decrease burden, study costs, and to improve data accuracy. Other appropriate information technology solutions will be embraced to reduce respondent burden and improve data quality.

Title II of the E-Government Act of 2002 requires federal agencies to conduct privacy impact assessments (PIAs) before developing or procuring information technology (IT) systems that collect, maintain, or disseminate personally identifiable information (PII). In 2007, NIH released Manual Chapter 1745-1, "Privacy Impact Assessments (PIAs)," which reinforces the Department of Health and Human Services (HHS) requirement for PIA completion, and details NIH employee roles and responsibilities in support of this process.

PIAs provide a documented process, the purpose of which is to identify and protect employee and public citizens' PII; and it ensures that the government has considered necessary safeguards for the PII passing through or being collected, maintained, or disseminated in its systems. The NCS must effectively manage participant safety while preserving data integrity and availability to carry out NCS activities. To do so, privacy risks associated with NCS systems are documented by having field contractors (Study Centers) complete PIAs and include risks in the system plan of action and milestones (POA&M).

A.4 Efforts to Identify Duplication and Use of Similar Information

Substudies of this nature will be utilized by the NCS as a way to demonstrate proof-of-concept in a manner that minimizes participant burden and study costs, prior to testing in the NCS Vanguard Study protocol if results warrant. Health disparities and health literacy have been identified as crucial indicators of health quality and level of access to health care, and as such, are critical issues to be addressed. High health care costs and negative health outcomes have been associated with limited health literacy. There has been a greater focus on understanding the state of child health disparities as compared to adults[5]. Health literacy may contribute significantly to child health outcomes, as shown by many studies.

Longitudinal impacts of racial discrimination on observed child health disparities have received minimal study except in demonstrations of added risk for lower birth weight infants among minority women who perceived racism. Also, studies have not yet sought to establish a standardized, validated method for measuring health disparities, health literacy, and feelings of racial discrimination in parents with young children. In this way, substudies will not duplicate, but rather, guide NCS Vanguard Study and Main Study information collection. The measures and procedures developed by this substudy will be nonproprietary and available to all.

A.5 Impact on Small Business and Other Small Entities

Small businesses will include translation and transcription services. The potential impact to small businesses and other small entities is minor.

A.6 Consequences of Collecting the Information Less Frequently

Phase 1 of the Child Health Disparities Substudy is a one-time collection of information. During Phase I, a cognitive interview will be administered to mothers of children ages 0-5.

A.7 Special Circumstances Relating to the 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

Comments in Response to the Federal Register Notice

The 60 day Federal Register Notice regarding the Child Health Disparities Substudy was published on pages 15780-15782 of the Federal Register on March 16, 2012 (Volume 77, No. 52). No public comments were received.

Efforts to Consult Outside Agencies

Strategic advice and oversight is also provided by independent advisors through several groups as described below. Some of these committees are independent of the NCS; other committees comprise the NCS Program Office, study location staff, and independent advisors.

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[5] *How Far Have We Come in Reducing Health Disparities? Progress Since 2000* - Workshop Summary, IOM, National Academies Press, Released: September 12, 2012.
http://www.iom.edu/Reports/2012/How-Far-Have-We-Come-in-Reducing-Health-Disparities.aspx

The Steering Committee consists of Principal Investigators from study locations as well as community representatives and provides first-level scientific guidance to the National Children's Study. It is the arbiter of issues referred to it by the Program Office, the Principal Investigators, and the Executive Steering Committee. It is empowered to make protocol modifications that do not change the direction or cost of the study, subject to confirmation by the Program Office. The full Steering Committee meets face-to-face twice a year. Interim meetings by conference call are scheduled as needed.

The National Children's Study Federal Advisory Committee (NCSAC), constituted under the Federal Advisory Committee Act, meets quarterly to provide strategic advice and recommendations to the Director of the National Institutes of Health, the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and the Director of the National Children's Study regarding critical aspects of the study. There are currently three designated NCSAC subcommittees: Scientific Review, Ethics, and Community Engagement. The National Children's Study Federal Advisory Committee meets quarterly. These meetings are open to the public.

The Interagency Coordinating Committee represents the lead agencies for the study and meets monthly to oversee broad study issues and ensures interagency collaboration. The representatives assure that at a high level, the mission and goals of the National Children's Study are maintained over time and that they reflect the scientific priorities of the study's four lead agencies. The committee is made up of staff from 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.

The Independent Study Monitoring and Oversight Committee (iSMOC) monitors National Children's Study data and the safety of study participants. The responsibilities of the iSMOC are to:

- Monitor human subject safety through review and evaluation of accumulated study data
- Review study conduct and progress
- Make recommendations concerning continuation or modification of the study.

During the study, the iSMOC will review data regarding procedure-related adverse events; unanticipated problems involving risks to subjects or others; adherence to the protocol; factors that might affect the study outcomes or compromise the data (for example, protocol violations, losses to follow-up, breach of subject confidentiality); and barriers to study progress or completion (such as slow enrollment, new data or findings, other milestones, change in resources, rate of endpoint accumulation). The iSMOC will recommend appropriateness of notification and referral of individual participants for significant abnormal findings on testing of stored samples. The committee consists of 5 to 10 individuals not associated with the study. Committee membership reflects the disciplines and clinical specialties necessary to interpret study data and to evaluate subject safety.

A.9 Explanation of Any Payment or Gift to Respondents

To maximize response rate, 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 1970s. Incentives are effective in

increasing response rates for in-person surveys and can help increase response rates especially for minorities and low-income households.

Participants in NCS substudies will receive monetary and non-monetary incentives for their time, effort, and any expenses incurred (for example, transportation costs). The incentive amount will be determined by the amount of time required of the participant, as well as the type of activities that will be required. Incentive amounts will be consistent with the approved incentive schedule for the NCS Vanguard Study, including the Initial Vanguard Study, the Recruitment Substudy, and formative research. In the proposed Child Health Disparities Substudy (Phase I only), the questionnaire will be 45 minutes in length. Participants agreeing to be interviewed will be offered a monetary incentive or equivalent not exceeding $25. Small gifts of appreciation for participation may be provided to participants. These may include items such as t-shirts, tote bags, etc., and are intended as tokens of appreciation.

Table A3. Maximum NCS Incentives, by Study Activity and Impact on Participants				
Data Collection Activity Characteristics	**Initial NCS Vanguard Study**	**NCS Recruitment Substudy and Formative Research**		
		Alternate Recruitment Substudy- Phase 1	Alternate Recruitment Substudy - Phase 2	Formative Research
Time for encounter	3 hours	0.5 to 1 hour	0.5 to 1 hour	0.5 to 1 hour
Sensitivity of questions	Sensitive, including sexual activity	Few sensitive questions	Few sensitive questions	Few sensitive questions
Physical measures	Yes	No	No	Yes*
Environmental specimens	Yes	No	Yes	Yes*
Biospecimens	Yes	No	Yes	Yes*
Participant observation	Yes	No	No	No
Monetary incentive, per visit	$100	$25	$25 for the group of study questionnaires, plus $25, in total, for any bio-specimens collected during a contact and, where appropriate for environmental specimens	$25, in total, for any bio-specimens collected during a contact. For questionnaires, or any environmental specimens – up to $25 when deemed necessary
Non-monetary incentives (tote bags, post its, key chains, etc.)	In addition to the monetary incentive, non-monetary incentives valued at $25 or less may be offered to participants	As an alternative to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants in lieu of cash or local incentives not exceeding $25 in value and deemed non-coercive by local IRBs	In addition to the monetary incentive, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs	Instead of monetary incentives, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs

*Specific information proposed for formative research purposes will align with approved generic clearance mechanisms (that is, generic clearances for Recruitment and Retention projects (OMB #: 0925-0590, expiration date 09/30/2014) and Biospecimen and Physical Measurements projects (OMB # 0925-0647, expiration date 01/31/2015)), 2011 Generic Clearance Request for Neuropsychosocial projects (OMB# 0925-0661, expiration date 06/30/2015), and the 2011 Generic Clearance Request for Environmental Science projects, in process.

A.10 Assurance of Confidentiality Provided to Respondents

The Child Health Disparities Substudy Phase I will follow the same procedures and standards of confidentiality applicable to the NCS Initial Vanguard Study and Recruitment Substudy. Participants will be informed about the Certificate of Confidentiality granted to NCS to protect data from involuntary disclosure.

The study centers, under contract to conduct the NCS, will have policies and procedures regarding confidentiality and protection of study data which will be reviewed and monitored by the NCS Program Office.

In addition to their own confidentiality procedures and policies, study centers will implement all federally required study-related confidentiality and data security procedures. All NCS Program Office staff, NCS study center staff, and other NCS contracting staff with access to NCS data must receive data confidentiality and security training provided by the NCS Program Office or its agent. These include completion of the NIH Information Security and Privacy Awareness Training completion of a Human Subjects Protection Training, and signing an Assurance of Confidentiality or similar pledge that NCS data will only be used for the intended scientific purpose. All NCS Staff are required to complete security background checks consistent with Office of Personnel Management requirements. Only those cleared for Security Level D or higher will be eligible to request NCS data access.

To further assure confidentiality of participant data, the study will employ rigorous methods to provide security for personal identifying information. Each study center and the NCS Program Office Data Warehouse will be required to submit an NCS Security Plan and Assessment that complies with the Federal Information Security Management Act (FISMA). This Security Plan will include: a) certification and accreditation of proposed data capture and case management software; b) configuration of those systems on study equipment; c) full disk encryption and two-factor authentication of study computers housing NCS data; and d) security assessment of the physical computing environment. After study centers complete the self-assessment of their security plans, the NICHD Chief Information Officer will review all study center security plans to determine study center's authority to operate. Frequent and regular monitoring visits will assist in compliance with these terms.

Specific NCS data and materials to be collected, disclosure review, and data access are described in detail in the Data Access and Confidentiality Committee Manual. Principles and policies are available at http://www.nationalchildrensstudy.gov/about/organization/dacc/Pages/PolicyManualandDataUseAgreements.aspx; the manual is available to the public upon request. Specifically, all NCS data files will undergo disclosure review for personally identifiable information, using procedures consistent with or exceeding those named in Working Paper 22 of the Federal Committee on Statistical Methodology, and steps will be taken to appropriately manage disclosure risk. For example, genome-wide scans conducted on NCS specimens will be considered personally identifiable information and treated as such. Some biologic analyses (for example, HIV status, exposure

to specific toxicants), results of some mental health screening tests, and reports of abuse are also considered sensitive.

A.11 Justification for Sensitive Questions

There are a number of questions that may be contained in NCS research questionnaires and in the measures of health disparities proposed for this substudy that could be considered sensitive. The questionnaires in this substudy include questions regarding socioeconomic status, literacy, stress, and discrimination. As part of the informed consent process, women will be informed that their participation in the NCS is voluntary and that they may refuse to answer any question. All study questionnaires that are proposed for use during this substudy have been or will be reviewed by Human Subjects Review Boards at NICHD and/or participating institutions.

Each of these sensitive questions is necessary to assess the validity of these important issues of health literacy, discrimination, stress, and education level.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Estimates of annualized hour burden and annualized cost to respondents are laid out in Tables A.12-1 and A.12-2, respectively. The total number of estimated respondents is 100 annually. The total number of annual burden hours is 68. The estimated total annual respondent cost is $683.

This Child Health Disparities Substudy Phase I is one-time data collection. Estimates of the total annual respondent cost for the collection of information use the wage rate of $10.00 per hour.

The cost of contracting out or paying outside parties for information collection activities is included in A.14.

A.12 - 1 Estimates of Hour Burden

Table A4. Estimated Hour Burden for the Child Health Disparities Substudy (Phase I)

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
Cognitive Interview Screener	Mothers of children ages 0-5	Members of NCS target population (not NCS participants)	100	1	5 / 60	8
Cognitive Interview	Mothers of children ages 0-5	Members of NCS target population	60	1	60 / 60	60

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
		(not NCS participants)				
Total			**100**			**68**

A.12 - 2 Annualized Cost to Respondents

Table A5. Estimated Cost for the Child Health Disparities Substudy (Phase I)

Data Collection Activity		Type of Respondent	Estimated Total Annual Burden Hours	Hourly Wage Rate	Estimated Total Annual Respondent Cost
Cognitive Interview Screener	Mothers of children ages 0-5	Members of NCS target population (not NCS participants)	8	$10.00	$83
Cognitive Interview	Mothers of children ages 0-5	Members of NCS target population (not NCS participants)	60	$10.00	$600
Total			**68**		**$683**

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

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

Participants will be reimbursed for any expenses resulting from their participation in this substudy in alignment with Table A.9. There are no capital, start-up, or maintenance costs for the respondents.

A.14 Annualized Cost to the Federal Government

The estimated cost to the federal government for Phase I of this substudy is $247,374. The annualized cost to the federal government is based on budgetary data for task orders that include costs of information collection, design, development, tests, printing forms, mailing list compilation and maintenance, mailing or enumeration, editing, coding, tabulation, analysis and publication of results. Salary and travel costs associated with project development, implementation, and monitoring are incorporated into the annualized cost to the federal government.

A.15 Explanation of Program Changes or Adjustments

This request proposes a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Cognitive interviews will be tape-recorded and transcribed. Spanish interviews will be translated to English. Data from cognitive interviews are qualitative in the form of transcripts from the interviews. Notes from the interviews containing interview observations and participant answers to any quantitative questions will also be collected but main analysis takes place with the qualitative transcripts. Transcripts will be analyzed using ATLAS.TI software which allows for team members to investigate the relevant themes and ideas using qualitative data coding. Content will be assessed using the grounded theory method in which investigators approach the data without a preset hypothesis and uses careful analysis of emergent themes to reach a theory or conclusion about the data. Once a list of codes common to all transcripts is developed, researchers can compare frequencies and co-occurrences of codes to draw conclusions about differences and similarities across sites. Sites can be separated each by their representative racial/ethnic group or grouped together by language. Analysis will also identify potential sources of response error and various interpretations of the question across groups of people.

Based on cognitive testing, if certain measures are found to generate significant response error or misinterpretation, these measures would not be recommended for the NCS Main Study. It is possible that some measures may not be valid in certain racial or ethnic groups. For instance, it may be that a specific instrument on discrimination is valid among African Americans but is not understood by another racial/ethnic group. If certain wording changes reduce response error and misinterpretation, a process of adaptation and, if in Spanish, translation and back translation would be recommended.

Table A6. Project Time Schedule

Activity	Time Schedule
Participant Recruitment & Screening	1-2 months after OMB approval
Data Collection Activities	2-4 months after OMB approval
Analyses	2-8 months after OMB approval

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 Exceptions to Certification for Paperwork Reduction Act Submissions

The NCS is not requesting any exceptions.