REQUEST FOR OMB CLEARANCE
Generic Clearance Request
Neuropsychosocial Measures Formative Research Methodology Studies for the National Children's Study (NICHD)

Part A only

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Introduction

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 7/31/2013. 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.

The NCS would continue to benefit from the burden and cost efficiencies generated by additional types of formative research projects that could be reviewed through the generic clearance mechanism. With this submission, the NCS seeks approval from OIRA/OMB to develop a topic-based, generic clearance, called the Neuropsychosocial Generic Clearance. Neuropsychosocial-related formative research can be organized into the areas of observation and assessment of individual and overlapping neurological, psychological and social parameters. This clearance will provide an approval mechanism solely focusing on formative research that will focus on gathering procedures and tools to assess children's neuropsychosocial growth and development, such as social/emotional development, language/communication development, cognitive development, and movement/physical development. An additional focus will be to refine procedures and tools to measure adult (birth mothers and fathers) neuropsychosocial and behavioral health related to overall child health. Measures may be gathered via physical examinations of neurological function, designed experimental tasks for testing neurocognitive processes, focused surveys, focus groups, and/or cognitive interviews. These components of neuropsychosocial-related formative research are structured in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard (Pilot) Study or Main Study. There are operational opportunities for improvements in best practices for each of these identified areas to achieve mechanisms that are better, less burdensome, and less costly than conventional approaches. This Neuropsychosocial Generic

Clearance will help address a number of outstanding areas within the Vanguard (Pilot) Study and Main Study. This clearance is the third of several topic-based generic clearances intended to streamline submission and review of formative research (Recruitment and Retention Generic Clearance – OMB #0925-0590, Expiration Date 9/30/2014; Biospecimen and Physical Measures Generic Clearance – OMB #0925-0647, Expiration Date 1/31/2015).

A.2 Purpose and Use of the Information Collection

This information collection involves the collection of neurodevelopmental and psychosocial measures gathered via physical examinations, designed experimental tasks, surveys, focus groups, and/or cognitive interviews to assess physical, emotional, and neurological development, psychosocial growth and adaptation, and behavioral changes in both children and adults. This Neuropsychosocial Generic Clearance will allow the NCS to develop best-practice protocols and by answering several questions surrounding child development:

(1) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's overall developmental status?

(2) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's social and emotional growth and development and adult emotional and behavioral adaptation?

(3) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's language development and ability to communicate and adult language and reading comprehension level?

(4) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's cognitive growth and development and measures to assess adult cognitive abilities and adaptation?

(5) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's physical development and motor function?

(6) Are there additional types of measures that the NCS should consider adding to the Vanguard (Pilot) Study or Main Study protocol to assess mental health, physical, emotional, and neurological development, psychosocial growth, and adaptation, and behavioral changes?

Each of these topics is considered separately below:

(1) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's developmental status?

We would like to develop shortened versions of previously validated tools measuring children's overall developmental status in specific samples of children with an added focus on developing associated training in tool administration. Formative research in this area will include developmental assessments at various age groups (infancy, toddlerhood, preschool, and school-age) in the Vanguard (Pilot) Study to inform use of these measurements in the Main Study. These activities would occur in the interest of streamlining the conduct of developmental assessments and increasing the acceptability of all types of neuropsychosocial information collections. These activities can assist in determining the feasibility, acceptability, and cost of implementation of these training techniques and assessments. Activities may include:

(a) Administering a limited number of questions about age-related, culturally-sensitive, developmental status in specified populations that might provide insight into how best to teach NCS staff, and confirm their understanding, performance accuracy, and reproducibility in documenting age-related development in children.
(b) Gathering information about the burden on clinics, hospitals, healthcare professionals, staff, and organizations with regard to training techniques and procedure development in documenting age-related development in children.
(c) Gaining cooperation of and insight from key stakeholder groups in training techniques and procedure development for age-related developmental assessments in targeted populations with a particular focus on cultural sensitivity. In some specific US populations (for example, urban areas, minorities, individuals with low socioeconomic status, etc.), scientific research funded by government entities is regarded cautiously and with skepticism. Conversations with key stakeholder groups, such as community leaders, community organizations, community members, cultural and faith-based centers, and other community stakeholders, may be necessary to fully evaluate how participants can be placed at ease with obtaining age-related developmental status collections. These conversations may take the form of small, focused surveys, focus groups, and/or cognitive interviews and would be aimed at evaluating how to approach individuals when recruiting for formative research, as well as how best to leverage community ties to achieve the goals of the NCS on a national level.

(2) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's social and emotional growth and development and adult emotional and behavioral adaptation?

Clinical assessment of children's social and emotional growth and development is continuously improving, and the scientific community is frequently learning additional information regarding how to assess delays or abnormalities and their influence on the well-being of children,

families, school environments and communities. Additionally, the scientific community is frequently learning the impact of genetics and environment on the social and emotional growth and behavioral development of children as well as adult emotional and behavioral adaptation. For example, research has shown that adult mental health and behavioral disorders are relevant risk factors for the development of similar disorders in biological offspring. Formative research to date in the NCS has not included mental health and behavioral measures in birth mothers and fathers. Incorporating validated shortened measures into the NCS would provide early identification of risk factors which can help mediate risk in offspring. Additionally formative research projects geared toward comparison of tools that assess delays and abnormalities in social interactions, communication patterns, mood, and attention will allow the NCS to ensure that questionnaires, recorded interviews, and observational videos will capture participant data in a manner that will enable the NCS to conduct analyses on these data in the future.

(3) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's language development and ability to communicate and adult language and reading comprehension level?

Smaller-scale formative research and pilot testing of tools assessing early language development in infancy to pre-school age children including speech, early reading and writing will enable the NCS to remain current with the contemporary research understanding of assessing language delays secondary to cognitive, neurological, emotional, or physical causes. As methods to detect language delays improve in quality, efficiency, and cost, it is necessary to pilot these improvements to determine feasibility prior to implementing them in the Vanguard (Pilot) Study and Main Study in order to minimize respondent burden.

(4) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's cognitive growth and development and measures to assess adult cognitive abilities and adaptation?

Neuropsychosocial formative research and pilot testing will assist in ensuring that the most current methods of assessing cognitive growth and development in children and adult cognition and adaptation measures are used in order to increase the acceptability of NCS information collections, and determine feasibility prior to implementing them in the Vanguard (Pilot) Study and Main Study in order to minimize respondent burden. Ultimately, less burdensome methods to assess cognitive development and adaptation involving assessment of learning, thinking, memory, visual perception and integration, problem-solving, and the ability to classify objects will result in more efficient and faster Study visits; and, therefore, a lower participant burden. Engagement with formative research study participants, parents, educators, health care

practitioners, pediatric professional organizations, public health organizations, and other health care team members via focus groups and cognitive interviews will also assist in establishing the acceptability of neuropsychosocial assessment methods.

(5) Are there less burdensome collection methods available that can provide similar accuracy and precision in measuring children's physical development and motor function?

The longitudinal nature of the NCS allows for children's physical development to be measured over time through physical examinations and measures that allow for the evaluation of trajectories of growth as well as comparisons to age and gender norms. Specific areas of focus may be variances in age and gender relative to the development of gross motor skills (for example, the ability to sit up, crawl, or walk) and fine motor skills (for example, ability to control precise movement like using a fork or spoon). Formative research will inform data collections related to physical developmental delays including height and weight measurements, cranial and skeletal nerve function, gross and fine motor function, nervous system function, and physical activity. Refinement of the physical measures and examinations, questionnaires, recorded interviews, and observational videos will capture participant data that will allow the NCS to conduct analyses on these tools for potential use in the Vanguard (Pilot) Study and Main Study.

(6) Are there additional types of measures that the NCS should consider adding to the Vanguard (Pilot) or Main Study protocol to assess physical, emotional, and neurological development, psychosocial growth, and adaptation, and behavioral changes?

The Vanguard (Pilot) Study uses a minimal visit configuration resulting in shorter study visit assessments. In turn, neurodevelopmental and psychosocial measures currently collected during visits under the Vanguard (Pilot) Study protocol do not represent an exhaustive set and could be expanded and refined. However, it will be necessary to evaluate the feasibility, acceptability, and cost of any new neurodevelopmental and psychosocial measures prior to implementation in either the Vanguard (Pilot) Study or Main Study.

The exemplar study in this clearance is *LOI2-QUEX-5*, *Bayley-3 Short Form for the National Children's Study*. In this information collection, study centers will pilot test a shortened form of a standardized assessment of young children's cognitive, language, and motor development in order to establish a cost-efficient, psychometrically sound direct assessment of key developmental indicators. This shortened assessment, if found to reliable and valid, will utilize fewer resources for assessments up to 3 years of age while maintaining similar accuracy and precision as compared to the complete version.

The following list of projects represents a set of examples of the types of information that will be gathered under the scope of this generic clearance. These projects will be forwarded for review under this clearance mechanism once it is established. Overall, these projects examine less burdensome, cost-effective methods for the collection procedures and tools used to assess neurodevelopmental and psychosocial measures. They are:

1. Bayley-3 Short Form for the National Children's Study (LOI2-QUEX-5)
2. Assessment of Executive Function for the National Children's Study (LOI2-QUEX-6)
3. Development and Validation of an Autism Case Confirmation Approach for use in the National Children's Study (LOI2-QUEX-8)
4. A Multi-Center Methodological study to Assess Mental Disorders for NCS Birth Mothers and Fathers (LOI3-MHLTH-09)

The purpose, study design, and intended study outcome(s) are listed below in Table A1.

Table A1. Formative Research Exemplar Study and Potential Future Projects

	Background/Purpose	***Study Design***	***Intended Study Outcome(s)***
LOI2-QUEX-5 Bayley-3 Short Form for the National Children's Study	Develop age-specific short forms of the Bayley Scales of Infant and Toddler Development-Third Edition ("Bayley-3") for the 6-month, 12-month, 18-month, 24-month and 36-month ages study visits.	Infants and toddlers born between 36 to 42 weeks gestation, no medical complications present at birth or currently, and not diagnosed or receiving treatment for mental, physical or behavioral difficulties will be invited to participate. Self-identified White, African-American, Hispanics, Asians and Other (American Indian) parents will be included and will reflect three parent education levels (less than high school, high school graduate, and some college and beyond). To obtain test-retest reliability, approximately 100 infants and toddlers from the larger sample of 1000 participants will be tested twice on the Bayley-3 short form with a test-retest interval of 5-7 days.	Brief, cost-efficient, and psychometrically sound direct assessment measure of early childhood cognitive, language, and motor development for infants and children ages 6, 12, 18, 24, and 36 months.
LOI2-QUEX-6 Assessment of Executive Function in the National Children's Study	Develop measures of executive function for 3 to 5 year old children and their parents.	Diverse families from 3 sites (university, homeless shelter, and community preschool) serving low-income families will be invited to participate.	Brief, cost-efficient, and psychometrically sound direct assessment of executive function with suitability for diverse samples, especially low-income minority families on a multi-center level.
LOI2-QUEX-8 Development and Validation of an Autism Case Confirmation Approach for use in the National Children's Study	Validation study comparing a parent report and laboratory observation assessments with a standardized autism and/or autism spectrum disorder questionnaire administered at the 36-month study visit.	Parents of 33-39 month-olds infants who have been diagnosed with autism or an autism spectrum disorder and are scheduled for an evaluation and a group of children with autism or an autism spectrum disorder will be invited to participate.	Brief, cost-efficient, and psychometrically sound direct assessment of behaviors associated with autism and autism-spectrum disorders, which can be administered by NCS field staff with no

	Background/Purpose	*Study Design*	*Intended Study Outcome(s)*
			previous autism spectrum disorder expertise on a multi-center level.
LOI3-MHLTH-09 A Multi-Center Methodological study to Assess Mental Disorders for NCS Birth Mothers and Fathers	Validation study involving an assessment of mental disorders in pregnant women and their male partners using a brief screening tool for parental mental health disorders against the longer 60-minute standard interviews.	English-speaking women between the ages of 18-49 who are pregnant and biological fathers will be invited to participate in the first screening scale interview. A portion of these respondents will also participate in the Structured Clinical Interview for DSM-IV (SCID) interview. Additionally, the study team will sample low-income, Hispanic and Non-Hispanic Black respondents for the SCID and to maintain dispersion in terms of urbanicity and census region.	Brief, cost-efficient, and psychometrically sound direct assessment of behaviors associated with parental mental health on a multi-center level.

A.3 Use of Information Technology and Burden Reduction

The specific focus of these formative research data collections is the improvement of neurodevelopmental and psychosocial measures for the NCS, and may include computer-assisted interviewing, automated data collection, and other procedures designed to decrease participant burden, study costs, and improve data accuracy. Other appropriate information technology solutions will be embraced to reduce respondent burden and improve data quality. The NCS will use methods that minimize burden and make use of available information technology.

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 employees' and public citizens' PII; and it ensures that the government has considered necessary safeguards for 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

Formative research projects will be used to demonstrate proof-of-concept in a manner that minimizes participant burden and study costs, prior to testing in the NCS Vanguard (Pilot) Study protocol if results warrant. For example, formative research projects submitted through this clearance mechanism may evaluate use of a short form of the Bayley Scales of Infant Development, 3rd Edition (Bayley-3) to measure infant and toddler development. In this example, if results suggest that the short form of the Bayley-3 Short Form is as reliable, less burdensome, and more cost-effective measure of development than the long form of the Bayley-3, the NCS may implement the piloted approach in the context of the NCS Vanguard (Pilot) Study to further test logistics of implementation among a larger, and perhaps more diverse, study population. In this way, formative research projects will not duplicate, but rather, guide NCS Vanguard (Pilot) Study and Main Study information collections.

A.5 Impact on Small Business and Other Small Entities

The potential impact of these formative research projects on small businesses will include largely health care providers such as physicians, nurses, social workers, and others. Local NCS staff may work with physicians and other medical care providers or facilities to provide information about the study to their patients. With the consent of the participant, key medical diagnostic and treatment information on study participants may also be requested of medical providers. Where requested, the study will reimburse providers for any expenses incurred as part of filling requests for information.

A.6 Consequences of Collecting the Information Less Frequently

These formative research data collections will be conducted as needed on an on-going and concurrent basis, and are designed to decrease participant burden and improve data collection for the both the NCS Vanguard (Pilot) Study (currently on-going) and the NCS Main Study, a crucial requirement given the mandated scope of the Study. Without these small studies, future NCS information collections for the Vanguard (Pilot) and Main Studies may implement full-scale tools that do not curb respondent burden and may be less efficient.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 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 24497-24498 of the Federal Register on May 2, 2011 [Vol. 76, No. 84].

Three written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. One of the individuals requested additional information about the study, particularly if the study was active in his local geographic area, and additional information was provided. The second verbal commenter requested a more detailed explanation of the formative research program, and expressed

satisfaction that the NCS was proposing to do formative research and pilot testing before committing scarce federal taxpayer dollars to the full-scale study.

Two of the three written comments were identical. They opposed the NCS in general, stating that it was too costly, and expressed concerns about the effects of federal programs. The comments are provided below:

Comments 1 and 2: I OPPOSE THIS LONGITUDINAL STUDY. I BELIEVE IT IS INEFFECTIVE AND IT IS ALSO TOO COSTLY. AND I DONT BELIEVE THE RESULTS WOULD BE TRUTHFUL BECAUSE THIUS AGENCY HIDES FROM THE PUBLIC. IT HAS SECRET, DECEPTIVE MEETINGS THAT NEVER INCLUDE MEMBERS OF THE PUBLIC TO SIT IN. IT HAS ALWAYS HAD SECRET MEETINGS WHERE THEY DO WHAT THEY WANT TO DO INSTEAD OF RESPONDING TO WHAT THE PUBOLIC WANTS AS PUBLIC SERVANTS. THIS AGENCY IS IN FACT OUT OF CONTROL. THIS IS MY COMMENT FOR THE PUBLIC RECORD. THIS AGENCY IN FACT HURTS CHILIDREN. 70 DOSES OF VACCINES WITH TOXICES LIKE MERCURY, ALUMINUM FORMALDEHYDE, GELATIN WHICH COULD BE FROM MAD COWS AND OTHER TOXICS ALL INJECTED INTO KIDS. WITH NO REAL CUMULATIVE TESTING AT ALL DONE. I DO NOT WANT ONLY FAT CAT FEDERAL BURAEUCRATS SITTING IN SECRET TO MAKE HEALTH DECISIONS ANY MORE. ALL OF THEIR COMMITTEES SHOULD INCLUDE MEMBERS OF THE AMERICAN PUBLIC, CHOSEN AT RANDOM TO SIT IN TO BRING SOME COMMON SENSE TO WHAT THIS AGENCY IS GETTING AWAY WITH. MEMBERS OF THE AMERICAN PBULIC WITH NO FINANCIAL INTEREST IN DRUGS OR VACCINES SHOUDL SIT IN AS 51% OF ALL MEMBERS OF ANY DECISION MAKING COMMITTEE AND YOU HAVE TO EXPLAIN TO THEM WHAT YOU PLAN. BECAUSE YOUR PLANS ARE GOING COMPLETELY OUT OF CONTROL. WE ARE NOT "HERDS" .WE ARE PEOPLE WITH DIFFERNT SYSTEMS, DIFFERENT DNA, ETC. YOU CANNOT CONSIDER US A "HERD". YOU ALSO SEEM TO BE WANTING TO VIOLATE THE NUREMBERG DECISIONS, WHICH SAID PEOPLE HAVE THE RIGHT TO CONTROL THEIR OWN BODY. WHERE DO YOU GET OFF THINKING YOU CAN INJECT ANYTHING you WANT INTO SOMEBODY'S BODY. THAT IS OUTRAGEOUS. THEY PUT PEOPLE TO DEATH AND IN JAIL IN GERMANY FOR THAT CRAP AND YOU ARE APPROACHING THE SAME STUFF HERE IN AMERICA. THE SAME APPROACH. THE SAME WANTING TO DO TO SOMEBODY'S BODY WHAT YOU WANT. GET OFF IT PLEASE. YOU HAVE CAUSED THE AUTISM EPIDEMIC IN AMEICA AND THEN YOU HIDE FROM INVESTIGATING IT BECAUSE YOU KNOW YOU CAUSED IT.

Comment 3: i do not believe that this study, which taxpayers have been paying through the nose for the last 30 years is necessary at all. i think the budget of this project should be cut to zero. the costs and expenses of this not necessary survey are costing American taxpayers their homes and food in their mouths. Taxpayers are being bludgeoned for taxes to pay for studies that nobody in America needs or wants. The agency wants power and budget so they load up. It’s time to downsize.

We do need autism research which has caused millions of American kids to become autistic to make profits for big pharma and big medicine. We need to spend our tax dollars on that. And this agency needs to admit it doesn’t know what it is doing about vaccines at all. this agency was careless in advocating so many vaccines so young in tiny babies of 6 lbs.

1. Not necessary
2. Agency always underestimates costs and then loads up afterward to bludgeon taxpayers
3. There is no way for the taxpayers to be able to pay for these unnecessary, wasteful studies and you can and should use your data from the 30 years previously funded. Your study and nothing to help America ever results. We are paying for perpetual students when we should be paying for researchers working directly on the issues
4. The best thing to do is cut the budget to zero of this project. It’s time to stop beating taxpayers over the head for stupidity like this. Taxpayers are being asked to fund crap that

shows nothing of promise for America.

Response to the comment(s): The National Children's Study was mandated by Congress through the Children's Health Act of 2000 (Public Law 106-310), which states:

PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.*
(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—*
(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; and
(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.
(c) REQUIREMENT.—The study under subsection (b) shall—
(1) incorporate behavioral, emotional, educational, 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 populations of children, which may include the consideration of prenatal exposures; and
(3) consider health disparities among children, which may include the consideration of prenatal exposures.

The NCS is designed to fulfill the Congressional mandate provided above. The generic clearance requested for formative research will enable the NCS to fulfill these requirements and produce research that benefits the American public, with the lowest possible burden and cost to taxpayers.

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) 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 formative research projects and pilot studies 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 activities that will be required. Incentive amounts will

be consistent with the approved incentive schedule for the NCS Initial Vanguard Study and Recruitment Substudy. Participants agreeing to provide biospecimen samples will be offered a monetary incentive or equivalent not exceeding $25. Should a particular formative research project proposed through this generic clearance request testing of a slight modification of the incentive structure described in Table A.1, we will provide appropriate justification in that request. Compensation amounts will be addressed specifically in IRB submissions for each pilot. Small gifts of appreciation for participation may be provided to participants in lieu of cash incentives. These may include items such as t-shirts, tote bags, etc., and are intended as tokens of appreciation.

Table A.1. Maximum NCS Incentives, by Study Activity and Impact on Participants

Data Collection Activity Characteristics	**Initial NCS Vanguard Study**	**NCS Recruitment Substudy and Formative Research**		
		Phase 1	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	In addition to the monetary	As an alternative to the monetary	In addition to the monetary	Instead of monetary

bags, post its, key chains, etc.)	incentive, non-monetary incentives valued at $25 or less may be offered to participants	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	incentive, NCS logo gifts valued at $25 or less may be offered to the participants if these are deemed acceptable by local IRBs	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)), the 2011 Generic Clearance Request for Environmental Science projects, and the 2011 Generic Clearance Request for Study Logistics Projects, in process.

A.10 Assurance of Confidentiality Provided to Respondents

NCS formative research projects 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, substudies 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 formative research questionnaires that could be considered sensitive such as pregnancy status, reproductive and medical histories, mental health status, and income. As part of the informed consent process, women will be informed that their participation in NCS is voluntary and that they may refuse to answer any question. Fathers and other family members may also be asked to participate through the informed consent process. All study questionnaires that would be proposed for formative research under this clearance mechanism have been or will be reviewed by Human Subjects Review Boards at NICHD and participating institutions.

Each of these sensitive questions is necessary to allow comparisons between the formative research sample and persons potentially eligible for the Main Study, thereby informing whether proposed questionnaire items and physical examinations would warrant further testing in the NCS Vanguard (Pilot) Study.

A.12 - 1 Estimates of Hour Burden

Table A.2 Estimated Annualized Hour Burden for Neuropsychosocial Measures

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 Requested
Physical measurement and examinations	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants)	4,000	1	1	4,000
Child Developmental Measures (cognitive)	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants)	4,000	1	1	4,000
Computer-based reaction time testing	NCS participants	4,000	1	1	4,000
	Members of NCS target population (not NCS participants)	4,000	1	1	4,000
Small, focused survey and instrument design and administration	NCS participants	4,000	2	1	8,000
	Members of NCS target population (not NCS participants)	4,000	2	1	8,000
	Health Care Providers	1,000	1	1	1,000
	Social Service Providers	1,000	1	1	1,000
	Community Stakeholders	2,000	1	1	2,000
Focus groups	NCS participants	2,000	1	1	2,000
	Members of NCS target population (not NCS participants)	2,000	1	1	2,000
	Health Care Providers	1,000	1	1	1,000
	Social Service Providers	1,000	1	1	1,000
	Community Stakeholders	2,000	1	1	2,000
Cognitive interviews	NCS participants	500	1	2	1,000
	Members of NCS target population (not NCS participants)	500	1	2	1,000
Total		**45,000**			**54,000 hrs**

A.12 - 2 Annualized Cost to Respondents

Table A.3 Estimated Annualized Cost for Neuropsychosocial Measures

Data Collection Activity	Type of Respondent	Estimated Total Annual Burden Hours Requested	Hourly Wage Rate	Estimated Total Annual Respondent Cost
Physical measurement and examinations	NCS participants	4,000	$10.00	$40,000
	Members of NCS target population (not NCS participants)	4,000	$10.00	$40,000
Child Developmental Measures (cognitive)	NCS participants	4,000	$10.00	$40,000
	Members of NCS target population (not NCS participants)	4,000	$10.00	$40,000
Computer-based reaction time testing	NCS participants	4,000	$10.00	$40,000
	Members of NCS target population (not NCS participants)	4,000	$10.00	$40,000
Small, focused survey and instrument design and administration	NCS participants	8,000	$10.00	$80,000
	Members of NCS target population (not NCS participants)	8,000	$10.00	$80,000
	Health Care Providers	1,000	$101.00[1]	$101,000
	Social Service Providers	1,000	$20.00[2]	$20,000
	Community Stakeholders	2,000	$10.00	$20,000
Focus groups	NCS participants	2,000	$10.00	$20,000
	Members of NCS target population (not NCS participants)	2,000	$10.00	$20,000
	Health Care Providers	1,000	$101.00[1]	$101,000
	Social Service Providers	1,000	$20.00[2]	$20,000
	Community Stakeholders	2,000	$10.00	$20,000
Cognitive interviews	NCS participants	1,000	$10.00	$10,000
	Members of NCS target population (not NCS participants)	1,000	$10.00	$10,000
Total		**54,000 hrs**		**$742,000**

[1]The hourly wage rate for an OB/GYN is $101.13 (http://www.bls.gov/oes/current/oes291064.htm).

[2] The hourly wage rate for a social service provider is $19.83 (http://www.bls.gov/oes/current/oes211798.htm).

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 formative research. This may include transportation costs to and from activities, and babysitting or elder care expenses. There are no other known costs to participants.

A.14 Annualized Cost to the Federal Government

The estimated cost to the federal government for these pilot and formative studies is $2,793,681 per year over the three-year period.

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

The proposed data collections include physical measurements and examinations, child development measures, computer-based reaction testing, focused survey and instrument design and administration, focus groups, and cognitive interviews intended to increase data and collection efficiency for the NCS. Each formative research project will adhere to a customized information collection evaluation and publication schedule, among other study deliverables. The studies will take place over the three-year period specified in this information collection request.

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.