

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

Part B only

CDR Colleen O. Lee, MS, CRNP
National Children's Study
***Eunice Kennedy Shriver* National Institute for Child Health and Human Development**
6100 Executive Boulevard
Room 3A01
Bethesda, MD 20892-7510
Phone 301-451-2135
E-mail: leeco@mail.nih.gov
General e-mail inquiries: ncs@mail.nih.gov
www.nationalchildrensstudy.gov

B. Collection of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

Each request for formative research and pilot testing submitted through this generic clearance will include a discussion of the target sample, the sampling method, and the recruitment approach. Although a convenience sample will be sufficient for most formative research and pilot tests, representative samples from one or more Study locations may be required in some cases.

In general, we envision the following groups will be enrolled in our proposed formative research and pilot studies:

- Women of child-bearing age/potential NCS participants
- Infants and children
- Fathers
- Legal guardians
- Health care facilities and professionals
- Hospital administrators and staff
- Pediatric professional organizations and practitioners
- Social service providers
- Educational professionals
- Public health organizations
- Community leaders
- Community organizations
- Community members
- Cultural and faith-based centers

Some formative research proposed through this generic clearance that aims to recruit NCS Vanguard (Pilot) Study participants will systematically invite participants among collaborating NCS study centers based upon formative research-specific eligibility criteria. Enrollment will continue until project-specific recruitment targets have been met. Generally, participants will be recruited to join substudies through their regularly scheduled NCS Vanguard (Pilot) Study interactions. However, invitations to join substudies will clearly indicate the separate and distinct nature of NCS substudies from the NCS Vanguard (Pilot) Study. Invited participants will be reminded that their participation in NCS substudies is voluntary and will not impact their participation in the NCS Vanguard (Pilot) Study.

Other formative research projects proposed through this generic clearance will adopt a convenience sample approach. Persons demographically similar, but who are not participating in the NCS Vanguard (Pilot) Study will be invited to join substudies using local advertising methods. Enrollment in these studies will continue until project-specific enrollment targets are met. For substudies involving community organizations, professional organizations and practitioners, health care professionals, and public health organizations, we will use a list frame sampling approach to identify potential participants in formative research to reach the substudy-specific desired enrollment target.

Formative research projects will be designed so as not to impair the ability of the NCS Vanguard (Pilot) Study to accomplish its goals of generating data to inform the feasibility, acceptability, and cost of recruitment strategies, study visit assessments, and study logistics for the Main Study.

B.2 Procedures for the Collection of Information

Neurodevelopmental and Psychosocial Measures: Tools to evaluate adult psychosocial and mental health constructs, infant and child development, and health literacy may be administered as part of some study visit procedures. Formative research incorporating these measures will help determine the feasibility, acceptability, and cost of incorporating measures or portions of measures into the NCS for adults and children.

Physical Examinations of Neurological Function: Examinations of neurological function may be designed to assess gross and fine motor skills, sensory skills, cranial and skeletal nerve function, overall nervous system function, hearing and speech, vision, coordination and balance, reflexes, mental status, and changes in mood or behavior, among other abilities. Formative research incorporating these measures will help determine the feasibility, acceptability, and cost of incorporating neurological function into the NCS for assessing child development and adult measures of neurological function.

Designed Experimental Tasks for Testing Neurocognitive Processes: Designed experimental tasks are usually computer-controlled, and are designed to link to specific neurocognitive processes, such as adult and child intelligence, responses to changes in the environment, reaction time, and visual perception and memory. Formative research may incorporate computer-based designed experimental tasks for the purpose of evaluating the feasibility, acceptability, and cost of use in the Vanguard (Pilot) and Main Studies for adults and children.

Small, focused survey and instrument design and administration: Study Centers may be conducting small focused surveys to test data collection methodologies and study materials on specific and/or targeted populations, including cultural sensitivity, validation studies of existing data collection instruments, and to develop and test Study materials and questionnaires. Additionally, study centers may administer small, focused surveys in conjunction with specific neurodevelopmental and psychosocial measures, physical examinations, and designed experimental tasks used to test neurocognitive processes. Information gained from small focused surveys of potential participants, such as instrument validation for a specific population or surveys to discover important issues in communities that are being addressed by the NCS, is crucial to the development of study protocols that work consistently with all Study participants. Survey instruments will be developed according to accepted survey methodologies.

Focus groups: Focus groups are group discussions that are guided by a moderator. They usually have 8-10 participants and generally last for 1.5 to 2 hours. Focus groups will be conducted with NCS participants, respondents who are members of the target population (but are not NCS participants), as well as with health care professionals and community members and officials who are potential NCS stakeholders. Study Centers may conduct focus groups to gather information from health care providers and practitioners, hospital administrators and staff, and other health care facilities and professionals, on

the feasibility, acceptability, and cost of refinement of the physical measures and examinations, questionnaires, recorded interviews, and observational videos that will capture participant data. Additionally, focus groups may be used to gather information on how to recruit participants from community groups, as well as how to approach tightly-knit community groups for participation in research involving neuropsychosocial information collections. Resulting data will be used to inform the development of study materials and messages including translated materials, to develop methods for reducing burden on participants, and to refine data collection methodologies.

Cognitive interviews: During cognitive interviews, participants will be asked about their comprehension of survey items, and their decision and response processes. Pretesting study instruments, including standard instruments, is important for training interviewers and improving measurement, as well as interpreting findings. Formative research protocols with cognitive interview components may utilize scripted probes and guides. Cognitive interviews may be used in situations necessitating greater depth and breadth of survey analysis, to help study centers develop questionnaires and surveys to be used in the Vanguard (Pilot) and Main Studies. Cognitive interviews with participants, health care facilities, community leaders, community organizations, community organizations, and other key stakeholders can be used to ensure that all NCS materials are developed in a way that addresses each targeted population and any associated cultural differences and sensitivities. Cognitive interviews will also help ensure that any additional materials associated with a physical examination or measure of neurological function are valid, acceptable, clear, and straightforward prior to being implemented in the field on a full scale in either the NCS Vanguard (Pilot) Study or Main Study, thereby improving the quality of survey questions and, subsequently, the data collected in formative research. Cognitive interviews will be conducted with respondents to ensure that questionnaire items or other materials are clear and elicit the expected response. This will include testing of translated items and materials to ensure that the translations are clear and understandable.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Each formative research and pilot test will recruit participants using methods appropriate to achieve their specific project goals. Some participants may be recruited at NCS-related activities and appointments, and others may be recruited using a convenience sample approach. Formative research recruiting non-NCS Vanguard (Pilot) Study participants benefits from the efficiencies of using a convenience sample as well as testing information collection techniques that would inform the NCS Vanguard (Pilot) and Main Studies. Formative research recruiting NCS Vanguard (Pilot) Study participants benefits from established rapport between participants and NCS data collectors and allows focused testing of items that complement the established Vanguard protocol. Special care will be taken so that proposed formative research projects under this generic clearance would not impair our ability to evaluate NCS Vanguard (Pilot) Study recruitment, retention, and study visit assessments.

B.4 Tests of Procedures or Methods to be Undertaken

The goal of formative research is to provide information that will maximize the rigor and efficiency (in terms of participant burden, infrastructure, and cost) of NCS procedures, materials, and methods.

Formative research and pilot tests may be pre-tested with fewer than 10 respondents; when this is adequate pre-testing for the purposes of these pilot activities.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Each formative research project team is staffed with appropriate statistical expertise, and is supported by a designated NCS Program Office subject matter expert and NCS statistical and field support staffs. Additionally, study centers continue to consult with federal agency representatives, advisory, and research groups, as well as individuals from statistical agencies on issues related to the NCS, including formative research and pilot testing.