

REQUEST FOR OMB CLEARANCE
Generic Clearance Renewal, OMB #0925-0590
Formative Research and Pilot Methodology Studies for the National Children's Study

Part B only

Jennifer Park, Ph.D.
Senior Scientist and Project Officer
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 301-402-7887
Fax: 301-480-1222
E-mail: jennifer.park@nih.gov
General e-mail inquiries: ncs@mail.nih.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
- Fathers
- Community leaders, members, and organizations
- Health care facilities and professionals
- Public health, environmental, social and cognitive science professional organizations and practitioners
- OB/GYN professional organizations and practitioners
- Hospital administrators and staff
- Cultural and faith-based centers
- Schools and child care organizations

Formative research proposed through this generic clearance that aims to recruit NCS Vanguard 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 interactions. However, invitations to join substudies will clearly indicate the separate and distinct nature of NCS substudies from the NCS Vanguard Study. Invited participants will be reminded that their participation in NCS substudies is voluntary and will not impact their participation in the NCS Vanguard Study.

Other formative research projects proposed through this generic clearance will adopt a convenience sample approach. Persons demographically similar to, but not geographically eligible to participate in the NCS Vanguard 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, OB/GYN practitioners, hospital administrators, cultural and faith-based centers, and schools and child care organizations, we will use a list frame sampling approach to identify organizations, practitioners, and other professionals who

would then be invited to participate 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 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

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 validation studies of existing data collection instruments, and to develop and test Study materials and questionnaires. Information gained from small, focused surveys of potential participants, such as instrument validation for a specific population or surveys to discover important issues when recruiting participants in a particular community is crucial to the development of rigorous and efficient study protocols appropriate for use among all Study participants. Survey instruments will be developed according to accepted survey methodologies. Both NCS Vanguard Study participants and their peers who are not participating in the Vanguard Study will be asked to participate.

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, their peers who are not NCS Vanguard Study participants, as well as with health care professionals and community members and officials who are potential stakeholders in the NCS. 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. Formative research protocols with cognitive interview components may utilize scripted probes and guides. 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. Both NCS Vanguard participants and their peers not participating in the NCS Vanguard Study will be asked to participate.

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 Study participants benefits from

the efficiencies of using a convenience sample as well as testing information collection techniques that would inform the NCS Vanguard and Main Studies without affecting our ability to evaluate Vanguard recruitment strategies or retention. Formative research recruiting NCS Vanguard 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 recruitment strategies.

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; 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.