

REQUEST FOR OMB CLEARANCE
Generic Clearance Request
Biospecimen and Physical Measurements Formative Research Methodology Studies for the National
Children's Study (NICHD)

Part B only

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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. A convenience sample will be sufficient for each formative research project and pilot tests.

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
- Health care facilities and professionals
- Hospital administrators and staff
- OB/GYN professional organizations and practitioners
- Pediatric professional organizations and practitioners
- Public health organizations
- Community leaders
- Community organizations
- Community members
- Cultural and faith-based centers

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, 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 convenience 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 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

Biospecimens and Physical Measures: Biospecimens from infants, children, and adults will be collected as part of some visit procedures. Biospecimens that may be collected include blood, urine, hair, nails, cervical fluid, breast milk, cord blood, infant meconium, placenta, and physical measurements such as height or length, weight, head circumference, upper arm circumference, and ulnar length.

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 biological sample and physical measurement collection, to obtain information about prior exposure and/or demographic characteristics. 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 stakeholders in the NCS. 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 a specific biological sample or physical measurement collection. 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 biospecimen and physical measure collection. 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 and biospecimen collection methodologies.

Cognitive interviews: During cognitive interviews, participants will be asked about their comprehension of survey items, and their decision and response processes. Cognitive interviewing methods can elicit information crucial to effective measurement. 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 conjunction with biospecimen and physical measure collections. Cognitive interviews with participants, health care facilities, community leaders, 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 biological sample or physical measurement collection are valid, acceptable, clear, and straightforward prior to being implemented in the field on a full scale in either the NCS Vanguard Study or the NCS 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 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. 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 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; 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.