

**National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
(NICHD)**

**Assessment of Communication Messages and Materials in Support of the Pilot Study for
the National Children’s Study (NCS)**

Section A

A.1 Circumstances Requiring the Collection of Data

These focus groups and interviews will help fulfill the requirements of: Executive Order 12862, Setting Customer Service Standards. The focus groups and in-depth interviews will also help fulfill the requirements of the Children’s Health Act of 2000 (Public Law 106-310) which states:

- (a) 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.*

A.2 Purposes and Uses of the Data

The findings of this study will be used to guide the development of future NCS materials. These insights will reveal what messages and formats for materials resonate best with the target audiences.

A.3 Use of Information Technology to Reduce Burden

N/A

A.4 Efforts to Identify Duplication

Focus group participants will be asked to participate in only one of the 24 focus groups. Participants in the in-depth interviews will be asked to participate in only one of the 8 interviews.

A.5 Small Business

The potential impact of this NCS assessment on small businesses will be limited to health care providers. Professional interviewers will interview eight health care providers to explore knowledge, attitudes, and beliefs about the National Children's Study and to test draft educational messages and materials to promote the National Children's Study and encourage participation.

A.6 Consequences of Not Collecting the Information

The overarching objectives of this study are to:

1. Assess audience perceptions of the NCS messages.
2. Explore knowledge, attitudes, and beliefs about the NCS among women of reproductive age.
3. Test draft educational messages and materials to promote the NCS and encourage participation among women of reproductive age.
4. Explore knowledge, attitudes, and beliefs about the NCS among health care providers.
5. Test draft messages and materials to support the provider-based recruitment strategy for the Pilot Study.

By collecting this information the NCS will be better able to determine what messages best reach the target audiences and thus be able to achieve the study goals to: 1) increase awareness and understanding of the NCS and its mission; 2) elevate support for and positive perceptions of the NCS; and 3) increase the participation rate of women recruited to the NCS.

A.7 Special Circumstances Justifying Inconsistencies with Guidelines in 5 C.F.R. 1320.5

There are no special circumstances that would cause this information collection to be conducted in a manner inconsistent with 5 C.F.R. 1320.5.

A.8 Consultation Outside the Agency

N/A

A.9 Payments of Gifts to Respondents

Participants will be paid a cash incentive for participation. Consumers will be paid \$75 and health care providers will be paid \$150.

A.10 Assurance of Confidentiality

This study was approved by the IRB of the NICHD subcontractors, the Academy for Educational Development (AED). Individual respondents will not be identified and participation will be strictly voluntary. In handling all data and records related to these focus groups and interviews, NICHD and AED staff will be responsible for ensuring the confidentiality of the participant contact information. Additionally, AED will:

- Maintain no identifiers connecting any data collected to any particular participant; neither will it provide any personal identifiers to NICHD or others; firms which conduct recruiting and host the sessions will be required to not provide personal identifiers to

- AED or NICHD;
- Retain one set of audio recordings;
- Develop a report in an agreed-upon format summarizing the responses provided by participants; the report will contain no personal identifiers, i.e., information sufficient to determine the identity of any participant (such as name or address);
- Deliver the report and one set of audio recordings and/or transcripts to NICHD as requested;
- Not deliver to NICHD or others any personal identifiers of participants; and
- Retain records, audio recordings, and transcripts for three years, then burn, shred, or otherwise destroy them.

Additionally, participants will be asked to sign an Informed Consent Form (Attachment E) before participating in focus group discussions or interviews. The Informed Consent form ensures the participants that although the focus groups and interviews will be recorded, what they say will be kept private, as required by law. Participants’ names will not be put in a report or on the recordings, and the recordings will be stored in a locked cabinet and destroyed within three years by AED. Participants will keep the top sheet of the informed consent document, which includes a phone number to call for concerns about their participation. AED will ensure that the participants’ contact information will not be shared with any outside entities and will only be used for the purposes of this study. To ensure the confidentiality of the focus group and interview participants, the Screening Form and Invitation will be kept in a locked cabinet and destroyed within in three years by AED.

A.11 Questions of a Sensitive Nature

Questions to respondents that may be sensitive are limited to the disclosure of personal information collected during the screening (see Attachments C and D). Participants’ contact information will be collected twice – once on the Screening Form and again on the Invitation. This will be done to confirm the screener has collected the correct information.

A.12 Estimates of Response of Burden

Type of Respondent	Number of Respondents	Frequency of Response	Average Response Time	Annual Hour Burden
Focus Group Screening Participants	576	1	5	48 (2,880 min)
In-Depth Interview Screening Participants	60	1	3	3 (180 min)
Focus Group Participants	192*	1	90	288 (1,7280 min)
In-Depth Interview Participants	20*	1	60	20 (1,200 min)

* Selected from the 576 who were screened

** Selected from the 60 who were screened

A.13. Estimate of Total Capital and Startup Costs/Operation and Maintenance Costs to Respondents or Record Keepers

N/A

A.14. Estimates of Costs to the Federal Government

We estimate the cost to the Federal government to conduct the focus groups and in-depth interviews to be \$150,000. The 24 focus groups to be conducted will cost approximately \$5000 each for a total of \$120,000. The 20 in-depth interviews are estimated to cost \$1,500 each for a total of \$30,000.

A.15. Changes in Burden

This is a new information collection.

A.16. Plans for Publication, Analysis and Schedule

For both the focus groups and the in-depth interviews, the NICHD contractor, AED, will produce the topline and final research reports.

A.17. Approval to Not Display Expiration Date

We are not requesting an exemption to the display of the OMB Expiration date.

A.18 Exceptions to Item 19 of OMB form 83-I

The focus groups and in-depth interviews will comply with the requirements in 5 CFR 1320.9.

Section B

B.1. Respondent Universe and Sampling Methods

To address the objectives of this study, two phases of research are proposed. The first phase will be a series of focus groups with women. The second phase will be in-depth interviews with health care providers who will be an integral facet of recruitment in all strategies, but particularly the health care provider-based strategies.

Focus Groups

A total of 24 focus group discussions will be conducted in commercial market research facilities whenever possible (it may be necessary to conduct groups in hotels or other venues in rural areas or smaller cities). Each focus group is expected to last approximately 90 minutes. A draft of the moderator's guide is included in Attachment A. The focus groups will consist of the following elements:

- Discussion of knowledge, attitudes, and beliefs about the NCS
- Review of draft messages and materials for the NCS
- Assessment of the NCS messages

A professional moderator will guide the discussion of all 24 focus groups. If necessary, we will hire moderators who speak languages other than English. Up to six observers from NICHD and its communications contractors may observe the groups from behind a one-way mirror. All focus groups will be audio taped, and transcripts will be prepared from the audio recordings.

Simultaneous interpretation will be provided for observers behind the one way mirror for focus groups conducted in languages other than English.

In screening participants for focus groups, recruiters will take care to ensure that only individuals meeting the recruitment criteria are invited to attend the groups (a copy of the screening instrument is included as Attachment C). For example, individuals will be excluded from participation if they:

- Are employed in the media, market research, healthcare, or public health fields; and/or
- Have participated in a focus group or market research study within the last six months.

Group participants will be segmented by education level and race/ethnicity. Within each race/ethnicity category, half of the groups will be composed of individuals with some college or less and the other half will have completed college or more. Groups will be segmented by education level to ensure adequate feedback on comprehension among individuals with varying educational attainment. Segmentation by education will help to further explore whether materials are perceived differently by women with higher educational attainment. Groups will be segmented by race because single-race groups facilitate openness and candor and there may be various cultural issues that could impact how people from diverse backgrounds respond to different materials and messages. Each woman is only required to participate in one of the 24 focus groups.

Groups will be conducted during the day and in the evening to allow participation by parents with a variety of work schedules.

In-Depth Interviews

Data from selected health care providers will be collected by means of in-depth interviews, either in-person or via telephone. In-person interviews will be conducted in professional market research facilities wherever possible.

Each interview is expected to last approximately 60 minutes. A draft of the semi-structured interview protocol is included as Attachment B. The interviews will consist of the following elements:

- Discussion of knowledge, attitudes, and beliefs about the National Children's Study
- Review of draft messages and materials for the National Children's Study

A professional interviewer will conduct the interviews. Up to six observers from NICHD and its communications contractors may observe interviews conducted in professional market research facilities from behind a one way mirror. All interviews will be audio taped, and transcripts will be prepared from the audio recordings.

In screening participants for the interviews, recruiters will take care to ensure that only individuals meeting the recruitment criteria are invited to attend the groups (a copy of the screening instrument is included as Attachment D).

For both the focus groups and in-depth interviews, AED will subcontract local research vendors to recruit participants, provide facilities for the research, and handle other logistics. AED will secure consultant moderators/interviewers to facilitate the discussions and interviews. In addition to procuring these services, AED will print all materials for testing, observe all interviews (along with NICHD staff), and produce the topline and final research reports.

B.2. Information Collection Procedures/Limitations of the Study

NICHD will collect all information in a manner that is consistent with the following principles:

- o Participation will be full voluntary, and non-participation will have no impact on the participants.

- o Collected information will be limited to that which is needed to assess audiences' perceptions of the NCS and guide the development of future NCS materials.

B.3. Methods for Maximizing the Response Rate and Addressing Issues of Non-response

Consistent with sound focus group and interview methodology, the design of the focus group and interview guides will include approaches to maximize response rates, while retaining the voluntary nature of the effort.

B.4. Tests of Procedures of Methods

All pre-testing will be carried out at a level and in a manner consistent with the specific focus group and interview guides.

Attachments:

- Attachment A: Moderator's Guide for Focus Groups
- Attachment B: Semi-structured Interview Protocol
- Attachment C: Screening Instrument for Focus Groups
- Attachment D: Screening Instrument for Interviews
- Attachment E: Informed Consent Document