REQUEST FOR OMB CLEARANCE

Formative Research and Pilot Methodology Studies for the National Children's Study

Part B

B. Collection of Information Employing Statistical Methods

B.1 Target respondents

Respondents will include the following types of individuals and organizations:

- Women of child-bearing age/potential participants,
- Fathers,
- Community leaders,
- Health care facilities and professionals,
- OB/GYN professional organizations and practitioners,
- Pediatric professional organizations and practitioners,
- Hospital administrators and staff,
- Community organizations,
- Community members,
- Cultural and faith-based centers,
- Public health organizations,
- Environmental organizations,
- Schools/child care organizations

B.2. Procedures for the collection of information

Survey Administration: The Coordinating Center, the seven Vanguard Centers and 15-20 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, as well as focus groups with healthcare providers, community officials and participants, and cognitive interviews to refine data collection materials and instruments, especially to develop and test translations of Study materials and questionnaires.

Survey Design: Survey instruments, including focus group and cognitive interview guides, will be developed according to accepted survey methodologies. Data may be collected utilizing the following methods:

Small focused surveys: 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 are consistent—and work consistently—with all Study participants.

Focus groups: Focus groups are group discussions that are guided by a moderator. They usually have between 8 and 10 participants and generally last for 1.5 to 2 hours. Focus groups will be conducted with both respondents who resemble potential NCS participants (women who are pregnant, may become pregnant and parents of young children) as well as with health care professionals who may become part of the study

(doctors, nurses, and others may refer patients to the NCS and/or collect data for the NCS) and community members whose support for the study is needed to insure its success (religious leaders, teachers and school administrators, politicians, etc.). One purpose of focus groups may be to identify issues that are important to the community. The focus groups will also discuss barriers to participation and support for the study. Resulting data will inform the development of Study materials and messages, including translated materials, and be used to refine data collection methodologies, and to develop methods for reducing reduce burden on health care providers as well as participants.

Cognitive interviews: Cognitive interviews will be conducted with respondents who resemble potential participants 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 to the target population. Attachment 1 provides some examples of the types of probes used for cognitive testing, and how the results will be used.

Medical provider feedback: Materials such as informational brochures and letters will be used during preliminary discussions with local hospitals and medical providers to inform them about the study.

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