

Title (up to 35 words):

Cognitive testing of five current informed consent documents

Names and Affiliations:

Jennifer Brustrom, PhD, Battelle

Andrew Davis, MA, Battelle

Tiffany Bernichon, BS, Battelle

Nicole Weinstein, MSW, Battelle

Julia Slutsman, PhD, NICHD

Jessica Graber, PhD, NICHD

Description of Research (up to 250 words):

Introduction:

The purpose of this study was to perform cognitive testing on the five informed consent documents currently being used for the National Children’s Study (NCS) to ensure that each consent booklet is interpreted as intended by target participants.

Methods:

Respondents were a demographically diverse sample of individuals (in each of the 5 NCS participant groups: Preconception, Pregnant, Father, New Adult, and Child). Respondents reviewed the appropriate consent booklet and were interviewed about a variety of topics including comprehension and retention of the booklet’s content and the risks/benefits of Study participation. Respondents also recommended ways the booklets could be improved.

Results:

- Respondents felt that information provided in each of the 5 consent booklets was generally clear and understandable;
- Interviewees retained the important information that was presented and were able to describe key aspects of the Study;
- About 88 percent of the respondents indicated they would lean toward participating in the NCS if they lived in an eligible area and were asked to participate;
- Respondents generally understood the messages in the booklets about their rights as a Study participant and the voluntary nature of participation in the NCS.

Conclusions:

We offer several recommendations to further refine the NCS consent materials. Prospective NCS participants’ comprehension could potentially be improved, for example, if an overview of the study was provided near the beginning of the consent booklet, if specific terms (e.g., “Vanguard Study”) were clarified, and if information about genetics were explained in greater detail.

Possible Table:

One table we would likely include in our poster is shown below. *Please note that the table content is not considered in the abstract word count.*

Summary of Key Findings

Thoughts Expressed, by Topic
Comprehension
Found term “sample” confusing on page 1
Unclear about the difference between the Vanguard Study and the Main Study page 1
Unclear about the difference between the Vanguard Study, the Main Study, and “all parts of the Study” later in the guide
Difficulty with phrase “how our genes act together with our surroundings”
Confusion related to physical, social, and/or family environments
Found genetic information section somewhat difficult to understand
Confused about when/if/how participants would receive information related to the Study
Confusion/concern related to mandated reporting
Thought that checking “no” to any/all would disqualify from participation or uncertain
Retention
Clearly stated nature and purpose of Study to include improving children’s health and recognizing influence of environment
Mentioned collection of samples as a key Study activity
Mentioned home visits as a key Study activity
Mentioned completion of survey items as a key Study activity
Mentioned statement related to voluntariness as a key Study concept
Mentioned statement related to security or confidentiality as a key Study concept
Able to recall some environmental samples
Able to recall some biological samples
Respondent Recommendations
Include more information regarding why and how samples will be collected, how samples will be used, and the purpose of collecting samples
Include more references to how Study activities are related to child health, improving child health
Include national contact information: Phone numbers for main office, web site, leadership names
Clarify difference between Vanguard and Main Study
Information on incentives/compensation should be included earlier, be more specific
Include a timeline of activities and visits, clarify number of visits to expect
State earlier in the booklet that there is no cost to the participant
Share parentage information if requested (respondents were in Father Group)
Provide more information about the researchers who will be accessing information and samples

Proposed Graphics:

