

NCS Formative Research Template for OIRA Clearance

TO BE COMPLETED BY STUDY CENTER AND NCS PROGRAM OFFICE SUBJECT MATTER EXPERT:

LOI #:	<u>LOI - 3 - INF - 04 - A</u>
Title of Formative Research:	<u>Development of an Assent Process for Children Enrolled in the NCS Vanguard Study</u>
Institution:	<u>University of New Mexico Study Center</u>
Study Location:	<u>Valencia County, NM</u>
Recruitment Arms:	<u>Enhanced Household Based Recruitment</u>
SME:	<u>Julia Slutsman</u>
COTR:	<u>Maria Lopez-Class</u>

Purpose of the Study: To determine the feasibility, acceptability, and cost of developing an assent process for children enrolled in the NCS, this study will research and develop an informed assent process based on the developmentally-appropriate presentation of research concepts to children ages 7 and 8. Additionally, this study will investigate how to enhance children's comprehension of research procedures.

Benefit to NCS Vanguard or Main Study: Effective engagement of children in the assent process is necessary to provide the greatest level of protection for a group that typically relies on parental opinion to inform their judgment about participating in a research study. There is little empirical evidence and an absence of best practices for administering assent in pediatric studies. This study will utilize recent advances in media and interactive technologies to ensure that children are engaged in assent in a way that provides the most beneficial protection and also assures that child participants in the NCS Vanguard and Main Studies are accorded their full rights.

Study Design: The study will be conducted in two parts. In part 1, we will use focus group methodology to examine the attitudes, beliefs and concerns of educators and parents (without children present) towards the development of a media-based assent tool for children ages 7-8 years old. For part 1, we will conduct focus groups for parents and educators of children 7-8 years of age. Focus groups will be audiotaped and then transcribed verbatim. Then, study investigators will analyze the transcripts for content and data will be entered into the ATLAS.ti software program for a systematic analysis of themes, attitudes, beliefs, and concerns.

In part 2, we will develop a prototype based on information gathered in part 1 and will invite the parents back (with their children present) to test the prototype and provide feedback to inform the final media content. For part 2, we will use information obtained from focus groups to build a storyboard of how an interactive media assent protocol would be presented to children aged 7-8. Parents and children will be presented with the interactive media concepts during face-to-face interviews. Interview questions will be structured to evaluate engagement, comprehension, and parental acceptance of the assent process.

(NOTE: This study will be submitted to OIRA in two separate information collection requests, as there are types of respondents: parents / children (households or individuals) and educators (state or local government). Above is the description of the full study design. This ICR focuses on parents and children only. A subsequent ICR will focus on educators only.

Target Respondents: Parents and children who are demographically similar to, but not currently enrolled in the NCS Vanguard Study, will be invited to participate in focus groups. To test attitudes, beliefs, and concerns, we will conduct 4-5 groups with about 6-11 participants each with parents. Following analysis of these results and

NCS Formative Research Template for OIRA Clearance

storyboard development of interactive media concepts, we will conduct an additional set of focus groups with about 55 total parents from the initial focus groups and their children. In past projects involving re-invitation at our site, we have experienced a return rate for the second focus group of about 95%.

Method of Recruiting: We will recruit parent/child participants via flyers posted at area elementary schools, and letters sent to parents of children aged 7-8 at elementary schools. Pre-identified school staff connected with the NCS will identify eligible parents by using specific inclusion/exclusion criteria; once appropriate approvals from participating schools are obtained, these staff will send letters providing preliminary information about the substudy to parents and requesting that they call to establish eligibility and to schedule a focus group appointment. Participants will also be invited to participate via flyers distributed through school media channels, until substudy-specific recruitment targets have been met.

***Confidentiality:** Study Centers must abide by the terms of their Data use agreement, which should reference all formative research efforts involving the collection of management of NCS restricted-use data. All participating Study Centers will have approved Data Use Agreements and Security Plans prior to launch.

***IRB Approval:** Local IRB clearance for this activity has been obtained. Please see the attached IRB approval letter.

Incentives: Consistent with the approved NCS Vanguard Study Phase 2 incentive structure, we propose to offer the parent a \$25 monetary incentive (each; \$50 in total) for completion of both the focus group interview and the parent/child interview, up to two hours each. Additionally, we propose to offer a nonmonetary incentive not to exceed \$10 for children who complete the interview with their parents.

Sensitive Questions: We will not ask sensitive questions as a component of this study.

Proposed Project Schedule: We will begin this project upon receipt of all regulatory approvals.

Data Collection Burden:

Estimates of Annual Hour Burden -- Generic Substudy: LOI3-INF-04-A, "Assent Process for Children Enrolled in the NCS" (Parents / Children Only)

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours
Recruitment Letter	Parents	55	1	0.08	4
Contact Information	Parents	55	1	0.03	2
Informed Consent	Parents	55	1	0.17	9
Focus Groups	Parents	55	1	1.50	83
Assent	Children	55	1	0.17	9

* To be completed before project proposal is submitted for OIRA clearance.

Send completed forms to ncs@mail.nih.gov

NCS Formative Research Template for OIRA Clearance

Parent / Child	Parents / Children	110	1	1.50	165
TOTAL		110			272

Annualized Cost to Respondents -- Generic Substudy: LOI3-INF-04-A, "Assent Process for Children Enrolled in the NCS" (Parents / Children Only)

Data Collection Activity	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Hourly Wage Rate	Respondent Cost
Recruitment Letter	Parents	55	1	\$10.00	\$40.00
Contact Information	Parents	55	1	\$10.00	\$20.00
Informed Consent	Parents	55	1	\$10.00	\$90.00
Focus Groups	Parents	55	1	\$10.00	\$830.00
Assent	Children	55	1	\$10.00	\$90.00
Parent / Child	Parents / Children	110	1	\$10.00	\$1650.00
TOTAL		110			\$2720.00

Please check here after ensuring that all calculations have been verified

Estimated Costs: Staff Hours: 544 hours.
 Supervisor Hours: 136 hours.

Attachments: [Recruitment flyer](#), [contact information form](#), [letter to parents](#), [consent form](#), [Part 1 focus group questions for parents](#), [Part 2 parent/child interview](#), [protocol description](#), [IRB application submission](#), [IRB approval letter](#)

