I. PROJECT TITLE: Development of an Assent Process for Children Enrolled in the NCS Vanguard Study

II. STUDY CENTER COLLABORATION

The University of New Mexico in conjunction with the Oregon Research Institute, Center for Family and Adolescent Research (ORI-CFAR) in Albuquerque, New Mexico propose to research and develop an informed assent process based on developmentally-appropriate presentation of research concepts within the NCS to children 7 and 8 years of age. We will develop a prototype for an interactive media-based assent tool and evaluate child engagement and comprehension, and parental acceptance of the assent process.

The research organizations involved have extensive expertise working with children, adolescents, and families in the areas of enhancing research assent/consent, research ethics and decision making, and web-based technology development (e.g., Brody, Scherer, Annett et al, 2003; Annett, Brody, Scherer, et al 2004; Brody, Annett, Scherer, et al, 2005; Scherer, Brody, Annett, et al, 2005; Brody, Scherer, Annett, et al 2006; Scherer, Annett, Brody, et al, 2007; Brody, Annett, Scherer, et al, 2009; Dalen, Annett, & Brody, 2009). Specifically, the research team has conducted several NHLBI-funded studies examining factors associated with voluntary assent in asthma youth research. One major aim of these studies was to address how parents and investigators approach research participation decisions for young children, how assent for young children is obtained, and what children are capable of understanding about research. In addition, ORI has over a decade of experience creating, adapting, and evaluating interactive CD-ROM and web-based programs for a variety of health behaviors for children, adolescent, and adults. These include tobacco prevention for children, improving access to early parent education and support, and promoting student social competence to improve academic and behavioral outcomes in children. Thus the current proposal represents a pooling of expertise to develop a prototype of an interactive media-based assent tool for young children.

III. RESEARCH PLAN

A. Goals.

The primary goal of the Assent Vanguard pilot study is to determining the feasibility, quality and cost of developing a robust assent process for children enrolled in the NCS. Unfortunately, little empirical evidence exists about the optimal procedures to gain the voluntary assent of children for biomedical research. Children bring different developmental capacities and experiences to treatment or research participation decisions (Scherer, Annett, Brody, et al, 2007). Consequently, they are apt to differ in the depth of their understanding and appreciation of research (Brody, Annett, Scherer, et al, 2005; Brody, Scherer, Annett, 2003), their perceptions of risks and benefits (Annett, Brody, Scherer, et al 2004), and their judgments about participation (Brody, Annett, Scherer, et al, 2009). For example, young children are typically less capable of understanding the research and more likely than adolescents to rely on parental opinions. Parents of younger children may also approach research participation decisions differently than parents of older children. Thus, we believe the most responsible and ethical first step for valid child assent in the NCS study is to approach this population directly, gaining first-hand knowledge and experience regarding age-appropriate assent methods.

The greatest need for guidance comes from the problem of how to engage children in the assent process in a way that provides the most beneficial protection, and yet assures that child participants are accorded their full rights. In addition, there have been rapid technological advances in media and interactive technologies that have provided important new opportunities for delivering programs to children and adolescent populations.

Aim 1: Research and develop an informed assent process based on developmentally-appropriate presentation of research concepts within the NCS to children 7 and 8 years of age.

Our objective is to have a dialogue with parents and separately with educators who work with children of this age range in order to gain their expert opinion on how to engage and present research concepts through

inteactive media to children. Specifically we will use these groups of individuals to 1) inform the NCS of how interactive media is used with children ages 7-8 years so as to promote engagement (*Presentation Medium*), and 2) how to enhance children's comprehension of research procedures (*Vernacular*). These procedures will provide a range of options to increase child engagement, comprehension, and retention of the research protocol.

Approach: *Two* separate focus groups will be conducted:

- parents of children ages 7-8
- educators of children ages 7-8

Sampling Strategy: Candidate participants will be drawn from the Albuquerque area and Valencia County, which is the actual recruitment site for the NCS protocol in New Mexico. Valencia County, New Mexico is predominantly rural and the population comprised of 55% Hispanic and 3% American Indian. The county has 3 villages with scattered farms, occasional clusters of homes or very large uninhabited areas. This unique mix of cultures and the rural nature of the community can provide a portion of the sample for this project. In addition, candidate participants may be drawn from the more urban greater Albuquerque area, thus providing a diverse group of both rural and urban participants. Thus, New Mexico's unique demographics provide an opportunity to inform assent procedures across ethnically diverse populations in both rural and urban communities.

Focus groups will be conducted until saturation of themes has been reached. Each group participant will be provided a handout of the research protocol and the following domains will be assessed within respective focus groups:

- **Parents of children 7 and 8.** 1*) Presentation Medium*: determine the preferences of parents for explaining the study to children (parent and child together, separate, with or without a research assistant present); what types of media are of greatest interest to their children; their child's perceived skill level with contemporary media (e.g., computer, hand held devices), and 2) *Vernacular*: determine how content within the consent/assent for the NCS can be presented to children; for example, we seek to understand the optimal content to characterize risks and benefits associated with an observational study such as the NCS, as well as the specific elements of the protocol and collection of samples from the children themselves.

- **Educators of children ages 7 and 8**. 1*) Presentation Medium*: what state-of-the-art media technologies are successfully being used in classroom and professional setting with children in this age range, and 2) *Vernacular*: determine how best to characterize risks and benefits associated with an observational study such as the NCS; how to provide information to children without undue influence; appropriate emphasis in consent; content information for parent-child discussion vs. media-child discussion, and appropriate length of assent administration.

Evaluation: 1) The audiotapes from the focus groups will be transcribed verbatim; 2) the investigators then will begin a process of content analysis of the transcripts from the focus group sessions to describe participants' attitudes, beliefs and concerns; content analysis is a method for making replicable and valid inferences from data to their context; 3) transcriptions will be compared to audiotape recordings and field notes to verify the accuracy of the data; 4) data will be entered into the Atlas/ti software program for systematic analysis; computer-aided content analysis contributes to high reliability because rules for coding are made explicit and consistently applied to text.

Strategies for increasing the reliability and validity (trustworthiness and credibility) of the content analysis have been incorporated throughout the design. Reliability will be strengthened by the use of a consistent moderator/assistant moderator for all focus groups, including participant verification and debriefing activities;

audiotapes and verbatim transcripts of focus group sessions; documentation of a clear decision trail with respect to data collection, coding, and analysis; and computer-aided content analysis.

Aim 2: Develop a prototype for an interactive media assent tool for children 7 and 8 years of age participating in the NCS.

Using the information obtained in Aim 1, we propose to build a storyboard of how an interactive media assent protocol may be presented to children 7 and 8 years old. The story board interactive media concepts will be tested with healthy children and their parents to evaluate child engagement and comprehension, and parental acceptance of assent process. The goal is to inform the final interactive media content and evaluate efficacy before significant resources are invested in a final product.

Approach: Parents who participated in the above focus group will be invited back with their children ages 7-8 and will be presented with the story board interactive media concepts. A private interview format will be used with each child/parent dyad. Both standardized and open/ended questions will be used to indicate any potential problem areas.

Evaluation: Specific evaluation factors include: 1) appropriateness regarding length of assent administration, 2) measures of children's comprehension of basic elements of participation in the NCS, 3) children's attention to and interest in the assent protocol, and 4) parental acceptance of assent process. Measures to assess children's comprehension and attention have been developed and extensively used by our research team and will be adapted for this study.

B. Methods. 4 phases of work will be completed over 9 months as follows:

IV. TIMELINE OF ACTIVITIES

ACTIVITY	MONTH
Phase 1: Develop focus group protocols and submit to UNM & ORI IRB	1-2
Phase 2: Recruit parents and educators for focus group participation	2-4
Phase 3: Develop a prototype of an interactive media-based assent tool	4-6
Phase 4: Evaluation of the prototype with children and parents	6-8
Phase 5: Finalize content for development	9

V. ANTICIPATED DELIVERABLES

1. The findings from this formative research project would provide information on how educators and parents use interactive media to enhance learning as well as using these experts to guide how contextual information in a NCS assent procedure can best be presented and comprehended by children ages 7-8 years.
2. The information obtained from the children ages 7-8 years will provide the NCS with validation feedback on child comprehension, attention, and how to best present NCS research concepts to children via interactive media.
3. The information obtained through these procedures, in collaboration with local technical expertise, will be used to develop a story board for the creation of an interactive media-based assent tool that can be developed for the NCS.

References

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