OMB #: 09250-0590 EXPIRATION DATE: 09/14/2014

Focus Group Questions for Parents

Welcome Script

- Good morning/afternoon!
- Thank you for taking the time to meet with us. We will honor your time by making sure that we wrap up in the next 90 minutes.
- Does anyone mind if we tape record this for our records?
- We are researchers under contract with the National Children's Study (NCS) to conduct an evaluation of how media-based technology can be used to obtain assent from children ages 7-8 years old enrolled in the study.
- Our evaluation is formative and qualitative. This means that our primary point is to gather information that helps to inform the development of an assent tool; and that the information we are collecting is by design *descriptive* rather than numeric. We have a system for quantifying qualitative information, but for now, we don't need to be concerned with counting things...we just want your words and your impressions.
- All information we collect is confidential as to who provided it. For example, we will not disclose
 who actually participated in this focus group nor will our final report make any attributions for
 quotes. We hope this encourages you (if you need encouragement) to speak freely.
- Any questions before we start?
- Be sure that everyone signs and completes the info on the sign-up sheet.

Overview of the National Children's Study

What is the purpose of the National Children's Study?

- The goal of the National Children's Study is to improve the health and well-being of the nation's children.
- The Study will help researchers understand how the social and physical environment affects children's health, growth, and development.
- The Study also is interested in how the environment acts together with a person's characteristics, such as genes, to prevent disease and promote health.

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0590). Do not return the completed form to this address.

- The National Children's Study is an observational study. Observational studies do not involve asking people to change what they normally do.
- They will not ask children to take any medicines or drugs.
- They will collect information about the parent, the child and the child's environment.

How many children will be in the National Children's Study?

• The Study will include about 100,000 children from all over the United States.

How long will the National Children's Study last?

• The National Children's Study will be studying women before and during pregnancy and children from the time they are born until they are 21 years old.

What information will be collected from the child at ages 7-8?

Though the study protocol has not been formalized, we know that the study will collect information by asking questions, having parents or teachers complete forms, and collecting biological and environmental samples in the home.

Examples of Child Questions:

- What kinds of food they eat
- How much TV they watch and what types of programs
- What types of pets live with them
- What kind of friendships they have

Examples of Child Tests:

- Cognitive ability
- General motor development
- Language development
- Parent-child interaction

Examples of Biological/Environmental Samples:

- Air
- Dust
- Water
- Child hair samples
- Child blood samples

Overview of ASSENT Procedures

- There are important laws that researchers have to follow in order to enroll participants in their studies.
- One of the most important laws is that participation in research must be voluntary. This law is true for children as well as adults. Parents provide permission for their children to be in research, but children must also agree to participate in order to be enrolled.
- The NCS will be obtaining permission or assent from every child enrolled in the NCS at the age of 7-8 years old.

Purpose of this Group

• We would like to get your thoughts about how to get permission from children who will be enrolled in the NCS. We would like opinions on how best to teach children 7-8 years of age about research participation using technology that is appropriate in this age group.

Parents: Focus Group Questions

Part I. Presentation Medium

A) Determine the preferences of parents for explaining the study to children.

Directions:

Proposed Questions:

I. A. If you were involved in the National Children's Study and we had a media-based presentation for your 7-8 year old child, would you prefer for the research assistant to show you how to work the media program and then you go through the presentation with your child to explain the study or would you prefer that a research assistant take the lead in explaining the study? Note: A research assistant would always be in the room in case questions came up.

- A) What method would make you more comfortable and why?
- B) What method would make your child more comfortable why?
- B) 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).
 - I. B.1. Describe the technological software/hardware you have at home that your child seems to enjoy the most? (the least)?

(Computers, Laptops, Hand held games, Phones, Ipad, Wii, xBox, Playstation)

- I.B.2. What does your child like about them? What draws their attention? (Colors, sounds, characters, specific activities)
- I.B.3. What is your child's perceived skill level with technological software/hardware?

Others potential questions:

How long is your child's average attention span with these devices?

Does your child still show interest in cartoons? What about computer animation characters? Which would be your child's preference?

Part II. Vernacular

B) Determine how best to characterize risks and benefits associated with an observational study such as the NCS.

<u>Directions:</u> The assistant moderator will hand out a list of the specific procedures that a child of 7-8 years old would be asked to do if enrolled in the NCS study.

Proposed Questions: Now that you have learned about the procedures involved in this study:

- II.B.1. What procedures would be difficult for your child to understand?
- II.B.2. What procedures would your child find uncomfortable or dislike?
- II.B.3. How would you try to explain difficult/uncomfortable procedures to your child?
- II.B.4. Overall, would your child be interested in participating in a study like this?
- C) How to provide information to children without undue influence.
 - II.C. Do you feel that using cartoon and/or animation characters would lead to confusion or misunderstanding that this is not real life but a game of some sort? (why or why not)
- D) Appropriate emphasis in consent.
 - II.D. Considering that there is so much information, which pieces do you consider essential that your child understand?

Is there anything else you would like to share with us?

Thank you for your time!