The University of New Mexico Health Sciences Center
Consent to Participate in Research

Development of an Assent Process for Children Enrolled in the National Children's Study (NCS)

Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. Robert Annett, who is the Principal Investigator, and his associate, Dr. Jeanne Dalen. The purpose of the study is to learn about educators', parents' and children's thoughts about how to get study permission from children who will be enrolled in the NCS study in the future. We would like to find out how best to teach children 7-8 years of age about participating in the research study using technology that is appropriate for this age group. You are being asked to participate because you are either an educator or a parent/guardian of a child ages 7-8 years old. Approximately 55 educators, parents and their child will take part in this study at the University of New Mexico. This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigators or study staff to explain any words or information that you do not clearly understand.

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things will happen:

Educators. You would participate in a discussion group with 6-10 other educators to talk about your opinions on how best to teach young children about research participation in the NCS study and your experiences using technology in this age group. Participation in this study will take a total of two hours over a period of one day or evening.

Parents/Children. First, you would participate (without your child) in a discussion group with 6-10 other parents to talk about your opinions on how best to teach young children about participating in the NCS research study. Then, at a later date, we would invite both you and your child to come back for a family interview. We would like to have your permission for your child to be part of this interview. We would present a video to your child about the NCS study and get his/her opinions about it. Neither you nor your child will be asked to be a part of the actual NCS study or provide any samples; you will just be asked your opinions about getting child permission in a research study. Participation in this study will take a total of 3-4 hours over a period of two days or evenings.

What are the possible risks or discomforts of being in this study?

Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality that may cause embarrassment if you did not want your opinions known by others. The time spent in the discussion group may also be inconvenient for you.

How will my information be kept confidential?

Your name and other identifying information will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying

information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications. All groups and interviews will be audio taped using a dual-taping system. Only self-chosen alias names will be used during group and interview discussions to insure the confidentiality (on audio-tape) of participants.

Information from your participation in this study may be reviewed by UNM Health Sciences Center Research Allocation Committee, which provided funding for this study, federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research.

What are the benefits to being in this study?
There may or may not be direct benefit to you from being in this study. However, your participation may help in finding out how best to educate and get permission from young children who will be enrolled in the NCS study in the future.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate.

Will I be paid for taking part in this study?
Educators will receive a $25 gift card to thank them for their time. Parents/guardians will receive a $25 gift card at both the focus group and the individual family interview ($50 total); and children will receive a gift.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your access to care in the future.

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation. The Sponsor may stop the study at any time.

Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: your name, address, telephone number, and email address. This information will be collected only to contact you to set up the discussion group. It will not be connected to any of your comments in the discussion group or your answers on the questionnaire.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a HIPAA Research Withdrawal Form or letter notifying them of your withdrawal to:

Dr. Jeanne Dalen
Center for Family and Adolescent Research
707 Broadway NE, Suite 402
Albuquerque, NM 87102

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign

If you choose not to sign this consent form and authorization for the use of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Dr. Robert Annett, and Dr. Jeanne Dalen will be glad to answer them at 505- 272-4462 or 505-842-8932. If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects.

What are my rights as a research subject?

If you have questions regarding your rights as a research subject, you may call the HRRC at (505) 272-1129 or visit the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this Consent Form, you are not waiving any of your legal rights as a research subject.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

_____ _____/_____
Name of Adult Participant (print) Signature of Adult Participant Date

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____ _____/ _____
Name of Research Team Member Signature of Research Team Member/Date

Child Assent Form

Thank you for being here today.

We want to show you a video about a research study. After you watch the video with your mom/dad, we would like you to tell us what you think about it. We want to find out if you were able to understand it and what you liked and disliked about the video.

Your mom/dad will be with you during the entire time.

There are no right or wrong answers; it doesn't help us to tell us what you think we want to hear, just tell us what you really want to say.

We will take notes of the discussion, but we won't put your name on anything. We won't tell anyone your name. Instead, we'll just say "a group of children said …"

You don't have to be in this study. You may ask to leave at any time with your parent. You don't have to answer any questions if you don't want to.

This meeting today will last about 1 – 1 1/2 hours.

Child Assent

You are making a decision whether to participate (or to have your child participate) in this study. Your signature below indicates that you read the information provided (or the information was read to you).

_____ _____/_____

Name of Child Subject Signature of Child Subject/Date

_____ _____/_____

Name of Parent/Child's Legal Guardian Signature of Parent/Legal Guardian/Date