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innovation Research & Training, Inc.

Address: 1415 W. NC Highway 54, Suite 121, Durham NC 27707
Voice: 919 493-7700 Fax: 919 493-7720

Dear Parent or Guardian,

We are asking permission for your child to be a part of a project that is developing a web-based resource to educate youth about participating in pediatric clinical trials or research studies. Your child will be asked about your child's knowledge and attitudes towards pediatric clinical trials and asked to provide feedback on the content and activities included in a new web-based resource. Your child will also be asked if he or she wants to participate before taking part in this study; even if you have given permission, your child can still say "no thanks".

Please read this letter to be sure you know what will take place and what we will be asking your child to do, so you can decide if you want your child to be invited to be a part of the project. Please contact us if you have questions after reading the letter.

What is the purpose of this project?

This project is funded by the National Heart, Blood, and Lung Institute a part of the National Institutes of Health (NIH). The purpose of the project is to develop a new web-based resource to educate youth who have a chronic illness or disease about pediatric clinical trials. The resource will include interactive learning modules, video testimonials, and an electronic comic book.

In this web-based resource, youth will learn about clinical trials in order to provide them with knowledge to inform their future decision-making around clinical trials.

What will my child's participation involve?

1. You and your child will meet a project staff at IRT's office. Your child will be asked to answer some questions about his/her knowledge about and attitudes toward clinical trials as well as his/her overall self-efficacy, that is, the feeling that you are able to do something. This should take less than 1 hour.
2. Your child will then be asked to review our web-based resource which aims to educate youth about pediatric clinical trials. This should take less than 2 hours.
3. Your child will then be asked to respond to the same set of questions related to his/her knowledge, attitudes, and self-efficacy. Your child will also be asked some questions about the usability and functionality of the web-based resource (e.g., "Did you find the program easy to use?") and the overall quality. This should take approximately 1 hour.

Your child may take a break at any time, as needed.

Will my child's answers be kept private?

The information your child provides will be kept private. This means that only project staff members will have access to the information. All of the responses will be kept in a locked file cabinet at IRT. Secret identification (ID) numbers will be used in place of names on the questionnaires so that none of the information can be linked directly to your child after the study.

What happens if my child does not participate in the project?

Participation by your child is voluntary. There will be no penalty if he/she decides not to participate in this study. In addition, your child has the right to decline to participate in any activity during the interview or to answer questions and can choose to withdraw from the study at any point without penalty or consequence.

Are there any risks involved in being in the project?

No risks are foreseen to your child from participating in this study. Your child will be told, and reminded from time to time, that he/she can refrain from answering questions. As noted above, your child may also leave the study at any time without consequence.

Will anything good happen as result of my child being in the project?

The feedback received from your child will contribute to the development of a web-based resource to educate youth about clinical trials that has the potential to greatly benefit many children.

Will my child be compensated for participation in the project?

Yes, your child will receive \$50 for participation in this study.

Who should I contact if I have any questions about the project?

The project is being done by Dr. Alison Parker and Dr. Tracy Scull of innovation, Research, & Training. If at any point during your child's participation in this project, you have any additional questions or concerns, please contact Dr. Parker, at (919) 493-7700, email: aparker@irtinc.us.

If you have any questions or concerns about your child's rights as a research participant or how your child was treated, you should contact Barbara Goldman, Ph.D., Chair of the iRT Institutional Review Board (IRB) that reviewed and approved this study, at barbara_goldman@unc.edu or 919-966-7169.

Thank you in advance for your cooperation and support. We hope that you will agree to let your child participate in this project.

Sincerely,

**Alison Parker, Ph.D.
Co-Principal Investigator
innovation Research & Training**

**Tracy Scull, Ph.D.
Co-Principal Investigator
innovation Research & Training**

Feedback Study

PARENT PERMISSION

The goal of this project is to investigate a newly developed web-based resource for youth.

In this study, youth will be asked to:

- Answer some questions about their knowledge, attitudes, and self-efficacy
- Participate in a web-based resource about clinical trials for young people
- Provide feedback on the content in the resource

Participation is voluntary and participants can stop at any time. All responses will be kept confidential. You have been given a copy of this entire 4-page letter to keep for your records.

In order for your child to participate, please check the box below and fill out the additional information so we can contact you.

I give permission for my child to participate in the *Feedback Study*.

Your name (signature): _____

Date: _____

Your name (please print): _____

Mailing address: _____

Phone number: _____

Email address: _____

Child's name (please print): _____