



## No More Hand-Me-Downs: Research Designed for Children

### Statement of the problem and intended outcome

Recruiting participants for pediatric clinical trials presents unique challenges not seen in adult trials. The most troublesome may be the lack of information for parents who must make a decision about whether to allow their child to participate in a clinical trial. To address this need, the National Heart, Lung, and Blood Institute, NIH and New England Research Institutes, Inc. have teamed up to develop a program to provide reliable and sensitive information for parents about trial participation.

### Description of the program

*Children and Clinical Studies* is a web-based program featuring documentary videos of researchers, children and parents sharing their personal experiences in pediatric studies. The videos, graphics, didactic information and resource links illustrate why research in children is important and what happens during a study. Information is provided in English and Spanish, is accessible at the 7<sup>th</sup> grade reading level and explains key concepts parents should know in order to make decisions about enrolling in a clinical study.

### Program evaluation

The site draws an international audience of parents, physicians and researchers who are interested in learning more about clinical studies. We conducted an evaluation to assess how parents regard and use the site in order to improve it.

Parents of children under age 18 attended six sessions organized by racial/ethnic group (Black, White, Hispanic parents). This was done to enable parents to speak comfortably about experiences and viewpoints including specific cultural concerns. Structured interviews were conducted to assess impressions of clinical research and the site, including suggested additions and modifications.

### Preliminary findings

We report on three preliminary findings. First, initial data suggest that the delivery approach (documentary video embedded with didactic web content) provides a useful resource for parents. Parents in all three groups reported that the site provided information that would help them make an informed decision but that they would also need information about the specific study. Second, they reported that the “like me” approach (video vignettes with parents speaking from their personal experiences) provided a familiarity that was comforting, friendly, and culturally sensitive. Third, there was agreement that there was not enough information on the role of healthy volunteers in research. Parents said they understood the necessity of testing treatments in sick children, but they did not understand that healthy volunteers could be included in some research studies or why a healthy child might be exposed to a treatment.

### Future program usage

The Children and Clinical Studies web site is part of a larger campaign including postcards, posters, and DVDs. We will continue to evaluate and refine the program to increase its usefulness to families. Future assessments include evaluating its use as a training tool for new pediatric research staff and IRB members as well as the site’s potential impact on clinical trial enrollment.