Supporting Statement B for

Activities Associated with Developing a Web-based Resource for Youth about Clinical Research
(NHLBI)

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Ellen Rosenberg
Contracting Officer's Representative
Division of Cardiovascular Sciences
National Heart, Lung and Blood Institute
Rockledge II, Room 8217
6701 Rockledge Drive
Tel: 301-594-1376
Email: rosenbeel@nhlbi.nih.gov

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B.1 Respondent Universe and Sampling Methods

Target Respondents:

The proposed web-based resource will be an interactive, multimedia, developmentally appropriate resource for youth to be educated about pediatric clinical trials. The resource will be developed for youth aged 8 to 14 years. Three sequential studies comprise this developmental work: 1) Individual Interview Study; 2) One-to-One Evaluation Study; and 3) Pre-Post Feedback Study.

Study 1: Individual Interview Study

a) **Age, sex, and approximate number:**

A convenience sample of nine youth aged 8-14 will be recruited to participate in individual interviews. Efforts will be made to ensure a sample that is approximately 50 percent female and represents diversity in ethnicity and race.

b) **Inclusion/Exclusion Criteria:**

Only youth (8 to 14 years) with a chronic illness or disease will be included in the interviews given that the web-based resource will be designed for this particular population. In addition, only youth who have not yet participated in a clinical trial will be included in the interviews; thus, excluding those who have already participated in a clinical trial. The reason is that the web-based resource seeks to educate youth who have not yet participated in a clinical trial. Youth must be able to speak and read English fluently.

Study 2: One-to-One Evaluation Study

a) **Age, sex, and approximate number:**

A convenience sample of five youth (aged 8-14) will be recruited to participate in the One-to-One Evaluation study. Efforts will be made to ensure a sample that is approximately 50 percent female and represents diversity in ethnicity and race.

b) **Inclusion/Exclusion Criteria:**

Only youth (8 to 14 years) with a chronic illness or disease will be included in the interviews given that the web-based resource will be designed for this particular population. In addition, only youth who have not yet participated in a clinical trial will be included in the interviews; thus, excluding those who have already participated in a clinical trial. The reason is that the web-based resource seeks to educate youth who have not yet participated in a clinical trial. Youth must be able to speak and read English fluently.

Study 3: Pre-Post Feedback Study

a) **Age, sex, and approximate number:**

A convenience sample of thirty-four youth (aged 8-14) with varying diseases/disorders and have not yet participated in a clinical trial will be recruited to participate in the Pre-Post Feedback Study. Efforts will be made to ensure a sample that is approximately 50 percent female and represents diversity in ethnicity and race.

b) **Inclusion/Exclusion Criteria:**

Only youth (8 to 14 years) with a chronic illness or disease will be included in the interviews given that the web-based resource will be designed for this particular population. In addition, only youth who have not yet participated in a clinical trial will be included in the interviews; thus, excluding those who have already participated in a clinical trial. The reason is that the web-based resource seeks to educate youth who have not yet participated in a clinical trial. Youth must be able to speak and read English fluently.

Targeted Enrollment

Durham County has the most diverse population of the major cities in North Carolina, and has the largest makeup of minority groups of the five largest North Carolina cities (http://www.durham-nc.com/secondary/faq/faq_gen.php). According to the 2012 US Census (www.census.gov), Durham County has approximately even proportions of male (47.6%) and female (52.4%). Fifty-three (53%) percent of residents reported White as their race, 38.8% of residents reported Black as their race, 4.9% reported Asian as their race, 2.3% reported two or more races, 1.0% reported American Indian or Alaskan Native as their race, and 0.1% reported Native Hawaiian or Other Pacific Islander as their race. With respect to ethnicity, 13.4% reported being of Hispanic or Latin origin. The Hispanic percentage has been distributed across the racial categories in the table below.

Targeted Enrollment Table Across the Three Studies

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		**Total**
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	0
Asian	2	2	0	0	4
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	9	9	2	2	22
White	12	12	2	2	28
More than One Race	1	1	0	0	2
Total	**24**	**24**	**4**	**4**	**56**

B.2 Procedures for the Collection of Information

Determination of Sample Size:

Power analyses were not conducted for the Individual Interview Study and the One-to-One Evaluation Study. It was determined by the program development team that nine youth participants in the Individual Interview Study would provide sufficient qualitative feedback on the web-based resource for the purpose of revisions. A sample size of five youth participants was chosen for the One-to-One Evaluation Study based on research suggesting that 85% of usability issues are identified with this sample size (Nielsen, 2000). Thirty-four youth will be recruited to participate in the Pre-Post Feedback Study. A power analysis revealed that with $\alpha = .05$ and power at .80, 34 participants will be needed to detect a medium effect size (.40).

Recruitment of Non-Probability Sample:

Convenience sampling methods will be utilized for the three studies. These sampling methods are appropriate given the objectives of each of the studies. The Individual Interviews will provide formative feedback that will be used to inform the development and refinement of the web-based resource. The One-to-One Evaluations will be used to examine the usability of the web-based resource to inform revisions that aim to enhance the ease of use and satisfaction with the resource. Finally, Pre-Post Feedback study will provide insight

into the overall feasibility of the web-based resource. The findings from the three studies will only provide an indication of the efficiency and effectiveness of the web-based resource; however, conclusions cannot be drawn regarding the absolute efficiency and effectiveness of the resource for a larger population of youth.

Study 1: Individual Interview Study

Individual interviews will be conducted with nine youth with a chronic illness or disease who have not yet participated in a pediatric clinical trial. The youth will be provided with information (prepared by the researchers) by project consultants who have access to pediatric patients involved in clinical trials. The consultants will be provided with a flyer (Appendix A) to pass along to families via email and post on listservs as well as pass along to other health professionals working with youth with chronic illnesses or diseases. Parents of the youth who are interested in participating will contact IRT. Interview dates will be tentatively scheduled with the families by a member of the research team. Once families have expressed interest, the parent permission and child assent forms will be emailed or mailed to those families and they will be instructed to review the forms together so they can decide about participation. Either the families will contact the research team, or the research team will contact them, to handle any questions they might have after they have received the forms and to confirm their appointment time, if they choose to participate. They will be reminded that they will need to return one signed form (parent permission and child assent) on the day of the interviews. Families will also be provided with details regarding the location of the interviews.

Study 2: One-to-One Evaluation Study

One-to-One Evaluations will be conducted with five youth with a chronic illness or disease who have not yet participated in a pediatric clinical trial. These youth will be asked to participate in individual sessions in which they will evaluate the web-based resource. The youth will be provided with information (prepared by the researchers) by project consultants who have access to pediatric patients involved in clinical trials. The consultants will be provided with a flyer (Appendix G) to pass along to families via email and post on listservs as well as pass along to other health professionals working with youth with chronic illnesses or diseases. Parents of the youth who are interested in participating will contact IRT. Interview dates will be tentatively scheduled with the families by a member of the research team. Once families have expressed interest, the parent permission and child assent forms will be emailed or mailed to those families and they will be instructed to review the forms together so they can decide about participation. Either the families will contact the research team, or the research team will contact them, to handle any questions they might have after they have received the forms and to confirm their appointment time, if they choose to participate. They will be reminded that they will need to return one copy of the signed forms (parent permission and child assent) on the day of the One-to-One evaluation session. Families will also be provided with details regarding the location of the sessions.

Study 3: Pre-Post Feedback Study

The Pre-Post Feedback Study will be conducted with approximately 34 youth (ranging in age from 8 to 14 years) with a chronic illness/disease who have not yet participated in a pediatric clinical trial. The youth will be provided with information (prepared by the researchers) by project consultants who have access to pediatric patients involved in clinical trials. The consultants will be provided with a flyer (Appendix K) to pass along to families via email and post on listservs as well as pass along to other health professionals working with youth with chronic illnesses or diseases. The flyers will also be posted in patient lobbies in pediatricians' offices. Parents of the youth who are interested in participating will contact IRT. Interview dates will be tentatively scheduled with the families by a member of the research team. Once families have expressed interest, the parent permission and child assent forms will be emailed or mailed to those families and they will be instructed to review the forms together so they can decide about participation. Either the families will contact the research team, or the research team will contact them, to handle any questions they might have after they have received the forms and to confirm their appointment time, if they choose to participate. They will be reminded that they

will need to return one copy of the signed forms (parent permission and child assent) on the day of the study. Families will also be provided with details regarding the location of the study.

Data Collection Cycle:

The three studies are single-time research studies. This design minimizes burden on participants and eliminates issues of attrition.

Data Collection Procedures:

Study 1: Individual Interview Study

On the day of the interviews, families will provide the research team with the signed parent permission and child assent forms, and then youth will be escorted to the assigned room to participate in the interview. The interview including snack break may last up to two hours. Parents will be told that they can wait in the waiting area or leave and return to pick up their child at the conclusion of the interview. During the interview, the youth will be instructed to review the designated content (e.g., interactive learning module/feature stories, video testimonials/family spotlights, or comic book) in the web-based resource. Dr. Parker or Dr. Scull will observe the youth as he/she navigates through the resource. After viewing the content, Dr. Parker or Dr. Scull will interview the youth regarding the content and feasibility of the specific component of the resource. The interviews will be audiotaped. The youth will also respond to a few background information questions.

Study 2: One-to-One Evaluation Study

On the day of the data collection, families will provide the research team with the signed parent permission and child assent forms, and then youth will be escorted to the assigned room to participate in the evaluation session. The evaluation including snack break will last up to 2 hours. Parents will be told that they can wait in the waiting area or leave and return to pick up their child at the conclusion of the session. During the evaluation, the youth will be instructed to review all of the content in the web-based resource. Dr. Parker or Dr. Scull will observe the youth as he/she navigates through the resource. During his or her review of the content, the youth will be asked to talk aloud during the session about what they are doing, how they are making decisions in their use of the website, and what they expect will happen when they perform each action. When the youth has concluded their review of the content, he or she will complete a questionnaire regarding their satisfaction with the overall web-based resource. The youth will also respond to a few background information questions.

Study 3: Pre-Post Feedback Study

On the day of the data collection, families will provide the research team with the signed parent permission and child assent forms, and then youth will be escorted to the assigned room to participate in the study. Parents will be told that they can wait in the waiting area or leave and return to pick up their child at the conclusion of the study. The procedure for the study will be as follows: 1) youth will be asked to complete a pre-test questionnaire that will assess their knowledge, attitudes, and self-efficacy regarding pediatric clinical trials. They will also respond to a few background information questions; 2) youth will be instructed to navigate and complete the web-based resource; 3) youth will be asked to complete a post-test questionnaire (same as the pre-test questionnaire except for the background information) to assess their knowledge, attitudes, and self-efficacy regarding clinical trials. They will also be asked to respond to questions about consumer satisfaction. This study will last up to 4 hours.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The web-based resource will educate youth about pediatric clinical trials to enhance their communication and decision-making around participation in clinical research. It is intended to be used by youth

ages 8-14. There are two potential sources of nonresponse error in this evaluation study: (1) bias in initial recruitment of study participants and (2) item nonresponse. We have established procedures to reduce the likelihood of each of these. First, the proposed data collection will maximize response rates among the target population of youth ages 8-14 with a chronic disease or illness by recruitment through organizations and venues that the target population trusts and frequents (e.g., groups for youth with chronic diseases and illness, medical professionals). Second, incentives will also help to motivate participation. We will also provide flexible scheduling for participants for the data collection appointments, in order to achieve a diverse sample and to motivate youth to participate. Third, our data collection procedures were chosen to maximize participants' comfort, efficiency, and feelings of privacy so that they will be willing to answer all of the questionnaire items.

The sample size for the Pre-Post Feedback Study was calculated based on predetermined effect sizes (see B.2: Determination of Sample Size).

B.4 Test of Procedures or Methods to be Undertaken

Not applicable.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The data collection and analysis is part of a SBIR Phase I contract between NHLBI and innovation Research and Training, Inc. The research team at iRT for this project includes Tracy Scull, PhD (Co-Principal Investigator), Alison Parker, PhD (Co-Principal Investigator), Cory Campbell (Research Assistant), and Elyse Keefe (Research Specialist). Data collection will be conducted by the research team. Data analysis and supervision of data collection will be conducted by Drs. Scull and Parker.