Initial Proposal Cover Sheet

1. IRT-IRB Number: 14-010-1-FEA Date Submitted: ____

2a. ☒ This IRB form does not supersede any previous request.
2b. ☐ This IRB form RELATES to previous application _____ approved on _____.
2c. ☐ This IRB form SUPERSEDES _____ which was most recently approved on _____

3. Principal Investigator	
Name: Alison Parker and Tracy Scull	
Phone: 919-493-7700	**Email: aparker@irtinc.us and tscull@irtinc.us**
Fax: 919-493-7720	**Affiliation:** innovation Research & Training

4. Project Title/Familiar Name: ___Development of web-based resource for youth_____
5. Grant Name: ___ Web-based resource for youth about clinical research_____
6. Project Type: ☐ Just-in-Time ☒ Specific Project
7. ☐ Approval required from other institution (e.g., prison, school): ☐ is attached ☐ is pending
   Name of institution(s): _____
8. ☒ Indicate grant number and funding agency: Phase I SBIR contract #HHSN268201400051C and NHLBI
9. Principal Investigator's Recommendation:
   - ☐ FULL Board Review
   - ☒ Expedited Review; Category number 7 IRB Manual Section VI.B.2
   - ☐ Exempt from further review following initial IRB review; Category number ____ IRB Manual Section VI.A.2

_____ _____ _____ _____
Signed by Principal Investigator Date Signed by IRT President Date

10. **IRB Decision:** (IRB use only)

- ☐ Exempted; no further review needed unless there is a modification.
- ☐ Approved as Specific Project
  - ☐ 45 CFR 46.404 applies—no more than minimal risk to children
  - ☐ 45 CFR 46.117 (c) (2) applies—waiver of requirement for documentation of consent through written signature
- ☐ Approved as "Just-in-Time" (grant proposal) under 45 CFR 46.118. **Specific Project approval needed prior to data collection.**
- ☐ Approved with special conditions, see attachment
- ☐ Not Approved (this decision can only be made by the convened IRB)

_____ _____ IRT IRB approval of this project EXPIRES _____
Signed by Chair, iRT IRB Approval Date
Barbara Davis Goldman, Ph.D.

11. Investigator Assurance

Each investigator has read the iRT Institutional Review Board Manual and agrees to abide by those standards. Each investigator agrees to report any significant and relevant changes in the procedures and or instruments already approved for this protocol to the Board for additional review. Each investigator further agrees to report any significant participant complaints to the IRB as they occur.

Signature(s) _____ _____
Principal Investigator Co-Investigator

12. Project Staff: All project personnel must complete appropriate Human Subjects Research Ethics Training, as approved by iRT, prior to contact with research participants or access to identifiable data.

List below all project personnel (anyone) who will have contact with research participants or access to identifiable research data from participants.

Following each name, indicate the individual's role within this application (e.g., Principal Investigator, Co-investigator, Project Director, Research Assistant, and so forth) AND telephone numbers and email addresses for the PI, Co-I, Project Director, and anyone else who could help answer any questions about this application.

1. Tracy Scull – Principal Investigator – 919-493-7700, tscull@irtinc.us
2. Alison Parker – Co-Principal Investigator – 919-493-7700, aparker@irtinc.us
3. Marina Ziemian – Research Assistant – 919-493-7700, mzieman@irtinc.us
4. Shelley Upton – Research Assistant – 919-493-7700, supton@irtinc.us
5. Janis Kupersmidt – President – 919-493-7700, jkupersmidt@irtinc.us
6.

etc.

13. Potential Conflict of Interest

In reference to the research proposed in this form, will any of the study investigators or staff, or their immediate family members such as a spouse, significant other, dependent children, or parents, HAVE A CONFLICT OF INTEREST? Conflicts of interest could include an intellectual property interest, patent rights, copyright, ownership interest (equity, stock options), and/or personal compensation in the form of salary, consulting fees, honoria, royalties, and gifts THAT COULD POSSIBLY BE VIEWED AS COMPROMISING THE INTEGRITY OF THE RESEARCH.

If the answer is "yes," please include an explanation below, noting the individual(s), the nature of the possible conflict(s), and if relevant, how the conflict(s) has/have been minimized.

☐ No, not for anyone listed above as project personnel

☒ Yes (include explanation as above)

Dr. Kupersmidt, is the owner of iRT and therefore has intellectual property interest in the products that will be developed as an outcome of this project. The eventual sale of these products would provide financial gain. However, this potential conflict of interest will be managed given the fact that Dr. Kupersmidt's role will be to provide assistance to the Co-PIs, if needed, during the product development process. She will not be directly involved in data collection, entry, or data analysis, so the objectivity of these tasks will not be affected by her involvement.

The project personnel, including the Co-PIs, Alison Parker and Tracy Scull, are employees of iRT and receive personal compensation in the form of salary which currently, is partially based upon this project and in the future, may be partially based upon subsequent sales from the final product. Their conflict of interest is minimal, and is further minimized through careful training of the data collectors and careful supervision of the data collection procedures. The data collected in the proposed studies will be entered into the computer by trained Research Assistants. These databases will be analyzed by a Research Scientist at iRT. The results of statistical analyses will be checked by two employees. The raw and analysis databases as well as the results of statistical analyses will be archived on the iRT server and are backed up on a regular basis. Both analysis databases and final statistical analyses can be made available for independent review, if requested.

Project Description

(Describe the project by providing a brief summary and answering the requests for information below)

Use as much space as necessary to respond to each prompt. Attach all supporting documents (recruitment scripts; advertisements; consent, parent permission and assent forms; measures (interview questions; questionnaires/surveys, etc.). See the IRT IRB Manual, Section IV for specific instructions and elaborations.

1. Project Description

Purpose and Rationale: The primary purpose of the project is to develop a web-based resource that will be an interactive, multimedia, developmentally appropriate resource for youth to be educated about pediatric clinical trials. There is a need for more clinical trials with children and adolescents. In fact, in a review of clinical trials conducted between 2007 and 2010, only 17.4% of the clinical trials were conducted with children under 18 years of age (Califf et al., 2012). The resource will be developed for youth aged 8 to 14 years and will be composed of an interactive learning module, video testimonials, and an electronic comic book. It will be developed with the intention of increasing awareness and knowledge of pediatric clinical research in children and adolescents as well as enhancing self-efficacy and positive attitudes of youth.

The goal of the IRB proposal is threefold: 1) conduct individual interviews with 9 youth to gain feedback on three components in the web-based resource (Study 1), 2) conduct One-to-One evaluations of the web-based resource with 5 youth to assess usability of the resource (Study 2), and 3) conduct a Pre-Post Feedback study with 34 youth to assess how the resource influences their knowledge, attitudes, and self-efficacy (Study 3).

Study 1: Individual Interviews

Procedure: 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.

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 youth 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.

Measures:

Interview Questions (Appendices B, C, and D): After the youth review one of the three components of the program (i.e., feature stories, family spotlights, comic book), they will be asked a series of open-ended questions specific to that component. Examples of these questions include: “Did you find the

feature stories easy to understand?" "Did you find the videos helpful in learning about clinical trials?"; Did you find it easy use the comic book?" Each question will be followed by prompts (e.g., If no, why not?). Responses will be recorded on an interview sheet. Youth will be asked to respond to background information questions including age, gender, grade, race, and ethnicity.

Analyses of Quantitative Data: At the end of the interviews, Drs. Parker and Scull will review the interview responses for each component of the resource. Based on the feedback from the interviews, they will generate a list of edits that need to be made to the content of the learning module, video testimonials, and comic book.

2. Participants:

a) Age, sex, and approximate number:

Youth aged 8-14 (*N*=9) will be recruited to participate in individual interviews.

b) Inclusion/Exclusion Criteria:

Only youth 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.

c) Recruitment:

Youth in the North Carolina area will be given recruitment flyers, prepared by the researchers, by Dr. Thompson, Dr. Helms, and Dr. Shashi (consultants) who have access to large networks of 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. Interested families will email or call IRT to inquire about their youth's participation in the individual interviews. 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. They will be reminded that they will need to return one signed form (parent permission and child assent) on the day of the interviews.

d) Incentives:

The youth will receive $25 for their participation.

3. Risks: The possible risks associated with the individual interviews are minimal.

Breach of confidentiality: It is possible that a breach of confidentiality could happen in the individual interviews. Although all interview responses will be anonymous and will contain no identifying information, the interview sheets could be misplaced or stolen. It is also possible that a project staff member could be overheard talking about a research participant in a public location or with someone who is not a project staff member.

Discomfort with interview procedures or content: Youth may experience possible discomfort due to the interview procedures or content. For example, youth might feel that the setting is not sufficiently private or may be uncomfortable with one or more questions asked during the interviews.

4. **Describe steps to minimize risk:**

Breach of confidentiality: Procedures to maintain the confidentiality of participants' responses to interview questions will be utilized. First, all IRT staff members are trained and instructed not to discuss specific cases, even without names, in any location where they might be overheard. Second, participants will be given randomly assigned ID numbers to be used for the interview responses. The interviews will not include names or individually identifying information; thus, there will be no way to directly link individuals' responses directly to their names. There will be a separate list for contact information and incentive distribution but it will not contain any ID numbers. All paper copies of project data will be stored in cabinets that are kept locked at all times that the data are not in use and electronic copies will be saved on IRT's secure server. Only the trained project staff involved in this project will have access to any data from this study.

Discomfort with assessment procedures or content: iRT staff members will be trained in advance on the importance of keeping the interviews safe and secure for youth. The interview questions are designed to easily allow for skipping of any questions that are uncomfortable for the participants. All participants will be reminded that they do not have to answer any question and can stop participating in the study at any time and leave without consequence. In the event that any youth expresses discomfort during his participation, appropriate steps would be taken to ensure the comfort and/or safety of the youth and to notify his or her parents, if necessary. Research staff members will be instructed to record any problems they observed during data collection, concerns about any participants, or any unusual occurrences during data collection. Drs. Parker and Scull will review and respond to these records immediately.

5. **Are illegal activities involved?**

No.

6. **Is deception involved?**

No.

7. **What are the anticipated benefits to participants and/or society?**

The youth will contribute to the development of a web-based resource that has the potential to help many children in the future make an informed decision about participating in a clinical trial.

While not considered a benefit, the youth will receive $25 each for their participation, which is likely to encourage them to feel, appropriately, that they have provided a service. Given the minimal risks associated with this program, the benefits are proportionate.

8. **How will prior consent be obtained?**

Parent permission (Appendix E) and child assent (Appendix F) forms will be emailed or mailed to families of the participants prior to the start of the interviews. The forms will include: 1) the general purpose of the interview study, 2) the length of commitment, 3) incentive for participation, 4) risks and benefits of participation, and 5) maintenance of confidentiality. The lead researchers' contact information will be provided on the permission form in case parents have questions about the study.

9. **Confidentiality:**

Confidentiality will be assured to all participants and the permission/assent forms will be stored in a separate location from any interview data collected. Participants will be given randomly assigned ID numbers to be used for the interview responses. The interviews will not include names or individually identifying information; thus, there will be no way to directly link individuals' responses directly to their names. Further, the contact information that is collected will only be used for incentive distribution and will be deleted once the incentives

have been received. No personal information will be used in the analyses of the data, nor will personal information be included in any written reports stemming from the analyses. All participants will also be instructed that they may choose to not answer any question they do not wish to answer and to leave the study at any time without penalty. Each interview will be audio recorded. No names will be used during the recorded interview. At the conclusion of the study, the taped interviews will be destroyed.

Treatment of Files: Interview responses will not contain any identifying information (only ID numbers will be used) and the audio recordings will not include any names. Paper copies of the interview sheets will be stored in locked, secure cabinets at IRT and any electronic data, including the audio recordings, will be stored on IRT's secure server. Participants' responses will not be shared with anyone outside of the project.

10. **Does your study require waiver of signature?** No, all youth participants will sign assent forms and parents will sign permission forms.

Appendices

Appendix A: Individual Interviews Flyer
Appendix B: Interview questions: Feature Stories
Appendix C: Interview questions: Family Spotlights
Appendix D: Interview questions: Comic Book
Appendix E: Parent permission for interviews
Appendix F: Child assent for interviews

Study 2: One-to-One Evaluation Study

1. **Project Description**

Procedure: 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.

On the day of the One-to-One evaluations, 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 youth 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 their 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 have concluded their review of the content, youth will complete a questionnaire regarding their satisfaction with the overall web-based resource. The youth will also respond to a few background information questions.

Measures:

One-to-One Evaluation Study Questionnaire (Appendix H) will assess consumer satisfaction in terms of: (1) **content** (e.g., The things I learned in the feature stories were helpful.); (2) **format** (e.g., I liked hearing from kids my age); (3) **usability** (e.g., It took a long time for the videos to play.); and (4) **overall quality** (e.g., I can use things I learned from this website to help me make decisions in the future.). Participants will rate each item on a 5-point Likert scale (1 = Strongly Disagree, 2 = Disagree, 3 = Undecided, 4 = Agree, and 5 = Strongly Agree). Higher ratings will indicate more positive feelings toward the resource. An open-ended area will allow participants to provide any specific recommendations for changes in the program. Youth will be asked to respond to background information questions including age, gender, grade, race, and ethnicity.

Analyses of Quantitative Data: Mean scores for constructs (e.g., format, overall quality) will be calculated and descriptive statistics will be examined. Usability and satisfaction with the resource will be determined by examining if mean satisfaction scores for constructs are 3.5 above or for 80% or more of the scales. Open-ended responses will also be examined to obtain recommendations about specific areas for revisions to the web-based resource.

2. Participants

a) Age, sex, and approximate number:

Five youth (aged 8-14) will be recruited to participate in the One-to-One Evaluation study.

b) Inclusion/Exclusion Criteria:

Only youth 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.

c) Recruitment:

Youth in the North Carolina area will be given recruitment flyers, prepared by the researchers, by Dr. Thompson, Dr. Helms, and Dr. Shashi (consultants) who have access to large networks of 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. Interested families will email or call IRT to inquire about their youth's participation in the One-to-One evaluations. 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. 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 evaluation.

d) Incentives: The youth will receive $25 for their participation.

3. Risks: The possible risks associated with the one-to-one evaluations are minimal.

Breach of confidentiality: It is possible that a breach of confidentiality could happen in the One-to-One evaluations. Although all questionnaire responses will be anonymous and will contain no identifying information, the questionnaires could be misplaced or stolen. It is also possible that a project staff member

could be overheard talking about a research participant in a public location or with someone who is not a project staff member.

Discomfort with interview procedures or content: Youth may experience possible discomfort due to the assessment procedures or content. For example, youth might feel that the setting is not sufficiently private or may be uncomfortable with one or more questions asked during the evaluation session.

4. Describe steps to minimize risk:

Breach of confidentiality: Procedures to maintain the confidentiality of participants' responses during the One-to-One evaluation sessions will be utilized. First, all IRT staff members are trained and instructed not to discuss specific cases, even without names, in any location where they might be overheard. Second, participants will be given randomly assigned ID numbers to be used on the questionnaires. The questionnaires will not include names or individually identifying information; thus, there will be no way to directly link individuals' responses on the questionnaires directly to their names. There will be a separate list for contact information and incentive distribution but it will not contain any ID numbers. All paper copies of project data will be stored in cabinets that are kept locked at all times that the data are not in use and electronic copies will be saved on IRT's secure server. Only the trained project staff involved in this project will have access to any data from this study.

Discomfort with assessment procedures or content: iRT staff members will be trained in advance on the importance of keeping the evaluation sessions safe and secure for youth. The questionnaire is designed to easily allow for skipping of any questions that are uncomfortable for the participants. All participants will be reminded that they do not have to answer any question and can stop participating in the study at any time and leave without consequence. In the event that any youth expresses discomfort during his participation, appropriate steps would be taken to ensure the comfort and/or safety of the youth and to notify his or her parents, if necessary. Research staff members will be instructed to record any problems they observed during data collection, concerns about any participants, or any unusual occurrences during data collection. Drs. Parker and Scull will review and respond to these records immediately.

5. Are illegal activities involved?

No.

6. Is deception involved?

No.

7. What are the anticipated benefits to participants and/or society?

The youth will contribute to the development of a web-based resource that has the potential to help many children in the future make an informed decision about participating in a clinical trial. They may also increase their knowledge, self-efficacy, and improve their own attitudes about participation in clinical trials.

While not considered a benefit, the youth will receive $25 each for their participation, which is likely to encourage them to feel, appropriately, that they have provided a service. Given the minimal risks associated with this program, the benefits are proportionate.

8. How will prior consent be obtained?

Parent permission (Appendix I) and child assent (Appendix J) forms will be emailed or mailed to families of the participants prior to the start of the evaluation session. The forms will include: 1) the general purpose of the one-to-one evaluation study, 2) the length of commitment, 3) incentive for participation, 4) risks and benefits of participation, and 5) maintenance of confidentiality. The lead researcher's contact information will be provided on the permission form in case parents have questions about the study.

9. Confidentiality:

Confidentiality will be assured to all participants and the permission and assent forms will be stored in a separate location from any questionnaire data collected. Participants will be provided with randomly assigned ID numbers that will be used for the questionnaires. The questionnaires will not include names or individually identifying information; thus, there will be no way to directly link individuals' responses directly to their names. Further, the contact information that is collected will only be used for incentive distribution and will be deleted once the incentives have been received. No personal information will be used in the analyses of the data, nor will personal information be included in any written reports stemming from the analyses. All participants will also be instructed that they may choose to not answer any question they do not wish to answer and to leave the study at any time without penalty.

Treatment of Files: The questionnaires will not contain any identifying information (only ID numbers will be used). Paper copies of the questionnaires will be stored in locked, secure cabinets at IRT and any electronic data will be stored on IRT's secure server. Participants' responses will not be shared with anyone outside of the project.

10. Does your study require waiver of signature? No, all participants will sign assent or consents forms.

Appendices

Appendix G: One-to-One Evaluation Study flyer
Appendix H: One-to-One Evaluation Questionnaire
Appendix I: Parent permission form
Appendix J: Child assent form

Study 3: Pre-Post Feedback Study

1. Project Description

Procedure: 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.

On the day of the study, 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 youth 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.

Measures:
Pre-Post Questionnaire (Appendix L) will include the following:

1. Pretest Questions:
   - Youth will be asked to respond to **background information** questions including age, gender, grade, race, and ethnicity.
   - General clinical research **knowledge** (e.g., What is a clinical trial?) rated using multiple choice;
   - **Attitudes** about clinical research (e.g., How do you feel about being part of a clinical trial some day?) rated on a three-point Likert Scale and adapted from Madsen et al. (2002);
   - **Efficacy** for making decisions (e.g., How sure are you that you can do the following things: Ask my parents questions for more information about clinical trials?) rated on a 5-point Likert scale and adapted from Bandura (2006)'s Self-Efficacy scale.

2. Web-based resource review by youth

3. Posttest Questions:
   - General clinical research **knowledge** (e.g., What is a clinical trial?) rated using multiple choice;
   - **Attitudes** about clinical research (e.g., How do you feel about being part of a clinical trial some day?) rated on a three-point Likert Scale and adapted from Madsen et al. (2002);
   - **Efficacy** for making decisions (e.g., How sure are you that you can do the following things: Ask my parents questions for more information about clinical trials?) rated on a 5-point Likert scale and adapted from Bandura (2006)'s Self-Efficacy scale.

- **Satisfaction** will be assessed in terms of: (1) **content** (e.g., The things I learned in the feature stories were helpful.); (2) **format** (e.g., I liked hearing from kids my age); (3) **usability** (e.g., It took a long time for the videos to play.); and (4) **overall quality** (e.g., I can use things I learned from this website to help me make decisions in the future.). Participants will rate each item on a 5-point Likert scale (1 = Strongly Disagree, 2 = Disagree, 3 = Undecided, 4 = Agree, and 5 = Strongly Agree). Higher ratings will indicate more positive feelings toward the resource. An open-ended area will allow participants to provide any specific recommendations for changes in the program.

Analyses of Quantitative Data: First, one-way repeated measures ANOVAs will be conducted to examine change in youth's knowledge, attitudes, and self-efficacy from pretest to posttest. Second, mean scores for satisfaction constructs (e.g., format, overall quality) will be calculated and descriptive statistics will be examined. Usability and satisfaction with the resource will be determined by examining if mean satisfaction scores for CSQ constructs are 3.5 above or for 80% or more of the scales. Open-ended responses will also be examined to obtain recommendations about specific areas for revisions to the web-based resource.

2. Participants

a) Age, sex, and approximate number:

Thirty-four youth (aged 8-14) will be recruited to participate in the Pre-Post Feedback Study.

b) Inclusion/Exclusion Criteria:

Only youth 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 <u>not</u> 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 <u>not</u> yet participated in a clinical trial.

c) Recruitment:

Youth in the North Carolina area will be given recruitment flyers, prepared by the researchers, by Dr. Thompson, Dr. Helms, and Dr. Shashi (consultants) who have access to large networks of 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. Interested families will email or call IRT to inquire about their youth's participation in the study. 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. They will be reminded that they will need to return one signed form (parent permission and child assent) on the day of the study.

d) Incentives: The youth will receive $50 for their participation.

3. Risks: The possible risks associated with the study are minimal.

Breach of confidentiality: It is possible that a breach of confidentiality could happen in the study. Although all questionnaire responses will be anonymous and will contain no identifying information, the questionnaires could be misplaced or stolen. It is also possible that a project staff member could be overheard talking about a research participant in a public location or with someone who is not a project staff member.

Discomfort with assessment procedures or content: Youth may experience possible discomfort due to the assessment procedures or content. For example, youth might feel that the setting is not sufficiently private or may be uncomfortable with one or more questions asked during the study.

4. Describe steps to minimize risk:

Breach of confidentiality: Procedures to maintain the confidentiality of participants' responses during the study will be utilized. First, all IRT staff members are trained and instructed not to discuss specific cases, even without names, in any location where they might be overheard. Second, participants will be given randomly assigned ID numbers to be used on the questionnaires. The questionnaires will not include names or individually identifying information; thus, there will be no way to directly link individuals' responses on the questionnaires directly to their names. There will be a separate list for contact information and incentive distribution but it will not contain any ID numbers. All paper copies of project data will be stored in cabinets that are kept locked at all times that the data are not in use and electronic copies will be saved on IRT's secure server. Only the trained project staff involved in this project will have access to any data from this study.

Discomfort with assessment procedures or content: iRT staff members will be trained in advance on the importance of keeping the assessments safe and secure for youth. The questionnaires are designed to easily allow for skipping of any questions that are uncomfortable for the participants. All participants will be reminded that they do not have to answer any question and can stop participating in the study at any time and leave without consequence. In the event that any youth expresses discomfort during his participation, appropriate steps would be taken to ensure the comfort and/or safety of the youth and to notify his or her parents, if necessary. Research staff members will be instructed to record any problems they observed during data collection, concerns about any participants, or any unusual occurrences during data collection. Drs. Parker and Scull will review and respond to these records immediately.

5) Are illegal activities involved?

No.

6) Is deception involved?

No.

7) What are the anticipated benefits to participants and/or society?

The youth will contribute to the development of a web-based resource that has the potential to help many children in the future make an informed decision about participating in a clinical trial. They may also increase their knowledge, self-efficacy, and improve their own attitudes about participation in clinical trials.

While not considered a benefit, the youth will receive $50 each for their participation, which is likely to encourage them to feel, appropriately, that they have provided a service.. Given the minimal risks associated with this program, the benefits are proportionate.

8) How will prior consent be obtained?

Parent permission (Appendix M) and child assent (Appendix N) forms will be emailed or mailed to families of the participants prior to the start of the study. The forms will include: 1) the general purpose of the study, 2) the length of commitment, 3) incentive for participation in study, 4) risks and benefits of participation, and 5) maintenance of confidentiality. The lead researcher's contact information will be provided on the permission form in case parents have questions about the study.

9) Confidentiality:

Confidentiality will be assured to all participants and the permission and assent forms will be stored in a separate location from any questionnaire data collected. Participants will be provided with randomly assigned ID numbers that will be used for the questionnaires. The questionnaires will not include names or individually identifying information; thus, there will be no way to directly link individuals' responses directly to their names. Further, the contact information that is collected will only be used for incentive distribution and will be deleted once the incentives have been received. No personal information will be used in the analyses of the data, nor will personal information be included in any written reports stemming from the analyses. All participants will also be instructed that they may choose to not answer any question they do not wish to answer and to leave the study at any time without penalty.

Treatment of Files: The questionnaires will not contain any identifying information (only ID numbers will be used). Paper copies of the questionnaires will be stored in locked, secure cabinets at IRT and any electronic data will be stored on IRT's secure server. Participants' responses will not be shared with anyone outside of the project.

10) **Does your study require waiver of signature?** No, all youth participants will sign assent forms and parents will complete parent permission forms.

Appendices
Appendix K: Pre-Post Feedback Study Flyer
Appendix L: Pre-Post Questionnaire
Appendix M: Parent permission form
Appendix N: Child assent form