



For Qualitative Focus Group

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.

OMB Number: 0925-XXXX
OMB Expiration Date: TBD

Consent for Participation in Research [Guardian]

Name of Research Study: Clinical Myth-eries: A Video Game About Clinical Studies

Principal Investigator & Institution: Lisa Marceau, New England Research Institutes, 9 Galen Street, Watertown, MA 02472

IRB Protocol Number: P-1418

Funded by: National Heart, Lung, Blood Institute

1. Who is performing this study?

New England Research Institutes or NERI, as we are known, is performing the study. NERI is partnering with Wisdom Tools, an interactive educational training company that works to blend all the most effective aspects of games, simulations, and immersive learning theory into learning. This study is being funded by the National Heart, Lung, Blood Institute, or NHLBI. NHLBI works to promote the prevention and treatment of heart, lung, and blood diseases, collaborating with patients, families, and organizations worldwide.

2. Why is this study being done?

NERI is creating a video game (rated E for everyone) as part of a research study to teach children about clinical studies through game play. The objective of this game is to help children understand the myths or misunderstandings about clinical studies and to help lessen fears about participating, and to educate about the different kinds of clinical studies. This game will generally educate adolescents about what clinical research is and does not require that they have been or will be in a clinical study.

3. Who will take part in this study?

Clinical Myth-eries: A Video Game About Clinical Studies
New England Research Institutes, Inc.
9 Galen Street, Watertown, MA 02472
Phone: 617-923-7747; Fax: 617-926-8246
V. 3. 04/18/2013

Children between the ages of 8 and 14 years will be able to be part of this study. Your child must be able to understand, read and speak English because the qualitative focus group will be conducted in English. The qualitative focus group will include children only – parents and guardians will not take part in the groups. The group will include 30 children (approximately ten children between the ages of 8 and 10, ten children between the ages of 11 and 12, and ten children between the ages of 13 and 14). The group will be held at the Cumberland Lincoln Boys and Girls Club in a quiet room with study staff from NERI.

4. What will my child's participation involve?

Your child will attend the qualitative focus group which will be held at NERI. The group will discuss a game prototype that has been developed by NERI about clinical studies. Your child may learn about clinical studies, but only in relation to how well an educational video game provides the information. Your child will not be asked about their personal health or personal experiences related to clinical studies. The group will focus on determining whether the game prototype (characters, formats, scenes) is appealing to your child. Your child will work together with other children in the group to express their ideas and views about what they like and would like to see different about this video game prototype. The session will take approximately 1 1/2 hours.

5. What will it cost me?

There are no costs for participation other than the time involved with the qualitative focus group discussion.

6. What are the possible risks and benefits of taking part in this study?

This videogame is an adventure where a young boy escapes into a book so he does not have to take his medicine. The reader (the player) follows him into the book to help understand his fears and give him the right information about clinical studies. It is rated E for everyone.

There are no known risks involved with participation in this study. Participation in this study will not impact school grades for your child, or medical care your child may receive.

There are no personal benefits to you or the children participating, except for the \$25 gift card provided to your child for participation in the group.

7. What will happen to my child's interview information?

In order to use the information for the study, information from the group will be tape recorded, and the children will also be asked to write down their ideas about their likes and dislikes about the prototype video game. No names will be maintained in tape recordings or documentation collected during the group discussions. If, in the group, someone referred to your child by name, it will be replaced with an anonymous identifier such as "Participant A" when the tapes are transcribed to written form. The data from the session will be kept in a secure location at NERI and the material will be destroyed after the study is completed.

The data collected from the qualitative focus group will be reviewed by members of the NERI research team and key topics or ideas will be summarized. The summary of the topics or ideas is what will be used in any report that is created by the NERI research team.

When your child is provided the \$25 gift card, they will sign a receipt that they received it. This information, which will bear your child's name, will be stored in a locked file cabinet at NERI under NERI's data security rules.

8. Will my child's information be kept private?

All information your child provides during the group is for research purposes only. It is private and will be kept secure to the extent permitted by law. The topic of this qualitative focus group discussion is related to game design preferences, and is not sensitive in nature.

Every group member will be asked to keep all information they hear during the group private. However, because NERI cannot control what participants discuss outside of the group, we cannot guarantee that all participants comply with this request.

The information your child provides during the qualitative focus group discussion will be identified by ID# only. Only the consent, assent forms and form stating they received the gift card will bear their name rather than ID#. This will be stored in a locked file cabinet at NERI. Your child's name, contact information and other identifying information will not be reported or published in papers or presentations that result from this research.

9. Will my child be compensated for his or her time?

After the qualitative focus group is completed and before your child leaves the group, your child will receive a \$25 gift card for his or her participation. He/She will be asked to sign a form stating that he/she received the gift card at the end of the group discussion. This will also be signed by a study staff member. This form will be stored in a locked file cabinet at NERI and destroyed at the end of the study. You will receive a thank you letter also indicating that your child has received this gift card.

10. What are my child's rights as a research participant?

Your child's participation is strictly voluntary. He or she can refuse to continue participation at any time. Your child's participation is completely voluntary and he or she may withdraw from the group, leave the group at any time (under parental or staff supervision), or refuse to answer specific questions. However, due to the nature of this activity, we will not be able to strike out or remove any information your child has contributed to the group other than his/her name or other identifying information. Your child must attend at least one hour of the focus group in order to receive the \$25 gift card.

In addition, the study has the right to end your child's participation at any time without your or his/her consent.

You may receive a copy of this consent form. Your child will be asked to sign an assent form.

11. Whom may I contact with questions?

If you have questions about the study you can contact Lisa Marceau, MPH, the Principal Investigator for this study, at the New England Research Institutes, Inc. (800) 775-6374, extension 511. If you have any questions about your child's participation as a research subject, you can contact Sue Hall, Ph.D., Chair, Institutional Review Board, New England Research Institutes, Inc., (800) 775-6374, extension 249.

I have read this consent form or it has been read to me. I have a copy. I understand the research study. I understand that my child will take part in a Focus Group. All of my questions have been answered.

I choose to allow my child to take part in this qualitative focus group. I know he or she is free to quit at any time. I understand that if I have any questions at any time, they will be answered.

Parent/Guardian's Signature

Date

Print Name

Print Child's Name

For Pre-Post Evaluation

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2. Why is this study being done?

NERI is creating a video game (rated E for everyone) as part of a research study to teach children about clinical studies through game play. The objective of this game is to help children understand the myths or misunderstandings about clinical studies and to help lessen fears about participating, and to educate about the different kinds of clinical studies. This game will generally educate adolescents about what clinical research is and does not require that they have been or will be in a clinical study.

3. Who will take part in this study?

Children between the ages of 8 and 14 years will be able to be part of this study. Your child must be able to understand, read and speak English because the questions they will be asked will be written in English. The Pre-Post Evaluation (Evaluation) will include children only – parents and guardians will not take part. The Evaluation will include 250 children across three different locations among three different age groups, 8-9, 10-11, and 12-14 year olds. The evaluation will take place in a room with study staff from NERI.

4. What will my child's participation involve?

Your child will be randomly assigned, like flipping a coin, to one of two groups (videogame or print material) for the Evaluation. One group (videogame) will be asked to answer some general questions about clinical studies, then play our video game for 45 minutes, and then answer some more questions based on the game and the information contained within the game. The total time will require between 1 and 1 ½ hours. The other group (print material) will be asked to answer some general questions about clinical studies, then read some materials about clinical studies, and then answer some questions based on the information they read. Your child will have a 2 out of 3 chance of being assigned to the first group. Your child, while part of one of these two groups, will participate individually in this Evaluation. That is, your child will complete the questions and either play the game or read the materials on his or her own. He or she will not be required to participate in any discussions as a part of this Evaluation. Your child will not be asked about their personal health or personal experiences related to clinical studies. The questions are aimed solely at testing if the video game helps teach children about clinical studies (compared with not playing the game). The session will take approximately 1 to 1 1/2 hours. If your child is randomly selected to the control group, he or she will be able to access the game after they have completed their participation activities should they have an interest.

5. What will it cost me?

There are no costs for participation other than the time involved with the evaluation.

6. What are the possible risks and benefits of taking part in this study?

This videogame is an adventure where a young boy escapes into a book so he does not have to take his medicine. The reader (the player) follows him into the book to help understand his fears and give him the right information about clinical studies. It is rated E for everyone. There are no known risks involved with participation in this study. Participation in this study will not impact school grades for your child, or medical care your child may receive.

There are no personal benefits to you or the children participating, except for the \$50 gift card provided to your child for participation in the evaluation of the video game.

7. What will happen to my child's interview information?

In order to use the information for the study, the children's answers to the questions will be stored and evaluated based on a predetermined analysis plan. All information will be grouped together and no individual responses will be analyzed. No names or individual identification will be collected during the evaluation. The data from the Evaluation will be kept in a secure location at NERI and the material will be destroyed after the study is completed.

The data collected from the Evaluation will be reviewed by members of the NERI research team. The answers provided by the children will be analyzed in a group to be used in any reports created by the NERI research team.

When your child is provided the \$50 gift card, they will sign a receipt that they received it. This information, which will bear your child's name and will be separate from the Evaluation responses, will be stored in a locked file cabinet at NERI under NERI's data security rules. You will receive a thank you letter also indicating that your child has received this gift card.

8. Will my child's information be kept private?

All information your child provides during the Evaluation is for research purposes only. It is private and will be kept secure to the extent permitted by law. The topic of this Evaluation is related to knowledge of clinical studies and is not sensitive in nature.

The information your child provides during the Evaluation will be identified by ID# only. Only the consent, assent forms and form stating they received the gift card will bear their name rather than ID#. This will be stored in a locked file cabinet at NERI. Your child's name, contact information and other identifying information will not be reported or published in papers or presentations that result from this research.

9. Will my child be compensated for his or her time?

After the Evaluation is completed and before your child leaves the setting where the Evaluation is conducted, your child will receive a \$50 gift card for his or her participation. He/She will be asked to sign a form stating that he/she received the gift card at the end of the Evaluation, and as staff member will also sign this form. This form will be stored in a locked file cabinet at NERI and destroyed at the end of the study.

10. What are my child's rights as a research participant?

Your child's participation is strictly voluntary. He or she can refuse to continue participation at any time. Your child's participation is completely voluntary and he or she may withdraw from the Evaluation, leave the Evaluation at any time (under parental or staff supervision), or refuse to answer specific questions. Your child must complete the post questions in order to receive the \$50 gift card. A \$25 gift card will be given if your child withdraws after completing the pre questions, but before completing the post questions.

In addition, the study has the right to end your child's participation at any time without your or his/her consent.

You may receive a copy of this consent form. Your child will be asked to sign an assent form.

11. Whom may I contact with questions?

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I have read this consent form or it has been read to me. I have a copy. I understand the research study. I understand that my child will take part in an Evaluation. All of my questions have been answered.

I choose to allow my child to take part in this Evaluation. I know he or she is free to quit at any time. I understand that if I have any questions at any time, they will be answered.

Parent/Guardian's Signature

Date

Print Name

Print Child's Name