

Funded by the National Heart, Lung, Blood Institute

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OMB Number: 0925-XXXX
OMB Expiration Date: TBD

Section A: Study Participant Identifier

[Note: this information will be included for all data forms, web or paper]

A1. PARTICIPANT STUDY ID:

A2. TODAY'S DATE:

		/			/				
M	M		D	D		Y	Y	Y	Y

1.0 Potential Participants' Families

Good morning/afternoon/evening, Mr./Mrs._____. My name is _____ and I am an employee at New England Research Institutes (NERI). NERI is conducting a research study to evaluate a video game. This study is being conducted by NERI on behalf of the National Institute of Heart, Lung, and Blood (NHLBI), National Institutes of Health (NIH).

NHLBI works to promote the prevention and treatment of heart, lung, and blood diseases, collaborating with patients, families, and organizations worldwide. We had posted signs at the [location where evaluation will take place] explaining the evaluation and your child has expressed interest in participating. Is your child still interested in participating in the Evaluation?

[If calling back] I am calling you because your child expressed interest in participating in the evaluation of our video game. Is your child still interested in participating?

PRIVACY STATEMENT - READ TO ALL RESPONDENTS

Before we begin, let me remind you that all the information we discuss is strictly private and will be kept secure to the extent permitted by law. Neither your name nor your child's name will be used in any reports. For quality assurance, my supervisor may monitor this call. Please answer each question as accurately as you can. Both this brief telephone call to screen your child for eligibility and, if eligible, participation is completely voluntary. Your decision whether to permit your child to participate in this evaluation will not affect his or her standing at the (location where the evaluation will take place). You may decide to stop the questions at any time. If you have any questions or concerns about this call, you may call the Principal Investigator Lisa Marceau, at 1-800-775-6374 x511. If you have any questions about your rights as a research subject, you may call Nancy Gee of NERI's Institutional Review Board at the same toll-free number at extension 249. There will be no charge for these calls.

If no:

Ok, well thank you for your time.

If yes:

First, let me thank you for you and your child's interest in this evaluation. This evaluation is being held to help us understand whether we were able to create a video game that is interesting and fun for kids to play while also educational, teaching them about clinical studies.

In this evaluation, we are *not* asking your child to tell us about their personal experiences with clinical studies, or their personal health. Your child will be randomly assigned to either a group that plays a video game, or a group that reviews printed material. Because of the study design, they cannot choose which group to be in.

Clinical Myth-teries Study Instruments

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.

All participants will complete a brief survey about clinical studies before they are randomly assigned to the video game or printed materials (handouts). All participants will also complete a brief survey which we will use to determine which method, the video game or reading the handouts, is more effective at educating kids about clinical studies. The evaluation will take one to one and a half hours to complete.

Your child does not have to know anything about clinical studies to participate in this evaluation.

This evaluation has a limited number of spaces so I need to ask you a few questions to determine if your child is eligible to participate. It should take no more than ten minutes. Is that ok?

If no:

Ok, is there a time that would be better when I could call you back?

If yes:

Ok, great. I will call you back then. (Record date and time here):

Date_____ ; Time_____

If no:

Ok, well thank you for your time.

If yes:

Ok, great. Do you have any questions before I continue? (Read through the form)

Clinical Myth-teries Study Instruments

SCREENING FORM

ID: ____ DATE OF SCREENING: ____ - ____ - ____
D D M M M Y Y Y Y

1. What is your child's age as of today: ____ Years [ELIGIBILITY CRITERIA]
2. What is your child's gender: Male Female
3. The following questions are intended to understand the racial group that you consider your child to be or the group with which s/he identifies. These categories are requested and defined by federal agencies for research purposes only. You do not have to answer these questions if you choose not to. [INFORMATIONAL ONLY]
 - 3.a. Is your child of Hispanic origin? Yes No
 - 3.b. What do you consider your child's race to be?

White or Caucasian	Y	N
Black or African American	Y	N
Asian	Y	N
American Indian or Native Alaskan	Y	N
Native Hawaiian or other Pacific Islander	Y	N

Thank you for your time in answering these questions. Do you have any questions before I continue?

If the child can be assigned to the evaluation:

Your child is **eligible** for the evaluation. Please read and sign the consent *and* review and have your child sign the assent forms that your child brought home recently. If you have any questions you can contact me (Michael Maura) at 1-800-775-6374 x675.

Alternative Text: If your child did not bring home a consent and assent form, I can mail them or email them to you. Would you prefer:

mail

email

Please provide your:

Mailing address _____

Email address _____

When you receive the forms, please read and sign the consent and review and have your child sign the assent forms.

You can send them back by fax (617-673-9535), or email to Mmaurao@neriscience.com, or send them by mail in the enclosed Self Addressed Stamped Envelope. Your child can only participate if we have both forms signed.

If child is not eligible (outside age range or cannot attend date):

Thank you for your interest. Unfortunately, your child is [*outside of the age range*] for this evaluation. We appreciate your interest.

Section C: General Knowledge of Clinical Studies {PRE and POST SURVEY QUESTIONS}

C1. How clearly do you understand information about clinical studies?

- a. Very clear
- b. Sort of clear
- c. Undecided
- d. Sort of unclear
- e. Very unclear

C2. Would you be willing to participate in a clinical study if you were asked by your doctor today?

- a. Yes
- b. No
- c. Not sure

SECTION D: Pre Test [Knowledge of Clinical Research] {PRE and POST SURVEY QUESTIONS}

Instructions: In the following section, we are going to provide some statements about clinical studies and ask you to choose whether they are True or False. This is called a pre test because we want to find out what you already know about clinical studies. Since you may not be familiar with this topic, we do not expect you to know the answers to all these questions. Please just do your best. During this test, we cannot help you by defining terms or giving you answers.

Later on, you will receive a similar version of this test again, and we will then compare what you learned between the two tests. Your individual score will be identified only through your identification number, which is known only by our research team. Individual scores will not be shared with anyone outside our research team.

D. Part 1: True/False {PRE and POST SURVEY QUESTIONS}

Instructions: For this next section, please indicate whether each statement is TRUE or FALSE, or NS for *Not Sure*.

- | | | | |
|--|---|---|----|
| 1. Clinical studies are used to learn whether a new medication or treatment works. | T | F | NS |
| 2. If I am participating in a clinical study, I can decide to stop at any time. | T | F | NS |
| 3. Clinical studies only involve kids who are sick. | T | F | NS |
| 4. You have to tell your school if you are in a clinical study. | T | F | NS |
| 5. If someone participates in a clinical study, they will always be required to get a shot. | T | F | NS |
| 6. As a minor (someone who is under 21 years old), I have the right to choose whether I want to participate in a clinical study. | T | F | NS |
| 7. My parents can force me to participate in a clinical study. | T | F | NS |
| 8. Healthy children may not participate in a clinical study. | T | F | NS |
| 9. My doctor will be disappointed in me if I don't stay in a study. | T | F | NS |
| 10. Participation in a clinical study can help kids who are sick, even if I am healthy. | T | F | NS |
| 11. Most drugs available today were studied in clinical trials. | T | F | NS |
| 12. Answering a survey or questionnaire can be part of a clinical study. | T | F | NS |

D. Part 2. Multiple Choice Questions {PRE and POST SURVEY QUESTIONS}

13. In addition to my parents, the person required to approve whether or not I can participate in a clinical study is (select the correct response)
- Myself
 - My doctor
 - My teachers
 - My friends
 - My siblings
14. Participating in a clinical study is important because:
- My parents say I have to.
 - My doctor will be disappointed if I say no.
 - It may help doctors learn the causes of diseases for other kids.
 - I have to participate if I am asked.
 - I will get special treatment from my school.
15. In a clinical study which of the statements below is NOT always true:
- If I join a study I will always have to have a shot.
 - If I join a study I can quit at any time.
 - If I join a study my information will be kept secret.
 - If I join a study I may help other sick kids.
 - If I join a study it is my choice, not my parents.
16. Which of the following **must** be part of a clinical study:
- Answering questions on a questionnaire.
 - Getting a shot.
 - Taking a medicine.
 - Staying overnight in a hospital.
 - Giving informed consent.
17. Which of the following is not a term used in clinical studies:
- Placebo
 - Randomize
 - Conform
 - Consent
 - Assent

Section E. Pre Survey ONLY [Interest/Exposure Pre Only]

Instructions: For each of the following, please answer whether each statement is True or False, or Not Sure.

E1. Have you ever thought about participating in a clinical study? (For example, have you ...)

- a) Yes
- b) No
- c) Not Sure

E2. Have you ever actually participated in a clinical study?

- a) Yes
- b) No
- c) Not Sure

E3. Have you known anyone that has participated in a clinical study (like a parent, sibling, friend)?

- a) Yes
- b) No
- c) Not Sure

E4. Please select your level of knowledge about clinical studies.

0	1	2	3	4
None	Low	Average	High	Very High

E5. Please select your level of interest in medicine.

0	1	2	3	4
None	Low	Average	High	Very High

Clinical Myth-teries Study Instruments

Part G. Post Survey ONLY: Game Feedback

G1. Please tell us what you thought of the game (rate the game) by selecting a number between 1 and 5, with **1 being a low rating (did not like it), 3 being an average rating, 5 being a high rating (really liked it)**, or you may choose *Unsure*.

GAME COMPONENTS	RATINGS				
a. The story or narrative used in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
b. The character you play in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
c. The way the non player characters talk to one another and to you	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
d. Graphics in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
e. Getting around in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
f. The goals and missions of the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
g. Information that you learned by playing the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
h. The non player characters you meet and interact with in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
i. The monsters in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
j. The ways you battle the monsters in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
k. Help and controls menu	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
l. Quest menu that lets you know about your progress in the game	Low	Average			High
	1	2	3	4	5
		<i>Unsure</i>			
m. Health meter	Low	Average			High

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	1	2	3	4	5
	<i>Unsure</i>				
n. Overall game design	Low		Average		High
	1	2	3	4	5
	<i>Unsure</i>				
o. The game was easy to play	Low		Average		High
	1	2	3	4	5
	<i>Unsure</i>				
p. The game was fun to play	Low		Average		High
	1	2	3	4	5
	<i>Unsure</i>				

Please rate how much you agree or disagree with each of the statements.

H1. The game is similar to entertainment games I have played.

1	2	3	4	5
Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree

H2. In the game, I liked recovering the lost paper folding designs from Tint's book.

1	2	3	4	5
Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree

H3. The game helped me learn that participants in clinical studies are not always sick.

1	2	3	4	5
Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree

H4. The ICE World had action that I liked.

1	2	3	4	5
Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree

H5. The JUNGLE World had action that I liked.

1	2	3	4	5
Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree

H6. I would like to use more games like this one to learn about clinical studies.

1	2	3	4	5
Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree

H7. I would like to play this game at home.

1 Strongly Disagree	2 Disagree	3 Not Sure	4 Agree	5 Strongly Agree
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H8. I liked the player graphics in the game.

1 Strongly Disagree	2 Disagree	3 Not Sure	4 Agree	5 Strongly Agree
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H9. Playing the game helped me understand the reason for clinical studies and how clinical studies work.

1 Strongly Disagree	2 Disagree	3 Not Sure	4 Agree	5 Strongly Agree
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H10. I would tell my friends about this game:

1 Strongly Disagree	2 Disagree	3 Not Sure	4 Agree	5 Strongly Agree
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H14. Would you prefer to play The Paper Kingdom on: (Select one)

- a. Your desktop or laptop
 - i. Mac
 - ii. PC
- b. A mobile device (iPad, iPhone, etc.)
- c. A game console (PlayStation, Xbox, etc.)

I. Open-Ended Responses [Free Text up to 250 Characters; qualitatively analyzed]

- I1. What did you like most about the game?
- I2. What did you like least about the game?
- I3. How can we better make this game appeal to both boys and girls?
- I4. How can we make this game to appeal to multiple age groups?
- I5. Do you have other comments or suggestions? **Yes / No**
 - F5a. If yes, what overall suggestions to you have for making the game better?