



## 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**

### Assent for Participation in Research [Child]

**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

#### **Who we are:**

We are researchers from **New England Research Institutes, Inc.** We conduct studies to try to help people be healthier. We work in Watertown, MA. This project is funded by the Federal Government (National Institute of Heart, Lung, and Blood, National Institutes of Health).

#### **These are some things we want to tell you about research studies:**

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

#### **What is the study about?**

We want to know what you think about a video game we made. We want to know if you think it would be fun to play. We will show you a part of the game and talk about what it teaches. It is about clinical studies. We will ask you what you think about the game and the characters.

#### **What will happen during this study?**

You can tell us what you like about the game. You can tell us what you do not like about the game. If you don't want to say anything, you don't have to.

If you want to be in the group you will learn about the game. You will talk about the game. We will ask what you like and don't like about the game. We will ask you what will make the game better.

For being part of the group you will get a \$25 gift card. You can leave the group at any time. You will still get the gift card if you stay for at least one hour.

**Will my comments be shared?**

The other kids in the group will hear what you say. We will ask everyone in the group to keep what we say private. We will record the group so that we know what the group said later. We need to remember what the group said. We ask the group not to talk about what other people in the group say, but we can't promise that they will not. We will use code names like Person A and Person B in reports about the group. We will not use your real name.

**How long is the study?**

The group will meet for about one and a half hours.

**Who should I ask if I have any questions?**

We will answer your questions. You can decide after you ask questions.

**What if I don't want to be in this study?**

Your parents/guardians have said it is okay for you to be in this group. It is still up to you. Whatever you say is okay. It is okay to check No!

If you don't want to be in this group – check No. Remember, being in the group is up to you. If you do not want to do it, no one will be mad at you. You can change your mind and stop whenever you want.

Nothing you do in this group will be part of your school grades or your medical care.

Now that I have asked my questions and think I know about the study, here is what I decided:

\_\_\_\_\_ **Okay**, I will be in the focus group.

\_\_\_\_\_ **No**, I do not want to be in the focus group.

The researchers have told me about the video game focus group. I had a chance to ask questions. I know I can ask questions at any time. I want to be in the video game focus group.

If you write your name below you agree to be in this focus group.

\_\_\_\_\_

Your Name (Printed)

\_\_\_\_\_

Date

\_\_\_\_\_

Your Signature

\_\_\_\_\_

Date

## For Pre-Post Evaluation

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### Assent for Participation in Research [Child]

**Name of Research Study: Clinical Myth-teries: 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

#### **Who we are:**

We are researchers from **New England Research Institutes, Inc.** We conduct studies to try to help people be healthier. We work in Watertown, MA. This project is funded by the Federal Government (National Institute of Heart, Lung, and Blood, National Institutes of Health).

#### **These are some things we want to tell you about research studies:**

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

#### **What is the study about?**

We want to know what you learn from a video game we made. We will let you play a part of the game and ask questions about what it teaches. It is about clinical studies. We will ask you what you think about the game and the characters. This is not part of your school grades or doctor care.

#### **What will happen during this study?**

You will be asked to be in one of two groups. You cannot choose which group you are in. That is an important part of the study. You will be asked to answer questions about the video game. If you are in one group you will play the video game. If you are in the other group you will read a booklet about the video game. You will answer questions after you play or read about the game. You do not have to answer all of the questions. You will not talk about your answers to anyone else. You can quit playing or answering questions any time.

For finishing the study you will get a \$50 gift card. You can leave the study at any time. You will get a \$25 gift card if you stop before the second set of questions.

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Clinical Myth-teries: 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

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**Will my comments be shared?**

None of the questions you answer will use your name. Instead, we will use a code with numbers.

**How long is the study?**

Being in the study will take one to one and a half hours.

**Who should I ask if I have any questions?**

We will answer your questions. You can decide after you ask questions.

**What if I don't want to be in this study?**

Your parents/guardians have said it is okay for you to be in this evaluation. It is still up to you. Whatever you say is okay. It is okay to check No!

If you don't want to be in this evaluation– check No. Remember, being in the evaluation is up to you. If you do not want to do it, no one will be mad at you. You can change your mind and stop whenever you want.

Nothing you do in this group will be part of your school grades or your medical care.

Now that I have asked my questions and think I know about the study, here is what I decided:

\_\_\_\_\_ **Okay**, I will be in the evaluation.

\_\_\_\_\_ **No**, I do not want to be in the evaluation.

The researchers have told me about the video game evaluation. I had a chance to ask questions. I know I can ask questions at any time. I want to be in the video game evaluation.

If you write your name below you agree to be in this evaluation.

\_\_\_\_\_  
Your Name (Printed)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Your Signature

\_\_\_\_\_  
Date