Public reporting burden for this collection of information is estimated to average 80/60 (1.33 hours) 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**

**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. We are conducting a research study to evaluate a video game. We had posted signs at the [*location where evaluation will take place*] explaining the evaluationand 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?

CONFIDENTIALITY STATEMENT - READ TO ALL RESPONDENTS

Before we begin, let me remind you that all the information we discuss is strictly confidential and that 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.

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)

**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 Maurao) 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 theassent 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?

1. Very clear
2. Sort of clear
3. Undecided
4. Sort of unclear
5. Very unclear

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

1. Yes
2. No
3. 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)

1. Myself
2. My doctor
3. My teachers
4. My friends
5. My siblings

14. Participating in a clinical study is important because:

1. My parents say I have to.
2. My doctor will be disappointed if I say no.
3. It may help doctors learn the causes of diseases for other kids.
4. I have to participate if I am asked.
5. I will get special treatment from my school.

15. In a clinical study which of the statements below is NOT always true:

1. If I join a study I will always have to have a shot.
2. If I join a study I can quit at any time.
3. If I join a study my information will be kept secret.
4. If I join a study I may help other sick kids.
5. If I join a study it is my choice, not my parents.

16. Which of the following **must** be part of a clinical study:

1. Answering questions on a questionnaire.
2. Getting a shot.
3. Taking a medicine.
4. Staying overnight in a hospital.
5. Giving informed consent.

17. Which of the following is not a term used in clinical studies:

1. Placebo
2. Randomize
3. Conform
4. Consent
5. 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 …)1. Yes
2. No
3. Not Sure

E2. Have you ever actually participated in a clinical study?1. Yes
2. No
3. Not Sure

E3. Have you known anyone that has participated in a clinical study (like a parent, sibling, friend)?1. Yes
2. No
3. 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 |

 |

**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** |
| 1. The story or narrative used in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The character you play in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The way the non player characters talk to one another and to you
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Graphics in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Getting around in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The goals and missions of the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Information that you learned by playing the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The non player characters you meet and interact with in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The monsters in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The ways you battle the monsters in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Help and controls menu
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Quest menu that lets you know about your progress in the game
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Health meter
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. Overall game design
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The game was easy to play
 | **Low Average High**1 2 3 4 5 ***Unsure*** |
| 1. The game was fun to play
 | **Low Average High**1 2 3 4 5 ***Unsure*** |

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

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

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

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

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

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

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

1. The ICE World had action that I liked.

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

1. The JUNGLE World had action that I liked.

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

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

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

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

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

1. I liked the player graphics in the game.

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

1. Playing the game helped me understand the reason for clinical studies and how clinical studies work.

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

1. I would tell my friends about this game:

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

H14. Would you prefer to play The Paper Kingdom on: (Select one)

* 1. Your desktop or laptop
		1. Mac
		2. PC
	2. A mobile device (iPad, iPhone, etc.)
	3. A game console (PlayStation, Xbox, etc.)

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

1. What did you like most about the game?
2. What did you like least about the game?
3. How can we better make this game appeal to both boys and girls?
4. How can we make this game to appeal to multiple age groups?
5. Do you have other comments or suggestions? **Yes / No**

F5a. If yes, what overall suggestions to you have for making the game better?