PEDIATRIC CLINICAL TRIAL PROFESSIONAL

[**IF RESPONDING TO MESSAGE FROM CT PROFESSIONAL:** Hello, my name is [NAME] from NOVA Research Company and I am returning your call about the focus group that we are conducting in the course of developing an educational game for the National Heart, Lung, and Blood Institute (NHLBI). You indicated that you were willing to participate in our focus group.]

[**IF CT PROFESSIONAL CALLS DIRECTLY:** Hello, my name is [NAME]. I am happy to talk with you about the focus group we are conducting in the course of developing an educational game for the National Heart Lung, and Blood Institute (NHLBI). I understand that you are willing to participate.]

First, let me ask if you are an NHLBI employee.

IF YES: I'm sorry. NHLBI employees are not eligible to participate in this study. Thank you for your interest. **END CALL.**

IF NO: Thank you. Now, let me tell you a little bit more about the purpose of the focus group.

NHLBI has contracted with us to develop an educational game that is designed to increase awareness of, knowledge about, empathy for, and acceptance of pediatric clinical research among elementary-school-age children. We would like to ask you to participate in a webinar focus group to talk about the game and help ensure that it achieves these objectives.

If you agree, we will ask you to join a live, online webinar. We will describe the game to you and show you some mockups of the game and then ask you to give us feedback.

The focus group will take place via webinar at [time] on [date]. You will need an Internet connection and telephone to participate. The webinar is expect to take between 30 and 45 minutes.

Should you choose to participate, each you will receive a \$50 gift card as a token of our appreciation for your participation time. Note: If you are employed by the U.S. Federal government, you are not eligible to receive the incentive.

Your participation is voluntary. We will not share information about you with anyone outside of this study.

Are you willing to participate?

IF YES: Thank you very much! We are looking for a diverse group of people to include in our studies. To make sure we include children of various ages, genders, and race/ethnicity, I need to ask you a few questions. **PROCEED TO QUESTIONS.**

IF NO: Thank you for your interest and your time. END CALL.

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private under the Privacy Act. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by telephone to complete this instrument so that we can determine whether you qualify to participate in a website usability study.

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 (0925-0648). Do not return the completed form to this address.

ATTACHMENT 1: Recruitment Screener Call Script

1. Are you now or have you ever received funding from the National Heart, Lung, and Blood Institute or worked on a research project that was funded by them?

No
×

Yes

2. Tell me about what you do that is related to pediatric clinical trials.

RECRUIT. We would like to invite you to participate.

3. We would like to send a confirmation email with the webinar details and a consent form that you can sign and return prior to the webinar. What is the best email address to use for that?

Email:

4. If we need to contact you about the webinar, what is the best way to reach you?

Cell phone:	 · · · · · · · · · · · · · · · · · · ·	
Email		
 1		

Other: -----

CT TITLE:	

ELEMENTARY SCHOOL TEACHER

[**IF RESPONDING TO MESSAGE FROM TEACHER:** Hello, my name is [NAME] from NOVA Research Company and I am returning your call about the focus group that we are conducting in the course of developing an educational game for the National Heart, Lung, and Blood Institute (NHLBI). You indicated that you were willing to participate in our focus group.]

[**IF TEACHER CALLS DIRECTLY:** Hello, my name is [NAME]. I am happy to talk with you about the focus group we are conducting in the course of developing an educational game for the National Heart Lung, and Blood Institute (NHLBI). I understand that you are willing to participate.]

First, let me ask if you are an NHLBI employee.

IF YES: I'm sorry. NHLBI employees are not eligible to participate in this study. Thank you for your interest. **END CALL.**

IF NO: Thank you. Now, let me tell you a little bit more about the purpose of the focus group.

NHLBI has contracted with us to develop an educational game that is designed to increase awareness of, knowledge about, empathy for, and acceptance of pediatric clinical research among elementary-school-age children. We would like to ask you to participate in a focus group to talk about the game and help ensure that it achieves these objectives.

If you agree, we will describe the game to you and show you some mockups of the game and then ask you to give us feedback. Parents and teachers will observe the children's focus group, which is expected to take 20–30 minutes. After the children's focus group ends, parents and teachers will break into two groups to discuss what they observed and provide feedback. The teacher-only portion of the focus group is expected to take 10–15 minutes to complete.

The focus group will take place at [location] between [X and Y p.m.] during the week of [Z].

Should you be selected, each you will receive a \$25 gift card as a token of our appreciation for your participation.

Your participation is voluntary. We will not share information about you with anyone outside of this study.

Are you willing to participate?

IF YES: Thank you very much! We are looking for a diverse group of people to include in our studies. To make sure we include children of various ages, genders, and race/ethnicity, I need to ask you a few questions. **PROCEED TO QUESTIONS.**

IF NO: Thank you for your interest and your time. END CALL.

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private under the Privacy Act. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by telephone to complete this instrument so that we can determine whether you qualify to participate in a website usability study.

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ATTACHMENT 1: Recruitment Screener Call Script

1. Are you now or have you ever received funding from the National Heart, Lung, and Blood Institute or worked on a research project that was funded by them?

Yes

2. What grade do you teach?

Fourth [Recruit no more than three]

Fifth [Recruit no more than three]

Sixth [Recruit no more than three]

IF SPACES FOR THIS GRADE ARE ALREADY FILLED: I'm sorry. We already have enough teacher volunteers for this grade. May we contact you if a slot on the focus group opens later? **COLLECT CONTACT INFORMATION.** Thank you for your interest and your time. **END CALL.**

OTHERWISE: We would like to invite you to participate.

3. We would like to send a confirmation email with the focus group details and a consent form so that you can look it over before we meet. What is your email address?

Email: _____

4. If we need to contact you about the focus group, what is the best way to reach you?

Cell phone: _____

Email

Other: -----

TEACHER NAME:

GRADE(S)/SUBJECT(S):

PARENT/CHILD PAIR

[IF RESPONDING TO MESSAGE FROM PARENT: Hello, my name is **[NAME]** from NOVA Research Company and I am returning your call about the focus group that we are conducting in the course of developing an educational game for the National Heart, Lung, and Blood Institute (NHLBI). You indicated that you were willing to participate in our focus group with one of your elementary school-aged children.]

[**IF PARENT CALLS DIRECTLY:** Hello, my name is [NAME]. I am happy to talk with you about the focus group we are conducting in the course of developing an educational game for the National Heart Lung, and Blood Institute (NHLBI). I understand that you are willing to participate with one of your elementary school-aged children.]

First, let me ask if you are an NHLBI employee.

IF YES: I'm sorry. NHLBI employees are not eligible to participate in this study. Thank you for your interest. **END CALL.**

IF NO: Thank you. Now, let me tell you a little bit more about the purpose of the focus group.

NHLBI has contracted with us to develop an educational game that is designed to increase awareness of, knowledge about, empathy for, and acceptance of pediatric clinical research among elementary-school-age children. We would like to ask you to participate in a focus group to talk about the game and help ensure that it achieves these objectives.

If you agree, we will describe the game to you and show you some mockups of the game and then ask you to give us feedback. Parents will observe the children's focus group, which is expected to take 20–30 minutes. After the children's focus group ends, parents will be asked to discuss what they observed and provide feedback. This parent-only portion of the focus group is expected to take 10–15 minutes to complete, during which time the children will be provided with some learning activities and/or materials.

The focus group will take place at [location] between [X and Y p.m.] during the week of [Z].

Should you be selected, each parent/child pair will receive a \$25 gift card, a token of our appreciation for your participation time.

Your participation is voluntary. We will not share information about you with anyone outside of this study.

Are you willing to participate?

IF YES: Thank you very much! We are looking for a diverse group of people to include in our studies. To make sure we include children of various ages, genders, and race/ethnicity, I need to ask you a few questions. **PROCEED TO QUESTIONS.**

IF NO: Thank you for your interest and your time. END CALL.

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private under the Privacy Act. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by telephone to complete this instrument so that we can determine whether you qualify to participate in a website usability study.

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ATTACHMENT 1: Recruitment Screener Call Script

- 1. Are you now or have you ever received funding from the National Heart, Lung, and Blood Institute or worked on a research project that was funded by them?
 - No

Yes

2. What grade is your child in?

Fourth [Recruit no more than three]

Fifth [Recruit no more than three]

Sixth [Recruit no more than three]

3. What gender is your child?

Male [Recruit no more than four]

- Female [Recruit no more than four]
- 4. What is your child's ethnicity? Is he/she:

Hispanic or Latino? [Recruit no more than three]

Not Hispanic or Latino? [Recruit no more than six]

5. What is your child's race? You can choose more than one. Is he/she:

American Indian or Alaska Native?

Asian?

- Black or African American? [Recruit no more than four]
- Native Hawaiian or other Pacific Islander?
-] White? [Recruit no more than four]

IF SLOTS FOR THIS CHILD'S AGE, GENDER, RACE/ETHNICITY ARE FILLED: I'm sorry. We already have enough volunteers who are the same **[age, gender, and race/ethnicity**] as your child. May we contact you if a slot opens on the focus group? **COLLECT CONTACT INFORMATION**. Thank you for your interest and your time. **END CALL.**

OTHERWISE: We would like to invite you to participate.

6. We would like to send a confirmation email with the focus group details and a consent form so that you can look it over before we meet. What is your email address?

Email: _____

7. If we need to contact you about the focus group, what is the best way to reach you?

Cell	phone:	 		_
1				_

Email

Other: -----

PARENT NAME:	
CHILD NAME:	

CHILD AGE/GRADE: