

ATTACHMENT 6: PARENT OR GUARDIAN PERMISSION FOR YOUTH INTERVIEW, YOUTH ASSENT, PARENT OR GUARDIAN CONSENT

Form Approved
OMB No. 0910-0753
Exp. Date 10/31/2016

PARENT OR GUARDIAN PERMISSION FOR YOUTH INTERVIEW

The FDA Health and Media Study is designed to collect data from boys about their attitudes related to health, health behaviors, and advertisements they may have seen on TV and/or online.

Selection of Youth

A random sample of household addresses was selected throughout 30 cities in the United States. A professional RTI interviewer will visit each sampled address to ask a few questions about whether any eligible boys live in the household. One or possibly more eligible children in your household might be asked to voluntarily participate in the survey. We must have permission from a parent before we talk with the child. At that point, your child may choose whether or not to participate in the study. Since the survey is based on a random sample, you will represent thousands of other United States residents.

Purpose of the Youth Survey

We want to interview your child about their views towards health, health-related advertisements, and related influences. The child's answers combined with the answers of other youth in the study will improve our understanding of how public education campaigns affect youths' health-related attitudes, beliefs, and behaviors.

Types of Questions for Youth

The interview with your child will last about 30-40 minutes, depending on their responses. Youth will be asked about their media use, as well as their attitudes and beliefs related to health, health behaviors, and advertisements they may have seen on TV and/or online. The interviewer will ask the first few questions and then youth respondents will answer questions directly into a laptop computer. The youth interviews will be completed in a part of their household that allows them to answer in private.

Voluntary Participation

Your child's participation in this study is also completely voluntary. He can refuse to answer any and all questions. Your child has the right to stop the interview at any time.

Risks

There are no physical risks to your child from participating in this interview. It is possible that some questions might make your child mildly uncomfortable, depending on their responses.

Benefits

There are no direct benefits to your child from answering our questions. However, he or she will be contributing to important research related to youth attitudes related to health, health behaviors, and advertisements they may have seen on TV and/or online. The information youth provide will also help researchers and policy makers understand how public education campaigns affect youths' health-related attitudes, beliefs, and behaviors. Because your child's contribution is important, we will offer your child an incentive of \$20 for participating.

Future Contacts

We will conduct three follow-up surveys every eight months to understand changes in health-related attitudes and behaviors over time. Each of these additional interviews will also be completely voluntary. If your child participates in future rounds, he will be offered an incentive of \$20 for each of the three follow-up in person interviews in which he participates.

Privacy

Your survey answers will be entered into a computer and labeled with a case identification number. Your name and that of your child will not be reported with any information your child provides. Information your child provides will be combined with answers of many others and reported in a summary form. To protect the privacy of both you and your child, neither of you will know the other's interview answers. All staff involved in this research are committed to privacy and have signed a Privacy Pledge. Information will be kept private to the fullest extent allowable by law.

Questions

If you have any questions about the study, you may call Melissa Helton at the RTI, 1-800-334-8571 extension 27168 (toll-free number). If you have any questions about your rights as a study participant, you may call RTI's Office of Human Research Protections at 1-866-214-2043 (a toll-free number).

You will be given a copy of this consent form to keep.

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Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 3 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

**ASSENT FOR YOUTH
FDA Health and Media Study**

I work for a company called RTI International (RTI). We are talking to boys in 30 cities across the United States for a research study sponsored by the U.S. Food and Drug Administration.

The survey asks boys ages 11-16 about their attitudes related to health, health behaviors, and advertisements they may have seen on TV and/or online. The survey will take about 30 minutes to complete. Up to 2,000 boys will take this survey. This survey is voluntary.

This survey is part of a research study being conducted by RTI International.

_____ has given permission for you to talk with me about these things. If it is okay with you, I would like to ask you some questions. Our talk today will last between 30 to 40 minutes, depending on your responses. We may contact you again in the future. It is up to you to decide if you would like to take any future survey.

You will enter your responses to the questions into a portable computer. Your name will be kept private. Your answers will be labeled with a special number instead of your name so that only research staff will know these are your answers. No one will see your answers to any of these questions. We will not share any information you give us with your parents, or anyone outside the research team. All of your answers will be kept private to the fullest extent allowable by law by the technology used. No absolute guarantees can be made regarding the interception of data sent via the Internet. However, we are taking extensive precautions to protect the confidentiality of your data.

If you don't want to talk to me, that is okay. If you don't want to answer a certain question, that is okay too. You may also choose to drop out of the survey at any time, for any reason. If you want to take a break at any time, just tell me.

You will be given a copy of this assent form to keep. When we finish I will offer you \$20 to thank you for taking time to talk to me.

If you have any questions about this study, you can call Melissa Helton, at 800 334-8571 extension 27168. If you have any questions about your rights as a study participant, you can call RTI's Human Research Protections Office at 1-866-214-2043 or send email to orpe@rti.org.

May I talk to you and ask you the questions?

YOUTH AGREES

YOUTH DOES NOT AGREE

YOUTH DID NOT APPEAR TO UNDERSTAND EXPLANATION

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PARENT OR GUARDIAN INTERVIEW CONSENT FORM

The FDA Health and Media Study is sponsored by the U.S. Food and Drug Administration and is designed to collect data from boys about their attitudes related to health, health behaviors, and advertisements they may have seen on TV and/or online. Follow-up surveys will be conducted to assess awareness of the campaigns and receptivity to campaign messages.

Types of Questions for Parents

The parent interview takes approximately 5 minutes, depending on your answers. The interviewer will ask questions about household characteristics and media use.

Voluntary Participation

Your participation in this study is also completely voluntary. You can refuse to answer any and all questions. You can stop the interview at any time.

Risks

There are no physical risks to you from participating in this interview.

Benefits

There are no direct benefits to you from answering our questions. However, you will be contributing to important research related to youth attitudes related to health, health behaviors, and advertisements they may have seen on TV and/or online. The information you provide will also help researchers and policy makers understand how public education campaigns affect youths' health-related attitudes, beliefs, and behaviors.

Future Contacts

To help us understand changes over time, we may contact you in the future to update our information. Each of these additional interviews will also be completely voluntary.

Privacy

Your answers will be entered into a computer and labeled with a case identification number. Your name and that of your child will not be reported with any information your child provides. Information you provide will be combined with answers of many others and reported in a summary form. To protect the privacy of both you and your child, neither of you will know the other's interview answers. All staff involved in this research are committed to privacy and have signed a Privacy Pledge. Information collected will be kept private to the fullest extent allowable by law

Questions

If you have any questions about the study, you may call Melissa Helton at the RTI, 1-800-334-8571 extension 27168 (toll-free number). If you have any questions about your rights as a study participant, you may call RTI's Office of Human Research Protections at 1-866-214-2043 (a toll-free number).

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