

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

Parent or Guardian Permission for Youth Interview Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT)

Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT) is designed to collect data from youth about their experiences with tobacco products, media use, as well as some questions about your background. Follow-up surveys will be conducted to assess awareness of the campaigns and receptivity to campaign messages.

Selection of Youth

A random sample of household addresses was selected throughout the United States. A professional RTI interviewer will visit each sampled address to ask a few questions about whether any eligible youth live in the household. One or possibly two 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 Interview

We want to interview your child about their views and experiences with tobacco use. 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' attitudes, beliefs, and behaviors toward tobacco use.

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 towards tobacco use. 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 or she 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 tobacco use among youth. The information youth provide will also help researchers and policy makers understand the impact and effectiveness of public education activities aimed at reducing tobacco-related death and disease.

Future Contacts

Follow-up surveys are planned in order to help us better understand how youth aged 11 to 16 begin using tobacco, how much and what kinds of tobacco they use, and whether they think about quitting tobacco use. 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 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 Jennifer Keeney at the RTI, 1-800-334-8571 extension 23525 (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).

Because your child's contribution is important, we will offer your child an incentive of \$20 for participating. If your child participates in future rounds, he or she will be offered an incentive for participating in the in-person interviews.

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

Assent for Youth Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT)

I work for a company called RTI International (RTI). We are talking to kids all over the United States about a research study sponsored by the U.S. Food and Drug Administration's Center for Tobacco Products.

The survey asks teenagers ages 11-17 what they think about tobacco use, media use, and illegal behaviors. The survey will take about 30-40 minutes to complete. Up to 8,000 youth will take this survey. This survey is voluntary.

This survey is part of a research study 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 an incentive of \$20 to thank you for taking time to talk to me.

If you have any questions about this study, you can call Jennifer Keeney, at 800 334-8571 extension 23525. . 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.

I have read and understand this information, and the study purpose and process are clear to me.

- Yes, I agree to participate in this study.
- No, I do not wish to participate in this study.

May I talk to you and ask you the questions?

- YOUTH AGREES**
- YOUTH DOES NOT AGREE**
- YOUTH DID NOT APPEAR TO UNDERSTAND EXPLANATION**

We are using a laptop quality control (QC) system. The system runs on the computer and may record what you and I say to each other during parts of the interview. Neither you or I will know when the computer is recording what we say. The recording will be reviewed by people at RTI to monitor my work. The recordings will only be used for those purposes, and will be kept private to the fullest extent allowable by law. The files will be destroyed after they have been used to review my work. Those project staff who listen to the recording will know who I am, but will not know who you are. Is it alright with you if this QC system runs during this interview?

Thank you for taking time to complete this survey.

OMB No: 0910-xxxx

Expiration Date: xx/xx/xxxx

Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 10 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

Parent Consent Form Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT)

The Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT) is sponsored by the U.S. Food and Drug Administration's Center for Tobacco Products and designed to collect data from youth about tobacco use, media use, and illegal behaviors. 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 tobacco use among youth. The information you provide will help researchers and policy makers understand the impact and effectiveness of public education activities aimed at reducing tobacco-related death and disease.

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 Jennifer Keeney at the RTI, 1-800-334-8571 extension 23525 (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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