

ATTACHMENT 6 E2b3: PARENT PERMISSION FOR YOUTH 3TH AND 4TH FOLLOW-UP SURVEY (ExPECTT II)

Form Approved
OMB No. 0910-0753
Exp. Date: 01/31/2023

Parent Permission for Youth Survey for the Evaluation of the Public Education Campaign on Teen Tobacco Cohort II (ExPECTT II)

The Evaluation of the Public Education Campaign on Teen Tobacco (ExPECTT) is a research study designed to collect data from approximately 4,000 youth about their experiences with tobacco products, media use, and other behaviors that are both legal and illegal. RTI International (RTI), a nonprofit research organization, was selected by the FDA to conduct this study.

We must have your permission as the parent or legal guardian before your child participates in the survey. Once we have your permission, your child may choose whether or not to participate in the study. Since the survey is based on a random sample, your child will represent thousands of other youth in the United States.

Purpose of the Youth Survey

This study will provide FDA, policy makers, and researchers important information about youth exposure to public education messages on the health risks of smoking or using other tobacco products. The information collected by this study will also improve our understanding of how public education campaigns affect youth's attitudes, beliefs, and behaviors toward tobacco use.

Types of Questions for Youth

The survey will last about 35-45 minutes. Your child will be asked about his or her beliefs, attitudes and behaviors. We will ask about your child's media use. We will ask about your child's use of substances that may be illegal for children to buy or use in your state, such as tobacco and marijuana. We will also ask about your child's experiences in school and in the home. The youth survey should be completed in a part of the household that allows them to answer in private. If you would like to see a copy of the survey that your child will be taking, call our project assistance line at (800) 608-2955 and we will provide one. However, you will not be able to see your child's response to the survey questions.

Voluntary Participation

Your child's participation in this study is completely voluntary. He or she can refuse to answer any and all questions. Your child has the right to stop the survey at any time. Because your child's contribution is important, we will offer your child a [ON OR BEFORE [ADD DATE]FILL: \$30 incentive if they complete the survey through the website on or before [ADD DATE], or a \$25 incentive after [ADD DATE]; ELSE (ON OR AFTER [ADD DATE]) FILL: a \$25 incentive] as a token of appreciation for participating. This incentive will be provided via email as a digital gift card. For each follow-up your child completes in the future, he or she will receive a token of appreciation.

Risks

There are no physical risks to your child from participating in this survey. It is possible that some questions might make your child mildly uncomfortable, depending on his or her 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 help researchers and policy makers understand the impact and effectiveness of public education activities aimed at reducing tobacco-related death and disease.

Privacy

Your child will enter his or her answers to the questions directly into the computer. Your child's name will be kept private. Your child's answers will be labeled with a number instead of his or her name. This makes it so only research staff will know these are his or her answers. Your child's answers may be shared with the FDA but not his or her personal information. We will not share any information your child gives us with you or anyone outside the FDA and RTI research teams. All of your child's answers will be kept private. It is not completely safe to send data through the Internet but we are doing everything we can to protect your child's data. For example, we will code the data and send it over a secure connection for added protection.

Your name and that of your child will not be reported with any information you or your child provides. Information you and your child provide will be combined with answers of many others and reported in a summary form. 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.

To help us protect your child's information, we have obtained a Certificate of Confidentiality. This means that the researchers cannot provide information that may identify your child in a court of law or other legal proceeding. However, researchers may share your child's information with the FDA or individuals who are responsible for evaluating this study. You should understand that the Certificate does NOT stop reporting that some federal, state or local laws require such as reporting of child abuse, communicable diseases, and threats to harm yourself or others. The Certificate also does NOT prevent your child's information from being used for other research if allowed by federal regulations. However, no information will be shared or used for other research that could identify your child, such as name or date of birth. Finally, you should understand that the Certificate does not prevent your child or a member of your family from willingly releasing information about yourself or your involvement in this research.

Future Contacts

If your child takes this survey, we will contact you again to invite your child to take one more survey over the next year. It is up to you and your child to decide if you would like to participate in future surveys. If your child is a minor, we will ask your permission and your child's assent before you will be asked to take any future survey. If your child is an adult at the time of the survey we will obtain their consent to participate.

Questions

If you have any questions about the study, you may call our project assistance line at (800) 608-2955. 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).

[IF MODE = CAWI FILL: After you select your answer, please press "Next."]

- 1 Yes, I agree to allow my [IF CAWI FILL: child] to participate in this study.
- 2 No, I do not want my child to participate in this study.

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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 PRStaff@fda.hhs.gov.

CONTACT_INFO [IF PARENT PERMISSION = 1 (YES)]

We would also like to be sure that we have the best contact information for you for future surveys. Can you provide the best name, telephone number, and email address, and mailing address where you can be reached? This information will be stored in a secure location (e.g., locked file cabinet, encrypted computer file) and destroyed after 3 years.

Parent First Name: _____

Parent Last Name: _____

Telephone Number: _____

Email Address: _____

Mailing Address:

Street _____

City _____

State _____

Zip code _____

IF MODE = CAWI GO TO INCEN

SMS_PERMISS [IF PARENT PERMISSION = 1 (YES)]

Do we have your permission to send you text messages about the study? We will not share your telephone number with anyone else and will only use it to communicate with you about the study.

-
1. Yes
 2. No
-

IF COMPLETING ONLINE:

INCEN [IF PARENT PERMISSION = 1 (YES) AND MODE = CAWI]

Thank you for allowing your child [FILL: child's first name] to take part in this important study. If your child completes this survey, he or she will receive a digital gift card for [BEFORE AND ON [ADD DATE] FILL: \$30] if the survey is completed through the website on or before [ADD DATE], or \$25 if it is completed on or after [ADD DATE]; ELSE (ON AND AFTER [DATE] FILL: \$25.

We will need to collect some information from you so that we can send this gift card. This information will be kept completely confidential in secure and protected data files and will be separate from the responses provided in the survey. If you would like to decline receiving this payment, you can leave the information blank and simply press "Next" to continue to the next screen.

Please provide your child's first and last name

First name: **YFNAME**

Last name: **YLNAME**

This gift card will be delivered via email. Please provide an email address where we will send the card.

Email address: _____

Confirm email address: _____

GO TO P_INTRO

ASK: Parents that have provided permission for their child to complete online survey (Mode = CAWI).

P_INTRO [MODE = CAWI]

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Next" when your child is ready to begin.

GO TO YOUTH ASSENT

ASK: Parents that have provided permission for their child to complete online survey (Mode = CAWI).
