

ATTACHMENT 6_E2c2: YOUTH ASSENT FORM (UNDER 18) (ExPECTT II)

Form Approved
OMB No. 0910-0753
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RIHSC No. 18-009CTP

Youth Assent Form (under 18) for the Evaluation of the Public Education Campaign on Teen Tobacco Cohort II (ExPECTT II)

We are talking to young people all over the United States about a study sponsored by the U.S. Food and Drug Administration (FDA).

The survey asks about some of your beliefs, attitudes and behaviors. It asks about media use and about your use of substances that may be illegal for you to buy or use in your state, such as tobacco and marijuana. It asks about your experiences in school and in your home. About [ADD NUMBER] youth will be asked to take this survey. This survey is being conducted by RTI International (RTI). There are no direct benefits for answering our questions but you will be helping with important health research.

Your parent or legal guardian has given permission for you to take this survey. However, you do not have to take this survey if you don't want to. The survey will last between 35 and 45 minutes.

To help us protect your information, we have obtained a Certificate of Confidentiality. This means that the researchers cannot provide information that may identify you in a court of law or other legal proceeding. However, researchers may share your 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 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 you, such as name or date of birth. Finally, you should understand that the Certificate does not prevent you or a member of your family from willingly releasing information about yourself or your involvement in this research.

You will enter your answers to the questions directly into the computer. Your name will be kept private. Your answers will be labeled with a number instead of your name. This makes it so only research staff will know these are your answers. Your answers may be shared with the FDA but not your personal information. We will not share any information you give us with your parents or anyone outside the FDA and RTI research teams. All of your 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 data. For example, we will code the data and send it over a secure connection for added protection.

There are no physical risks but some questions might make you uncomfortable. If you don't want to take this survey, that is okay. If you don't want to answer a certain question, that is okay too. You can drop out of the survey at any time, for any reason. If you want to take a break, you can stop and start it again when you are ready.

IF COMPLETING ONLINE, FILL: We will send you a [BEFORE [DATE] FILL: \$25 check if you complete the survey through the website on or before [ADD DATE], or \$20 after [ADD DATE]; ELSE (ON AND AFTER [DATE] FILL: \$20 check]to thank you for taking time to complete the survey.

IF COMPLETING VIA CAPI, FILL: We will give you \$20 in cash to thank you for taking time to complete the survey.

If you take this survey, we will contact you again to invite you to take [IF BASELINE FILL: three more surveys over the next two years; IF FOLLOW-UP1 FILL: two more surveys over the next year and a

half; IF FOLLOW-UP2: FILL one more survey over the next year]. You will be paid for each survey you take. It is up to you to decide if you would like to take any future surveys.

You can call us if you have questions about the study. The phone number is (800) 608-2955. If you have a question about your rights as a study participant, you can call RTI's Office of Research Protection at (866) 214-2043.

[DISPLAY FOR IN-PERSON INTERVIEWS ONLY] Do you have any questions about what I just read?
[FI: IF YES, ANSWER ANY QUESTIONS TO HELP THE YOUTH UNDERSTAND THE ASSENT.]

1. Do you agree to take part in the study?
 - 1 Yes
 - 2 No

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Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 5 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