

ATTACHMENT 14A: QUESTIONS AND ANSWERS ABOUT THE EVALUATION OF THE FRESH EMPIRE CAMPAIGN ON TOBACCO (EFECT) FOR USE WITH THE ABS SAMPLE

What is the Evaluation of the Fresh Empire Campaign on Tobacco (EFECT)?

The Evaluation of the Fresh Empire Campaign on Tobacco (EFECT) is designed to collect data from youth in order to understand attitudes and beliefs towards tobacco use, as well as youth media use.

Why should I/my child participate?

This is an opportunity for your child to contribute to important research related to tobacco use and to help researchers and policy makers understand the impact and effectiveness of public education activities aimed at reducing tobacco use and the health risks of using tobacco.

Who is sponsoring this study?

The study is sponsored by the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). CTP is responsible for creating strategies to prevent youth from starting to use tobacco and to encourage tobacco users to quit. RTI International (RTI) has been selected by the FDA to conduct each round of the study and collect further data between each round.

Who is RTI International?

RTI International (RTI) is a not-for-profit research organization located in North Carolina. RTI conducts research projects for a wide variety of government agencies, universities, and private companies. Professional RTI interviewers in your area are conducting the interviews with eligible youth.

How was I chosen?

A random sample of households is selected throughout the United States. A professional RTI interviewer makes a personal visit to each household to one or possibly two children in your household to voluntarily participate in the survey. Since the survey is based on a random sample, your child will represent thousands of other United States residents.

How will I/my child be involved?

The interviewer will ask your permission to speak with your child about participating in the study. The interviewer will read some questions off of a computer screen and enter the responses into a computer. Your child will also read questions and answer choices from the computer screen and enter their responses directly into the computer.

How is the study being conducted?

A professional RTI interviewer will visit each selected address to ask adults aged 18 or older whether any children age 12 to 17 live in the household. In each household where one or more children are eligible, interviewers will request permission from the parents or legal guardian of eligible youth to participate in the study. Once parental permission is provided for eligible youth to participate, interviewers will use a laptop computer to first ask parents a few questions about the household and then begin interviews with eligible youth(s).

How will I recognize the RTI interviewer?

The interviewer will carry an RTI identification badge with his or her picture on it.

How long will it take?

The youth interview will take about [30 minutes for the pre-campaign survey; 45 minutes for the post-campaign survey] to complete, on average. Interviewers can schedule visits to your household when it is most convenient for you and your child.

What happens to the information?

Each computerized interview data file—which is identified only by code number—will be electronically transmitted to RTI on the same day the interview is conducted. The answers will then be combined with all other participants' answers, and then coded, totaled, and turned into statistics for analysis. As a quality control measure, your household might receive a telephone call from RTI to verify that the interviewer followed the correct steps in completing the survey with you and your child.

What about Privacy?

All RTI staff members and interviewers have signed a Privacy Agreement guaranteeing that they will not reveal any information to anyone other than authorized project staff. All information collected as part of the study will be kept private to the fullest extent allowable by law, and nothing you tell us will be reported with your name.

The interviewer will ask for your permission before approaching your child for an interview. At that point, your child may choose whether or not to participate in the study. To protect your privacy and that of your child, you will not be able to see his/her answers to the interview questions. Answers obtained during the survey will be combined with those from thousands of others from around the country.

Where do I get more information about the study?

If you have other questions about this survey, you may call toll-free: XXXX, 800 334-8571 extension XXXXX. If you have questions about your rights as a study participant, call toll-free: **RTI's Office of Human Research Protections** at 1-866-214-2043.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 1 minute per response to review the frequently asked questions (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.