

ATTACHMENT 14A: QUESTIONS AND ANSWERS ABOUT THE EVALUATION OF THE FRESH EMPIRE CAMPAIGN ON TOBACCO (EFECT) FOR USE WITH LONGITUDINAL 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 consider allowing my child to 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 U.S. 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.

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?

Six months ago 1a random sample of households were sent a short paper survey in the mail. A small portion of the households that returned that paper survey were eligible for an additional in-person interview. A professional RTI interviewer made a personal visit to each eligible household to ask the child that completed the paper survey to voluntarily participate in an in-person survey. We are now conducting a follow-up survey with the youth that completed the in-person interview 6 months ago. Since the survey is based on a random sample, your child will represent thousands of other United States residents.

How will my child be involved?

If your child is under 18 years old, the interviewer will ask your permission to speak with your child about participating in the study. Your child will read questions and answer choices from the computer screen and enter his/her responses directly into the computer. The interviewer will also read some questions off of a computer screen and enter the responses into a computer.

How is the study being conducted?

A professional RTI interviewer will visit each household that does not complete this survey online. At each household, interviewers will request permission from a parent or legal guardian of the eligible youth under the age of 18 to participate in the study. Once parental permission is provided for the eligible youth to participate, the eligible youth will read questions and answer choices from the computer screen and enter his or her responses directly into the computer. We will ask 18 year old youth directly about their participation in the study.

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 interview will take about 40 minutes to complete, depending on your answers.

What happens to the information?

Each computerized interview data file—which is identified only by code number—will be electronically transmitted to RTI and removed from the laptop. Survey answers will 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 while completing the survey.

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 in strict confidence and used only for statistical purposes, and nothing your child tells us will be reported with your child's 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 our research team toll-free at XXXX, extension XXXXX, or contact us via email at [CONTACT EMAIL]. If you have questions about your rights as a study participant in the EFECT study, 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 PRStaff@fda.hhs.gov.