

# **ATTACHMENT 11: QUESTIONS AND ANSWERS ABOUT THE FDA HEALTH AND MEDIA STUDY**

**Form Approved  
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## **What is the FDA Health and Media Study?**

The FDA Health and Media Study is designed to collect data from boys about their attitudes related to health, health behaviors, and advertisements they may have seen on TV and/or online.

## **Why should I participate?**

This is an opportunity for you and your child to contribute to important research related to improving our understanding of how public education campaigns affect youths' health-related attitudes, beliefs, and behaviors.

## **Who is sponsoring this study?**

The study is sponsored by the Food and Drug Administration (FDA). 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 and their parents.

## **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 ask several initial questions. One or possibly more children in your household may be asked to voluntarily participate in the survey. Since the survey is based on a random sample, you will represent thousands of other United States residents.

## **How will 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 male children age 11 to 16 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). We will conduct three follow-up surveys every eight months to understand changes in health-related attitudes and behaviors over time. Each of these additional interviews will also be completely voluntary.

**How will I recognize the RTI interviewer?**

The interviewer will carry an RTI identification badge with his or her picture on it. The interviewer will also have a letter of authorization from RTI.

**How long will it take?**

The brief interview with parents will take 10 minutes or less to complete. The interview with eligible youth will take about 30 minutes, 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.

**Will my child be compensated for his time?**

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 will be offered an incentive of \$20 for each of the three follow-up in person interviews in which he participates.

**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, neither of you will know the other's 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: Melissa Helton, 800 334-8571 extension 27168. 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.

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**Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 2 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](mailto:PRASStaff@fda.hhs.gov).**