

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

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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, online, or heard on the radio. This survey is being conducted in five rounds over time.

Why should I allow my child to participate?

This is an opportunity for you and your child to continue 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 U.S. Food and Drug Administration (FDA). 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.

How will my child be involved?

We will ask your permission for your child to continue to participate in the study. Your child will read questions and answer choices from the survey and enter his responses.

How is the study being conducted?

For in-person interviews, field interviewers will request permission from one of the parents or legal guardians of the eligible youth to continue to participate in the study. Once parental permission is provided for the eligible youth to participate, interviewers will use a laptop to begin interviews with eligible youth(s).

The interviews may also be completed online. The parent or legal guardian of eligible youth will log on to the study website provided in the enclosed letter. Permission will be requested for the youth to continue to participate in the study. Once parental permission is provided, the youth will complete the interview online. If the youth completes the interview online, he will not complete the in-person interview.

This is the third of four follow-up surveys, conducted every eight months, to understand changes in health-related attitudes and behaviors over time. Each additional interview is also completely voluntary.

How will I recognize the RTI interviewer?

The interviewer conducting the in-person interview 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 interview with eligible youth will take about 45 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 within 48 hours. 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.

For surveys completed online, an encrypted link between a web server and your browser is used. This link ensures that all data passed between the web server and browser remain private.

Will my child be compensated for his time?

Because your child's continued contribution is important, we will offer him a check for \$25 if he completes the survey through the website on or before [Early Bird Date], or a check for \$20 after [Early Bird Date], as a token of appreciation for participating. Your child will receive \$20 in cash if he completes the survey in person.

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 your child tells us will be reported with your name or your child's name. To protect your child's privacy, you will not know his answers to the interview questions. Answers obtained during the survey will be combined with those from thousands of others from around the country.

If the survey is completed in person, the interviewer will ask for your permission before approaching your child for a follow-up interview. At that point, your child may choose whether or not to continue to participate in the study.

Where do I get more information about the study?

If you have other questions about this survey, you may call our project assistance line toll-free at (866) 214-2039 or email us at mediastudy@rti.org. If you have questions about your rights as a study participant, call toll-free: **RTI Office of Research Protection** at (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 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 PRASStaff@fda.hhs.gov.

