

**PARENT/GUARDIAN PERMISSION FORM
For Parents of Minor Participants Ages 11 to 13**

Sponsor / Study Title: RTI International / “The Real Cost Campaign Outcomes Evaluation Study: Cohort 3”

**Principal Investigator:
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Key Information

We are talking to young people all over the United States about a study sponsored by the United States Food and Drug Administration (FDA). We are asking your child to take part in the Health and Media Study about tobacco and marijuana products, media use, beliefs, and behaviors. If your child takes part in this study, which involves completing an online survey, they will be one of about 7,500 people to do so. We randomly chose your household for this study. The FDA selected RTI International (RTI), a nonprofit research organization, to conduct this study.

This study will provide the FDA, policy makers, and researchers with important information about youth exposure to a public health education campaign and messages on the health risks of smoking or using other tobacco products. The mission of the FDA is to promote public health. The FDA does not support or encourage tobacco use. The information we collect will help us understand how public education campaigns affect youth attitudes, beliefs, and behaviors toward tobacco use.

It is your child’s choice to take part in this study, and you are not under any obligation to allow your child to take part in this study. There is no penalty for not taking part. You and your child will not lose any benefits or rights as a result of not participating. If you give your permission, you may change your mind at any time.

Your child can take the survey on a personal computer, smartphone, or tablet. It should take them about 30 minutes. To protect your child’s privacy, they may not go back to questions they already answered, and they will be logged out if they do not enter any responses for 20 minutes (to reduce the chance that someone else might see survey responses on the screen). They can take a break at any time and start again when they are ready. Please allow them to take the survey in a private place so that no one can see their answers.

Your child will not personally benefit from taking part in this study, but their answers will contribute to important research.

Some of the questions in the survey might make them feel bad or upset. They can respond “prefer not to answer” to any question they don’t want to answer and may drop out of the survey at any time for any reason.

The study staff understands that the security of online transmissions is not guaranteed due to the risk of interception by third parties, or the possibility of monitoring software installed on research participants’ electronic devices. Your child’s identity will not be known in the results of the study. Everything your child shares will be kept private to the extent allowed by law. Only the authorized study staff will have access to your child’s responses. Your child’s answers will be combined with everyone else’s responses and shared with the FDA but will otherwise be kept private. We will not share your child’s name or other personal information with the FDA. We will not share their individual survey responses with anyone outside of the FDA and RTI staff. However, your child’s answers could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. If that happens, all identifiable private information will be removed before your child’s answers are shared.

There is no guarantee that the information they send online will not be seen by others, but we will do everything we can to keep their information private.

There is no cost to you or your child for participating. Because your child’s contribution is important, we will mail \$30 to them if they complete the survey before [ADD DATE], or \$25 after [ADD DATE]. Your child can choose between cash or a Visa gift card.

You may not move on to the next question in the survey if an item is left blank, but you may move on to the next question if you select “prefer not to answer”.

If your child does not complete the survey, they will not receive a Visa gift card or cash. Your child may be asked to take another survey at a later time. They will receive a Visa gift card or cash for each additional survey they complete.

If your child takes this survey, we may contact you again to invite your child to take another survey. We have planned follow-up surveys to help us better understand how young people begin using tobacco, how much and what kinds of tobacco they use, and whether they think about quitting tobacco use. It is up to you and your child to decide whether you would like to participate in future surveys. If your child is under the age of 14, we will ask your permission and your child’s assent before asking your child to take any future survey.

The investigator can stop your child’s participation at any time without your or their consent for the following reasons:

- If your child fails to follow directions for participating in the study;
- If it is discovered that your child does not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

This study is for research purposes only. The only alternative is to not participate in this study. Any new important information that is discovered during the study and which may influence your willingness to allow your child to continue participation in the study will be provided to you.

Whom to Contact About This Study

During the study, if you have questions, concerns, or complaints about the study such as:

- Payment or incentive for being in the study, if any;
- Your child's responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw your child from participation;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your child's rights as a research participant, contact:

- By **mail**:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00065019.

Certificate of Confidentiality

This study is covered by a special protection called a Certificate of Confidentiality (CoC). The CoC requires staff involved in this study to protect your child's privacy. We cannot provide information that could identify them to anyone who is not connected with the study. We cannot share your child's information in legal proceedings, even if there is a court order, unless you and your child agree. We may share your child's information if:

- You and your child agree to share information (for example, to get medical treatment).
- The study information is used for other scientific research that follows federal law.
- The FDA, which is paying for the study, needs information to check how their money is being spent.
- A law requires sharing information (for example, when we must report to the FDA, or if we hear about threats of harm or reports of child abuse).

The CoC does not prevent you or your child from sharing personal information or talking about this study with others. You and your child can tell others that your child is in this study or about their history of tobacco use.

I understand the study purpose and process.

Do you agree to allow your child to participate in this study?

Yes, I agree to allow my child to participate in this study.

No, I do not want my child to participate in this study.

CONTACT INFO [IF PARENT PERMISSION = 1 (YES)]

Thank you for allowing your child, [FILL: child's first name], to take part in this important study.

Please provide the full first and last name for [CHILDNAME].

First name: **YFNAME**

Last name: **YLNAME**

To ensure we are able to contact you about your child's participation in the study, could you please provide your contact information?

First Name: _____

Last Name: _____

Telephone Number: _____

E-mail Address: _____

SMS_PERMISS [IF PARENT PERMISSION = 1 (YES)]

Do we have your permission to send you text messages about the study? We will not share your telephone number with anyone else. We will only use it to communicate with you about the study.

1. Yes
2. No

INCENTIVE INFO [IF PARENT PERMISSION = 1 (YES)]

Your child will be offered a \$25 Visa gift card or \$25 cash if they complete the survey before [END DATE] [IF DATE IS BEFORE EARLY BIRD DATE ADD]: and a bonus \$5 if they complete it on or before [EARLY BIRD DATE].

The gift card or cash will be mailed to you within 2 weeks of your child completing the survey, but first we need to collect your mailing address. This information will be kept completely confidential in secure and protected data files and will be separated from the responses provided in the survey.

Mailing Address:

Address: _____

City _____

State _____

ZIP code _____

P_INTRO

It is important that your child be allowed to answer the questions in privacy. From this point on, your child should be able to read and answer all questions on his or her own. Press "Next" when your child is ready to begin.

GO TO YOUTH ASSENT

OMB No: [FILL NUMBER]

Expiration Date: [FILL DATE]

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. PRASStaff@fda.hhs.gov.