

OMB No: 0910-0915

Expiration Date: 06/30/2026

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. 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 PRStaff@fda.hhs.gov.

**YOUNG ADULT INFORMED CONSENT FORM (Main Data Collection)
(FOR PARTICIPANTS WHO ARE Age of Majority (AOM) TO 20 YEARS OLD)**

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

**Principal Investigator:
(Study Investigator)** Anna MacMonegle

Telephone: [866-800-9177 OR 877-834-7065] (24 Hour)

Address: RTI International
3040 Cornwallis Rd
P.O. Box 12194
Research Triangle Park, NC 27709

Email Address: [HealthAndMediaStudy@rti.org OR HMS@rti.org]

Key Information

We are talking to young people about a study sponsored by the United States Food and Drug Administration (FDA). You have been asked to take part in a national study, which involves completing an online survey, called the “Health and Media Study”. This study is being conducted by RTI International (RTI is a research organization). We are doing this research to learn about media, tobacco, and marijuana use among young people. We will ask about [INSERT NUMBER OF STUDY PARTICIPANTS] people in the United States to take this survey.

We are asking for your consent to participate. It is your choice to take part in this study or not. You do not have to take this survey if you don't want to. If you complete this survey, we may ask you to complete another survey in the future. There are no benefits to you from taking this survey, but your answers will contribute to important research. This information will help keep the FDA up to date on tobacco use among people your age. The mission of the FDA is to promote public health. The FDA does not support or encourage tobacco use.

Some of the questions might make you feel bad or upset. You can choose “prefer not to answer” for any question. 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 you are doing the survey and decide you don't want to anymore, you can stop. If you don't want to answer a certain question, that is okay too. You can drop out of the survey at any time, for any reason. Nothing bad will happen and no one will be upset if you do not take this survey or if you change your mind after you start.

You can take the survey on your computer or another device like a smartphone or tablet. It should take you about 30 minutes. To protect your privacy, you may not go back to questions

you already answered, and you will be logged out if you do not enter any responses for 20 minutes (to reduce the chance that someone else might see survey answers on the screen). You can take a break at any time and start again when you are ready. Please take the survey in a private place so no one sees your answers.

The research team 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 answers will be combined with everyone else's and shared with the FDA. We will not share your name or other personally identifiable information with the FDA. Data from this study could be made available to the public, but all identifiable private information will be removed before the data are shared. Your identity will not be known in the results of the study. Data will not be analyzed or reported in such a way that it will be possible to identify any individual participant. There is no guarantee that the information you send online will not be seen by others, but we will do everything we can to keep your information private.

The investigator can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do 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 continue participation in the study will be provided to you.

As a thank you for completing this survey, we will mail you **\$30** if you complete the survey on or before **[EARLY BIRD DATE]**, or **\$25** after **[EARLY BIRD DATE]**. You can choose between cash or a Visa gift card. If you do not complete the survey, you will not receive a Visa gift card or cash. If asked to take another survey at a later time, you will receive a Visa gift card or cash for each additional survey you complete.

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 responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;

Please contact the Investigator at the telephone number listed at the top of the page.

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 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 privacy. We cannot provide information that could identify you to anyone who is not connected with the study. We cannot share your information in legal proceedings (for example, in a court case), even if there is a court order, unless you agree. We may share your information if:

- You 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 from sharing personal information or talking about this study with others. For example, you can share that you are in this study or your history of tobacco use.

☐ **I understand the study purpose and process.**

Would you like to participate in this survey?

☐ Yes, I want to take the survey.

☐ No, I do NOT want to take the survey.

CONTACT INFO

Thank you for taking part in this important study. You will be offered a \$25 Visa gift card or \$25 cash if you complete the survey before [END DATE]_[IF DATE IS ON OR BEFORE EARLY BIRD DATE ADD: and a bonus \$5 if you complete it on or before [EARLY BIRD DATE].

The gift card or cash will be mailed to the address provided within 2 weeks of when you complete the survey, but first we need to collect your name and 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.

Please provide your name, address, telephone number, and email address.

[PROGRAMMER: ALLOW FIELDS TO REMAIN BLANK]

First Name: _____

Last Name: _____

Mailing Address:

Street _____

City _____

State _____

ZIP code _____

Cell Phone Number: _____

☐ I do not have a cell phone

Email Address: _____

☐ I do not have an email address

Please reenter your email address: _____

**[PROGRAMMER: CONFIRM THE EMAIL ADDRESSES MATCH. IF NOT, DISPLAY:
These email addresses do not match. Please reenter your email address.]**

**[PROGRAMMER: IF ANY ITEM LEFT BLANK DISPLAY MESSAGE. 'YOU HAVE
LEFT THIS ITEM BLANK. YOU DO NOT HAVE TO ENTER A RESPONSE.
HOWEVER, YOU MAY NOT RECEIVE THE INCENTIVE IF THIS RESPONSE IS LEFT
BLANK.']**

SMS_PERMISS

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

-
1. Yes
 2. No