

**YOUTH ASSENT (Supplemental Social Media Data Collection)
FOR MINOR PARTICIPANTS AGES 14 TO (Age of Majority) (AOM)**

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

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

Telephone: 866-800-9177 (24 Hour)

Address: RTI International
3040 Cornwallis Rd
Research Triangle Park, NC 27709

Email Address: HealthAndMediaStudy@rti.org

We are talking to young people about a study sponsored by the United States Food and Drug Administration (FDA). We would like you to be part of a study called the “Health and Media Study”, which involves completing an online survey. RTI International (RTI is a research organization) is doing this study to learn about media, tobacco, and marijuana use and beliefs in young people. We’re asking about 7,500 people in the United States to take this survey.

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 do it, we might ask you to take another survey. Taking this survey won’t help you, but you will be helping the FDA learn important things about how people your age use tobacco. The mission of FDA is to promote public health. The FDA does not support or encourage tobacco use.

You can take the survey on a computer, smartphone, or tablet. It should take about 30 minutes. You can take a break any time and start again when you’re ready. Take the survey where no one can see your answers. You won’t be able to go back to questions you already answered. You will be logged out if you don’t answer any questions for 20 minutes. This is to make sure other people don’t see your answers. 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. We’ll do everything we can to keep what you share private, but we can’t say for sure that what you share online won’t be seen by others.

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. There is no penalty if you do not take this survey. 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.

We'll keep your answers private. Your parent or guardian (the person who takes care of you) won't see them. We will share your answers with the FDA, but we won't share your name or anything else about you with the FDA. We won't share anything about you with people who don't work at FDA or RTI. 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. However, your 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 answers are shared.

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.

If you do this survey, we'll mail you \$25. You can choose whether you want cash or a Visa gift card. If you do not complete the survey, you won't get a Visa gift card or cash. We will look at your survey to make sure that you are the person who took it and that you only took it once. If we find that there is a problem with the survey, then you will not receive the \$25. 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 on the first page of this consent document.

Certificate of Confidentiality

This study is protected by something called a Certificate of Confidentiality (CoC). This means that the people who work on this study have to protect your privacy. We can't share anything that would tell people who don't work on the study who you are. We can't share anything about you in legal settings (for example, in a court case) unless you say we can. We may share things about you if:

- You say we can share it (for example, if you want your doctor to have it).
- The study information is used for other studies that follows federal law.
- The FDA, which is paying for the study, needs to check how their money is being spent.
- A law says we have to share information (for example, when we must report to the FDA, or if we hear that a person is going to hurt someone or has hurt a child).

The CoC does not apply to what you do. You can choose whether to tell others you are in this study or if you have used tobacco.

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 [IF 14+ & ASSENT = 1 (YES)]

Thank you for taking part in this important study. You will be offered a \$25 Visa gift card or \$25 cash when you complete the survey.

The gift card or cash will be mailed to you within 2 weeks of completing 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, and telephone number.

First Name: _____

Last Name: _____

Mailing Address:

Street _____

City _____

State _____

Zip code _____

Telephone Number: _____

Email Address: _____

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

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 2.5 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.