

Expiration Date: [FILL DATE]

PARENT/LEGAL GUARDIAN PERMISSION FORM
For Parents of Minor Participants Ages 12 to 17 (12 to 18 in AL and NE)
(VERSION 2-4-2025)

Quantitative Study

Sponsor / Study Title: RTI International / “Monthly Implementation Assessment Study”

Study Provider: Ipsos KnowledgePanel

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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 time required to complete this information collection is estimated to average 3 minute(s) per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov.

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 Media and Advertisements Study. We are interested in hearing your child's thoughts about advertisements that they may have seen on digital channels such as Hulu, YouTube, and Instagram. If your child takes part in this study, which involves completing an online survey or participating in a discussion group, they will be one of about [FILL WITH FINAL SAMPLE SIZE] people to do so. 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 how aware teens are of advertisements, whether the advertisements are effective, as well as teen attention and understanding of the advertisements. The mission of the FDA is to promote public health.

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/participate in the discussion group] on a personal computer, smartphone, or tablet. It should take them approximately [25 minutes to complete the survey/60 minutes to participate in the discussion group]. [Survey instruction only: 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 10 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. Your child can skip 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 RTI and the FDA but will otherwise be kept private. We will not share your child's name or personal identifiable information with RTI or the FDA. We will not share their individual survey responses with anyone outside of the Ipsos, 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. Your child may be asked to take another survey at a later time. If asked to take another survey at a later time, your child will receive panel points for each additional survey they complete. 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 majority, we will ask your permission and your child's assent before asking your child to take any future survey.

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 compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;

Please contact Ipsos KnowledgePanel at the telephone number or email address 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 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:
Pro00073709.

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.

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.

Please click next and have your child take the survey as soon as possible.

[NEXT]

Mixed Methods Study

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 time required to complete this information collection is estimated to average xx minute(s) per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov.*

Please read this form carefully. You can ask as many questions as you want. If there is any information you do not understand, the researchers will be happy to explain it to you. **You must sign, date, and return this form to study staff before your child can take part in the discussion group.**

Introduction: About the study

The purpose of this research study, which will take the form of a discussion group, is to gain insight from teen and young adults about different kinds of messages and ideas designed to prevent and reduce teen tobacco use. There will be a total of up to [X] participants in this study.

RTI International is a research company working with the U.S. Food and Drug Administration's Center for Tobacco Products to hold discussion groups with teen and young adults ages 13-20 years old. During a 90-minute discussion group, participants will be asked to complete individual polls and participate in a group discussion. Five minutes before the group begins, participants will be asked to complete technology check to ensure their camera and microphone are connected for the group discussion. We will use the information from this study to develop a campaign to reduce teen tobacco use.

The Food and Drug Administration (FDA) is sponsoring this study. The mission of the FDA is to promote and protect public health. In conducting this study, FDA does not intend to sell tobacco, nor promote, condone, normalize, or encourage its use. The questionnaires, surveys, and messages in this study are not intended to promote, directly or indirectly, other behaviors that may be a gateway to subsequent risky behaviors, such as illegal drug use, binge drinking and smoking.

Procedure: What will my child do during this study?

If you agree for your child to participate, they will join a virtual discussion group with no more than 5 other participants. The discussion group will last 90 minutes. The groups will be held virtually using a video conference platform. All participants will need to join 5-minutes before the group begins for a technology check to ensure your camera and microphone are connected for the group discussion. Discussion group leaders will ask questions about images, ideas, and potential creative advertisements to inform a tobacco prevention campaign. All participants will be asked to share your opinions.

Your child must be on camera to participate. If participants do not adhere to requirements of participation, or if we find that participants have misrepresented themselves in any way, they may be asked to leave and forego the token of appreciation. The discussion will be audio recorded. We will use the recordings of all the groups to prepare a summary; however, your child's name will not be associated with your responses in any reports. We will not video record the discussion.

There may be other observers from RTI and FDA viewing the discussion, but they will not participate, and your child will not be able to see these observers on camera. RTI and FDA observers will be able to see video and hear audio from participants when viewing discussion groups live.

Privacy: Who will see the information I provide during this study?

What your child says during the discussion group can be heard by others in the group, the group leader, and other study staff members. All participants will be asked to respect the privacy of the others in the group. Everyone will be asked not to share anything said during the group. Your child must be visible on camera to participate.

All participants must agree not to obtain or use any of the other participant's images or voices by the use of a recording (for example, video or audio of a computer, tablet, or mobile device output). In addition, all participants will be asked to remain on video at all times or will be asked to leave the discussion group.

Group discussions will be audio recorded, transcribed, and turned into notes to write a report. Transcripts and audio recordings will be redacted of any personally identifiable information (any identifying information, like names, will be removed) and delivered to FDA for review. Study staff may also watch or listen to the group. Groups will not be video recorded. The report will not link your child's comments to him/her. No one (including parents or guardians) outside of the group participants and study staff will know what your child said during the discussion. The group leaders will ask participants not to share any private, personal, or inappropriate information. If such information is shared, it will be removed from the notes, audio files, and transcripts.

All data will be kept for three years after the completion of the study. Data will be redacted of all personally identifiable information (such as names) and stored on a password-protected computer or in a locked cabinet. Three years after the completion of the study, we will destroy all of the data by securely shredding paper documents and permanently deleting electronic records. All identifiable information (for example, contact information such as name and phone number to confirm your child's invitation to the group) will be destroyed one month after the conclusion of discussion groups to ensure incentive delivery. The FDA will not receive any data that could identify your child.

This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection requires that staff involved in this study protect your child's privacy. This means study staff generally cannot provide your child's name, or any other information that could identify your child, to anyone who is not connected with the study. Study staff cannot share this information in court or during other legal proceedings, unless you or your child agree, even if there is a court order for the information. However, in other settings, study staff may share study information that could identify your child if:

- You or 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 research money is being spent; or
- A law requires sharing information (for example, when study staff must report to FDA, or if study staff hear threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you from sharing any personal information or information about your involvement in this study with others. For example, you can share that you are in this research study or your history of tobacco use.

Information that your child shares during the interview discussions about his/her e-cigarette or tobacco-related attitudes, beliefs, and behaviors will not be shared with anyone outside of the research team, including parents/guardians, to protect your child's privacy.

General information from this discussion group, including sample descriptions, may appear in professional journals or at scientific conferences, but will never include any identifying information about your child.

What will my child get for being in this study?

Each participant and their parent/guardian will receive an [\$X] token of appreciation for being in this study for a total of [\$X]. The token of appreciation will be delivered to you and your child via email or mail depending on the vendor and you and your child's preference. There is no cost to you or your child for taking part in this study. Your child does not have to answer any questions that he or she does not want to. You and your child will still receive the [\$X] each even if your child chooses not to answer some questions. If we find that you or your child have misrepresented yourselves in any way during this study, you may not receive the incentive.

Study Benefits: What good will come from this study?

This discussion group is not expected to directly benefit you or your child. However, your child's feedback will help us decide what ideas, images, and messages may prevent teen tobacco use.

Anticipated Risks: Could anything bad happen to my child during this study?

The risks for taking part in this study are low. Your child can ask the interviewer any questions they have about this interview discussion. Your child may want to discuss cigarette or e-cigarette use or prevention with you or another trusted adult. Your child may also have questions or concerns about the images or concepts he/she sees during this study. If your child becomes upset or wants to stop participating, **your child may stop participating in this study at any time.**

We will take care to protect the information you and your child provide. However, as with all studies, there is a chance that privacy could be broken because of an accidental error or a security breach. In the event such a breach occurs, all participants will be contacted and notified as to the extent of the breach, any damages incurred, and future potential risks. We will provide you with contact information for additional inquiries.

Participation and Withdrawal: Does my child have to be in this discussion group? What if my child changes his/her mind?

This study is completely voluntary. You can choose whether or not to give permission for your child to take part in this study. Your child can stop participating at any time. Your child can choose to leave the discussion group at any time and does not have to answer any questions he/she does not want to. If your child decides to participate and later changes their mind, they will not be contacted again about this study or asked for further information. You and your child will still receive the token of appreciation for participating in the study even if your child chooses to not answer some questions or leaves the discussion group. Anyone who is found to have

misrepresented themselves and would not have normally qualified for the study (e.g., is not within the required age range), will be removed from the discussion group, and forego the incentive.

Research Questions and Contacts: Whom do I call if my child or I have questions?

If you have any questions or concerns about this study, you may call Anna MacMonegle (RTI Researcher) at 919-990-8427 or email at amacmonegle@rti.org. If you have questions about your rights as a research participant, please contact RTI's Office of Research Protection at 1-866-214-204.3 An IRB is a group of people who review research studies to protect the rights and safety of research participants. Please keep a copy of this form for your records. If you would like an additional blank copy of this form, you can email Anna MacMonegle at amacmonegle@rti.org.

Do you agree for your child to participate in this discussion group and be audio-recorded as part of the group?

1. Yes
2. No [TERMINATE]