OMB No: [FILL NUMBER]
Expiration Date: [FILL DATE]

YOUTH ASSENT AGES 12 - AGE OF MAJORITY (AOM)
For Participants Ages 12 to 17 (12 to 18 in AL and NE)

Quantitative Study

Sponsor / Study Title:	**RTI International / "Monthly Implementation Assessment Study"**
Study Provider:	**Ipsos KnowledgePanel**
Telephone:	**1-800-782-6899**
Address:	**Ipsos KnowledgePanel** **Panel Relations** **1 Upper Pond Rd #D-2** **Parsippany, NJ 07054**
Email Address:	**support@knowledgepanel.com**

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 minutes 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 you to take part in the Media and Advertisements Study. We are interested in hearing your thoughts about advertisements that you may have seen on digital channels such as Hulu, YouTube, and Instagram. If you take part in this study, which involves completing [an online survey/participating in a group discussion], you will be one of about [FILL WITH FINAL SAMPLE SIZE] people to do so each month. 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 attention and understanding of the advertisements. The mission of the FDA is to promote public health.

It is your choice to take part in this study or not. You do not have to take part of this study if you don't want to.

If [you are doing the survey/taking part of the discussion] 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 study 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 will not personally benefit from taking part in this study, but your answers will contribute to important research.

[survey instructions] You can take the survey on your computer or another device like a smartphone or tablet. It should take you approximately 25 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 10 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. [discussion group instructions] You can take part of the group discussion on your computer or another device like a tablet. It should take you approximately 60 minutes.

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 answers will be combined with everyone else's and **shared with RTI and the FDA** but will otherwise be kept private. We will not share your name or personal identifiable information **with RTI nor the FDA**. We will not share your individual survey responses **with anyone outside of the Ipsos, FDA and RTI staff**. However, your answers could be used for future research studies [missing text]. If that happens, all identifiable private information will be removed before your answers 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.

You may be asked to [take another survey/participate in another group discussion] at a later time. It is up to you to decide whether you would like to participate in future [surveys/group discussions].

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.

Whom to Contact About This Study
During the study if you have questions, concerns, or complaints about the study such as:

- 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 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 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.

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

Would you like to participate in this [survey/group discussion]?

☐ Yes, I want to take the [survey/group discussion].

☐ No, I do NOT want to take the [survey/group discussion]

If you would you like to participate, please click “next” to [take the survey/join the group discussion]

[NEXT]

Mixed Methods Study

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Please read this form carefully. You can ask as many questions as you want. If there is anything you do not understand, we will be happy to answer your questions. We can also read this to you out loud to help you understand. **You must sign, date, and return this form to study staff before you can take part in the discussion group.**

Introduction: About this study

The purpose of this research study, which will take the form of a discussion group, is to gain insight from youth 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, you will be asked to complete individual polls and participate in a group discussion. Five minutes before the group begins, you will be asked to complete technology check to ensure your 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 I do during this study?

If you agree to participate, you will join a virtual discussion group with no more than 5 other participants. The discussion group will last 90 minutes. The group will be held virtually using a video conference platform. You 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. You and the other participants will be asked to share your opinions.

You must be on camera to participate. If you do not adhere to requirements of participation, or if we find that you have misrepresented yourself in any way, you 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 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 you 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 you say during the discussion group can be heard by the 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. In addition, we ask that all participants remain visible on video at all times.

In the case of virtual group participation, you agree not to obtain or use any of the other participant's images or recorded voices (for example, video or audio recordings or screen shots from a computer, tablet, or mobile device). Additionally, you agree not to upload, email, post, publish or otherwise transmit through any online site **any** content from the virtual 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). Study staff [including FDA] may also watch or listen to the group. Groups will not be video recorded. Any written notes will not be used to link your comments to you. No comments you make will be traced back to you personally. 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.

The audio files, transcripts, and notes will be stored on a password-protected computer and/or in locked cabinets. Only study staff members will have access to these items. We will collect some personal information such as sex, age, and race. We will not keep any data that can be used to identify you, such as your full name.

All data, including anything you say in the discussion group, will be kept for three years after 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 and permanently deleting records.

No one, including parents or guardians, beyond the other participants and researchers will know what you said in the discussion group unless it is necessary to protect you, or if it is required by law (for example, abuse, neglect, self-harm, etc.). **Information you share, including your tobacco attitudes, beliefs and behaviors, will not be shared with your parent(s)/guardian(s).** General information from this discussion group may appear in professional journals or at scientific conferences. We will not use any identifiable information, like your name, in any report or presentation.

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

- A law requires sharing information (for example, when researchers must report to FDA, or if researchers 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 you share during the interview discussions about your e-cigarette or tobacco-related attitudes, beliefs, and behaviors will not be shared with anyone outside of the research team, including parents/guardian, to protect your 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 you.

What will I get for being in this study?
Every teen (ages 13-17) who is invited and participates in this discussion group will receive a [$X] incentive in the form of a prepaid debit card or the equivalent in points awarded by their research panel. There is no cost to you for taking part in this study. You do not have to answer any questions you do not want to. You will still receive the [$X] even if you choose not to answer some questions. If we find that you have misrepresented yourself in any way during this study, you may not receive the incentive.

Study Benefits: What good comes from my participation?
This study may not directly help you. However, your feedback will help us decide what ideas, images, or messages may help prevent teen e-cigarette use.

Anticipated Risks: Could anything bad happen to me during this study?
The risks for taking part in this study are low. We will protect the information you give us. However, there is always a chance that privacy could be broken because of a mistake or a security breach. If this happens, all participants will be told about the breach, how serious the breach is, and any bad things that have happened or could happen because of the breach. We will provide a phone number and email address if you have any questions.

You can ask the interviewer any questions you have about the topics in the interview. You can also talk to your parents or another trusted adult. **Remember that you can stop participating in this study at any time.**

Participation and Withdrawal: Do I have to be in this study? What if I want to drop out?
This study is voluntary, which means you can freely choose whether or not to participate in the interview. You can stop at any time, for any reason. You do not have to answer any questions you do not want to. If you decide to participate and later change your mind, you will not be contacted again about this study or asked for further information. You will still receive the [$X] even if you choose to stop. 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 contact if I have questions about this study?
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.

STATEMENT OF ASSENT

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

1. Yes
2. No [TERMINATE]