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Attachment E1: *AI/AN* Youth Assent Form (Social Media Recruit)

YOUTH ASSENT FORM

Sponsor:	**Food and Drug Administration (FDA)**
	Center for Tobacco Products (CTP)
Principal Investigator:	**Shane Mannis, Ph.D.**
Telephone:	**571-858-3757 (24 Hours)**
Address:	**Fors Marsh Group, LLC (FWA00011194)** **1010 N. Glebe Road** **Suite 510** **Arlington, VA 22201**

You are being asked to take part in this research study about evaluating tobacco facts. This form explains the study. After reading this form, you can decide to be in the study or you can decide not to be in the study. Either choice is OK. If you decide to start the study and then change your mind, you can stop being in the study at any time. **You must complete this form before you can take part in the study.**

About this study
The goal of this study is to understand what youth think about different facts about tobacco. Fors Marsh Group is a research company partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) to conduct a survey with 400 youth ages 13-17. We would like your thoughts about different facts about tobacco.

What will I do during this study?
You will be asked to complete a survey that will take approximately 20 minutes. The survey will ask you to evaluate tobacco facts and will ask about your experience and opinions about tobacco use.

Study Benefits: What good comes from my participation?
There is no direct benefit to you from participating in this study. However, your feedback will help us decide which facts are most effective at preventing youth tobacco use.

What will I get for being in this study?
You will receive a $10 Visa gift card for completing the survey.

Do I have to be in this study? What if I want to stop participating?
This study is completely voluntary. You can stop at any time. You also do not have to answer any questions that you do not want to. If you do not want to answer a question, you may skip that question. You will still receive the $10 gift card if you choose to skip a question, as long as you submit the survey.

Could anything bad happen to me during this study?
Though unlikely, there is a small chance that you may experience some discomfort from potentially sensitive questions. **Remember that you can choose to skip any question you don't want to answer or stop being in this study at any time.**

Privacy: Who will see the results of this study?
Only the authorized research staff will have access to your responses. Some personal information, like your first name and last initial, will be gathered, but no personal information will be kept after screening. Your name will not be linked to your responses. We will be very careful to allow only people working on the study to see the responses you provide, which will not be linked back to any personal information that could be used to identify you. However, as with all studies, there is a chance that privacy could be broken because of an accidental error or a security breach.

Everything you share will be kept private to the extent allowed by law. This means that we will not share any information you provide, including your tobacco-related attitudes, beliefs, and behaviors, with anyone outside of the study unless we are required to do so by law.

All of the information we collect will be de-identified (your name or personal information will be removed) and will be kept for at least three years. The information will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. Stored data will not contain any information that could identify you. After three years, all of the collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

Results from this study may appear in professional journals or at scientific conferences. No individual participants will be identified or linked to the results. We will not disclose your identity in any report or presentation, and you will not be re-contacted for this study. Results may also be used in future research.

Who do I contact if I have questions about the study?

If you have questions or concerns about the study, you can contact:
Shane Mannis, Fors Marsh Group
(571) 858-3757
pi@forsmarshgroup.com

If you have questions about your rights as a research participant, please contact the FDA Research Involving Human Subjects Committee at RIHSC@fda.hhs.gov. This committee is a group of people that reviews research studies to protect the rights and safety of research participants.

This research is covered by a special protection (called a Certificate of Confidentiality) from the Food and Drug Administration (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 or your parent 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 or your parent 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 yourself or 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.

Please select one of the responses below.

☐ Yes, I agree to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.

☐ No, I do not agree to participate in this study. I have read, understand, and had time to consider all of the information above. My questions have been answered and I have no further questions.

If you choose YES, we will email you a copy of the form.

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Informed Assent Form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.