

Attachment C2: Fresh Empire Parent/Guardian Notification/Opt-Out Form (Survey)**PARENT/GUARDIAN NOTIFICATION/OPT-OUT FORM
(Survey)**

Sponsor: **Food and Drug Administration (FDA)
Center for Tobacco Products (CTP)**

Principal Investigator: **Shane Mannis, Ph.D.**

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Your child has the opportunity to participate in a research study. The goal of this study is to understand what youth think about different tobacco facts intended to prevent tobacco use.

Please read this form carefully. It contains important information about this research study. 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. Please contact the researchers if you have any questions or if you do not want your child to participate in the study. **If you do not want your child to participate, you must contact the researchers within the next 24 hours. Contact information is listed on the first and last page of this document.**

Introduction: About this study

The goal of this study is to understand what youth think about tobacco facts intended to prevent youth tobacco use.

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. We would like your child's thoughts about tobacco facts intended to prevent teens from using tobacco. We plan to conduct research with youth 13 to 17 years old.

Procedure: What will my child do during this study?

Your child has been invited to take part in a survey and share his/her thoughts about several tobacco facts. The survey will take approximately 20 minutes.

What good comes from this study?

There is no direct benefit to your child from participating in this study. However, your child's feedback will help us decide which facts are most effective at preventing youth tobacco use.

What will my child get for being in this study?

Your child will receive a \$10 Visa gift card for participating.

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

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Though unlikely, there is a small chance that your child may experience some discomfort from potentially sensitive questions. If your child becomes upset or wants to stop participating, **he/she may stop participating in this study at any time** and will still receive a \$10 gift card even if he/she drops out of the study.

If you or your child has any questions about this research study, you may call Shane Mannis of Fors Marsh Group via phone at 571-858-3757 or email pi@forsmarshgroup.com.

Privacy: Who will see the results of this study?

Only the authorized research staff will have access to your child's responses. Your child's name and other personal information will not be linked to his or her responses and you or your child will not be re-contacted for this study. A code will be used instead of names. We will be very careful to only allow people working on the study to have access to the responses your child provides, which will not be linked back to any personal information that could be used to identify him/her. However, as with all studies, there is a chance that privacy could be broken because of an accidental error or a security breach.

Everything your child shares will be kept private to the extent allowed by law. This means that we will not share any information your child provides, including his/her tobacco-related attitudes, beliefs, and behaviors, with anyone outside of the study unless we are required to do so by law. The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) will have access to de-identified study data.

FDA does not encourage the use or sale of tobacco products. It is illegal in most states for adolescents younger than 18 years old to use tobacco, and it is illegal in all states for adolescents under 18 to buy tobacco.

All of the information we collect, including all of your child's responses and data collected during screening, will be de-identified 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. Retained data will not contain any information that could identify your child. 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 child's identity in any report or presentation. Results may also be used in future research.

Participation and Withdrawal: Does my child have to be in this study? What if he/she changes his mind?

This study is completely voluntary. Your child can choose to stop the survey at any time. Your child does not have to answer any questions he/she does not want to. Your child will still receive a gift card even if he/she chooses to skip a question, as long as he/she submits the survey.

IMPORTANT

If you do not want your child to participate, you must contact within 24 hours:

Shane Mannis, Fors Marsh Group
(571) 858-3757
pi@forsmarshgroup.com

If you have questions about your child's 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

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research studies to protect the rights and safety of research participants. If you would like an additional blank copy of this form, you can email Shane Mannis at pi@forsmarshgroup.com.

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 child's privacy. This means researchers generally cannot provide your child's name, or any other information that could identify your child, 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 child agree, even if there is a court order for the information. However, in other settings, researchers 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 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 and your child from sharing any personal information or information about your child's involvement in this study with others. For example, you can share that your child is in this research study or your child's history of tobacco use.

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 Parental Notification/Opt-Out 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.