

FOCUS GROUP PARENT/GUARDIAN PERMISSION FORM

TITLE OF INFORMATION COLLECTION: Creative Concept Testing Designed to Prevent Youth ENDS, Cigarette and Other Tobacco Product Use

FDA Project Lead: Food and Drug Administration (FDA)
Center for Tobacco Products (CTP)

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Please read this form carefully. You can ask as many questions as you want. If there is any information you do not understand, 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 focus group. Please either email this to us within 24 hours [AT EMAIL ADDRESS] or have your child bring this with them to the facility.**

Introduction: About this study

The purpose of this study, which will take the form of a focus group, is to understand what youth think about different kinds of messages and ideas designed to prevent and reduce youth TOBACCO use.

FCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP) to conduct up to 180 focus groups with 1620 youth across the United States. KDH Research & Communication will oversee these groups. Youth participating in this study will view marketing ideas developed to help prevent youth from using tobacco. We will collect your child's thoughts and opinions about marketing ideas. We will use his/her feedback to develop advertisements and messages that may help prevent youth from beginning to use tobacco products.

Procedures: What will my child do during this study?

Your child will be one person in a group of up to nine youth participating in an in-person focus group at a research facility.

The study will take place on [DATE] at [RESEARCH FACILITY] for 95 minutes. A group leader will ask questions about images, ideas, and tobacco prevention messages. Your child and the other participants will be asked to share his/her thoughts and opinions in response to these questions.

Privacy: Who will see the information my child provides during this study?

All participants will be asked to respect the privacy of the other focus group members. Everyone will be asked not to disclose anything said during the discussion.

Focus group discussions will be audio recorded and transcribed for reporting purposes. They may also be livestreamed so that researchers who cannot travel can watch the groups. Groups will not be video recorded. The report we create using information collected during the focus group will not link your child's comments directly to him/her or include his/her full name. No one outside of the focus group participants and researchers will know what your child said during the discussions. Only your child's first name will be used during the check-in process and during the discussions. Your child's full name will not be shared with the group leader or other participants.

The audio files and transcripts from the groups will be stored on a password-protected computer. Only the research team will be able to access them. Although we will collect some personal information about your child (e.g., gender, age, race, and reactions to messages and ideas), we will not collect any information during the focus groups that could identify your child personally. When we spoke to your child about the study, we asked for his/her name and phone number. We use this information to call him/her to schedule the focus group, but we will not connect this information to his/her focus group responses. This means that after your child agrees to participate, his/her answers will not be connected to his/her name or contact information. No one will know what answers your child gave us.

All personally identifiable information retained after the completion of this study, which in this case means the parental permission and youth assent forms, will be destroyed three years after the completion of the study either by shredding paper documents or the permanent deletion of electronic information.

All information your child provides will be kept private to the extent allowable by law. This means that we will not share information with anyone outside of the study unless it is necessary to protect your child, or if it is required by law.

Information that your child shares during the focus group discussions about his/her 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.

Anonymous data from this study may be published in professional journals or at scientific conferences, but no individual participant 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 or shared with other researchers. Other researchers will not have your child's name or any identifying information.

As required by the Health and Human Services, this research is covered by a Certificate of Confidentiality to help us protect your child's privacy. This means that the researchers cannot disclose your child's name or other information that could identify him/her in any civil, criminal, administrative, legislative, or other proceedings (like a court trial), without your consent. Information collected for this research that could identify your child also cannot be used as evidence in a legal proceeding without your consent.

In addition, with the Certification of Confidentiality, researchers involved in this study generally may not provide your child's name, or any other information that could identify your child, to anyone who is not connected with the research. However, in the following situations, the Certificate does not prevent the researchers involved in this study from disclosing study information that could identify your child:

- if you consent to someone receiving your child's information from this study, including situations in which the information is necessary for his/her medical treatment;
- when your child's study information is used for other scientific research, as allowed by federal regulations protecting research subjects;
- when information is needed by FDA, which is funding this study, in order to audit or evaluate federally funded studies;
- when a law otherwise requires disclosure (such as requirements to make certain reports to FDA, reporting threats of harm to self/others, or reports of child abuse), except this does not apply to disclosure in a legal proceeding.

The Certificate does not prevent your child from voluntarily providing information about him or herself or his/her involvement in this research study to others. The Certificate of Confidentiality will not be used to prevent disclosure of your child's vaping and tobacco use history as indicated in this informed consent document.

What will I and my child get for being in the study?

As a token of appreciation, each focus group participant will receive a \$25 prepaid debit card for being in this study and the participant's parent/guardian will also get a \$25 prepaid debit card for travel to and from the focus groups, providing parental permission, and any disruption to the normal routine participation in this focus group may result in. 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 doesn't want to. You and your child will each still receive the \$25 prepaid debit cards even if your child chooses not to answer some questions.

Study Benefits: What good will come from this study?

This study 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 youth tobacco use.

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

The risks for taking part in this study are low. Some of the images your child may see during this study may be graphic, which could cause discomfort. There is a chance that other participants in the focus group could disclose information discussed in the focus group even though we will ask them not to.

Your child can ask the group leader any questions they have about this focus group. Your child may want to discuss tobacco use or tobacco 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 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 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 study? What if my child changes his or 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 also choose whether or not to take part in or complete this study. You or your child can stop participating at any time. Your child can choose to leave the focus group at any time and does not have to answer any questions he/she does not want to. You and your child will still both receive the \$25 debit cards for participating in the study even if your child chooses to not answer some questions or leaves the group.

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 Kristen Holtz (404-395-8711) or email at kholtz@kdhrc.com. If you have questions about your or your child's rights as a research participant, please contact the KDHC Research & Communication IRB Chair, Mr. Edward Morgan, at 443-546-3953. 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 Kristen Holtz at kholtz@kdhrc.com.

PLEASE CHECK ONE OF THE BOXES AND SIGN BELOW.

Yes, I agree to allow my child 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 allow my child 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.

Signature

Date

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average five minutes per response to complete the Parent Permission 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 PRASStaff@fda.hhs.gov.