

Name: _____ Room: _____

OMB# 0910-0796
Exp. 6/30/2018

**INFORMATIONAL PACKET
(PARENTAL OPT-OUT)**

CONGRATS!

You have been selected to participate in a discussion group on
_____ in room _____ at _____ pm!

You should plan to stay after school for 90 mins.
You will receive a \$25 [VISA or American Express] Gift Card for participating!

Before you participate, there are 3 things you have to do:

1. Read the yellow form called "**PARTICIPANT ASSENT FORM**" and sign it on the last page if you want to participate.
2. Tonight, give your parents or guardians the form in this packet called "**PARENTAL OPT-OUT FORM**." They should read it over and contact us if they want you to opt-out.
3. **Return the yellow PARTICIPANT ASSENT FORM (that you signed) to us tomorrow at lunch!**

Feel free to stop by tomorrow during lunch to ask questions or just check in with us!

If you or your parents have any questions about this study,
call or email Dana Wagner at Rescue (619-231-7555 x 331; dana@rescueagency.com).

PARENTAL / GUARDIAN CONSENT FORM**Opt out form**

TITLE OF INFORMATION COLLECTION: Multicultural Campaign: Wave 3 focus group study of reactions to creative advertising concepts designed to prevent multicultural youth tobacco use.

Sponsor: U.S. Food and Drug Administration's
Center for Tobacco Products

Principal Investigator: Dana Wagner, PhD

Email Address of Investigator: dana@rescueagency.com

Telephone: 619-231-7555 ext 331 (24 Hours)

Address: Rescue Social Change Group
660 Pennsylvania Ave SE
Suite 400
Washington, DC 20003

Please read this form carefully. You can ask as many questions as you want. We will be happy to answer your questions. **Please contact the researchers if you do not want your child to be in the study. Contact information is listed above.**

Introduction: About this study

The purpose of this research is to understand teen culture and gain insights from teens to inform a tobacco prevention brand.

Rescue Social Change Group (Rescue) is a health communications and research company. Rescue has partnered with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP). We are working together to conduct focus groups. Youth ages 12 to 17 will participate in focus groups to provide information that we will use to develop a campaign to reduce youth tobacco use.

Procedure: What will my child do during this study?

Your child will be one of 180 youth participating in this study. Your child is invited to take part in an in-person focus group. You and your child can choose to take part in the study or not, regardless of what other parents, guardians, or students choose to do. Your child can choose to leave the focus group at any time. You can also withdraw your consent for your child to participate at any time.

Each group will have no more than 12 participants. The study will take place on _____ at your child's school after school hours for 90 minutes. The group leader will ask for feedback on campaign materials. Your child and the other participants will be asked to share their opinions. Responses your child provided to screening questions will also be included in the final study.

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

Everything your child says during the focus group can be heard by the other teens, the group leader, research assistants, and FDA study monitors. All youth will be asked to respect the privacy of the other focus group members. Everyone will be asked to not reveal anything said during the focus group.

Focus group discussions may be audiotaped and transcribed for reporting. Your child can opt out of being audiotaped at the start of the discussion. The report created using the audio transcripts will not link your child's comments to him/her. No one outside of the focus group participants and researchers will know what your child said during the discussions. Your child's name will be used only during the check-in process. The group leader will also instruct youth not to share any private, personal, or inappropriate information during the focus group. Such comments will be removed from the transcripts.

The audio files and transcripts will be stored on a password-protected computer and/or in locked cabinets that only the research team can access. We will collect some personal information including gender, age, and race. However, we will not keep any information that could identify your child, such as his/her full name. **Your and your child's contact information will not be shared with others.**

All information will be kept for three years after the study ends. It will be stored on a password-protected computer or in a locked cabinet. Three years after the study ends, we will destroy all of the data by securely shredding paper documents and permanently deleting electronic information.

All information your child provides will be kept private to the extent allowed 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 your child shares about their tobacco-related attitudes, beliefs and behaviors will not be shared with others. This includes parent(s)/guardian(s).**

De-identified data from this study, including sample descriptions, may appear in professional journals or at scientific conferences. We will not disclose your child's identity in any report or presentation. The Department of Health and Human Services and Chesapeake IRB may have access to the study data.

Study Benefits: What good will come from this study?

This study is not expected to directly benefit you or your child. 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 my child during this study?

We will take care to minimize the potential risks of participating in this study. However, as with all research, there is a chance that privacy could be compromised. For example:

- Everyone will be asked not to discuss any information other participants shared during the study. However, other participants may not keep all information private.
- The research team will do their best to maintain the confidentiality of information collected during the study. A breach may occur from an accident or as a result of hacking.
- Teens will be reminded to not share any private information in the group. However, they may accidentally share such information. This information will be removed from the audio transcripts. Other focus group participants could still hear and react to the information.

Your child may want to discuss tobacco use or prevention with you. Your child may also have questions or concerns about the images or ideas he/she sees during this study. **Your child may stop participating in this study at any time if he/she becomes upset or wants to stop participating.**

Reimbursement: Will my child be paid for being in this study?

Every child who takes part in this study will receive a \$25 VISA or American Express gift card. If

your child does not arrive on time to the focus group, he/she may be disqualified. There is no cost for taking part in this study.

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

Your child does not have to take part in this study. Your child's participation in this study is completely voluntary. You and your child can choose to take part in the study or not, regardless of what other parents, guardians, or students choose to do. Your child can choose to leave the focus group at any time. You can also withdraw your consent for your child to participate at any time. No matter what decision you make, there will be no penalty or loss of benefits to your child. Contact the principal investigator or the study staff at the telephone number or email address listed on page 1 of this form.

Your child does not have to answer any questions he/she does not want to. Your child will receive the \$25 gift card for his/her participation even if he/she chooses to leave the focus group early or chooses to not answer some questions.

Getting answers to your questions or concerns about the study

You and your child can ask questions about this consent form or the study (before you decide to let your child start the study, at any time during the study, or after completion of the study).

Contact the investigator or study staff listed on the first page of this form with any questions, concerns or complaints.

Getting answers to your questions about your rights as a research subject

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your child's rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your child's rights as a research subject, contact:

- By mail:
Study Subject Adviser
Chesapeake IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00019800.

In accordance with the Protection of Public Rights Amendment (PPRA), as a parent or guardian you are entitled to view any surveys of students taking place in your child's school. To request materials, contact the principal investigator or the study staff at the telephone number or email address listed on page 1 of this form.

IMPORTANT:
If you do not want your child to participate, you must contact the principal investigator or the study staff at the telephone number or email address listed on page 1 of this form.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Parental Opt-Out Form (the time estimated to read and review). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.