OMB No. 0910-0810
Exp. Date: 10/31/2021

Attachment B: Assent Form

PARTICIPANT ASSENT FORM

TITLE OF INFORMATION COLLECTION:
FDA Tobacco Prevention Broad Quantitative Research Package

Principal Investigator: **Kristen Holtz, Ph.D.**

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Please read this form carefully. **You must submit this form by clicking the button at the bottom of the last page before you can take part in the study.**

Introduction: About this study
The purpose of this research is to determine whether TV ads designed to prevent youth from using tobacco are understandable and engaging. FDA does not encourage the use or sale of tobacco products.

We are partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products to conduct a study with youth ages 13 to 17. The study includes youth in multiple cities across the United States. The study will show draft versions of TV ads to learn if the messages are understood. Tested TV ads will be close to final versions that still need small edits. You will complete a survey to help make the TV ads final.

What will I do during this study?
You are invited to do a survey. You will complete the survey on your his/her own device such as a mobile phone or computer. You may be asked to view TV ads and tell us your opinions about the ads. You will be one of a group of up to 5,500 youth participating in this study.

The survey will take up to 20 minutes to complete, plus the time needed to take the screener . You will be asked to respond to a series of tobacco related facts and messages. You will also be asked questions related to tobacco use and your attitudes about tobacco. We may combine information you provide from both the screener and the study survey.

You can choose to take part in the study or not, regardless of what other teens choose to do. You can choose to stop taking the survey at any time. You do not have to answer any questions you do not want to. You will receive the points for participating in the study even if you choose to skip questions.

Who will see the information I provide during this study?

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We will take care to protect your privacy. Your answers will be kept private to the extent allowable by law. That means we will not share your answers with anyone outside the study unless it is necessary to protect you, or if required by law. Some personal information, like gender, age, race, and ethnicity, will be gathered. Any personal information that identifies you will be destroyed at the end of the study. No one will know what answers you gave us. **Information you share about your tobacco attitudes, beliefs and behaviors will not be shared with others. This includes your parent(s)/guardian(s).**

We will keep answers you provide for three years after the completion of the study. The data will be 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.

Data from this study may appear in professional journals or at scientific conferences. We will not disclose your identity in any report or presentation. Data from this study may be used in future research. We may share the data with other researchers. Anyone who looks at this data will not have your name or any other data that could reveal your identity.

Will I be paid for being in this study?
You will receive the point amount equivalent to approximately $10.00 from <<COMPANY>> after you submit this survey. There is no cost for taking part in this study. You will receive an email with a link to the survey. You will receive the points via email within 72 hours of submitting the survey.

There is no cost to you for taking part in this study.

What good will come from this study?
This study is not expected to directly benefit you. Your answers will help us make TV ads about the harms of tobacco use.

Could anything bad happen to me during this study?
We will take care to protect the data you provide. However, as with all studies, there is a chance that privacy could be broken because of an accident or a security breach.

All images will be presented in the context of tobacco use prevention. You should talk to your parents, guardian, or school counselors about any concerns you have about how these images made you feel. You should also talk with them about any questions or concerns you have about using tobacco. If you have any questions about this research study, you may call or email the Principal Investigator at the telephone number or email address listed on the first page of this form.

Remember that you can stop participating in this study at any time.

Do I have to be in this study? What if I want to drop out?
This study is completely voluntary. You can choose to take part in the study or not, regardless of what other teens choose to do. You can choose to stop taking the survey at any time. You do not have to answer any questions you do not want to.

Questions and Contacts: Who do I call if I have questions now or later?

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If you have any questions about this study, please contact the principal investigator or the study staff at the telephone number or email address listed on the first page of this form.

The KDHRC IRB has reviewed this research. An institutional review board (IRB) is a group of people who are responsible for ensuring that the rights of participants in research are protected. The IRB does not conduct the study but ensures that proper procedures were followed.

If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact Ed Morgan, Chair of the KDHRC IRB, at emorgan593@aol.com

I have read, understand, and had time to consider all of the information above. I have no more questions about this study at this time. I agree to take part in this study.

Do you want to continue?

○ **Yes, I want to participate.***

○ **No, I do NOT want to participate.**

*If you choose YES, we will email you the form for your records

Submit