CONSENT FORM

TITLE OF INFORMATION COLLECTION: Qualitative Research to Design Advertising to Encourage Quitting Among Adult Cigarette Smokers (General Population)

FDA Project Lead: **Atanaska Dineva, MS**
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 anything you do not understand, we will be happy to answer your questions. We can also read this to you out loud to make sure you understand. **You must sign, date, and return this form to study staff before you can take part in the focus group. You can either email this form to us within 24 hours [AT ADDRESS] or bring it to the facility.**

Introduction: About this study

The purpose of this research study is to understand the perceptions of adults to smoking and quitting and find out what adults think about different kinds of messages to encourage quitting. FCB is an advertising company partnering with the U.S. Food and Drug Administration's Center for Tobacco Products (CTP) to hold focus groups with adults across the United States. KDH Research & Communication will oversee these groups. A focus group is a group of people who are brought together to talk about a product or topic. Participants in this study will view and discuss ideas for ads and resources to encourage quitting. We want to hear your thoughts about these ideas. We will hold up to 30 in-person focus groups around the country with adults who are 19 to 54 years old.

Your Role in This Study: What will I do during this study?

You will participate in an in-person focus group with up to nine participants at a research facility.

The study will take place on [DATE] at [RESEARCH FACILITY] for no more than 95 minutes. A group leader will ask questions about perceptions, experiences, ideas, images and smoking cessation messages. You will be asked to share your thoughts on each question.

What will I get for being in this study?
Everyone who participates in this study will receive a $75 in the form of a prepaid debit card as a token of appreciation for participating. There is no cost to you for taking part in this study. You do not have to answer any questions you do not want to. You will each still receive the $75 prepaid debit card even if you choose not to answer some questions.

What good comes from my participation?
This study may not directly help you. However, your feedback will help us decide what ideas, images, or messages may encourage adults to quit smoking.

Could anything bad happen to me during this study?
The risks for taking part in this study are low. We will protect the information you give us. However, there is always a chance that privacy could be broken because of a mistake or a security breach. If this happens, all participants will be told about the breach, how serious the breach is, and any bad things that have happened or could happen because of the breach. We will provide a phone number and email address if you have any questions.

There is a chance that another person participating in the focus group could share information you discussed after the group has ended, even though we will ask everyone not to share.
Some of the images you see during the study may be graphic, which could cause discomfort.
You can ask the group leader any questions you have about this focus group. **Remember that you can stop participating in this study at any time.**

Privacy: Who will see the information I provide during this study?
All people participating in the focus group will be asked to respect the privacy of the other focus group members. Everyone will be asked not to talk about anything that was said once the focus group is over.

Focus group discussions will be audio recorded and turned into notes to write a report. The groups may also be livestreamed so that researchers who cannot travel can watch the groups. Groups will not be video recorded.

The report we create will not link your comments to you or include your full name. No one, aside from other participants and researchers, will know what you said during the discussions. Only your first name will be used during check-in and during the discussions. Your full name will not be shared with the group leader or other participants.

The audio files and notes will be stored on a password-protected computer and/or in locked cabinets. Only the research team will be able to access them. Some personal information was gathered during the screening process, but none will be collected during the focus group.

All personal information will be destroyed three years after the study is over. It will be destroyed either by shredding the documents or permanently deleting electronic files.

Information you share about your tobacco-related attitudes, beliefs, and behaviors will not be shared with anyone outside of the research team.

Data from this study may be published in professional journals or at scientific conferences. No participants will be named in these publications. We will not reveal your name in any report or presentation.

This research is covered by a special protection (called a Certificate of Confidentiality) from 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 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 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 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 smoking or tobacco use.

Participation and Withdrawal: Do I have to be in this study? What if I want to stop participating?

This study is voluntary, which means you can freely choose whether or not to participate in the focus group. You can stop at any time, for any reason. You do not have to answer any questions you do not want to. You will still receive the incentive even if you choose to stop or are asked to leave the group.

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

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 rights as a research participant, please contact the KDH 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 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.**

_____ _____

Signature *Date*

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 five minutes per response to complete the Consent 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.