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RETAIN

PARTICIPANT CONSENT FORM

TITLE OF INFORMATION COLLECTION: LGBT Campaign: Focus Group Study of Brand and Creative Concepts Designed to Prevent LGBT Young Adult Tobacco Use

Sponsor:	**U.S. Food and Drug Administration's Center for Tobacco Products**
Principal Investigator:	**Mayo Djakaria, MPH**
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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. If there is anything you do not understand, researchers can explain it to you. Any question you may have needs to be addressed before you sign this form.

Introduction: About this study
The purpose of this study is to gain insights from lesbian, gay, bisexual, and transgender (LGBT) young adults ages 18 to 24 to inform a tobacco prevention brand and/or creative concepts.

Rescue Social Change Group (Rescue SCG) is a research and marketing company. Rescue SCG has partnered with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). We are working together to conduct focus groups. LGBT young adults ages 18 to 24 will participate in focus groups to provide information that we will use to develop a campaign to reduce LGBT young adult tobacco use. The study plans to have up to 224 participants.

Procedure: What will I do during this study?
You are invited to take part in an in-person focus group with no more than 10 participants. You can choose to take part in the study or not. You can choose to leave the focus group at any time.

The study will take place on [DATE] at [VENUE] for 90 minutes. The group leader will ask questions about tobacco use prevention brands and messages. You and the other participants will be asked to share your opinions about the ideas.

Privacy: Who will see the information I provide during this study?
Everything you say during the focus group can be heard by the other participants in the group, the group leader, research assistants, and FDA study monitors. All participants will be asked to respect the privacy of the other participants. Everyone will be asked to not share anything said during the focus group.

Focus group discussions may be audiotaped and transcribed for reporting purposes. You can choose not to be audiotaped at the start of the session. The report created using the audio transcripts will not link your comments to you. No one outside of the focus group participants and researchers will know what you said during the discussions. Your name will be used only during the check-in process. The group leader will also instruct participants 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. Only research team members will have access to these items. We will collect some personal information such as sexual orientation, gender identity, education, age, and race. We will not retain any information that can be used to identify you, such as your full name and phone number. Your full name and phone number was used for recruiting purposes only and will not be entered in any database, or connected to the survey or focus group answers you provided to us.

All data, including anything you say in the focus group, will be kept for three years. It will be stored on a password-protected computer or in a locked cabinet. After three years, we will destroy all of the data by securely shredding and permanently deleting records.

We will not share information with anyone outside of the study unless it is necessary to protect you, or if it is required by law.

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?
Everyone who participates in this study will receive $75 as a token of appreciation.

Study Benefits: What good will come from this study?
This study is not expected to directly benefit you. However, your opinions will help us decide what ideas may prevent tobacco use amongst LGBT young adults.

Anticipated Risks: 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. For example:

- Everyone will be asked not to discuss anything other participants share during the study. However, other participants may not keep all information private.

- We will try our best to maintain the privacy of data collected during the study. Still, a privacy breach could occur by accident or as a result of hacking.

- Participants will be reminded to not share any private, personally identifiable, or inappropriate information. However, they may accidentally share such information. This data will be removed from the transcripts, but other participants could still hear it.

If you have any questions about tobacco use or prevention, you can ask research staff. You can also talk to a health care professional or your local health department.

Remember that you can leave the focus group at any time.

Participation and Withdrawal: Do I have to be in this study? What if I want to drop out?
You can choose to take part in the study or not, regardless of what other participants choose to do. You can choose to leave the focus group at any time. You do not have to answer any questions you do not want to. You will receive $75 as a token of appreciation after participating.

Questions and Contacts: Who do I call if I have questions now or later?
If you have any questions about this study, you may call Mayo Djakaria at Rescue SCG (619-231-7555 x 120) or Jeff Jordan at Rescue SCG (619-231-7555 x 110). If you have any questions or complaints about your rights as a research participant, you may contact FDA IRB RIHCS (OC_RIHSC@fda.hhs.gov), referencing protocol #[TBD]. An IRB is a group of people who review research studies to protect the rights and safety of research participants.

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.

_____
Printed Name of Participant

_____ _____
Signature of Participant **Date**

_____
Printed Name of Witness

_____ _____
Signature of Witness **Date**

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Participant 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.