

OMB# 0910-0674 Exp. 3/31/2016
RETAIN FOR YOUR RECORDS

PARTICIPANT CONSENT FORM

LGBT Young Adult Tobacco Use Prevention Campaign: Copy Testing

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

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Please read this form carefully. If you are completing this with a researcher, the researcher can answer any questions you may have. If you are taking this survey online, you can contact the PI of this study at the above email address or phone number. You can ask as many questions as you want. Any question you may have needs to be addressed before you submit this form.

Introduction: About this study

The purpose of this research is to determine whether advertisements (ads) designed to prevent lesbian, gay, bisexual, and transgender (LGBT) young adults ages 18 to 24 from using tobacco are understandable and engaging.

Rescue Social Change Group (Rescue SCG) is a health communications and research company. We are working with the U.S. Food and Drug Administration's Center for Tobacco Products to conduct a study with LGBT young adults ages 18 to 24. The study will show draft versions of ads. We will then try to learn if the messages are understood. Some participants will view two ads. Others will not view any ad. Whether or not you see the ads are randomly assigned. If you see the ads, they will be close to the final version and may still need small edits. You will complete a survey to help us make the ads final. We want to know which ads you think are understandable and engaging.

What will I do during this study?

You will be one of 1,150 LGBT young adults participating in this study. The study will take up to 15 minutes to complete, plus the screener survey you already completed.

You may be asked to view two ads and tell us your opinions about them. You will be asked questions related to tobacco use and your attitudes about tobacco. We may collect information you provide from both the screener and the study survey, but the data will not be linked for your name or contact information.

You can choose to take part in the study or not. You can choose to stop taking the survey at any time.

Privacy: Who will see the information I provide during this study?

We will take care to protect your privacy. The survey will be on a secure website that is password protected. 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. The answers you provided earlier, which include gender, sexual identity, age, race, and ethnicity, will be used for study analysis but will not be connected to your personal information such as email or phone number. The research team may contact you about the survey using the contact information you provide such as your e-mail address or phone number. The research team will not use your contact information for any other purpose than contacting you about the survey or delivering your incentive. **Your contact information or information you share about your tobacco attitudes, beliefs and behaviors will not be shared with others.**

We will keep answers you provide for three years after the study is complete on a password-protected computer. After three years after the study is complete, we will destroy all of the data by 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.

Incentive: What will I get for being in this study?

Everyone who completes and submits this survey *in person with a researcher* will receive a \$25 cash incentive. Everyone who completes and submits this survey *online* will receive a \$25 online gift card incentive via e-mail. The cash incentive will only be distributed to participants who complete the Copy Testing study survey onsite. Participants who complete the Copy Testing study survey online will receive the \$25 online gift card incentive securely via e-mail within 48 hours of completing the survey.

Participants completing the Copy Testing study survey online through the [insert company name] online research panel will receive their \$25 online gift card securely via the [insert company name] distribution process.

All participants must fully complete the Copy Testing study survey to receive the incentive. The survey may only be submitted once.

Study Benefits: What good will come from this study?

This study is not expected to directly benefit you. However, your answers will help us determine whether ads about the harms of tobacco use are understandable and engaging and 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 by accident or the result of hacking. We will try our best to maintain the privacy of data collected during the study by providing standard online data safeguards.

All ads will be presented in the context of tobacco use prevention. If you have any questions about tobacco use or prevention, you can ask a health care professional or your local health

department. If you have any questions about this research study, you may call or e-mail the Principal Investigator at the telephone number or email address listed on this form.

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

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

Your participation in this study is completely voluntary. You can choose to take part in the study or not, regardless of what other participants choose to do. You can choose to stop taking the study survey at any time. You do not have to answer any questions you do not want to. Participants who willingly choose not to complete the study survey will not receive the incentive. You will receive the incentive upon completion and submission of the Copy Testing study survey.

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 Dana Wagner at Rescue SCG (619-231-7555 x 331). 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 # [will insert]. 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. If you choose to participate, a copy of this form will be automatically emailed to you for your records.

- Yes, I want to participate.
- No, I do NOT want to participate.

Submit

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the consent 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 PRStaff@fda.hhs.gov.