

**FDA DOCUMENTATION FOR THE GENERAL CLEARANCE
OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS
(#0910-0674)**

TITLE OF INFORMATION COLLECTION: LGBT Young Adult Tobacco Use Prevention Campaign: Copy Testing; OMB Control Number 0910-0674.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance 0910-0674 to conduct focus groups with Lesbian, Gay, Bisexual, and Transgender (LGBT) young adults aged 18 – 24 years old ($N = 1,150$) who have smoked a cigarette at least 1 day within the past 30 days, but not every day, and who participate in LGBT culture.

The research will be fielded for the purpose of assessing FDA's first wave of draft (or "rough-cut") advertisements for its LGBT Young Adult Tobacco Prevention Campaign prior to launch. Research results will be used to assess whether rough-cut advertisements provide an understandable and engaging message about the harms of tobacco use without potential unintended adverse or counterproductive effects.

2. Intended use of information:

Information obtained through this study will inform the implementation of FDA's LGBT Young Adult Tobacco Prevention Campaign. This study follows a series of focus groups that assessed LGBT young adults' perceptions of advertising concepts designed to reduce tobacco use among LGBT young adults ages 18-24 years old.

The study will consist of showing three (3) rough-cut campaign advertisements to a sample of the target audience. Copy testing results for each rough-cut advertisement will be assessed individually, as well as compared across all three (3) tested rough-cut advertisements to answer the following questions:

- Does the rough-cut advertisement provide an understandable message about the harms of tobacco use?
- Does the rough-cut advertisement provide an engaging message about the harms of tobacco use?
- Does the rough-cut advertisement have any potential unintended adverse or counterproductive effects related to beliefs around the harms of tobacco use?

Results will be used to refine and finalize rough-cut ads.

3. Description of respondents:

Study participants will consist of up to 1,150 LGBT young adults ages 18–24 that report having smoked cigarettes at least 1 of within the past 30 days, but not every day, and who participate in LGBT culture. Approximately 767 respondents will be randomly assigned to the ad-viewing study group and approximately 383 respondents will be randomly assigned to the non-ad-viewing (control) group. Approximately 11,500 young adults will be screened in order to obtain a sample size of 1,150.

4. Date(s) to be conducted:

The fieldwork for this study is projected to occur between October and December 2015.

5. How the information is being collected:

The information is being collected using a self-administered electronic. Participants will be randomly assigned to view two (2) of the three (3) rough-cut ads (ad-viewing group) or no ad (control group).

Participants selected to view advertisements (ad-viewing group) will first be provided with two (2) questions about close friend tobacco use and own past 30-day tobacco use. Following these questions, participants in the ad-viewing group will view a randomly selected rough cut ad and will then be prompted to complete series of questions designed to assess whether the advertisement provides an understandable and engaging message about the harms of tobacco use. Participants will then view a second randomly selected advertisement and will then be prompted to complete the same series of questions provided after viewing the first advertisement. The rough-cut ads will average sixty (60) seconds in length.

Both ad-viewing and control participants will be asked to answer general questions about their attitudes and beliefs about the harms of tobacco use as well as three (3) additional demographic questions. The questions targeting general attitudes and beliefs about the harms of tobacco use are being collected to assess potential unintended consequences.

Participants will be recruited using three strategies; (1) onsite at or near LGBT social venues in up to 8 metropolitan cities; (2) targeted recruitment via social media; and (3) an online research panel.

6. Confidentiality of respondents:

All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law.

Researchers will inform participants in the informed consent form that the information they provide will only be viewed by the researchers and will not be connected with any other identifiable information they provide. Participants may be asked to provide their contact information including email address and/or cell phone number for study reminders and incentive delivery. All participant contact information will be deleted at the conclusion of data collection and will not be included in databases for analysis.

Additionally, all identifying information will not be included in the reports delivered to the agency. All data received by FDA will remain in a secured area or on a password-protected computer. No data will contain identifying information.

Neither contractors nor subcontractors associated with this project will share personal information regarding participants with any third party without the participant's written permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. All data will remain on a password-protected computer and/or in locked cabinets for a period of three years after the end of the study, and then will be shredded and/or destroyed. Aggregate data from this study may be used in future research and/or shared with other researchers.

7. Amount and justification for any proposed incentive:

The amount of the incentive as a token of appreciation is \$25 cash or \$25 non-retailer specific electronic gift card. As participants often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research, we are asking respondents to provide thought-intensive, ratings, and open-ended feedback on rough-cut ads that require a high level of engagement. This incentive amount is considered an adequate compensation for time spent participating in the study, and not an inducement for participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation¹.

In an effort to provide convenient and timely incentives to participants either cash or electronic incentives, depending on the mode of recruitment. Only participants completing this study onsite (in person, after recruitment) will receive the \$25 incentive in cash. Providing cash incentives to onsite participants allows individuals to receive their incentive directly upon study completion and is the most efficient option for onsite participation. Participants completing this study independently online will receive the \$25 electronic gift card incentive. Distributing electronic gift cards to participants completing the study independently online is the most efficient option for providing incentives to online participants.

Incentives must also be high enough to equalize the burden placed on participants with respect to their time and cost of participation,² as well as provide enough motivation for them to participate in the study rather than another activity. Inadequate compensation for time spent participating in a study may result in a difficult and lengthy recruitment process and/or participants who agree to participate and then drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with facility rental and facilitator and observer time.³ Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research, both of which lead to increased costs. Incentives are also necessary to ensure adequate representation among harder-to-recruit and high-risk populations such as LGBT young adults.⁴

8. Questions of a sensitive nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about race/ethnicity, sexual orientation, income, education, health behaviors and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds of people for whom its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will

¹ Halpern, SD., Karlawish, JH., Casarett, D., Berlin, JA., Asch, DA. Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine*. 2004; 164(7), 801-803.

² Russell, ML, Moralejo, DG., Burgess, ED. Paying research subjects: Participants' perspectives. *Journal of Medical Ethics*. 2000; 26(2), 126-130.

³ Morgan, DL, Scannell, AU. *Planning Focus Groups*. Thousand Oaks, CA: Sage, 1998.

⁴ Groth, SW. Honorarium or coercion: use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*. 2010.

fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (<http://www.whitehouse.gov/omb/fedreg/1997standards.html>).

In order to identify LGBT young adults, researchers need to ask sensitive survey-based questions about gender identity and sexual identity. The FDA acknowledges such questions are potentially sensitive. However, because onsite recruitment is occurring at or near LGBT social venues and online social media and research panel recruitment will occur via interest-based and sexual identification targeting, it is assumed that the large majority of potential respondents already self-identify as LGBT.

Raw data that include both personally identifiable and sensitive information (e.g., contact information and gender and sexual identity in screening questionnaires) will be managed so personally identifiable information is not retained once the data have been extracted and aggregated. Personally identifiable information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

9. Description of statistical methods:

This research relies on quantitative methods and will use convenience samples rather than probability samples. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

LGBT young adult participants will be directly identified using social venue-based intercept recruitment, interest-based social media advertisement recruitment, and online research panel recruitment procedures that employ screening questions about sexual identity, gender identity, age, current and past tobacco use, race, and ethnicity. Recruitment will continue until a sample of the required number of participants is obtained.

BURDEN HOUR COMPUTATION *Number of respondents (X) estimated response or participation time in minutes (/60) = annual burden hours:*

Screener | estimated participation time: 5 minutes

Copy Testing Participants | estimated participation time ~ Ad View Group: 15 minutes

Non Ad View Group (Control): 5 minutes

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Screener	11,500	5	958
Copy Testing Participants			
Participant Consent Form	1,150	5	96
Questionnaire Ad View	767	15	192
Questionnaire Non Ad View	383	5	32
Total¹	11,500		1,278

¹ The total number of respondents is 11,500; one-tenth of those (1,150) represent the total number of participants in this study.

REQUESTED APPROVAL DATE: 09/21/2015

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