

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

TITLE OF INFORMATION COLLECTION: LGBT Campaign: Focus Group Study of Brand and Creative Concepts Designed to Prevent LGBT Young Adult Tobacco Use; 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 ($n = 224$) who have smoked at least 1 cigarette within the past 30 days, but not every day. The research will be fielded to assess participants' perceptions about campaign brands and creative concepts designed to reduce LGBT young adults' tobacco use.

2. Intended use of information:

Information obtained through this study will inform the development and implementation of FDA's LGBT Campaign designed to reduce LGBT young adult tobacco use. Specifically, focus group participants will answer questions regarding comprehension, relevance, and potential impact of campaign brand and creative advertising concepts. Specifically, the results will be used identify the most promising brand and creative concepts as well as indicate areas for further refinement to guide creation of effective advertisements for the LGBT Campaign.

3. Description of respondents:

The study will consist of twenty-eight (28) focus groups, each with approximately eight (8) LGBT young adults aged 18 – 24 years old who report having smoked at least 1 cigarette within the past 30 days, but not every day. Focus group participants will be assigned to either female-centric (i.e. primarily attracted to females) or male-centric (i.e. primarily attracted to males) focus groups, and group assignment will be based on their sexual orientation. This information will be gathered during the screening process. Groups will be otherwise diverse by race/ethnicity. Approximately 672 LGBT young adults will be screened in order to obtain a sample size of 224.

4. Date(s) to be conducted:

The study is projected to occur between March 2, 2015 and March 2, 2016.

5. How the information is being collected:

The information will be collected through twenty-eight (28) in-person focus groups led by a professional moderator who will be assisted by an experienced research team. The research team will engage participants in a series of activities and questions using semi-structured discussion guides and surveys; encourage participants to respond openly and spontaneously; and, with participants' permission, audio-record participants' answers and reactions. Data will be collected in professional meeting rooms or focus group facilities. Each focus group will last 90 minutes. The focus groups will also be observed by FDA and campaign contractor staff.

Brand and Creative Concept Testing Focus Groups: 90 minutes

After a study introduction (5 min.), the first activity that participants will complete is *Campaign Brand Testing* (30 min.). This involves a *Brand Test Survey*. The order in which the brands are shown will alternate between focus groups for counterbalancing purposes. After participants complete each brand-related question on the *Brand Test Survey* individually, the moderator will ask a series of questions to obtain qualitative feedback from the group. Then, participants will engage in *Creative Concept Testing* (50 min.) where they will be shown campaign creative concept storyboards. Similar to the *Brand Test Survey*, the order in which the creative concepts are shown will be alternated between focus groups for counterbalancing purposes. Additionally, focus group participants will be assigned to either female-centric (i.e. primarily attracted to females) or male-centric (i.e. primarily attracted to males) focus groups, and group assignment will be based on their sexual orientation and gender identity as reported on the screening survey. As such, female-centric focus groups will be exposed to mostly female-centric creative concepts and vice versa. Additionally, both female- and male-centric focus groups will be exposed to general LGBT creative concepts. After each creative concept is shown, participants will individually complete the relevant portion on the *Creative Concept Survey*, and the moderator will ask a series of questions specific to the creative concept to obtain qualitative feedback from the group. Finally, the research team will end the focus group and assist participants with collecting their incentives and checking out of the focus group (5 min.).

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 consent form that the information they provide in the screener for recruitment will only be viewed by the researchers. Additionally, focus group questions will not ask participants to provide identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency.

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 transcripts or analysis will contain identifying information.

Neither the contractor nor subcontractors associated with this study will share personal information regarding research participants with any third party without the participants' permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or another legal process.

7. Amount and justification for any proposed incentive:

The amount of the incentive as a token of appreciation is \$75. 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, open-ended feedback on brands and creative concepts 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.

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

FDA tobacco use communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, and some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature require some sensitivity in how they are worded and approached. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation.

In order to identify LGBT young adults, researchers need to ask sensitive survey-based questions about gender identity and sexual orientation. The FDA acknowledges such questions are potentially sensitive. However, since recruitment is occurring at LGBT social venues, it is assumed that the large majority of potential respondents already identify as LGBT.

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.

Raw data that include sensitive information (e.g., screening questionnaires) are not retained once the data have been extracted and aggregated. The 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 qualitative methods to collect data. 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 procedures that employ screening questions about sexual orientation, gender identity, age; current and past tobacco use; and 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

Consent | estimated participation time: 5 minutes

Participants | estimated participation time: 90 minutes

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Screening Questionnaire ¹	672	5	56
Consent		5	56
Total			112
Focus Group Participants			
Focus Group Discussion	224	90	336
Total			448

¹The total number of Screener respondents are 672; one-third of those (224) represent the total number of focus group participants in this study.

REQUESTED APPROVAL DATE: 03/02/2015

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