

**FDA DOCUMENTATION FOR THE GENERIC CLEARANCE
OF TESTING COMMUNICATIONS ON TOBACCO PRODUCTS
(0910-0796)**

TITLE OF INFORMATION COLLECTION: Multicultural Campaign: Wave 3 focus group study of reactions to creative advertising concepts designed to prevent multicultural youth tobacco use

OMB Control Number 0910-0796.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration’s (FDA) Center for Tobacco Products (CTP) is seeking Office of Management and Budget (OMB) approval under generic clearance 0910-0796 to conduct focus groups with Multicultural (African American, Hispanic Latino and Asian/Pacific Islander) youth aged 12–17 (n=180) who are influenced by the Hip Hop peer crowd and are either experimental tobacco users or at-risk non-triers. The research will be used to assess advertising concepts designed to reduce youth tobacco use.

For FDA’s Fresh Empire Multicultural Campaign, youth ages 12-17 were selected as the target audience. It is estimated that more than 80% of adult smokers begin smoking before age 18. The Centers for Disease Control and Prevention (CDC) report that youth cigarette use declined sharply from 1997-2003, but declines have slowed in recent years (CDC, 2010). Additionally, other tobacco products such as e-cigarettes, cigar products, and hookah have become increasingly common among US teens, even as cigarette smoking continues to decline. From 2011 to 2015, the National Youth Tobacco Survey found that while cigarette smoking decreased significantly among high school teens, use of e-cigarettes and hookah increased significantly (Singh et al., 2016). Additionally, in 2015 a greater percentage of high school students reported past 30-day use of e-cigarettes (16.0%) than cigarettes (9.3%) (Singh et al., 2016). These trends indicate a need for youth public education campaigns to include a variety of tobacco products in their messaging efforts. Therefore, the target audience of this campaign represents a population that is at high risk of using tobacco products, and thus is in need of health education messaging.

Additionally, for FDA’s Multicultural Campaign, the Hip Hop peer crowd was selected as the target audience as they are a prominent youth peer crowd and demonstrate above average rates of smoking prevalence (Lee et al., 2014; van der Rijt et al., 2002). Research has consistently noted higher rates of tobacco use among youth influenced by the Hip Hop peer crowd as compared to other youth peer crowds (Lee et al., 2014; Rescue research; van der Rijt et al., 2002). In one study, the odds of smoking were roughly twice as high for Hip Hop youth as compared to youth primarily influenced by the Mainstream peer crowd (OR=1.97, 95% CI: 1.03, 3.76) (Lee et al., 2014). The Hip Hop peer crowd, therefore, represents a peer crowd at high risk of smoking or initiation, and thus is in need of health education messaging.

2. Intended use of information:

The information obtained through this study will inform the implementation of FDA's Multicultural Campaign. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

Refine and optimize creative concepts to be developed into video ads for FDA's Multicultural Campaign.

Inform FDA and other stakeholders on the potential impact of campaign messaging.

Inform future programs that may be designed for similar purposes.

3. Description of respondents:

Participants will be enrolled via in-person recruitment at middle and high schools across the US. The screening criteria are based on age, tobacco use status, intention to use tobacco in the future, and Hip Hop peer crowd influence

All potential participants will complete a Screener to determine their qualification for inclusion into the focus groups. The Screener survey will be distributed as a paper survey in middle and high school cafeterias during lunch periods. Researchers will sample as many individuals as well as entire groups as possible from every area of the lunchroom so that they represent different ages, genders, grades, and races/ethnicities. Researchers will never turn away individuals who ask to fill out a Screener. Potential participants will be informed that any information they provide will be private and not shared with the school or their parents.

All enrolled participants will be asked to answer questions about their tobacco-related knowledge, attitudes, and beliefs, and psychographics, in addition to demographic information which will be collected during the screening process.

4. Date(s) to be conducted:

The study is projected to occur between April 1, 2017 and July 31, 2017.

5. How the information is being collected:

The study will consist of showing seven to eight (7-8) rotated concepts from up to ten (10) creative concept storyboards to a sample of the target audience during in-person focus groups. Participants will provide quantitative and qualitative feedback about creative concepts viewed in the focus groups.

Following lunchtime recruitment, researchers will review completed Screeners and identify eligible youth. Twelve eligible youth will be selected for invitation to attend each focus group. Eligible youth who are invited to participate in a focus group will be notified during their last period class on the day of recruitment. Eligible youth ages 13-17 will be provided a Parental Opt-Out Form, and eligible youth age 12 will be provided a Parental Consent Form. The contractor (Rescue) understands that local jurisdictions and/or schools may have different requirements for consent procedures and will follow those local requirements. The after school focus group will be held one or two days after recruitment to allow for parental opt-out or consent documentation, respectively. Researchers will attempt to obtain verbal parental consent using the Verbal Parental Consent Script for youth age 12 who do not return a signed consent form but still wish to participate in the focus group. All youth regardless of

age will complete the Participant Assent Form before beginning the focus group. Youth must complete the Participant Assent Form, and have obtained written/verbal parental consent or have not been opted-out by their parents in order to participate in the focus groups; youth who do not meet these criteria will not be able to participate in the focus groups.

Each focus group will occur after school hours on the school campus where youth were recruited. Upon arrival to the group, participants will complete a five minute task answering a short series of questions (Check-In Survey) to assess participants' tobacco-related knowledge, attitudes, and beliefs, and psychographics. Once all participants have arrived, the moderator will begin the focus group using the Moderator Guide. The moderator will obtain verbal consent from all participants to audio record the focus group. If a participant does not provide verbal consent for audio recording, the group will not be recorded and instead the focus group assistants will take notes. In total, the check-in survey, general instructions for participation and request for consent to audio record will take fifteen minutes.

Following a brief introduction to the focus group, the moderator will begin the seventy five minute creative concept testing activity. Preliminary creative concepts storyboards will be presented as a series of still images with voiceover or actors reading scripts. Each storyboard will be 45-60 seconds long. Each creative concept will be revealed one at a time. Up to ten creative concepts total will be tested in this study. Each focus group will view seven of the concepts, with the opportunity to view an eighth if there is sufficient time. To collect views on all concepts, concepts and the order in which they are shown will be rotated across focus groups.

Throughout the focus group discussion, following exposure to each creative concept storyboard, respondents will be asked to rate their initial reaction to the concept for each item on the Creative Concept Survey before the group discussion for that creative concept starts. During the discussion, the moderator will guide participants with a series of questions designed to assess their initial reactions to the creative concept, including what they liked or disliked, how the ad made them feel, and overall comprehension of the concept. Additionally, questions will be asked on whether the ad influenced the participant's thoughts about smoking, the degree to which the claims in the ad were believable, and the actions they might take in response to the ad (e.g. sharing the ad, mentioning it to a friend). These questions are used to assess the target audience's comprehension, evaluations, and perceptions of the creative concepts viewed. The Creative Concept Survey will be completed throughout the general focus group discussion and will take five minutes in total to complete.

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.

Prior to focus group facilitation, youth focus group participants will be asked by research staff to complete an assent form and for their parents to complete a consent form. At the beginning of the focus group, the facilitator will review the content of the consent/assent form. The consent/assent form will contain a statement that no one will be able to link the respondent's identity to his/her responses. Additionally, focus group questions will not ask participants to provide identifying information as part of their responses.

Before each group begins, the moderator will obtain verbal consent/assent from the participants to audio record the session. In the event consent is not given, the contractor will refrain from audio recording the session, although live notes/transcriptions may still be taken. The consent form will also contain a statement notifying participants that audio recording will occur.

Neither independent contractors nor focus group agencies will share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. 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.

7. Amount and justification for any proposed incentive:

The amount of the incentive for participation is a physical \$25 Visa or American Express gift card, distributed directly to the participant at the conclusion of the focus group or when the participant leaves the group, whichever is earlier. If a participant is removed from the focus group for any reason, he/she will still receive compensation.

In this research, we are asking participants to provide both survey responses and thought-intensive, open-ended feedback on creative concept storyboards that require a high level of engagement. The use of incentives shows respect by recognizing and acknowledging time burden placed on participants and the effort they expend to participate. The incentive is similar to incentives that are offered for other studies of this type.

Numerous empirical studies have shown that incentives can significantly increase response rates in cross-sectional studies and reduce attrition in longitudinal studies (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002). The use of modest incentives is expected to enhance focus group participation rates without being an inducement for participation. Incentives must be high enough to equalize the burden placed on participants with respect to their time and cost of participation. A smaller incentive would not appear sufficiently attractive to participants as compensation for their time and effort expended. 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 do not show up or drop out early. We also believe that the incentives will result in higher data validity as participants will be more likely to attend and engage in the focus group activities.

8. Questions of a sensitive nature:

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess tobacco use. These questions are essential to the objectives of this information collection. Questions about messages concerning tobacco use behavior and some demographic information, such as race/ethnicity, could be considered sensitive, but not highly sensitive.

To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise youth that these topics will be covered during the study. In addition, this study includes the following procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer, and that they may leave the focus group at any time without penalty.

The Screener, Check-In Survey, and Creative Concepts Survey are entirely self-administered and maximize respondent privacy without the need to verbalize responses. Participants will be informed that the focus group will be audio recorded and they will have an opportunity to provide or reject consent for the group to be recorded at the start of the focus group.

Participants will be provided with an email address and phone number for the Principal Investigator and the IRB should they have any questions or concerns about the study or their rights as a study participant.

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. The sample drawn here is designed primarily to provide information on youth perceptions of up to 10 creative concepts developed for the FDA’s Multicultural Youth Tobacco Prevention Campaign (Multicultural Campaign).

The campaign contractor Rescue has conducted rigorous internal review of the survey instruments. Trained researchers reviewed the Screener, Check-In, and Creative Concept Surveys to verify that all questions are worded correctly. Researchers who will be involved in recruitment and data collection will be trained on administration of the instruments to ensure efficiencies in data collection. Moderators will be provided training on the content of the creative concepts and moderator guide to ensure they are equipped to facilitate constructive discussions that address the goals of the research.

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

Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
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Screened Youth	Screener completion	540	1	540	0.083	45
Parents of Invited Youth	Parental consent or opt-out process	180	1	180	0.083	15
Participants	Youth Assent	180	1	180	0.083	15
	Focus Group (Check-in Survey, 5 minutes; General instructions, 15 minutes; Discussion, 70 minutes; Creative Concept Survey 5 minutes)	180	1	180	1.5	270
Total Annualized Hours						0

REQUESTED APPROVAL DATE: January 10, 2017

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FDA CENTER: **Center for Tobacco Products (FDA/CTP)**

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