

FDA DOCUMENTATION FOR GENERIC CLEARANCE FOR THE COLLECTION OF QUALITATIVE DATA ON TOBACCO PRODUCTS AND COMMUNICATIONS (0910-0796)

TITLE OF INFORMATION COLLECTION: Focus Group Study of Youth Reactions to Creative Advertising Concepts Designed to Prevent Youth Tobacco Use among Multicultural Youth; 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 OMB approval under generic clearance 0910-0796 to conduct focus groups with multicultural youth aged 12-17 ($n = 360$) who are either experimental tobacco users or who are at risk of initiating.

The research will be fielded for the purpose of assessing perceptions of advertising concepts designed to reduce youth tobacco use among multicultural youth aged 12–17.

2. Intended use of information:

Information obtained through this study will inform the development and implementation of FDA's Multicultural Campaign designed to prevent youth tobacco use among youth who are influenced by Hip Hop peer crowd. Peer crowds are aggregates of individuals and peer groups that have similar interests, lifestyles, and habits across geographic areas. While a teen has a local peer group she/he socializes with, the teen and his/her peer group belong to a larger peer crowd that shares significant cultural similarities across geographic areas. Focus group participants will be asked to answer questions regarding comprehension, relevance, and impact of several campaign creative concepts and their perceptions of various tobacco facts and products.

Results will be used to develop and refine creative concepts for the Multicultural Campaign.

The study will consist of a series of focus groups with youth aged 12 to 17. Focus group discussions and activities will be designed to answer the following questions:

- How do youth react to various tobacco-related facts and products?
- How do youth evaluate and perceive preliminary campaign creative concepts?

3. Description of respondents:

Three hundred and sixty (360) youth aged 12-17 will participate in Creative Development focus groups. Study participants will consist of youth who either self-report as experimenters or at-risk non-triers. Approximately 1,800 youth will be screened in order to obtain a sample size of 360.

4. Date(s) to be conducted:

The study is projected to occur between November 1, 2015 and July 30, 2016.

5. How the information is being collected:

The information is being collected using a professional moderator and up to two research assistants with experience leading youth focus groups. The moderator and assistants will engage participants in a series of 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 to those answers. Data will be collected in school settings. Each focus group will last 90 minutes.

Youth will first be asked to complete a *Check-In Survey* (5 min.) that includes questions regarding tobacco use and social media use. This survey will be completed individually by each participant. During this time, the moderator will provide a brief study introduction. Next, participants will be shown pictures of various tobacco products and asked for their common names and perceived use prevalence (10 min.). Then, participants will engage in *Creative Concept Testing* (65 min.) where they will be shown campaign creative concept storyboards. 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. After completing the Creative Concept Survey, the moderator will lead youth through a discussion of the relevance of select tobacco facts (10 min.) to the youth. Finally, the moderator and research assistants will end the focus group and assist participants with collecting their incentives.

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 youth in the assent form and parents in the consent/opt-out 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 data 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 a \$25 non-retailer specific 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, open-ended feedback on creative concepts, tobacco facts, and tobacco products 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 populations such as youth, low socio-economic groups and high-risk populations (experimenters and at-risk non-triers).⁴

Also, this study requires participants to comment on an activity that may be sensitive subject matter to the participants and could cause them to be reluctant to participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among potential youth respondents.

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, 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

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.

audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, for instance, still 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.

FDA tobacco communications may also be concerned with discouraging tobacco use by youth before they start. It is important to understand perceptions about smoking from youth who use tobacco or who are susceptible to use because their opinions are valuable in informing campaign development. In order to identify youth who have used tobacco, researchers need to ask sensitive survey-based questions about current tobacco use. The FDA acknowledges such questions are potentially sensitive since tobacco use among youth under 18 years of age is illegal in some states and selling tobacco use to minors is illegal in all states.

Raw data that include sensitive information (e.g., screening questionnaires, youth or parent contact information) 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.

Youth participants will be directly identified using school-based intercept recruitment procedures that employ screening questions about age; current, past, and intended tobacco use; race and ethnicity; gender; and peer crowd affiliation. Recruitment will continue until a sample of the required number of participants for each focus group is obtained.

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

Youth Screener and Assent | estimated participation time: 10 minutes

Parental Opt-Out/Consent | estimated participation time: 5 minutes

Youth Participants | estimated participation time: 90 minutes

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Youth Screening Questionnaire and Assent	1,800	10	300
Parental Opt-Out or Consent	360	5	30
	Total		330
Youth Focus Group Participants			
Creative Development	360	90	540
	Total¹		870

¹The total number of respondents are 1,800; one-fifth of those (360) represent the total number of participants to be recruited in this study.

REQUESTED APPROVAL DATE: 10/30/15

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