

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

TITLE OF INFORMATION COLLECTION: Wave 3 Phase 1 Qualitative Research: General Market (“The Real Cost”) At-Risk Youth Tobacco Prevention Focus Groups; 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 OMB No. 0910-0674 to conduct focus groups with youth aged 12–17 (n=220) who have experimented with cigarettes and/or e-cigarettes (i.e., have reported smoking fewer than 100 cigarettes/using fewer than 100 e-cigarettes in lifetime) and youth aged 12-17 who are at risk of initiating cigarettes or e-cigarettes (e.g., would smoke/use an e-cigarette if a friend offered them one). The purpose of these focus groups is to assess participants’ emotional and cognitive reactions to draft strategic and creative advertising concepts designed to reduce youth tobacco use.

2. Intended use of information:

Information obtained through this study will inform the development and implementation of the third and fourth wave of FDA’s General Market At-Risk Youth Tobacco Prevention Campaign (“The Real Cost”) designed to reduce youth tobacco use. Specifically, focus group participants will answer questions regarding comprehension, relevance, and potential impact of draft campaign strategic and creative advertising concepts. Study result will help identify the most promising creative and strategic concepts as well as indicate areas for further refinement to guide creation of effective advertisements.

3. Description of respondents:

The study will consist of 36 focus groups, each with approximately six youth aged 12–17 who report having smoked fewer than 100 cigarettes and/or e-cigarettes in their lifetime (“experimenters”) or indicate they have never smoked but are open to trying cigarettes or e-cigarettes in the future (“at-risk non-trier”), for a total sample size of 220 participants. Groups will be segmented by age, gender, and self-reported tobacco product use. This information will be gathered during the screening process. Groups will be otherwise diverse by race/ethnicity. Approximately 21 groups will include experimenters (n=~130) and 15 groups will include at-risk non-triers (n=~90). It is estimated that a total of 660 youth will be screened in order to obtain a sample size of 220.

4. Date(s) to be conducted:

The study is projected to occur between July 31, 2015 and April 3, 2016.

5. How the information is being collected:

The information will be collected through 36 in-person focus groups led by a professional moderator with experience leading focus groups with youth. Each group will be exposed to either creative concepts or strategic concepts and asked a series of questions using a semi-structured discussion guide to encourage participants' feedback around understanding, relevance, impact and motivation of the shared concepts and strategic concepts. The moderator will encourage participants to respond openly and spontaneously. If all participants provide assent before discussions begin, their responses will be audiotaped and transcribed. 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.

Creative Concepts Focus Groups (90 minutes)

): After a study introduction (5 minutes), the first activity will consist of a discussion about advertising, "TV Ads," which will include questions regarding favorite television advertisements and advertisements (ads) related to the dangers of smoking cigarettes and/or using e-cigarettes (5 minutes). Next, participants will discuss "Tobacco: Experience and Associations," which will involve a group discussion regarding smoking cigarettes/using e-cigarettes and perceptions of cigarettes/e-cigarettes (10 minutes). Then, participants will engage in a discussion of "Reactions to Creative Concepts and Ads," when they will be shown three campaign creative concepts (50 minutes). The Creative concepts will be presented in different formats, including TV, print, and digital formats. See the Stimuli attachment for examples. After each creative concept is shown, the moderator will ask a series of questions specific to the creative concept (such as feelings about the concept and perceived main message of the concept) to obtain qualitative feedback from the group. Once all of the creative concepts have been viewed, the moderator will lead youth through a discussion to garner their "Reactions to Creative Concepts as a Whole" as a means to query their reactions to all of the creative concepts and to gain comparative information across the concepts (20 minutes). Finally, the moderator will end the focus group and assist participants with collecting their incentives and checking out of the focus group.

E-Cigarette Strategic and Creative Concepts Focus Groups (90 minutes)

): After a study introduction (5 minutes), the first activity will consist of a discussion about advertising, "TV Ads," which will include questions regarding favorite television advertisements and regarding advertisements (ads) related to e-cigarettes (5 minutes). Next, participants will discuss "E-Cigarettes: *Experience and Associations*," which will involve a group discussion regarding using e-cigarettes and perceptions of cigarettes (15 minutes). Then the moderator will present up to four e-cigarette-specific strategic concepts to gauge "*Reactions to Strategic Concepts*" (30 minutes). See the Stimuli attachment for examples. After each strategic concept is shown, the moderator will ask a series of questions specific to the strategic concept (such as main message and intended audience) to obtain qualitative feedback from the group. the moderator will also ask the participants to compare the strategic concepts in the "Strategic Concept Comparison" section (10 minutes). Then, participants will engage in a discussion of "Reactions to Creative Concepts and

Ads,” when they will be shown two e-cigarette-specific creative concepts (20 minutes). After each creative concept is shown, the moderator will ask a series of questions specific to the creative concept (such as feelings about the concept and perceived main message of the concept) to obtain qualitative feedback from the group. Once both creative concepts have been viewed, the moderator will lead youth through a discussion to garner their “Creative Concepts Comparison” responses as a means to query their reactions to both of the creative concepts to gain comparative information between the two concepts (5 minutes). Finally, the moderator will conclude the focus group and assist participants with collecting their incentives and checking out of the focus group.

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.

Parents/guardians of all participants will complete a consent form prior to participation. The parent/guardian will provide verbal consent on the phone, and then be e-mailed the consent information that they will review to either sign electronically or during the check-in process on the day of the focus group. The consent form clearly states that youth participants must be accompanied to the research facility by a parent/guardian who can give consent.

Qualifying focus group youth participants will be asked to provide verbal assent on the phone during screening. They will also be e-mailed an assent form to review and either sign electronically or during the check-in process at registration.

Before each group begins, the moderator will obtain verbal assent from the youth participants to audiotape the session. In the event assent is not given, the contractor will refrain from audiotaping the session, although live notes/transcriptions may still be taken.

The contractor will also produce transcriptions of the tapes to assist in report writing and to provide the FDA with a written record of the sessions. One paper and one electronic copy of the transcripts will be supplied. The audiotape and transcript for a given group will be available to the FDA within two weeks of the completion of that data collection. To ensure participant privacy, the contractor will redact the recordings and transcripts.

All data will be collected with an assurance that the respondents’ discussions will remain private to the extent provided by law. The moderator’s guide and consent form will contain a statement that no one will be able to link a respondent’s identity to his/her responses. Identifying information will not be included in the data files delivered by contractors to the agency.

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 transcripts and digital recordings delivered to the agency. All data received by the FDA will remain in a secured area. No data will contain identifying information.

7. Amount and justification for any proposed incentive:

The amount of the incentive is a \$50 prepaid 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 concepts that require a high level of participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.¹

Incentives must be high enough to equalize the burden placed on respondents 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. If the incentive is not adequate, participants may agree to participate and then not show up or 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 moderator 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 (current or former tobacco users and those susceptible to tobacco use).⁴

In the context of this study, the target population is considered a harder-to-recruit population on multiple accounts (youth aged 12–17 who are also at-risk of or currently experimenting with tobacco use). The study also requires respondents to comment on an activity that is a sensitive subject matter and could cause them to be reluctant to participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of 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

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.

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 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. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

FDA tobacco communications may also be concerned with discouraging tobacco use by youth before they start. The FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is illegal for minors in most states. Because questions are being asked of youth aged 12–17, interviews will be conducted by moderators specifically trained for interactions with youth.

Raw data from data collections that include sensitive information (e.g., screening questionnaires and audiotapes) 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 and is not intended to yield results that are statistically projectable. Participants will be identified using standard telephone recruitment procedures that employ screening questions about age; current, past and intended tobacco use; race and ethnicity; and gender. Recruitment will continue until a representative sample of the required number of participants for each group is obtained.

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

First Approval

Respondent and Participation Type	No. of Respondents	Max Participation Time (Minutes)	Burden (Hours)
Screened Potential Participants			
Parent Screener	540	2	18
Youth Screener		5	45
Parental Consent	180	5	15
Youth Assent		5	15
Total Screened	540		93
Youth Focus Group Participants			
Creative Concepts Focus Group	90	90	135
Strategic Concepts Focus Group	90		135
Total Participant	180		270
Total Burden	540*		363

* The total number of respondents is 540; one-third of those (180) represent the total number of participants in this study

New Burden

Respondent and Participation Type	No. of Respondents	Max Participation Time (Minutes)	Burden (Hours)
Screened Potential Participants			
Parent Screener	660 (+80)	2	22 (+4)
Youth Screener		5	55 (+10)
Parental Consent	220 (+40)	5	18(+3)
Youth Assent		5	18(+3)
Total Screened	660 (+120)		113 (+20)
Youth Focus Group Participants			
Creative Concepts Focus Group	170 (+80)	90	255 (+120)
Strategic Concepts Focus Group	50(-40)		75
Total Participant	180		330 (+60)

Total Burden	660* (+120)	443 (+80)
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* The total number of respondents is 660 (parents and youth); one-third of those (220) represent the total number of participants in this study.

REQUESTED APPROVAL DATE: July 21, 2015

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