

U.S. Food and Drug Administration

FDA Tobacco Prevention Broad Quantitative Research Package

OMB Control No. 0910-0810

SUPPORTING STATEMENT

Part B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The one-time actual burden figures are listed in Tables 1 & 2, Part A.

The primary outcome of this study would be based on a non-random sample provided by an online panel (e.g. Market Cube) of up to 5,500 youth ages 13-17 years old who are either tobacco users or susceptible non-users, and up to 5,500 adults ages 18-54 who are current or former tobacco users.

Participants will be recruited through an existing panel of adults, including adults with children ages 13-17 who give their permission for their youth to complete the survey. The screening criteria are based on age, tobacco use status, and intention to use tobacco in the future. As this study is considered part of formative research for campaign development and planning, these methods are not intended to generate nationally representative samples or precise estimates of population parameters. Additionally, a secondary aim of this study is to better understand how Hispanic populations respond to messaging.

The sample drawn here is designed primarily to provide information on the perceived effectiveness of various tobacco-related facts and messages that may be used in future tobacco prevention and cessation campaigns.

The study is a cross-sectional design, and participants will be enrolled via panel. The screening criteria are based on age, tobacco use status, valid email address, personal or close family or friends' employment in the tobacco industry, and past participation in tobacco research.

Sampling Methods

The sample provided will be of a sample of youth ages 13-17 and adults ages 18-54. Participants will be recruited via a participant panel composed of adults in the United States and includes adults with children ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys. For adult recruitment, adults will be recruited directly from the panel. For youth recruitment, the parent will determine if they are interested in their child participating in the survey. As this study is considered part of formative research for campaign development and planning, these methods are not intended to generate nationally representative samples or precise estimates of population parameters. The sample

drawn here is designed primarily to provide information on the tobacco related messaging effectiveness of tobacco-related facts and messaged.

After initially accepting the invitation to join the panel, participants are asked to complete a short demographic survey (the initial profile survey); answers to these questions allow efficient panel sampling and weighting for surveys.

Sample Size

To obtain a final sample of 5,500 youth ages 13-17 who have experimented or are susceptible to tobacco use, we will need to screen approximately 8,250 potential respondents. To obtain a final sample of 5,500 adult current or former tobacco users, we will need to screen in approximately 8,250 potential respondents. Because we are using a panel provider with a proven track record of being able to recruit participants that fit specifications for inclusion, we anticipate we will need to recruit 1.5 times our desired sample for this study.

2. Procedures for the Collection of Information

This section describes the procedures for the survey data collection. The survey will be conducted via a web-based survey. For youth to be eligible to participate, the parent must not optout of allowing their child to participate, the youth must give their assent, and the youth (age 13-17) must be either a person who has experimented with tobacco or a youth (ages 13-17) who is susceptible to using tobacco in the future. For adults to be eligible to participate, they must consent to participate, and either be a current or former smoker. The screener is outlined in Attachments D and E. The survey instrument (Attachment F and G) will include the survey questions and contact information for the IRB who will be available to respond to questions posed by participants. The survey will be hosted on cloud-based servers. All surveys will be conducted using a self-administered, online questionnaire.

Summary of Protocol

The list of study procedures is as follows:

1. Youth and adult panelists are recruited through an online panel. For adult recruitment, adults will be recruited directly from the panel. They will be sent a consent form (Attachment C).
2. For youth recruitment, adult panel members are prescreened for their child's age as well as their willingness for their child to participate in online surveys.
3. For youth recruitment, adult panel members will receive an email invitation and a notification and opt-out form that indicates their child has been invited to participate in a new survey (Attachments A and A1). If the parent decides they would like their child to participate in this survey, an introductory email will be sent to the youth. The notification and opt-out form will invite them to participate and request the child's assent (Attachment B). The assent forms will provide a description of the purpose, implementer and confidentiality standards associated with the study.

4. If the youth gives their assent/adults give their consent, then they will be redirected to the online screener questions (Attachment D and E).
5. If the respondent qualifies for the survey, he or she will begin the survey questions (Attachment F and G).
6. If the respondent does not qualify for the survey, he or she will receive text thanking them for their time and explaining that they do not qualify for the survey.

It will not be possible for anyone to enter the survey who has not been recruited through their parent, or for a respondent to complete the survey more than once. In addition, the same-worded invitation will be sent at regular intervals after the original invitation is sent to those respondents who have not yet responded.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Use of Periodic Data Collection Cycles to Reduce Burden

This is a one-time survey data collection effort.

3. Methods to Maximize Response Rates and Deal with Non-response

The ability to obtain the cooperation of potential respondents in the survey will be important to the success of this study. FDA will minimize the non-response rate by employing the following measures:

1. Working with an existing panel of adult participants, including parent participants who have previously indicated their willingness for a child in their household ages 13-17 to participate in youth studies.
2. Sending a reminder email for initial non-response.
3. Provide incentives.

Panel participants consist of individuals who have expressed interest in completing surveys. By opting in to the pool of potential survey respondents and being familiar with responding to surveys as a member of a panel we will be increasing the likelihood of participant response.

Tokens of appreciation will be offered in the form of non-monetary 'points' valued up to \$10.00. These points can be redeemed through the panel's system for goods or gift cards. The approximate value of the points is \$10 per survey. We estimate that the survey will take 20 minutes to complete. This token of appreciation is intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for contributing to this important study and are similar to incentives that are offered for most surveys of this type. Numerous empirical studies have shown that incentives can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002).

At CTP, OHCE, we have successfully utilized this type of token of appreciation for previous web-based surveys of similar length, including the following studies: *The Real Cost* Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use OMB Control No. 0910-0810; Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging OMB Control No. 0910-0810. With this incentive structure, we have been able to meet our data collection goals within required time frames. __

4. Tests of Procedures or Methods to be Undertaken

FDA will conduct rigorous internal testing of the online survey instrument prior to its fielding. Evaluators will review the online test version of the instrument that we will use to verify that instrument skip patterns are functioning properly, delivery of campaign media materials is working properly, and that all survey questions are worded correctly and are in accordance with the instrument approved by OMB.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals inside the agency have been consulted on the design of the campaign evaluation plan, audience questionnaire development, or intra-agency coordination of information collection efforts:

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References

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Castiglioni, L., Pforr, K., & Krieger, U. (2008, December). The effect of incentives on response rates and panel attrition: Results of a controlled experiment. In *Survey Research Methods* (Vol. 2, No. 3, pp. 151-158).

Jäckle, A., & Lynn, P. (2008). Offre de primes d'encouragement aux répondants dans une enquête par panel multimodes: effets cumulatifs sur la non-réponse et le biais. *Techniques d'enquête*, 34(1), 115-130.

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