Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

0910-0810

Supporting Statement Part B

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The respondent universe for the quantitative testing may include a wide range of consumers, including current tobacco users, adults and youth, as well as non-users of tobacco products. The samples will be selected from an appropriate target audience, which could be online panel members or samples obtained through in-person intercepts (e.g., in malls and schools). Sampled panel members will receive an email inviting them to participate in the study. Sampled intercept participants will be invited to participate in the study by trained recruiters. Participants who choose to participate will complete a screener and, if eligible, receive a questionnaire. Completed interviews will be monitored to ensure samples are diverse in terms of age, gender, education, and ethnicity/race. Other sources of samples may also be employed.

Generally, studies under this collection rely on quantitative methods and use convenience samples rather than probability samples. As a result, the results are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters. When probability samples are employed (such as through an online panel), representative estimates to the national population will not be made.

2. Procedures for the Collection of Information

For most studies submitted under this generic clearance, FDA will use an online panel or market research vendor experienced in conducting in-person intercepts. When participants are recruited through online panels, the vendor will send email invitations to the target audiences using their market research panel. Each invitation will contain the title, the length of the participation, amount provided for successful completion of the survey (if any), and instructions for accessing the secure website. Once a participant enters the secure web site, a brief introduction will be presented informing the participant of the confidential and voluntary nature of the survey. Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL.

When participants are recruited through online panels, the vendor will recruit the target audiences using in-person intercepts. Participants will be invited to complete a screener to determine study eligibility. During the screening process, potential participants will be asked for personal information including their email address and questions about their tobacco use behavior. This

information will be used to determine eligibility, and to send email invitations to the target audiences. Similar to the process of using online panels, each invitation will contain the title, the length of the participation, amount provided for successful completion of the survey (if any), and instructions for accessing the secure website. Once a participant enters the secure web site, a brief introduction will be presented informing the participant of the confidential and voluntary nature of the survey. Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL.

In both cases the questionnaire will be designed to measure responses to the study stimuli and collect demographic and smoking status information from the participants. Participants may view study stimuli prior to answering questions to assess responses to the stimulus or indicating their opinions.

Summary of Protocol

- Survey screener — confirm eligibility.
- Random assignment to view stimulus, such as an image or video or message (if appropriate).
- Respondents provide information about behavior, knowledge and attitudes about tobacco products and/or other key study outcomes identified.

Potential Measures

Key Outcomes (measured post-exposure and/or at 1-week follow-up):

- Recall (aided and/or unaided)
- Reactions
- Beliefs
- Intentions
- Knowledge
- Openness to tobacco use (youth)

Covariates and controls:

Age, gender, race, SES (income and education), personal and family tobacco use history

Analysis Plan (example for experimental studies)

Note: the analysis plan will be developed according to the study protocol, and will be guided by the study purpose, design, research questions, and hypotheses tested (if appropriate). The following is an example related to an experimental study design, which would be tailored based on specific study protocol.

Tests:

1. Tests of treatment effect: comparison of outcomes in treatment group(s) to control
2. Contrasts between treatment groups

The sample design for each quantitative test will be adequately powered to test the primary research hypothesis:

- The key outcomes for the groups viewing a different version of the stimulus will be significantly different from each other.

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

Experience with online studies suggests that about 15 percent of those who are sent survey invitations will complete a study. Despite, this low baseline value, FDA will implement several procedures to increase participation wherever possible. We will conduct cognitive interviews and pretests to help improve understandability of the questionnaire, to reduce participant burden, and to enhance interview administration. We will keep the questionnaire at a reasonable length to minimize break-offs. Tested recruitment and data collection procedures will be used to maximize cooperation and to achieve the desired response rates.

4. Tests of Procedures or Methods

FDA may conduct cognitive interviews to evaluate and refine the draft questionnaire or study materials. If the number of cognitive interview respondents exceeds nine members of the public, the Agency will submit the cognitive interview protocol for review. The cognitive interviews will help identify areas where the instrument was ambiguous, burdensome, or confusing for respondents and the survey will be revised accordingly.

Additionally, FDA may conduct a pretest with individuals who are Federal employees to thoroughly test the programmed questionnaire. At the conclusion of the pretest, all strategies, algorithms, and programs for sampling, survey administration, and data compilation will be tested, validated, and readied for launch of the data collection instrument. The instrument will be revised based on the pretest findings.

5. Individuals Involved in Statistical Consultation and Information Collection

In general, FDA plans to use a contractor for recruiting and survey programming. If needed, the contractor will also provide an analysis of the data and provide a summary report.