

United States Food and Drug Administration

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

0910-0810 -- Extension

Supporting Statement Part B

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The respondent universe for the quantitative research may include a wide range of adult and youth stakeholders, including current tobacco users, as well as non-users of tobacco products. The samples will be selected various-audiences, which could be online panel members or samples obtained through ads presented via social media (e.g., Facebook, Instagram), or in-person intercepts (e.g., in malls and schools). Sampled panel members will receive an invitation (e.g. email or other notification) inviting them to participate in the study. Sampled participants recruited via social media will be invited to participate in the study through ads posted online. 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 questionnaires will be monitored to ensure samples are diverse in terms of age, gender, education, and ethnicity/race, or other key demographics. There may be times where certain groups are oversampled in order to determine the effects of messaging, as well as risk factors, for that subgroup. 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, social media advertisements, and/or market research vendor experienced in conducting in-person intercepts to recruit respondents. When participants are recruited through online panels, the vendor will send-invitations to the target audiences using their panel, or partner panels. The contents of these invitations will vary based on the panel used, but may 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. 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 ads on social media or 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. Similar to the process of using online panels, invitations may 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. 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 some cases, the questionnaire will be designed to measure responses to study stimuli and collect demographic and smoking status information from the participants. Participants may answer questions before and/or after viewing study stimuli indicating their opinions.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Use of Periodic Data Collection Cycles to Reduce Burden

Information collected under this generic will be a one-time survey data collection effort.

3. Methods to Maximize Response Rates

FDA will implement several procedures to increase participation wherever possible. We may 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 breakoffs. 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.