

**U.S Food and Drug Administration
Center for Tobacco Products
OMB Control No. 0910-0810
Promising Themes Studies
Supporting Statement: Part B**

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The one-time actual burden figures are listed in the tables in the Part A Supporting Statement.

For this study, data collection will be split between two surveys. We will recruit up to 1,500 respondents for each survey with no more than 6,000 total respondents over the course of one year. The surveys will be conducted with a new cross-sectional sample for each survey. The study will use the surveys to measure the participants' level of agreement with belief statements to understand their potential as targets for public education. Respondents will be allowed to complete an additional, cross-sectional survey after 6 months. 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 is designed primarily to understand the relationship between beliefs about tobacco products and intentions to use tobacco products so that the FDA can develop new media campaign messages related to tobacco products that resonate with youth and adults ages 15 to 24 years old in the United States. The results of the Promising Themes studies will be used to inform specified recommendations around the U.S. Food and Drug Administration's (FDA's) public education programs' impact and effectiveness in reducing tobacco-related death and disease. These data will also be used to inform the development of new campaign messages for future FDA media campaigns.

Sampling Methods

The study sample will be comprised of participants that are: (1) youth ages 15 to 17 in the United States who are both non-users and users of tobacco products and (2) adults ages 18 to 24 years in the United States who are both non-users and users of tobacco products. This study is considered part of formative research for campaign development and planning, and these methods are not intended to generate nationally representative samples or precise estimates of population parameters. The sample is designed primarily to look at the association between beliefs and tobacco product use and between beliefs and intentions to use tobacco products.

Participants will be recruited through targeted social media advertising on Facebook and Instagram. After clicking on the advertisement, participants will be directed to the screener (Attachment 1). After completing the screener, participants will be asked to include a personal email address to receive their incentive. The online screener will take approximately 3 minutes to complete. Screener instructions note that respondents may only complete the surveys one time. The screener does not include questions that are especially sensitive or that we anticipate will be upsetting to those who read or complete it. The primary purpose of the online screener is to screen out participants that are not eligible to complete the online survey. Individuals may decline to participate in the online screener if they wish. Individuals also must acknowledge that

they read the Facebook or Instagram Authorization Statement depending on the social media website from which they access the survey. The Authorization Statement describes the information that could be learned about the participant as part of the process that Facebook and Instagram use to make sure that they have a real account. Facebook and Instagram will not share any other information about their account with RTI International (RTI).

Sample Size

To obtain a final sample of 6,000 participants ages 15–24, we will need to screen approximately 20,000 potential participants.

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 disseminated by RTI International. All surveys will be conducted using a self-administered, online survey. To be eligible, youth ages 15–17 years old must give their assent (Attachment 3), and adults ages 18–24 years old must give their consent (Attachment 4). The screener is included in Attachment 1. Links to the survey instrument (Attachment 2) will only be provided to participants after they complete the screener and give their assent or consent. As a check for validity, the birthdate in the screener and the age that the participant completes as part of the instrument must match one another for the participant to be eligible.

OMB Control Number 0910-0810 is covered underneath an approved PIA. FDA IRB will not be the IRB of record and will defer to RTI IRB’s policies and oversight. This study has received a “not human research” determination from RTI’s Institutional Review Board and will not be conducted under their oversight. The study team is committed to the protection of human subjects and the privacy and security of participant data, and we engaged RTI’s Privacy Officer and Risk Management team to assess the risks to participants and our risk mitigation approach. For this study, we are not collecting any data, including personally identifiable data, from parents. We consulted with the RTI Privacy Officer and with Risk Management and based on the content of the online survey and study design, received confirmation that it is permissible to contact participants ages 15 to 17 without parental permission. Eligible youth who are 15 to 17 years old will not require parental permission and will therefore encounter the assent language once they are routed to the survey. We recognize that some of the behaviors we are asking about are not legal for some respondents (e.g., respondents under 21 who use tobacco). The central purpose of this study is to measure beliefs, behaviors, and tobacco use intentions for specific tobacco products among youth and young adults. Participants’ responses will not be linked to their names or email addresses. RTI’s Privacy Officer and Risk Management allowed us to waive parental permission based on the nature of this study, the lack of linkage between youth respondents answers to the online survey and their name, as well as the need for accurate and truthful responses from this population.

This study poses only a minimal risk to participants and would not adversely affect their rights or welfare in any foreseeable way.

Summary of Protocol

The list of study procedures is as follows:

Promising Themes Study participants recruited through social media

1. Participants are recruited through targeted social media advertising on Facebook and Instagram.
2. After clicking the link in one of the social media advertisements, participants will be directed to the screener link.
3. Participants will complete the screener and, if they qualify, will be directed to the one of the online surveys.
4. Eligible participants who provide their email address upon completing one of the online surveys will receive one \$5 digital gift card from Amazon as compensation for their time after we have confirmed that they have only taken the survey one time in the past six months.
5. We will work with an incentive distribution vendor, Creative Group, Inc., by purchase order to send a thank you message via email along with a digital gift card to participants who complete one of the two online surveys.

E-mail addresses will be collected in the Qualtrics survey platform and stored in an isolated survey that will contain an RTI-assigned unique ID and email address. IP address will be collected in the survey platform in an isolated survey that contains IP address, RTI-assigned unique ID, and screener responses. Date of birth will be collected in an isolated survey that will contain an RTI-assigned unique ID and date of birth. Responses to the body of the survey will be collected in the Qualtrics survey platform and stored in an isolated survey. IP address, e-mail address, and date of birth will not be collected in the same file.

All three survey data files (IP address, PII, and survey responses) will be downloaded separately from Qualtrics (which requires a password). Since the Federal Information Processing Standards (FIPS) 199 does not permit access to the internet (and downloading the data from Qualtrics requires an internet connection), the files will be downloaded to the secure RTI study share drive and stored on the study share drive for no more than 24 hours after download. Study staff will be given as-needed access to the data files on the share during that 24-hour period to conduct fraud detection procedures, at which point data from the individual will be combined to check for fraudulent responses.

Once fraud detection procedures have been completed (within 24 hours after download), we will send a password protected file of just the e-mail addresses (that get incentives) to Creative Group. We will then send the password to Creative Group in a separate e-mail. Password protected/encrypted files with just e-mail addresses will be stored on the share drive until the study is completed. After completion of the study, all files containing e-mail address and/or IP address will be moved to the Federal Information Processing Standards (FIPS) 199. Once these files have been transferred any files on the study share that contain e-mail, date of birth, and/or IP addresses will be deleted. The file containing participant ID (but not e-mail address, date of birth, and/or IP address) and the survey responses will remain on the study share drive for analysis. At the completion of data collection, all response data will be deleted from the survey

platform (Qualtrics) and remain only on RTI's secure shared drive and Federal Information Processing Standards (FIPS) 199.

At the end of data collection, a member of the project staff will export the data from the survey and out of the ESN, saving them directly onto the project share drive. Only RTI project staff directly involved in programming, sampling, recruitment, or analysis will have access to the survey data or sampling frame. No respondent identifiers will be contained in reports to FDA, and results will only be presented in aggregate form.

To reduce the potential of participants completing multiple surveys and to reduce non-U.S. based youth from completing surveys, IP addresses from outside of the U.S. will be blocked from taking the screener. Additionally, we may maintain a list of IP addresses from which we receive repeated fraudulent activity as defined above. IP addresses appearing on this list may be blocked from accessing the screener or main survey. We also block VPNs with an IP address from a potential spoofing site.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Use of Periodic Data Collection Cycles to Reduce Burden

The surveys to assess agreement with specific beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco will be repeated with a new cross-sectional sample up to two times a year over a period of 12 months. Respondents will be allowed to complete additional, cross-sectional surveys after 6 months.

3. Methods to Maximize Response Rates

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

1. Employ targeted advertising to best reach the desired sample
2. Provide a token of appreciation in the form of a \$5 digital gift card from Amazon to participants who complete and submit the survey

We will use targeted advertising on Facebook and Instagram to reach the target population. We estimate that the survey will take 20 minutes to complete. As a token of appreciation, participants recruited through social media who complete and submit the survey will receive a \$5 digital gift card from Amazon. As participants often have competing demands for their time, a token of appreciation for participation in research is warranted. The use of a token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort participants expend to participate. Numerous empirical studies have also shown that a token of appreciation can significantly increase response rates in cross-sectional studies and reduce attrition in longitudinal studies (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Shettle & Mooney, 1999; Singer, 2002). Additionally, evidence indicates that at-risk and multicultural populations may be particularly difficult to recruit and retain in health research (Hooven, Walsh, Willgerodt, & Salazar, 2011; Zand et al., 2006; Post, Gilljam, Bremberg, & Galanti, 2012; Patel,

Doku, & Tennakoon, 2003; Siddiqui, Flay, & Hu, 1996; Giuliano et al., 2000; Murthy, Krumholz, & Gross, 2004), but that the use of a token of appreciation can be an effective means of recruiting and retaining participants from these populations (Martinson et al., 2000; Booker, Harding, & Benzeval, 2011; Caldwell, Hamilton, Tan, & Craig, 2010; Walter, Burke, & Davis, 2013).

4. Tests of Procedures or Methods

RTI International will conduct rigorous internal testing of the online survey instruments prior to fielding. Survey testers will review the online test version of the instrument that we will use to verify that instrument skip patterns are functioning properly, delivery of the \$5 gift card as a token of appreciation is working properly, and that all survey questions are worded correctly and are in accordance with the instrument approved by OMB.

5. Individuals Involved in Statistical Consultation and Information Collection

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

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