U.S. Food and Drug Administration
Center for Tobacco Products
Nicotine Education Project

OMB Control Number 0910-0810

SUPPORTING STATEMENT B

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe for this study is youth aged 15 to 17 years or young adults ages 18 to 24 who fall into one of the following groups based on tobacco use (uptake is of nicotine via cigarettes, e-cigarettes, and/or cigars):

- Never user, susceptible to at least one nicotine product (cigarettes, e-cigarettes and/or cigars)
    - Susceptibility is determined by the Pierce Susceptibility Scale (1995). The Pierce susceptibility scale is a 3-item scale that assesses susceptibility by asking the participant if they will try the product soon, in the next year, or if one of their best friends offered the product. If respondents answer anything other than "definitely not" to at least one of the three items, they are defined as being susceptible to that product.
- Past experience (ever, not past 30 days)
- Current user non-frequent (1-19 of past 30 days)
- Current user frequent (20-30 of past 30 days)

We aim to recruit 167 participants from each of the following groups (for a total of 2,004 participants):

Stage of uptake	**Age**		
	15-17	**18-20**	**21-24**
Never user, susceptible	167	167	167
Past experience (ever, not past 30 days)	167	167	167
Current user non-frequent (1-19 of past 30 days)	167	167	167
Current user frequent (20-30 of past 30 days)	167	167	167

We do not intend to generate nationally representative results or precise estimates of population parameters from the experimental study; generating a representative sample of the size necessary for this study, using random digital dialing or another similar method, would be cost prohibitive. The study will use convenience samples rather than probability samples. Despite the attempt to match the study's

sample and the respondent universe using age and tobacco use quotas, matching is used solely to produce a sample with a reasonable degree of diversity in key demographic characteristics.

2. Procedures for the Collection of Information

This section provides an overview of the study procedures, provides information on the degree of accuracy required for the study, and discusses the estimation procedures. There are no unusual problems requiring specialized sampling procedures.

2a. *Study Procedures*

Youth and young adults who click on the link via the social media ad will proceed to a Qualtrics survey that begins with a screener consent and screener questions. If eligible, they will proceed to an online consent form or assent form. Those eligible will be sent directly to the full online survey, which will take approximately 15 minutes to answer. At the end of the survey, participants will be thanked, given information about quitting tobacco use. Participants who complete the survey will receive a $5 Amazon gift card at the email address they provide. RTI will process the incentives by sharing the provided email addresses (via a password-protected Excel document) with the vendor Creative Group Inc.

2b. *Degree of Accuracy Required for the Study*

For the purposes of estimating statistical power, we assumed a sample size of 2,004 participants with equal allocation (n = 167) to each of six groups based on age and tobacco uptake. With an N of 2,004, we estimate being able to detect a 5.8% difference between age groups, 6.7% difference between stage of uptake groups, and a 10.9% difference between age and stage of uptake groups on key outcomes (e.g. perceived harms).

2c. Estimation Procedures

Statistical analyses will be conducted to address the study's primary research questions. Following the recommendation of the U.S. Food and Drug Administration's (FDA's) Center for Tobacco Products' (CTP's) Office of Science (Yang, 2017), analytic procedures will be based on nonparametric tests of statistical significance.

3. Methods to Maximize Response Rates and Deal with Nonresponse

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 gift card to participants who complete and submit the survey

We will use targeted advertising on Facebook and Instagram to reach the target population. As a token of appreciation, participants recruited through social media who complete and submit the survey will receive a $5 gift card. 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. Test of Procedures or Methods to be Undertaken

RTI will conduct a small pretest to test the questionnaire by conducting a set of cognitive interviews with nine participants. The questionnaire and study protocol will be revised, if necessary, based on the pretest findings. 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, and that all survey questions are worded correctly and are in accordance with the instrument approved by IRB and 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 and statistical aspects of this information collection as well as plans for data analysis:

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The following individuals outside of the agency have been consulted on questionnaire development and/or will be collecting and/or analyzing data:

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Reference

Pierce JP, Choi WS, Gilpin EA, Farkas AJ, Merritt RK. Validation of susceptibility as a predictor of which adolescents take up smoking in the United States. Health Psychol. 1996;15(5):355–361.https://doi.org/10.1037/0278-6133.15.5.355.