**OMB Control No. 0910-0810**

 **Exp. Date: 12/31/2024**

**U.S. Food and Drug Administration**

**Center for Tobacco Products**

**Increasing Understanding of Digital Advertising: Hookah Beliefs Survey**

**Generic IC Supporting Statement: Part B**

**B. Statistical Methods**

**1. Respondent Universe and Sampling Methods**

We will recruit approximately 1,500 young adult respondents (aged 18-24) living in the United States. The study is designed primarily to understand endorsement of hookah-related beliefs which will inform a future experimental digital campaign intended to shift knowledge, attitudes, and beliefs (KABs) about hookah use.

*Sampling Methods*

The study sample will be comprised of participants that are young adults ages 18 to 24 in the United States who are both non-users and users of tobacco products. This study is considered formative research for campaign development and planning; these methods are not intended to generate nationally representative samples or precise estimates of population parameters. The sampling methods are designed primarily to look at participants’ levels of endorsement with hookah-related beliefs. Respondents will be recruited across gender and racial/ethnic groups to align with U.S. demographics (please see Statement Part A Section 11).

Participants will be recruited through targeted social media advertising (e.g., Facebook and Instagram). After clicking on the advertisement, participants will be directed to the screener (Attachment 2). The online screener will take approximately 3 minutes to complete. Screener instructions note that respondents may only complete the survey 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. If individuals do not complete the screener, they will not be invited to be in the study. Individuals may decline to participate in the online screener if they wish. The social media platforms will not share any other information about their account with RTI International (RTI), the organization conducting the survey on behalf of FDA.

*Sample Size*

Based on previous similar recruitments RTI has conducted, we estimate that to obtain a final sample of 1,500 participants ages 18–24, we will need to screen approximately 5,000 potential participants.

**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***

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. Participants who complete the survey will receive a $5 token of appreciation 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.

If individuals comment on the recruitment ads we will reply using a set of predetermined responses. Any comments that reveal qualification requirements to screen into the survey as an eligible participant or have vulgar/inappropriate language will simply be deleted.

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

For the purposes of estimating statistical power, we assumed a sample size of 1,500 participants. With an N of 1,500, we estimate the margin of error for a population proportion that is 50% to be 3.6%.

#### *2c. Estimation Procedures*

Statistical analyses will be conducted to address the study’s primary research questions. We will conduct descriptive analyses to assess endorsement of hookah-related KABs that have room-to-move. We will conduct bivariate and multivariate analyses to understand differences in mean levels of beliefs among tobacco users and non-users. Following the recommendation of the U.S. Food and Drug Administration’s (FDA’s) Center for Tobacco Products’ (CTP’s) Office of Science, analytic procedures will be based on nonparametric tests of statistical significance.

#### 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 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 Amazonto participants who complete and submit the survey, and
3. Complete survey programming testing and a soft launch to monitor for possible technical difficulties with the survey to minimize potential dropout rates due to user issues.

We will use targeted advertising on social media (e.g., Facebook and Instagram). We estimate that the survey will take 15 minutes to complete, which we intentionally aimed for to keep the survey at a reasonable length to minimize non-completion. As a token of appreciation, eligible participants (determined by completing the screener) 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.

**4**. **Tests of Procedures or Methods**

RTI will conduct 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. Based on skip pattern testing and instrument length, some items may be excluded. Survey testing will aid survey clarity (e.g., address typos and decrease confusing wording) and will ensure that all survey questions are in accordance with the instruments approved by OMB and IRB.

**5. Individuals Involved in Statistical Consultation and Information Collection and/or Analyzing Data**

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

Elizabeth Petrun Sayers

Office of Health Communication & Education

Center for Tobacco Products

Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: 240-750-5297

E-mail: Elizabeth.Petrun@fda.hhs.gov

Alexandra Budenz

Office of Health Communication & Education

Center for Tobacco Products

Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: 202-423-8075

E-mail: Alexandra.Budenz@fda.hhs.gov

Lindsay Pitzer

Office of Health Communication & Education

Center for Tobacco Products

Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: 240-620-9526

E-mail: lindsay.pitzer@fda.hhs.gov

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

Matthew Farrelly

RTI International

3040 Cornwallis Road

Research Triangle Park, NC 27709

Phone: 919-541-6852

E-mail: mcf@rti.org

Kim Hayes

RTI International

3040 Cornwallis Road

Research Triangle Park, NC 27709

Phone: 919-541-1215

E-mail: khayes@rti.org

Jessica Sobolewski

RTI International

3040 Cornwallis Road

Research Triangle Park, NC 27709

Phone: 919-541-6657

Email: [jsobolewski@rti.org](file:///%5C%5Cfda.gov%5CWODC%5CCTP_Sandbox%5COR%5CPRA%5CPRA%20Collections%5C0910-0810%20Quantitative%20Generic%5C2021-2024%20Studies%5CHookah%20Beliefs%5C2.%20CTP%20feedback%20080222%5Cjsobolewski%40rti.org)

Jamie Guillory

Prime Affect Research, Ltd

64 Dame Street

Dublin D02RTY72, Ireland

Phone: 919-695-9264

Email: jamieguillory.contractor@rti.org

Vaughn Armbrister

RTI International

3040 Cornwallis Road

Research Triangle Park, NC 27709

Phone: 919-248-8521

Email: [aarmbrister@rti.org](file:///%5C%5Cfda.gov%5CWODC%5CCTP_Sandbox%5COR%5CPRA%5CPRA%20Collections%5C0910-0810%20Quantitative%20Generic%5C2021-2024%20Studies%5CHookah%20Beliefs%5C2.%20CTP%20feedback%20080222%5Caarmbrister%40rti.org)