OMB 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 A

- The purpose of the Digital Advertising Study is to assess current knowledge, attitudes, and beliefs (KABs) about hookah use and identify KABs that could be targeted in a digital campaign. We will focus on these two target audiences: (1) young adults 18 to 20 in the United States who are both non-users and users of tobacco products and (2) young adults ages 21 to 24 years in the United States who are non-users and users of tobacco products.

- RTI International (RTI) will conduct an online survey with young adults in the United States recruited through social media (e.g., Facebook and Instagram). The Digital Advertising Study will measure perceived harms of hookah use, perceived benefits of hookah use, reasons for hookah use, and socio-demographics. Once approvals are received, we will begin data collection for a national, online, self-administered survey of approximately 1,500 young adults aged 18-24.

- The results of the Digital Advertising Study will be used to support the development of a future experimental digital campaign intended to shift KABs about hookah use.

- Results of the survey will help the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) better understand:
    - The level of agreement with hookah-related beliefs among young adults ages 18-24 years old in the United States, and
    - Whether hookah-related beliefs are likely to change as a result of exposure to a future digital media campaign among young adults ages 18-24 years old in the United States.

- **REQUESTED APPROVAL DATE: 1/15/2023**

Study Materials (attached):
Attachment A: Screener and Survey
Attachment B: Digital Survey Recruitment Ads
Attachment C: Digital Survey Recruitment Ads FAQ
Attachment D: Informed Consent

Generic IC Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This information collection is proposing to inform recommendations around the FDA's public education programs' impact and effectiveness in reducing tobacco-related death and disease. More research is needed to understand the potential for digital anti-tobacco advertising to influence tobacco-related beliefs. Digital marketing has clear value in the commercial space; advertising research on thousands of online advertising campaigns shows that digital advertising drives brand and ad awareness and positive attitudes toward brands (Twose & Elmore, 2015). However, there is still much to be learned about the use of digital advertising for public education campaigns, such as those discouraging tobacco use. Digital media metrics can reveal a lot about consumer experiences in aggregate: how often consumers were exposed to a video, how much of the video they watched, whether they shared it with their friends, and whether they reacted positively or negatively. We have used some of these metrics to develop a better understanding of the relative effectiveness of digital and broadcast advertising in generating ad/campaign awareness in the context of FDA CTP campaigns (described in detail in Section 2). However, many questions remain that can only be addressed in experimental studies or prospectively with campaign implementation approaches that have sufficient flexibility to manipulate media buying.

2. Purpose and Use of the Information

RTI International (RTI) will conduct a national, online, self-administered survey with young adults in the United States recruited through social media (e.g., Facebook and Instagram) to assess agreement with specific beliefs about hookah. We will survey approximately 1,500 young adults ages 18 to 24. The primary purposes of the survey are to:

- Characterize current KABs about hookah use; and
- Identify KABs that could be targeted in a digital campaign.

The results of the Digital Advertising Study will be used to inform development of new campaign messages for a future experiment to test if digital advertising can influence young adults' beliefs about hookah use.

3. Use of Information Technology and Burden Reduction

This study will rely on web-based survey data collection to collect primary data to understand young adults' KABs related to hookah use. Using an online survey allows the respondent to be candid with their responses. This increases accuracy of the data because respondents provide more honest responses than when other types of data collection methods are employed. In addition, using an online survey is more cost-effective than in-person, mail, or telephone surveys and will allow for more participants to respond in a timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., coding and data entry). Data are transmitted electronically, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. An added benefit is increased data protection by limiting the amount of personally identifiable information (PII) collected from participants, reducing the risk of data security issues. Finally, as noted above, this technology permits respondents to complete the survey in privacy. The use of a more private data collection method makes reporting potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

In designing the proposed data collection activities, we took several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. We carefully reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on beliefs about various tobacco products. We reviewed data collected to evaluate other national tobacco-focused media campaigns such as CDC's Tips From Former Smokers® campaign and FDA's The Real Cost. We also examined ongoing national surveillance systems such as the National Youth Tobacco Survey (NYTS), the Youth Risk Behavior Surveillance System (YRBSS), the National Health Interview Survey (NHIS), and the Population Assessment of Tobacco and Health (PATH) to see if they included survey items that would address our research questions. Although these data sources measure tobacco use and beliefs, they do not include the full range of measures or utilize a study design that would allow us to determine the association that may exist between beliefs about tobacco products and intentions to use tobacco products, which is necessary to inform a future experimental digital campaign intended to shift KABs about hookah use

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations, or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

This is a one-time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

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

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FDA collaborates with other agencies that sponsor or endorse health communication projects. These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

The following individuals outside of the agency have been consulted on questionnaire development.

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9. Explanation of Any Payment or Gift to Respondents

As a token of appreciation, participants who complete the survey and are deemed non-fraudulent or non-duplicate will receive a $5 token of appreciation. This token of appreciation amount reflects the burden of spending an average of 15 minutes taking the survey. There is no incentive for completing the web screener.

A token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. The token of appreciation must be high enough to equalize the burden placed on participants with respect to their time and cost of participation. Too low of an amount may result in a difficult and lengthy recruitment process and/or respondents who agree to participate and then drop out early. Empirical studies show that incentives can increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys within some respondent populations (Singer & Ye, 2013; LeClere et al., 2012; Cantor et al., 2003; Singer, 2002; Singer et al., 1998) Several studies have shown the effects of incentives within the context of a web-based survey. For example, a 2006 meta-analysis of 32 studies indicates that incentives increase the odds that potential respondents will begin a web survey, and a second meta-analysis of 26 studies shows that incentives increase the odds of completing a web survey once respondents have begun it (Goritz, 2006).

A reasonable token of appreciation is standard practice for research and is suggested by organizations that set the standards for conducting ethical industry-led research among human subjects (Code of Ethics and Standards for Market Research and Data Analytics, 2021) (Insights Association (2021)

A previous "Promising Themes" study (OMB control number 0910-0810) of a similar length took 13 weeks to recruit 2,622 youth and young adults of a targeted 3,000 completes with while offering a $5 token of appreciation. Studies with that focused on similar products and participants, such as the Monthly Monitoring Studies (OMB control number 0910-0810) and had success recruiting 1,501 participants when a $5 token of appreciation was offered.

10. <u>Assurance of Confidentiality Provided to Respondents</u>

OMB Control Number 0910-0810 is covered underneath a Privacy Impact Assessment that has been approved by the Department of Health and Human Services (PIA Unique Identifier: P-9008729-198376).

<u>PII Collection</u>

As part of this study, RTI International, the contractor acting on behalf of FDA, is collecting and maintaining personally identifiable information (PII) about participants who complete the online screener and the online survey. The only PII RTI will be collecting is email address, IP address, zip code, and birthdate; each of these pieces of information will be stored separately from one another and from survey responses (except for 48 hours after download while the fraud detection procedures are completed). We are not collecting any Protected Health Information, defined as "Personally identifiable information that relates to a person's health, medical treatment or payment, and which was obtained from a "covered entity" (health care provider, health plan, or healthcare clearinghouse), as defined by HIPAA (Health Insurance Portability and Accountability Act) regulations." Survey data will be kept separate from PII and/or stored on the Federal Information Processing Standards (FIPS) 199 except for the 48-hour period after download when the combined dataset is stored temporarily on the study share drive so that the fraud detection procedures can be conducted.

This study is funded by the FDA, a Department of Health and Human Services supported agency, and is covered by a Certificate of Confidentiality (CoC). The study involves Human Subjects as defined by 45 CFR Part 46.

Data management procedures will be carried out so that personally identifiable information is stripped from individual records so it is not possible to disclose individual identities and experiences. No respondent identifiers will be contained in reports to FDA, results will only be presented in aggregate form, and all data will be deidentified before delivery to FDA. Any data made available for public use will undergo additional scrutiny to remove small cell sizes with data, or combinations of data, that could be used to deduce the identity of participants.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, web-based data collection system. Approximately 1,500 participants will be recruited via social media. All participants will be screened for eligibility prior to administration of the survey instrument. The screener is designed not to reveal specifically why a respondent is ineligible. All respondents, regardless of age, gender, race/ethnicity, tobacco use behavior, and residence will complete the full screener. Respondents must complete all screener questions to find out whether they can move on to the survey. To recruit for the survey, RTI will place ads on social media (e.g., Facebook and Instagram). As much as possible, these ads will target potentially eligible respondents who are thought to be age 18-24.

Each participant will answer items about their hookah use behavior, hookah-related KABs, and demographic information. Participants will complete the survey at the time of their choosing. There is no website content directed at children younger than 13 years of age.

Data management procedures will be carried out so that personally identifiable information is stripped from individual records so it is not possible to disclose individual identities and experiences. No respondent identifiers will be contained in reports to FDA, results will only be presented in aggregate form, and all data will be deidentified before delivery to FDA. Any data made available for public use will undergo additional scrutiny to remove small cell sizes with data, or combinations of data, that could be used to deduce the identity of participants.

Overview of How Information will be Shared and for What Purposes

All data will be downloaded from Qualtrics (which requires a password) and stored in databases only on RTI's Federal Information Processing Standards (FIPS) 199 moderate network, which is only accessible by RTI study staff trained in human subjects. At the completion of data collection, the data will be deleted from RTI's Qualtrics account and remain only on RTI's FIPS 199 moderate network.

Overview of the Impact the Proposed Collection will have on the Respondent's Privacy

The following procedures will be used to ensure participant privacy before, during, and after fielding: (1) PII in the form of participants' IP address, email address, zip code, and birthdate will be stored separately from screening-related data and survey data, and IP and email addresses, zip code, and birthdate will be deleted after study completion; (2) datasets of screener and survey responses and reports will not contain any PII; and (3) respondents' information will not be tied to their individual responses and all analyses will be conducted in the aggregate (i.e., any data used in reporting will not be attributed to individual participants). All datasets and reports delivered to FDA will not include PII.

RTI will collect email addresses for the purposes of distributing the token of appreciation and birthdate to confirm age. IP addresses will be collected to verify participants are taking the survey from within the United States. No additional personal identifiers (e.g., full name, phone number, social security number) will be collected aside from basic demographic information (e.g., gender, age, and race). PII will be stored separately from any survey responses.

Overview of Voluntary Participation

Potential participants will be advised of the nature of the survey, the length of time it will require, and that participation is voluntary. Participants will be assured that they will incur no penalties if they wish not to respond to the data collection as a whole or to any specific questions. Participants will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Survey respondents will have the option to only answer the items that they select to answer. They may end the end a survey at their discretion. We will take every measure to ensure that respondents are aware of their choices and provide consent to participate. Before requesting any information from participants, RTI will provide information about data security and ways to request data removal from RTI databases. RTI will also inform participants that they can select "prefer not to answer" to any question and will recommend that participants complete the survey where no one can see their answers. RTI will provide study information through informed consent and conclude the survey immediately for participants who state that they do not want to take the survey after reading the study information.

Overview of Data Security

Data security procedures are of the highest standard and actively implemented to ensure data are used as intended. Data will be collected through a web-based survey hosted on Qualtrics for the social media recruitment. Qualtrics is used widely for statistical and scientific research and is secure. To date, no known breaches of data in this platform have occurred in RTI studies.

The social media recruitment will be hosted on Qualtrics' secured servers. RTI will use a unique alphanumeric variable (i.e., Case ID) to connect screener data (that contain Personally Identifiable Information (PII)) and survey data (that do not contain PII) and to determine if a participant has completed the survey. Screener data and survey data will be stored separately on Qualtrics servers and encrypted. RTI will use a Secure Sockets Layer (SSL) connection to download data from Qualtrics servers to RTI servers. RTI servers are restricted, requiring credentials to access. Each project team is granted as-needed access only to the projects they are assigned and only RTI project team staff who need access to the data (for programming, sampling, recruitment, or analysis) will be granted access within project folders. FDA will not have access to survey data files during data collection. Data files containing PII will be stored on the FIPS 199 moderate server for five years after the project has ended.

E-mail addresses, zip code, and birthdate will each be collected separately in the Qualtrics survey platform and stored in separate isolated datasets that will contain an RTI-assigned unique ID. IP address will be collected in the survey platform in an isolated dataset that contains IP address, RTI-assigned unique ID, and screener responses. 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, zip code, and birthdate will not be collected in the same file.

All survey data files (i.e., separate files for IP address, e-mail, zip code, birthdate, and screener/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 48 hours after download. RTI study staff will be given as-needed access to the data files on the share during that 48-hour period to conduct fraud detection procedures, at which point data from the individual will be combined to check for fraudulent responses.

At the end of data collection, a member of the RTI project staff will export the data from the survey and out of the FIPS 199 moderate network, 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.

11. Justification for Sensitive Questions

Most questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be of a sensitive nature in order to assess tobacco use among respondents under 21 years old (the minimum age for legal purchase of tobacco products). These questions are essential to the objectives of this data collection. Although we do not anticipate any risks from these health questions, some participants may perceive them to be sensitive. Questions about lifestyle (e.g., tobacco product use) and some demographic information, such as race and ethnicity and gender identity and sexual orientation, could also be considered sensitive, but not highly sensitive. Collection of these data is necessary in order to assess disparities in tobacco use and possible differences in campaign impact across different populations.

Decades of research has shown significant disparities in tobacco use by race/ethnicity (e.g., Harlow et al., 2019; Odani et al, 2018), gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019), and sexual orientation (e.g., Johnson et al, 2019; McCabe et al., 2018). Therefore, collecting detailed information on these demographic characteristics will allow us to measure these differences with the goal of reducing these disparities.

The questions asking about race and ethnicity are modeled after the 2020 U.S. Census which includes country of origin/national background when asking about Hispanic/Latino ethnicity. We are including the top3 countries of origin based on the 2020 U.S. Census data. This level of detail is necessary as data shows disparities in tobacco use and susceptibility depending on Hispanic/Latino country of origin (Slobig, 2014; Kaplan et al., 2014; Parrinello et al., 2015; Bandiera et al., 2015). It is important for CTP to capture this information to better understand Hispanic/Latino tobacco use and prevention.

As multiple studies of youth and young adults have reported approximately 12-15% of the sample identified as gender non-conforming/non-binary (e.g., The Human Rights Campaign 2018 LGBTQ+ Youth Report; The Trevor Project 2020 National Survey on LGBT Youth Mental Health; CTP's evaluation of This Free Life campaign), including gender non-conforming/non-binary response options is necessary to identify and assess tobacco use and campaign effectiveness among this population. Along with the extensive and increasing body of literature showing tobacco use disparities among LGBTQ+ populations, the White House issued the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals which includes obligations for federal agencies to collect SOGI data. The order states that, "advancing equity and full inclusion for LGBTQI+ individuals requires that the Federal Government use evidence and data to measure and address the disparities that LGBTQI+ individuals, families, and households face." It also states that federal agencies must "describe disparities faced by LGBTQI+ individuals that could be better understood through Federal statistics and data collection" (White House, 2022). Gender identity questions with gender queer/gender non-conforming/non-binary response options have been approved by OMB for ExPECTT (0910-0753), and for RESPECT (0910-0808), and Formative Research Support: Outcomes and Awareness Measurement Research (0910-0810).

To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. This study includes several procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer;
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses; and
- Participants will be provided with an email address to contact should they have any questions or concerns about the study.

Survey respondents will have the option to only answer the items that they select to answer. They may end the end a survey at their discretion. We will take every measure to ensure that respondents are aware of their choices and provide assent or consent to participate.

Before requesting any information from participants, RTI will provide information about data security and ways to request data removal from RTI databases. RTI will also inform participants that they can select "prefer not to answer" to any question and will recommend that participants complete the survey where no one can see their answers. RTI will provide study information through informed consent and conclude the survey immediately for participants who state that they do not want to take the survey after reading the study information. The project team will not conduct or report on statistical analysis for demographic groups for which there is insufficient statistical power.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 700 hours annually (Table 1). This includes the time burden associated with the screener and informed consent. We will obtain a final sample size of 1,500 young adults aged 18-24.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Young Adult aged 18-24	Recruiting and Screening	5,000	1	5,000	0.05 (3 minutes)	**250**
Young Adult aged 18-24	Consent	1,500	1	1,500	0.05 (3 minutes)	**75**
Young Adult aged 18-24	Online Survey	1,500	1	1,500	.25 (15 minutes)	**375**
Total Annualized Hours						**700**

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. RTI has conducted many tobacco-related surveys of similar length among young adults. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 6 minutes per respondent for screening and informed consent, and approximately 15 minutes per respondent for the online survey.

To calculate the estimated annual cost, we used the mean hourly wage $28.01 from the U.S. Department of Labor Bureau of Labor Statistics (May 2021 data). There are no direct costs to respondents associated with participation in this information collection. RTI has conducted many tobacco-related surveys of similar length among young adults. We have examined diagnostic data from each of these prior surveys and estimate that data collection for this study will take, on average, 6 minutes per respondent for screening and informed consent and 15 minutes per respondent for the online survey. Thus, assuming an average hourly wage of $28.01, the estimated one-year cost to participants will be $19,608. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost[1]
Young adult aged 18–24	Recruiting and Screening	250	$28.01	$7,003
	Consent	75	$28.01	$2,101
	Online Survey	375	$28.01	$10,504
Total				**$19,608**

[1] Cost was rounded up to the next dollar.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this data collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this study is $73,523 as shown in Table 3. Contractor costs attributable to this information collection are $42,545. This includes costs to program the survey, recruit the sample, and collect the data. Other contractor activities outside this data collection estimate include coordination with FDA to develop the instrument and deliver the final data set and reporting deliverables.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total[1]
GS-13	15%	$135,308	$20,296
GS-13	10%	$106,823	$10,682
Total salary costs			$30,978
Contractor costs			$42,545
Total			**$73,523**

[1] Cost was rounded up to the next dollar.

15. Explanation for Program Changes or Adjustments

This section in not applicable as this is a new study under the generic data collection package.

16. Plans for Reporting and Project Time Schedule

Data from this information collection will be used to enable the FDA to identify, monitor, assess, or investigate attitudes about hookah use. This activity will allow the FDA to set priorities and raise situational awareness because hookah and the use of other tobacco products are a threat to public health. These data will allow us to identify hookah-related beliefs that may be effectively targeted by tobacco campaigns, so that the FDA can test digital media campaign messages related to hookah that resonate with young adults ages 18 to 24 years old in the United States. Findings from these analyses will be used to inform future experiments to test the potential for digital advertising to influence tobacco-related beliefs.

Reporting

At the end of the study, a draft report and a final report containing background information on the project objectives, scope, methodology, key findings, and conclusions will be completed. The approximate dates for completing project tasks are listed in Table 4.

Table 4. Approximate Project Schedule

Project Activity	Date
Survey	Approximately 6 weeks after OMB approval
Preparation of analytic data file	Approximately 1–2 weeks after completion of data collection
Data Analysis	Approximately 3–5 weeks after completion of data collection
Report Writing	Approximately 6-8 weeks after completion of data collection

16. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.

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