Promising Themes Studies
Supporting Statement: Part A

- The purpose of the Promising Themes Studies is to assess agreement with specific beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco. We will focus on these two target audiences: (1) youth ages 15 to 17 in the United States who are both non-users and users of tobacco products and (2) young adults ages 18 to 24 years in the United States who are both non-users and users of tobacco products.

- RTI will conduct online surveys with youth and young adults in the United States recruited through social media (i.e., Facebook, Instagram). The Promising Themes Studies will measure the existing level of agreement with belief statements to understand their potential as targets for public education. We will also look at the association between beliefs and tobacco product use and between beliefs and intentions to use tobacco products. The surveys will focus on one or more of the following products: 1. E-cigarettes, 2. Cigarettes, 3. Little cigars (aka filtered cigars), cigars, and cigarillos (LCCs), and 4. Smokeless tobacco. Once approvals are received, we will begin data collection for a national, online self-administered social media survey of approximately 6,000 youth, ages 15-17, and young adults ages 18-24 per year. The survey will be repeated with a new cross-sectional sample up to two times a year over a period of 12 months.

- 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.

- Results of the survey will help CTP better understand-

    - the level of agreement with tobacco-related beliefs in youth and young adults ages 15-24 years old in the United States.
    - if tobacco-related beliefs are associated with behavior, intention to engage in a specific behavior, or other predictors of future behavior among youth and young adults ages 15-24 years old in the United States.
    - if tobacco-related beliefs are likely to change as a result of exposure to advertising or a media campaign among youth and young adults ages 15-24 years old in the United States.

- **REQUESTED APPROVAL DATE: 12/11/2020**

Study Materials (attached):

Attachment 1: Screener
Attachment 2: Survey
Attachment 3: Youth Assent
Attachment 4: Adult Consent
IRB Letter

Promising Themes Studies
Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

In support of the U.S. Food and Drug Administration's (FDA) efforts to refresh campaign messaging, the Center for Tobacco Products (CTP) will conduct a quantitative study to inform the development of appropriate messaging for FDA's The Real Cost campaign. In 2019, 53.3% of high school students and 24.3% of middle school students reported trying a tobacco product (Wang et al., 2019). Approximately 27.5% high school students reported vaping and 31.2 % reported use of any tobacco product in the past 30 days (Wang et al., 2019). Smokeless tobacco use has remained constant with a slight increase in prevalence since the early 2000s (Chang et al., 2018). In 2012, approximately 7.1% of adult males in the United States were smokeless tobacco users (Chang et al., 2018). As a way to reduce the enormous public health burden of tobacco, the Family Smoking Prevention and Tobacco Control Act has given the FDA the authority to take action to protect children, encourage smokers to quit, and reduce tobacco-related disease and death. The law also enables FDA to educate the public, especially young people, about the dangers of tobacco products. Research shows that public education mass media campaigns can be used to change attitudes and beliefs about tobacco use and reduce smoking prevalence. In fact, the Centers for Disease Control and Prevention (CDC) considers mass media campaigns to be a "best practice" for tobacco control.

In an effort to inform specified recommendations around FDA's public education programs' impact and effectiveness in reducing tobacco-related death and disease, more research is needed 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 young adults ages 15 to 24 years old in the United States. The purpose of the Promising Themes Studies is to collect primary data to assess agreement with specific beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco.

The studies will be conducted using web-based surveys that are self-administered on personal computers or web enabled mobile devices. Over a one-year period, the study will use two online surveys to survey up to 6,000 youth and young adults ages 15 to 24 years to measure their existing level of agreement with belief statements to understand their potential as targets for public education. The surveys will focus on one or more of the following products: 1. E-cigarettes, 2. Cigarettes, 3. Little cigars (aka filtered cigars), cigars, and cigarillos (LCCs), and 4. Smokeless tobacco. The surveys will take approximately 20 minutes to complete per participant. The surveys will ask participants to provide feedback on their tobacco product beliefs and use.

2. Purpose and Use of the Information

RTI will conduct online surveys with youth and young adults in the United States recruited through social media (i.e., Facebook, Instagram) to assess agreement with specific beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco. As soon as approvals are received, we will begin data collection for two national, online self-administered social media surveys. We will survey approximately 6,000 youth and young adults ages 15 to 24. The two surveys will be conducted over the course of one year with a new cross-sectional sample for each survey. We will recruit up to 1,500 respondents for each survey with no more than 6,000 total respondents. Respondents will be allowed to complete additional cross-sectional surveys after 6 months.

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.

The studies aim to answer the following questions:

- What is the level of agreement with tobacco-related beliefs?
- Are tobacco-related beliefs associated with behavior, intention to engage in a specific behavior, or other predictors of future behavior?
- Are tobacco-related beliefs likely to change as a result of exposure to advertising or a media campaign?

3. Use of Information Technology and Burden Reduction

This study will rely on web-based survey data collection to collect primary data to access youth and adult beliefs and intentions to use tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco. 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, especially when it is clear that the answers will remain private. In addition, using a survey will allow for more participants to respond in a cost-effective and timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including 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

With so many tobacco products on the market, it is important to develop messages that incorporate tobacco products currently being used by at-risk populations in order to be salient and have the best chance of affecting change in tobacco use. 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. Data sources we examined for this purpose include 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). We also 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 concluded that these data sources do not include the measures, and frequency of data collection, needed to assess agreement with specific beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco as well as consumer intentions to use those tobacco products. Although the other data sources measure youth and adult tobacco use and beliefs, they do not include the full range of measures that would allow us to determine the association that may exist between beliefs and tobacco product use and between beliefs and intentions to use tobacco products, which is necessary to inform the FDA's campaign development.

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

Respondents to this data collection will answer only once in a six-month period to ensure the participant burden is as low as possible. Without the data collection requested for this study, it would be difficult to understand the association between consumer beliefs and intention to use tobacco products and assess the types of effective messages for use in upcoming tobacco prevention campaigns. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for youth in the United States.

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). The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

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 proposed messages for advertisements;
- 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 recruited through social media who complete and submit the survey will receive a $5 digital Amazon gift card. We estimate that the surveys will take about 20 minutes to complete. A respondent who completes any survey will not be allowed to complete additional surveys for a period of six-months. This incentive amount reflects the burden of spending an average of 20 minutes taking the survey. There is no incentive for completing the web screener. Participants will be informed that they will receive their incentive within 5-7 business days of completing the survey. As participants often have competing demands for their time, a token of appreciation for participation in a study 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).

10. Assurance of Confidentiality Provided to Respondents

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).

PII Collection

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 surveys. The only PII we will be collecting is email address, IP address, and birthdate, but this information will be stored separately from each other and from survey responses (except for 24 hours after download when 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 24-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 does involve Human Subjects as defined by 45 CFR Part 46.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, online, web-based data collection system. Approximately 6,000 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 to not reveal specifically why a respondent is not eligible. 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 one of the surveys. To recruit for the surveys, RTI will place ads on Facebook and Instagram. As much as possible, these ads will target potentially eligible respondents who are thought to be age 15-24 and are non-users, ever users, non-susceptible or susceptible to tobacco use.

Each participant will give feedback on their tobacco use status, followed by a series of questions about their knowledge, attitudes, and behaviors in regard to specific tobacco products, and complete the survey by answering basic demographic information. The participant will complete the survey at the time of his or her choosing. There is no website content directed at children younger than 13 years of age.

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 secure shared drive and/or Federal Information Processing Standards (FIPS) 199, which are only accessible by study staff trained in human subjects. At the completion of data collection, the databases will be deleted from our Qualtrics account and remain only on RTI's secure shared drive and Federal Information Processing Standards (FIPS) 199.

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' email addresses and birthdate will be stored separately from screening-related data and survey data, and email addresses and birthdate will be deleted after survey completion; (2) datasets 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.

PII will be collected in the form of email addresses for the purposes of distributing the incentive and birthdate to confirm age. 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.

Overview of Data Security

E-mail addresses and birthdate will each be collected separately in the Qualtrics survey platform and stored in separate isolated surveys that will contain a RTI-assigned unique ID and email address or birthdate. IP address will be collected in the survey platform in an isolated survey 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, and birthdate will not be collected in the same file.

All survey data files (IP address, e-mail, birthdate, 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.

At the end of data collection, a member of the project staff will export the data from the survey and out of the Federal Information Processing Standards (FIPS) 199, 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. <u>Justification for Sensitive Questions</u>

The majority of questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors such as tobacco product use in respondents under 18 years old. 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 messages concerning lifestyle (e.g., tobacco product use) and some demographic information, such as race and ethnicity could also be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, participants will be fully informed of the applicable privacy safeguards. The informed consent protocol will notify the parents and the participants that these topics will be covered in the survey. This study includes a number of 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 a phone number and email address for the Principal Investigator should they have any questions or concerns about the study.

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 3,200 hours annually (Table 1). This includes the time burden associated with the screener and informed consent. We will obtain a final sample size of 6,000 youth and young adults. Data collection will be split among two surveys. We will survey approximately 1,500 youth ages 15-17 and 1,500 young adults ages 18-24 for each of the two surveys over 12 months to assess agreement with specific beliefs about various tobacco products including e-cigarettes, cigarettes, little cigars, cigars, cigarillos (LCCs), and smokeless tobacco. Respondents will be allowed to complete additional, cross-sectional surveys after 6 months. We will need to screen approximately 20,000 potential participants per year for the two surveys.

Table 1. Estimated Annual Reporting Burden[1]

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours[1]
Screening						
Youth aged 15–17	Youth Recruiting and Screening	10,000	1	10,000	0.05 (3 minutes)	**500**
Young Adult aged 18-24	Adult Recruiting and Screening	10,000	1	10,000	0.05 (3 minutes)	**500**
Informed Consent						
Youth aged 15–17	Youth Assent	3,000	1	3,000	0.03 (2 minutes)	**100**
Young Adult aged 18-24	Adult Consent	3,000	1	3,000	0.03 (2 minutes)	**100**
Survey						
Youth aged 15–17	Online Survey	3,000	1	3,000	0.33 (20 minutes)	**1,000**
Young Adult aged 18-24	Online Survey	3,000	1	3,000	0.33 (20 minutes)	**1,000**
Total Annualized Hours						**3,200**

[1] One-time burden

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 smoking-related surveys of similar length among youth and young adults. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 5 minutes per respondent for screening and informed consent, and approximately 20 minutes per respondent for the online surveys.

To calculate the estimate annual cost, the mean hourly wage of $7.25 was used for youth and $26.95 was used for young adults. The youth price represents the minimum wage, and the young adult costs represent the mean hourly wage for other occupation earnings from the U.S. Department of Labor Bureau of Labor Statistics (May 2020 data). There are no direct costs to

respondents associated with participation in this information collection. RTI has conducted many smoking-related surveys of similar length among youth and 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, between 5 minutes per respondent for screening and informed consent, and 20 minutes per respondent for the online surveys. Thus, assuming an average hourly wage of $7.25 and $26.95 (youth and adult), the estimated one-year cost to participants will be $54,720. 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]
Youth aged 15–17	Youth Recruiting and Screening	500	$7.25	$3,625
	Youth Assent	100	$7.25	$725
	Online Survey	1,000	$7.25	$7,250
Young Adult aged 18-24	Adult Recruiting and Screening	500	$26.95	$13,475
	Adult Consent	100	$26.95	$2,695
	Adult Survey	1,000	$26.95	$26,950
Total				$54,720

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

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

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

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with RTI. The total estimated costs attributable to this data collection are $338,414 (Table 3). There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, instrument development, reporting, RTI IRB, project management and progress reporting. This information collection will occur from 2020 through 2022.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total[1]
GS-12	5%	$86,335	$4,317
GS-13	10%	$102,663	$10,266
GS-13	10%	$102,663	$10,266
		Total Annual Salary Costs	$24,849
		Contract Cost	$313,565
		Total	**$338,414**

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

15. Explanation for Program Changes or Adjustments

This is a new individual generic data collection.

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 vaping and other tobacco product use. This activity will allow the FDA to set priorities and raise situational awareness because vaping and the use of other tobacco products are a threat to public health. These data will allow us to track and determine trends in tobacco brand and device choices so that the FDA can develop new media campaign messages related to tobacco and vaping products that resonate with youth and young adults ages 15 to 24 years old in the United States. Findings from these analyses will be used to inform FDA CTP health communication strategy and messaging.

Reporting

Reporting will consist of quarterly summaries of key results and findings. At the end of the study, a draft report and a final report containing background information on the project objectives, scope and methodology, and 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	September 2020 to September 2022 (Approximate)
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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