U.S. Food and Drug Administration
Center for Tobacco Products
Testing Message Evaluation Measures Using Youth-focused Vaping Prevention Messages
OMB Control # 0910-0810

Supporting Statement: Part A

Supporting Statement: Summary

- This study will use an online survey to determine valid measures to use in evaluating youth-targeted anti-tobacco messaging. The results of this study can be used to inform the selection of optimal message evaluation measures for evaluating the relative potential effectiveness of campaign messages prior to campaign launch.
- The study will be conducted using a web-based survey that is self-administered by participants using their personal computer. Participants will consist of approximately 2,400 youth who are 13-17 years old, and who have experimented with vaping or who are at risk of vaping. The study will take approximately 15 minutes for each participant to complete.
- Respondents will answer questions about tobacco use, watch four 15- or 30-second anti-tobacco videos, and answer questions about their beliefs, behavioral intentions, and reactions to the messages. Survey questions will also collect information about respondents' demographics.
- The resulting data will be analyzed using descriptive and inferential statistics to describe the sample and answer the study research questions.

Consent Forms

- Appendix A: Parent Permission Form
- Appendix B: Youth Assent Form

Data Collection Instruments

- Appendix C: Study Screener and Survey Instrument

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

FDA develops and implements multi-strategy youth-targeted public education campaigns to reduce the public health burden of tobacco that will consist of general market paid media campaigns, geo-targeted campaigns to reach specific target audiences, community outreach activities, and a comprehensive social media effort.

To inform these efforts, CTP is interested in identifying valid measures of message effectiveness that can help guide the selection of messages to include in tobacco education campaigns such as the Real Cost tobacco prevention campaign. There is currently a lack of consensus in the literature as to which message evaluation (ME) measures are most strongly associated with actual message effectiveness (AME). Thus, the purpose of this task is to identify valid measures and methods of evaluating messages for use in future formative research and message testing.

2. Purpose and Use of the Information

The FDA has contracted with RTI International (RTI) to conduct a message testing study among youth ages 13-17 to examine whether key ME measures (e.g., perceived message effectiveness, reactance in response to messages, perceived argument strength) often used in formative research demonstrate criterion validity by investigating the strength of their relationship with outcomes of message exposure, such as beliefs and behavioral intentions. We will also aim to compare ME measures on the strength of their association with AME and to examine whether the relationship between ME measures and message outcomes varies depending on characteristics of the vaping prevention messages and user groups.

The information obtained from the proposed data collection activities will be used to inform social/behavioral scientists in FDA's Center for Tobacco Products and other health communication professionals of optimal ME measures for evaluating the relative potential effectiveness of campaign messages. This study aims to address the following research questions:

- RQ1: To what extent are aggregate ME scores predictive of AME?
- RQ2: To what extent does the strength of the ME-AME association vary across different ME measures?
- RQ3: Which measures, when used together, are more predictive of AME than as independent predictors (examining incremental validity)?

- RQ4: To what extent does the relationship between ME and AME vary by message characteristic?
- RQ5: To what extent does the relationship between ME and AME vary by participant characteristics (e.g., user group, demographics)?

3. Use of Information Technology and Burden Reduction

This study will rely on web-based survey data collection for all respondents to evaluate anti-tobacco messaging among youth ages 13-17 who have either experimented with vaping or are at risk of initiating vaping. Using an anonymous, fillable survey allows the respondent to be more candid with their responses. This allows for more accurate data because respondents provide more honest responses than other types of research methodology, especially since it is clear that the answers will remain confidential. In addition, using a survey will allow for more participates 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 at the end of the day, 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. Finally, this technology permits respondents to complete the interview in privacy. Providing the respondent with a methodology that improves privacy makes reporting of 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 order to ensure no duplication of efforts, we have reviewed relevant literature and existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's objectives for this data collection. Through this review, a variety of ME measures used to predict AME were identified. These measures have been used to evaluate health messages in terms of perceptions of message effectiveness, argument strength, and credibility; emotional reactions; cognitive elaboration; as well as other reactions. We also collected information about methodological approaches used in studies that provide some evidence of the predictive validity of ME measures. The findings from the literature were useful for informing the selection of ME measures to include in this message testing study.

The literature review also highlighted several gaps in the literature on ME measures. First, research assessing the validity of ME measures has largely relied on individual correlations between ME and AME. Individual ME-AME correlations provide information about whether individuals' ME scores predict their AME scores. However, for message-pretesting purposes, we want to know whether a message's relative standing on ME is predictive of its relative standing on AME (O'Keefe, 2020). Some research has started to address this gap by aggregating ME scores so they are no longer individual-level scores. However, the research that has aggregated ME scores has generally created campaign-level rather than message-level ME scores (e.g., Bigsby et al. 2013; Morgan et al., 2020). Aggregating ME scores at the message level instead would not only allow for an assessment of whether message-level ME is predictive of AME, but also whether the ME-AME relationship varies depending on message characteristics.

Second, only a small number of ME measures have been included in research using message- or campaign-level aggregate scores and few studies assessing the validity of ME measures have included more than one ME measure to either compare measures in terms of how well they predict AME or to examine whether including more than one measure improves the prediction of AME (Baig et al., 2021a; 2021b). Third, little is known about the performance of ME measures in the context of youth-targeted vaping prevention ads, as much of the previous research has focused on smoking prevention and cessation.

Based on this review of the relevant literature and existing data sets, we concluded that no comparable data have been collected by any other entities. We are also consulting with an FDA- and NIH-funded academic (Seth Noar, University of North Carolina) who conducts research on this topic to ensure relevance and reduce the potential for duplication of efforts. There is no duplicative collection of this information.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection of information.

6. Consequence of Collecting the Information Less Frequently

Respondents to this collection of information will answer only once to ensure the participant burden is as low as possible. Without the information collection requested for this evaluation study, it would be difficult to determine the most effective messages to use in upcoming tobacco prevention campaigns. Failure to collect these data could prevent the identification of more effective methods for selecting messages to include in FDA tobacco education campaigns, thereby limiting the benefit of FDA's 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 federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health National Cancer Institute (NIH/NCI). 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

Lightspeed, the online survey vendor, will provide a nonmonetary reward valued at approximately $1.00-1.25 to participants who complete the survey through the parent's/guardian's Lightspeed account. The reward is a routine part of Lightspeed's panel maintenance strategy and can be accrued and traded for material items with Lightspeed partner vendors (e.g., Amazon.com, Starbucks) or for cash. For parents who are recruited from partner survey vendors, the partner company will provide equivalent compensation in the form typically used by that company with its panelists.

The use of compensation treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this research, we are asking participants to provide thought-intensive feedback on video ads that require a high level of engagement. We estimate that the survey will take approximately 15 minutes to complete. The incentive is intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for contributing to this important study. This incentive is similar to incentives that are offered for most surveys of this type and is consistent with the rate for minimum wage.

This token of appreciation is warranted since we aim to recruit youth via their parents, who have many competing demands for their time. We also aim to overrecruit racial and ethnic minority participants, who are often difficult to reach, to align our sample with population distributions.

10. Assurance of Confidentiality Provided to Respondents

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

How Information will be Shared and for What Purposes

Concern for privacy and protection of respondents' rights will play a central role in the study implementation, storage and handling of data, and data analysis and reporting. The Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection has reviewed and approved the protocols for the survey. FDA's Research Involving Human Subjects Committee (RIHSC) conducted a courtesy review before submission to RTI IRB. The primary concern of IRB is protecting respondents' rights, one of which is maintaining the privacy of respondent information.

Privacy for survey respondents will be ensured in a number of ways:

- Although demographic information (e.g., gender, age, and race) will be gathered, no direct personal identifiers (e.g., full name, phone number, social security number, etc.) will be collected or maintained as part of the screener or survey. As such, because it does not exist, no directly identifying information will be transmitted to FDA or RTI.
- Additionally, each respondent will be known to FDA and RTI only by a unique alphanumeric ID variable provided by Lightspeed. That ID variable is specific to the study. Although Lightspeed and any partner survey vendors maintain databases of names and email addresses of potential participants as part of their normal operations, neither FDA nor RTI will receive or request this information from Lightspeed.
- Lightspeed will not use the data it collects through the screener or survey to update panelists' profiles. Because Lightspeed will not share the data it collects from the screener or survey with the companies they partner with for recruitment, it will not be possible for the partners to use this data to update profiles of their own panel members.

Voluntary Participation

- Lightspeed will invite youth of adult panel participants to complete the survey through an email invitation to their parent. If affirmative parental informed consent is provided online, parents will be asked to allow their child to complete their consent, screener, and survey in private, so they cannot see the responses. Youth participants will also be informed that their answers will not be shared with their parents.
- The online survey is self-administered, and respondents will participate on a voluntary basis. Questions in the screener are required for determining eligibility; however, respondents can exit the survey by closing the browser if they do not wish to answer these. All other questions are optional. The voluntary nature of the information collection is described in the online parental consent and youth assent forms to which participants provide online affirmative agreement.

Data Security

Online data collection:

- Lightspeed Research collects survey data via their platform, which has a Domain Validation certificate issued. Lightspeed Research may store data from this study using cloud-based services. Lightspeed was approved by RTI's Cloud Technology Committee, which assesses the security and confidentiality of cloud computing providers. A full copy of Lightspeed LLC's privacy policy can be found at: https://www.lifepointspanel.com/en/privacy. Partners might be used to assist with recruiting; however, they only provide links to the Lightspeed survey.
- We require affirmative parental consent and youth assent prior to participation. Following the parental consent form, parents will be asked to allow their youth to complete the survey in a place where no one can look over their shoulder and view their answers. Youth will also be asked to complete each survey in private and informed that RTI and Lightspeed will not share their answers with their parent.

- Respondents cannot back up in the survey to view previous responses. For example, if a youth were to exit the survey, the parent could not view previously entered responses.
- The surveys will be administered online using participants' own computers/tablets/mobile devices in a location of their choosing. Parents and youth respondents access the survey through a unique link provided by Lightspeed. The link cannot be shared for others to use because it is unique.
- Respondents on the web-based survey 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.

Datasets:

- Though Lightspeed and its recruitment partners maintain databases of names and email addresses of potential participants as part of their normal operations, this information will not be paired with responses and neither FDA nor RTI will receive this information from Lightspeed as part of the data set.
- Each respondent will be known to FDA and RTI only by a unique alphanumeric variable provided by Lightspeed. The survey datafile that will be shared with FDA will not contain any PII. Lightspeed will store data for 1 year before deletion.
- When data collection is complete, the data file will be transmitted from Lightspeed to RTI via a website with an SSL certificate applied.
- Data will consist of responses to the permission/assent forms and online surveys, which are only available electronically.
- RTI analysts will perform additional data cleaning. The data file will be stored by RTI and FDA on a restricted-access folder on a shared network drive, and only authorized project members will have access. All data maintained by RTI will be maintained in a secure manner in accordance with RTI standard policies and procedures.
- At this time, FDA does not plan to make the data available as a public-use dataset but reserves the right to do so in the future.
- To ensure compliance with all applicable information security laws, statutes, and agency directives, RTI has implemented the IT security guidelines and principles published by the National Institute of Standards and Technology (NIST). RTI's network meets all NIST confidentiality, integrity, and availability security standards for both low and moderate risk. RTI's security practices include the use of a virtual private network (VPN) and SSL and IPsec for encryption of data in transit when required based on project needs.
- RTI will send the data to FDA via a password protected zip file in an encrypted email.
- RTI will store data for 5 years before deletion.

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). Section 2012 of the 21st Century Cures Act includes significant amendments, to the previous statutory authority for such protections, to enhance privacy protections for individuals who are the subjects of federally

funded research, under subsection 301(d) of the Public Health Service Act (42 U.S.C. 241). Specifically, the amended authority requires the FDA to issue a CoC to investigators or institutions engaged in research funded by the Federal government to protect the privacy of individuals who are subjects of this research. We will notify participants in the assent form (and parental permission form) of the protections that the Certificate provides.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN). 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 and to collect demographic information. For example, questions about tobacco use and demographic information, such as race, ethnicity, family origin, and family income could be considered sensitive. These questions are essential to the objectives of this information collection because they provide insight into how past behavior and demographic factors (e.g., level of acculturation determined by questions about family origin) may influence perceptions of and reactions to vaping prevention messages. Specifically for individuals from Hispanic/Latino origin this level of detail is necessary as data shows disparities in tobacco use and susceptibility depending on Hispanic/Latino country of origin. It is important for CTP to capture this information to better understand Hispanic/Latino tobacco use and prevention. This question is modeled after the 2020 U.S. Census which includes country of origin/national background when asking about Hispanic/Latino ethnicity. We are including the top 5 countries of origin based on the 2020 U.S. Census data.

Questions about tobacco use are potentially sensitive because tobacco use among adolescents under age 18 is illegal in a few states, and sales to individuals under age 21 are illegal nationwide. These questions are essential to the objectives of this information collection because participants' risk perceptions of nicotine use are influenced by whether or not the participant uses or has used tobacco products. Questions intended to collect demographic information, such as participant race, ethnicity, family income status, and family country of origin (for biologic parents) could also be considered sensitive. For example, the question about family origin could potentially be unsettling for youth participants who may be undocumented. This particular question will be used to measure level of acculturation, a demographic factor that has been identified as playing a role in tobacco use behaviors. These demographic questions are essential to the objectives of this information collection because they will be used to measure the participant characteristics identified in the research question: To what extent does the relationship between ME and AME vary by participant characteristics (e.g., user group, demographics)?

To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents that these topics will be covered during 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:

- Respondents 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.
- Participants will be provided with a toll-free phone number for the RTI project director and a toll-free phone number for the RTI IRB hotline should they have any questions or concerns about the study or their rights as a study participant.
- Finally, as with all information collected, these data will be presented with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for both adults and youth combined for this collection will be approximately 1,367 hours (Table 1). This includes a reporting burden of approximately 267 hours for adults and approximately 1,100 hours for youth. The total time burden for adults includes time associated with the parental consent process, which we anticipate will require 2 minutes per response to complete (0.033). Among youth, we anticipate the assent process will also require 2 minutes per response to complete (0.033) and screening will require 3 minutes per response to complete (0.05).

To obtain a final sample of 2,400 youth aged 13-17 who have either experimented with vaping or are at risk of initiating vaping, we will need to administer the study invitation and parental consent to 8,000 parents of potential participants. Based on experience from previous surveys, we anticipate about 75% of parents who review the parental consent form will provide permission for their child to participate in the study. Of the potential youth participants who have parental permission to participate in the study, we anticipate approximately 40% have either experimented with vaping or are at risk of initiating vaping (CDC, 2021) and will consent to participate.

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]
Adult, general population	Invitation and Parental Consent	8,000	1	8,000	0.03333	**267**
Screened Potential Participants						

Youth aged 13 to 17	Youth Assent	6,000	1	6,000	.0333 **200**
Youth aged 13 to 17	Youth Screening	6,000	1	6,000	.05 **300**
Survey Participants					
Youth aged 13 to 17	Survey	2,400	1	2,400	0.25 **600**
Total Annualized Hours					**1,367**

[1] The total number of adult respondents that will need to be invited to achieve the desired youth sample is 8,000; 2,400 represents the total number of participants in the study.

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 youth. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 15 minutes per respondent. We have also allocated a two minutes for parents to give their consent for their child to participate and for youth to give their assent to participate.

To calculate this cost, the mean hourly wage of $7.25 was used for youth and $22.33 was used for parents. The youth price represents the minimum wage, and the parental costs represent the Department of Labor estimated mean for state, local, and private industry earnings. There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $7.25 and $22.33 (youth and parent), the estimated one-year annualized cost to participants will be $13,937. 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
Parent	Invitation and Parental Permission Form	267	$ 22.33	$5,962
Youth	Assent, Screener, and Survey	1,100	$ 7.25	$7,975
Total		**1,367**		**$13,937**

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 information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this study is $129,068 as shown in Table 3. This value was calculated using the step 1 federal government salaries for the Washington DC locality (OPM.gov). Contractor costs attributable to this information collection are $90,709. This includes costs to program the survey, draw the sample, collect the data, analyze the data, and report findings. 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
GS-13	20%	$106,823	$21,365
GS-13	10%	$106,823	$10,682
GS-14	5%	$126,233	$6,312
Total Salary Costs			$38,359
Contractor Costs			$90,709
Total			**$129,068**

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

The analyses will examine whether key ME measures demonstrate criterion validity by investigating the strength of their relationship with outcomes of message exposure, such as beliefs and behavioral intentions. We will also aim to compare ME measures on the strength of their association with AME and to examine whether the relationship between ME measures and message outcomes varies depending on characteristics of the vaping prevention messages and user groups. Findings from these analyses will be used to inform FDA CTP health communication strategies. The reporting and dissemination mechanism will consist of a comprehensive evaluation report summarizing findings from this information collection. The key project milestones are listed in Table 4 below. Data collection will begin after OMB approval has been obtained. The estimated timeframe is below.

Table 4. Project Schedule

Project Activity	Approximate Dates
Survey Data Collection	July 2022 to August 2022
Data Analysis	August 2022 to October 2022
Draft Report Writing	October 2022 to November 2022
Final Report Writing	November 2022 to January 2023

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

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. The OMB approval and expiration date will be displayed on the relevant materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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