U.S. Food and Drug Administration
Formative Research Support: Outcomes and Awareness Measurement Research

OMB Control Number 0910-0810

SUPPORTING STATEMENT A

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA's Center for Tobacco Products (CTP) is interested in developing reliable and valid measures of media campaign awareness and targeted outcomes to inform the evaluation of CTP's Real Cost media campaign. In this study, we will conduct two waves of an online survey among 2,400 youth ages 13-17 to: 1) examine the extent to which the distribution and accuracy of self-reported awareness varies across different awareness assessment approaches; and 2) develop comprehensive and valid, multi-item scales to measure outcomes such as addiction perceptions, expectations of feeling anxious after using tobacco, and other key predictors of tobacco use that campaign messages aim to change.

2. Purpose and Use of the Information Collection

The Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP) has contracted with RTI to conduct an online survey of 2,400 youth participants (ages 13-17). The objectives of this task are to 1) to examine the extent to which the distribution and accuracy of self-reported awareness varies across different awareness assessment approaches; and 2) develop comprehensive, valid, multi-item scales to measure outcomes such as addiction perceptions, expectations of feeling anxious after using tobacco, and other key predictors of tobacco use that campaign messages aim to change.

To achieve these objectives, we will conduct an online survey with the following components: 1) a cross-sectional message exposure study to examine variation in and sensitivity of different awareness assessment approaches; 2) a longitudinal message exposure study to assess variation in accuracy of different awareness assessment approaches; and 3) creation and evaluation of comprehensive, multi-item scales assessing outcomes targeted by the campaign. Findings from this study can be used to inform the evaluation of FDA's Real Cost anti-tobacco campaign.

Health communication campaign evaluations have employed a wide variety of approaches for assessing media campaign awareness, but little is known about how self-reported awareness varies across these approaches, and which approaches are most accurate and sensitive to variation in campaign exposure. Effective anti-tobacco media campaign evaluation also requires valid and reliable measurement of predictors of tobacco use (e.g., addiction perceptions) that are targeted by the campaign (in this case, the Real Cost campaign). The proposed research will provide valuable insights to inform the ongoing evaluation of the Real Cost media campaign. To the extent that we are able to validate brief awareness measures, research findings may also lead to reduced respondent burden in future studies.

3. Use of Improved Information Technology and Burden Reduction

Because this is a web-based study, 100% of the respondents will submit the information in an electronic format. Web-based surveys reduce respondent burden, minimize possible administration errors, and expedite the timeliness of data processing. Furthermore, web-based surveys are less intrusive and less costly compared with face-to-face interviews and mail and telephone surveys. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information. No comparable data have been collected by any other entities. We carefully reviewed the literature and existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's needs. We concluded that the existing literature and existing data sources do not include the measures needed by FDA.

5. Impact on Small Businesses or Other Small Entities

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

6. Consequences of Collecting the Information Less Frequently

The collection of information will provide important data needed for FDA to evaluate ongoing media campaigns, particularly among youth. 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

This information collection fully complies with 5 CFR 1320.5(d)(2). No special circumstances are associated with this information collection that would be inconsistent with the regulation.

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

Emily Sanders
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Phone: 240-402-4269
E-mail: emily.sanders@fda.hhs.gov

Matthew Walker
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850
Phone: 240-402-3824
E-mail: matthew.walker@fda.hhs.gov

Erin O'Brien
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-4047
E-mail: erin.obrien@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

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:

Matt Eggers
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-6683
E-mail: meggers@rti.org

Jessica Pepper
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-316-3180
E-mail: jpepper@rti.org

Jim Nonnemaker
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-6683
E-mail: jnonnemkaer@rti.org

9. Explanation of Any Payment or Gift to Respondents

For parents recruited from the Lightspeed panel for the online survey, Lightspeed will provide nonmonetary "LifePoints" valued at approximately $1.00-1.25 to parents of youth who complete each survey. LifePoints are 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. Lightspeed also partners with other survey panel vendors. For parents who are recruited from partner survey vendors, the partner company will provide equivalent reward points in the form typically used by that company with its panelists. Lightspeed will provide the unique, alphanumeric survey IDs of individuals who should be given reward points to the partner company.

Upon youths' completion of the online survey, Lightspeed will post Lifepoints to the parents' accounts within a few hours. Lightspeed requests that the timing of the reward points for parents recruited through partner companies is similar.

In general, empirical studies show that incentives can increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys within some respondent populations.[1] Although the vast majority of published research on this topic is based on mail,

[1] Singer E & Ye C. (2013). The use and effects of incentives in surveys. The Annals of the American Academy of Political and Social Science. 645(1), 112-141; LeClere F et al. (2012). Household early bird incentives: leveraging family influence to improve household response rates. In American Statistical Association Joint Statistical Meetings, Section on Survey Research; Cantor D et al. (2003). Comparing promised and pre-paid incentives for an extended interview on a random digit dial survey. In Presentation for the Annual Meeting of the American Association for

telephone, or in-person surveys, there are now several studies on 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.[2]

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

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; RIHSC determined that FDA is not engaged in the research. The primary concern of IRB is protecting respondents' rights, one of which is maintaining the privacy of respondent information. 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).

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

- 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 e-mail addresses of potential participants as part of their normal operations, neither FDA nor RTI will receive or request this information from Lightspeed.
- The online survey requests date of birth, which is considered PII. Lightspeed will remove the DOB variable from the dataset that is provided to RTI and only provide data on a derived age variable. The survey datafile that will be shared with FDA will not contain any PII.
- Lightspeed will invite youth of adult panel participants to complete the survey via an initial generic communication to their parent through the Lightspeed panelist portal. If affirmative permission is provided online, parents will be asked to allow their child to complete the 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.
- 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. During survey testing, the test links will include the ability to back up, but

Public Opinion Research, Nashville, TN; Singer E. (2002). The use of incentives to reduce nonresponse in household surveys. In Survey Nonresponse, eds. Groves RM et al. 163-78. New York, NY: Wiley; Singer E et al. (1998). Does the payment of incentives create expectation effects? Public Opin Q. 62, 152-64.

[2] Göritz AS. (2006). Incentives in web studies: methodological issues and a review. Int J Internet Science. 1(1), 58-70.

this will not be possible in the actual survey that participants complete. RTI will confirm this with Lightspeed after testing and before survey launch.

- 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.
- 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 permission and assent forms to which participants provide online affirmative agreement.
- 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.
- When data collection is complete, the deidentified data file will be transmitted from RTI to FDA via a website with an SSL certificate applied. The data file, which contains no PII, 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. 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

Most questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered of a sensitive nature in order to assess specific health behaviors, such as tobacco use and marijuana/cannabis use. Asking such questions is critical to the objectives to this information collection.

Some 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. One question assessing ever having vaped marijuana/cannabis may also be sensitive because youth possession of marijuana/cannabis is illegal in the U.S. These questions are essential to the objectives of this information collection. Questions concerning tobacco use and demographic information, such as race and ethnicity, could be considered sensitive but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The assent form will

apprise respondents that the topic of tobacco use 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 do not need participate and that if they choose to participate, they do not need answer any question on the survey (aside from required screening questions) that makes them feel uncomfortable or that they simply do not wish to answer.
- The web survey is entirely self-administered to maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number for the RTI Office of Research Protection and the RTI Principal Investigator to contact in case they have a question or concern about the sensitive issue.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Information will be collected through a self-administered, online screener and two survey waves of youth (ages 13-17), with a target of 2,400 completes at each wave. Approximately 11,667 parents will review a Wave 1 generic invitation/permission form estimated to take approximately 2 minutes per response, for a total of 389 hours. After receiving parental consent to participate in the study, approximately 9,600 youth will complete an assent form and screener to determine eligibility for participation in the study, estimated to take approximately 2 and 3 minutes per response, respectively, for a total of 800 hours for assent and screening activities. We estimate that 2,400 respondents will complete the Wave 1 survey at an average of 20 minutes per response, for a total of 800 hours. We estimate that up to 2,400 parents will review a Wave 2 permission form at an average of 2 minutes per response, for a total of 80 hours. Up to 2,400 respondents will complete a Wave 2 assent form and survey at an average of 2 and 15 minutes per response, respectively, for a total of 680 hours. This data collection will take place in 2022. Thus, the annualized response burden is estimated at 2,749 hours. Table 1 provides details about how this estimate was calculated.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Parent—Wave 1 Generic invitation, Permission	11,667	1	11,667	0.03 (2 minutes)	389
Youth—Wave 1 Assent	9,600	1	9,600	0.03 (2 minutes)	320

Youth—Wave 1 Screener	9,600	1	9,600	0.05 (3 minutes)	480
Youth—Wave 1 Survey	2,400	1	2,400	0.33 (20 minutes)	800
Parent—Wave 2 Permission	2,400	1	2,400	0.03 (2 minutes)	80
Youth—Wave 2 Assent	2,400	1	2,400	0.03 (2 minutes)	80
Youth—Wave 2 Survey	2,400	1	2,400	0.25 (15 minutes)	600
Total Burden Hours					**2,749**

12b. ***Annualized Cost Burden Estimate***

To estimate the annualized cost burden, 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 $27,003. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annualized Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Parent	469	$22.33	$10,473
Youth (13–17)	2,280	$7.25	$16,530
Total	**2,749**		**$27,003**

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

No capital, start-up, operating, or maintenance costs are associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this study is $97,327.20 as shown in Table 3. Contractor costs attributable to this information collection are $65,961. This includes costs to program the survey, draw 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
GS-13	20%	$121,065	$24,213.00
GS-14	5%	$143,064	$7,153.20
Total Salary Costs			$31.366.20
Contractor Costs			$65,961.00
Total			**$97,327.20**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The project schedule is shown in Table 4. Future development and research activities are dependent on the timely completion of the present study.

Table 4. Project Schedule

Activity	Approximate Date
Data Collection	April 2022
Draft Reporting Deliverables	June 2022
Final Reporting Deliverables	July 2022

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. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>

There are no exceptions to the certification.