The Real Cost Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use

Supporting Statement: Summary

- The goal of this project is to conduct quantitative copy testing of video ads for FDA's *The Real Cost* tobacco prevention campaigns among youth ages 13 to 17 (N = 3000 enrolled) and adults aged 19 to 54 (N = 1000 enrolled).

- Participants will be recruited via panels and enrolled via a screener survey. Participants who qualify for study inclusion will complete the questionnaire online using their own device. The screener will take no more than ten minutes to complete, and the questionnaire will take no more than twenty minutes for participants to complete.

- Four thousand youth who are 13-17 years old, tobacco users or open non-users will be enrolled. Youth must be ages 13-17 to participate in order to comply with Children's Online Privacy Protection Act (COPPA) regulations.

- Additionally, 1000 adults who are adult smokers and dual users of cigarettes and ENDS interested in quitting cigarettes will be asked to complete questionnaires to assess if ENDS messages aimed at preventing use among youth have any unintended consequences among adult smokers interested in quitting smoking.

- Participants will be randomly assigned to either the ad-viewing group or the "no ad" control group; if in the ad-viewing group, participants will be randomly assigned to view one ad. Participants will be randomly assigned so that an approximately equal number of participants are in the control group as view each individual ad.

- The outcome of the study will be an understanding of overall ad performance and potential unintended consequences for FDA's *The Real Cost* campaign. Understanding the target audience's receptivity of these video ads and possible unintended consequences with these ads among adults can help optimize messaging for FDA's *The Real Cost* campaign.

- The resulting data will be analyzed using conventional tabulation techniques for quantitative data. Qualitative analysis of open-ended items will also be conducted. The study questions collect information about respondents' reactions to video ads for FDA's *The Real Cost* campaign and also include basic demographic and tobacco use information in order to understand whether and how these factors may influence individuals' responses to the video ads.

- **REQUESTED APPROVAL DATE: June 1st, 2018**

Data Collection Instruments

- Attachment A: Youth Screener
- Attachment B: Adult Screener
- Attachment C: Youth Questionnaire
- Attachment D: Ault Questionnaire

Participant Assent/Consent & Parental Opt-Out Forms

- Attachment E Parental Notification and Opt-Out Form
- Attachment F: Youth Assent Form
- Attachment G: Adult Participant Consent Form

Additional Materials

- Attachment H: Stimuli
- Attachment I: IRB Approval Letter

***The Real Cost* Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use**

0910-0810

SUPPORTING STATEMENT: PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Introduction

The Centers for Disease Control and Prevention (CDC) report that youth cigarette use declined sharply from 1997-2003, but declines have slowed in recent years (CDC, 2010). Today, cigarette use continues to be a significant health risk to youth, as 8.0% of high school students and 2.2% of middle school students reported current cigarette use in 2016 (Jamal et al., 2017). Additionally, other tobacco products such as e-cigarettes and smokeless tobacco (SLT) have become increasingly common among US teens, even as cigarette smoking continues to decline. Currently, smokeless tobacco is the third most prevalent form of tobacco among high school students, with 860,000 students reporting past 30-day SLT (chewing tobacco, snuff, dip, snus, and dissolvable tobacco) use nationwide. From 2011 to 2016, the National Youth Tobacco Survey found that while use of cigarettes decreased significantly among teens, increased use of other tobacco products, including e-cigarettes, offset these decreases, resulting in no significant change in the overall rate of any tobacco product use among teens (Jamal et al., 2017). This trend indicates a need for public education campaigns designed to inform youth about the harms of tobacco use.

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) (Public Law 111-31) into law. The FSPTCA granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Part of the FDA's responsibility is to inform the public on health-related issues. To develop the appropriate messaging to inform the public, it is important for the FDA to conduct research to assess youth perceptions of tobacco prevention messaging. Information obtained through this study will be used to assess the performance of ads developed to reduce tobacco initiation and use among at-risk youth as part of CTP's *The Real Cost* campaign.

As part of FDA's *The Real Cost* campaign, FDA will implement video advertising that highlights the negative health and addiction consequences of tobacco use (see Attachment H for stimuli). Before these video ads may be used in this campaign, they must undergo copy testing to assess overall ad performance and the potential for unintended consequences related to viewing the ads. The objective of the proposed data collection is to measure ad perceived effectiveness and unintended consequences of viewing the ads among the campaign target audience of youth who are at risk for

tobacco use. In instances where there is concern that there might be unintended consequences for adults, stimuli will also be tested with adults. To this end, a subsample of the ads that message on ENDS will be tested on adult smokers and dual users of cigarettes and ENDS interested in quitting cigarettes to assess if ENDS messages aimed at preventing use among youth have any unintended consequences among adult smokers interested in quitting smoking.

This study is designed to measure youth and adult reactions to rough-cut videos to prevent youth tobacco use. The study will be conducted using an online screener and questionnaire. Four thousand youth who are 13-17 years old, have a valid email address, and who are either tobacco users or non-users susceptible to using tobacco (susceptible non-users) will be enrolled. Participants must be ages 13-17 to participate in order to comply with Children's Online Privacy Protection Act (COPPA) regulations. Although part of FDA's *The Real Cost* campaign target audience, youth age 12 will not be permitted to participate in this online study due to COPPA regulations. Additionally, up to 1,000 adults aged 19-54 who are current cigarettes smokers (assessed as having smoked 100 or more cigarettes in their life time and report currently smoking every day or some days), ever e-cigarette users (assessed as having ever used an e-cigarette) and have an interest in quitting smoking (assessed as thinking about quitting cigarettes) will be enrolled.

Adult and youth participants will be randomly assigned to the control group, where they will not view any ads, or to the ad-viewing group, where they will be asked to view one randomly assigned ad and provide responses to quantitative items and give qualitative feedback about the ad (see Attachment H: Stimuli). All youth participants will be asked to answer questions about their knowledge, attitudes, and beliefs about tobacco use as a check for potential unintended consequences of viewing the video ads. Adult participants will be asked questions related to their perceptions of the benefits of quitting smoking, intentions to quit smoking, products they would consider using to quit smoking, and perceptions of tobacco products.

2. Purpose and Use of the Information Collection

The information obtained through this study will inform the implementation of FDA's *The Real Cost* campaign. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Optimize video ads for FDA's *The Real Cost* campaign
- Inform future programs that may be designed for similar purposes

Participants will be recruited via panel. Data collection will be completed by participants independently on their own electronic devices, such as a mobile phone, tablet, or home computer. All potential participants will complete a screener (see Youth and Adult Screeners) to determine their qualification for inclusion into the study. Upon screener completion, participants will be immediately notified if they qualify. Both the screener and copy testing questionnaire will be compatible for use on smartphones, tablets, and computers.

All qualified youth participants will then be prompted to provide their parent/guardian's email address, to facilitate emailing the parental notification and opt-out form (Attachment E) to a potential participant's parent or guardian, and if desired to provide their cell phone number to receive the study link and up to two reminders by text message. Qualified youth whose parents' email does not bounce back and whose parents do not opt them out will be emailed and texted (if they selected the option) a link to complete the participant assent form (see Attachment F: Youth Assent Form) and the questionnaire (see Attachment C: Youth Questionnaire) no less than 24 hours after the parental opt-out form is emailed to their parent/guardian, to allow sufficient time for parental-opt out to occur.

All youth participants will complete a participant assent form before beginning the questionnaire. The participant assent form will be presented electronically at the start of the questionnaire to collect assent from youth ages 13-17. Youth will be prompted to read the form and provide their assent by selecting a radio button option. If they do not provide assent, they will not be able to complete the questionnaire. Additionally, youth who will turn 18 by the time the survey takes place will be ineligible to participate. After providing assent, participants will automatically receive an electronic copy of the form via email. Qualified participants who complete the screener but do not complete the questionnaire will be contacted up to two times via email and text message (if selected) with a reminder to complete the questionnaire (see Attachment C: Youth Questionnaire).

All qualified adult participants will review and provide consent via an electronic Participant Consent Form (see Attachment G: Adult Participant Consent Form) presented prior to the start of the Questionnaire (see Attachment D: Adult Questionnaire). At the start of the Adult Questionnaire, participants will be prompted to read the form and provide consent by selecting a radio button option. Adult participants must complete the Participant Consent Form to continue to the Questionnaire; if they do not provide consent, they will not be able to complete the Questionnaire.

Questionnaire items that youth participants see will vary depending on their screener responses (i.e., their use of or susceptibility to experimentation with cigarettes, ENDS, or SLT) (see Attachment C: Youth Questionnaire). Adult participants will all see questions specifically tailored for that portion of the data collection (see Attachment D: Adult Questionnaire). For both the youth and adult studies, participants will be randomly assigned to either the ad-viewing group or the "no ad" control group; if in the ad-viewing group, participants will be randomly assigned to view one ad. Participants will be randomly assigned so that an approximately equal number of participants are in the control group as view each individual ad.

Control and ad-viewing participants will complete a series of questions in the questionnaire related to household tobacco use and personal tobacco use. These questions will be used to assess effectiveness of the randomization process, ensure there are no confounding differences between groups, and act as control variables (i.e., covariates) in analyses. Following exposure to an ad, ad-viewing participants will be presented with a series of questions designed to assess their initial reactions to the ad,

including what they liked or disliked, how the ad made them feel (e.g. sad, afraid, inspired), and, among other things, whether they felt the ad was powerful, informative, meaningful, convincing, terrible, or silly. Additionally, questions will be asked on whether the ad influenced the participant's thoughts about smoking, the degree to which the claims in the ad were believable, and if anything about the ad was confusing or unclear. Finally, all participants will complete a series of questions assessing tobacco-related knowledge, attitudes, and beliefs, which are used to examine for the presence of unintended consequences.

3. Use of Improved Information Technology and Burden Reduction

The use of electronic screener and questionnaire surveys offers a number of benefits. First, computerized administration permits the instrument designer to incorporate into the instruments routings that might be overly complex or not possible using a paper-based survey. For example, screener surveys can be programmed to implement skip patterns based on a respondent's previous answers. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, electronic administration increases the consistency of the data. The electronic screener and questionnaire can be programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving time and money. In addition, it is likely that respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. Third, electronic data collection permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry, will be minimized). 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 instruments 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.

This study will recruit both youth and adult participants through online panels. The campaign contractors, FCB and Marketing Workshop, subcontract to the panel provider, Market Cube, which has a proven and demonstrated ability to orchestrate and support the sampling plan specifications of these studies. The panel includes over 600,000 adults age 19-54, over 25,000 teens 13-17 years old, as well as hundreds of thousands of households that include teens. During recruitment for this study, participants will complete the screener electronically on their own device such as a mobile phone, tablet, or computer. This allows for more accurate data collection because respondents provide more honest responses, since it is clear that the answers will remain private.

This study, which relies on electronic data collection to provide accurate records of questionnaire completion, will reduce burden by increasing participation rates, thereby reducing the number of participants needed to complete the Screener in order to achieve the desired sample size.

4. Efforts to Identify Duplication and Use of Similar Information

The video ads being tested in this study are original to FDA's *The Real Cost* campaign and have not previously been copy tested or publicly aired. As such, there are no existing datasets that can be used or modified to address FDA's need for information on reactions to the video ads for FDA's *The Real Cost* campaign. This type of focused recruitment of youth in the target audience and adults in instances where there are concerns of unintended consequences to individuals outside of the target is necessary to test the effectiveness of ads developed for FDA's *The Real Cost campaign*. Therefore, we have determined that the proposed information collection does not duplicate previous efforts.

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. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the participant burden. 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, it would be difficult to measure target audience and adult reactions to video ads for FDA's *The Real Cost* campaign. Failure to collect this data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of this messaging campaign.

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 the Agency

The following individuals inside the agency have been consulted on the design of the copy testing plan, survey development, or intra-agency coordination of information collection efforts:

Gem Benoza
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-0088
E-mail: Maria.Benoza@fda.hhs.gov

Mario Navarro
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-4963
E-mail: Mario.Navarro@fda.hhs.gov

Matthew Walker
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-3824
E-mail: Matthew.Walker@fda.hhs.gov

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

Todd Sussman - FCB New York
SVP, Group Strategy Director
100 West 33rd Street, New York, NY 10001
Phone: 917 685 6580
Email: Todd.sussman@fcb.com

Dimas Adiwiyoto-FCB New York
VP, Account Director
100 West 33rd Street, New York, NY 10001

Phone: 212 885 3283
Email: Dimas Adiwiyoto@fcb.com

Xiaoquan Zhao
Department of Communication
George Mason University
Robinson Hall A, Room 307B
4400 University Drive, 3D6
Fairfax, VA 22030
Phone: 703-993-4008
E-mail: xzhao3@gmu.edu

9. Explanation of Any Incentive or Gift to Respondents

As is customary with online surveys conducted via panel sampling, panelists are invited by the panel management company to respond to the survey opportunity incentivized with award points that are accrued and redeemable with the panel company for cash or other rewards. For example: 100 points is equivalent to $1 which can be redeemed through Amazon E-Gift voucher or E-Visa. The award points offered for participation in these studies will be valued at not more than $10. A participant must be eligible to participate (per the screener) and submit the questionnaire to receive the token of appreciation.

Numerous empirical studies have shown that a token of appreciation can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002). The use of a modest incentive is expected to enhance survey response rates without biasing responses. An incentive must be high enough to address competing demands for participants' time and to equalize the burden placed on participants with respect to their time and cost of participation. An inadequate incentive may also result in a significantly more difficult and lengthy recruitment process and/or increases in the number of participants who agree to participate and then drop out early. An inadequate incentive may thus result in a more costly and lengthy period of data collection by increasing recruitment and other associated data collection costs.

In this research, we are asking participants to respond to close-ended questions and provide thought-intensive, open-ended feedback on video ads, which requires a high level of engagement. The use of an incentive is provided as a thank you for the participants' time and the effort they expend to participate. We believe that utilizing $10 as a token of appreciation in the current study will reduce overall burden by increasing participation rates, thereby reducing the number of participants needed to complete the screener in order to achieve the required sample size.

10. Privacy Impact Assessment Information

This study has been reviewed and approved by FDA IRB. The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

The screener will be completed independently online using the participant's personal electronic device. All potential participants will be required to provide electronic informed assent/consent before they begin the questionnaire. The participant assent/consent form will inform participants that the information they provided on the screener and questionnaire will only be viewed by the researchers and that their responses will not be connected with any identifiable information they provided. All analyses will be conducted in the aggregate and participant contact information will not be appended to the data file used.

IP address, zip codes, and participant email address will be collected from all respondents. IP address will be automatically collected, and will be used to manage

potential duplicate entries and confirm study completion from US-based respondents. All respondents will also be asked to provide their zip code, which will be used to determine geographic eligibility. All respondents will be asked to provide their email address, which will be checked against all current respondent data to avoid duplicates and reduce fraudulent activity.

Only youth participants who qualify on the screener will be prompted to provide parent/ guardian's email address. Therefore, this additional contact information will only be collected from qualified youth. Parent/ guardian email will be collected from all qualifying youth to facilitate distribution of the parental opt-out form. Researchers will only contact participants via email (if selected) to share the link to the questionnaire and up to two reminders, and via email to deliver the token of appreciation. Researchers may also contact participants in the unlikely case that there is a breach of privacy, for example as a result of hacking.

After data collection is complete, screener and questionnaire databases will be merged together for analysis, but all personally identifiable information (i.e., email address, cell phone number, IP address, etc.) will be deleted after final data cleaning is conducted and prior to data analysis. That is, all identifying information will be removed from the database before analysis.

The research team will not share personal information regarding participants with any third party unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. All data will remain on a password-protected computer and/or in locked cabinets for a period of three years after the end of the study, and then will be securely shredded and/or destroyed. As with any research study, there is a chance that privacy could be compromised. However, great effort is taken to protect participant identity and all responses will be private.

Data Management

All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations.

Confirmit will be the software used for data collection and storage. Confirmit is a trusted survey tool used by both researchers and marketing companies alike. Confirmit is provided as a web application, accessed using a modern Internet browser where data are stored in a single secure data center. The database servers that store respondent and response data are placed behind two tiers of firewalls, and data can only be accessed through the Confirmit applications. No application users have direct database access; the servers are only accessible for database administrators. Remote server access is only available to our system administrators through network controls and secure VPN tunnels. If outside the corporate network, dual factor authentication is required to establish a secure VPN tunnel into the corporate network (in order to access the production VPN through a hop-server), and only computers that are under Confirmit's control are allowed to connect to the VPN. Confirmit surveys do not require

any user-identifiable information to be transmitted between page submissions. Surveys use a combination of hidden form fields and system generated identifiers to identify the respondent and the correct state in the interview when moving from page to page. Interview pages include meta code to prevent them from being cached on the client. No information is stored on a respondent's computer when the browser is closed. To further prevent caching, all surveys are available over HTTPS. Data will be stored on dedicated servers with a redundant multi-tier network security infrastructure.

Confirmit and Market Cube will follow the Standard of Good Practice (SoGP, https://www.securityforum.org/ research/thestandardofgoodpractice2016/) security practices which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and safety of the end-user environment. Following these guidelines, the monitoring of data and sensitive information will take place following the SoGP security practices such as limiting access to information and data encryption. Members of the CTP research team will receive de-identified data that will be in an encrypted format when it is transmitted. This data transfer will occur via an encrypted and secure broadband connection.

11. Justification for Sensitive Questions

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about age, sex, race/ethnicity, and/or health behaviors on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds of people for whom its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

In order to identify participants for this study, researchers need to ask sensitive survey-based questions about race/ethnicity and tobacco use behavior. Raw data that includes both personally identifiable and sensitive information (e.g., contact information and tobacco use in the screener survey) will be managed so personally identifiable information is not retained once the data have been extracted and aggregated. Personally identifiable information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

In addition, this study includes the following procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- The screener and questionnaire are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

- Participants will be provided with contact information for the Principal Investigator of this study and for FDA RIHSC if they have any questions or concerns about this study or about their rights as study participants.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection is 1,732 hours (Exhibit 1). This includes the time burden associated with the Screener.

To obtain a final sample of 3,000 youth enrolled participants, we estimate that we will need to screen up to 4,500 potential youth respondents. Additionally, to obtain the final sample of 1000 adults enrolled, we estimate that we will need to screen up to 1,500 adults. Because we are using a panel provider with a proven track record of being able to recruit participants that fit specifications for inclusion, we anticipate we will need to recruit 1.5 times our desired sample size for this study.

Based on previous experience, we estimate that screener completion will take no more than five minutes per participant. The parental opt-out process will take an estimated two minutes to complete. The youth assent and adult consent are estimated to take two minutes to complete. Questionnaire completion will take an estimated 20 minutes for ad-viewing participants and 10 minutes for control participants.

Exhibit 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
Screened Youth	Screener completion	4,500	1	4500	0.083 (5 min)	374
Screened Adults	Screener completions	1,500	1	1500	0.083 (5 min)	125
Parents of Invited Youth	Parental opt-out process	3,000	1	3000	0.033 (2 min)	99
Youth Participants	Youth assent	3,000	1	3000	0.033 (2 min)	99
	Questionnaire completion (ad-viewing group)	1,500	1	1500	0.333 (20 min)	500
	Questionnaire completion (control	1,500	1	1500	0.167 (10 min)	251

	group)					
Adult Participants	Adult consent	1000	1	1000	0.033 (2 min)	33
	Questionnaire completion (ad-viewing)	500	1	500	0.333 (20 min)	167
	Questionnaire (control)	500	1	500	0.167 (10 min)	84
Total Annualized Hours						**1,732**

12b. Annualized Cost Burden Estimate

Respondents participate on a voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. Rescue has conducted many studies of similar length and content among youth.

To calculate this cost, an hourly wage of $7.25 was used for youth and $23.86 for parents. These prices represent the federal minimum wage and average hourly wages for US youth and adults, respectively, according to the U.S. Department of Labor (DOL) Bureau of Labor Statistics. There are no direct costs to respondents associated with participation in this study. Thus, assuming an average hourly wage of $7.25 for youth and $23.86 for parents, the estimated cost to participants will be $20,994.88. The estimated value of respondents' time for participating is summarized in Exhibit 2.

Exhibit 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Youth	Screener completion	374	$7.25	$2,711.5
Screened Adults	Screener Completions	125	$23.86	$2,982.5
Parents of Invited Youth	Parental opt-out process	99	$23.86	$2,362.14
Youth Participants	Youth assent	99	$7.25	$717.75
	Questionnaire completion (ad-viewing group)	500	$7.25	$3,625
	Questionnaire completion (control group)	251	$7.25	$1819.75
Adult	Adult consent	33	$23.86	$787.38

Participants	Questionnaire completion (ad-viewing)	167	$23.86	$3,984.62
	Questionnaire (control)	84	$23.86	$2,004.24
Total				**0**

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

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

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with Rescue. The total estimated costs attributable to this data collection are $899,219.40 (Exhibit 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, data collection plan development, instrument development, reporting, IRB, and progress reporting and project management. This information collection will occur in 2018.

Exhibit 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	5%	$ 94,796	4,739.80
GS-13	10%	$ 94,796	9,479.60
		Total Salary Costs	$14,219.40
		Contract Cost	$885,000.00
		Total	**$899,219.40**

15. Explanation for Program Changes or Adjustments

This is a new individual generic data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The analysis will examine perceived effectiveness scores by ad, and knowledge, attitudes, and beliefs about tobacco use. Perceived effectiveness scores will be analyzed for all viewers of each ad, and may also be analyzed by demographic characteristics (i.e., gender, race/ethnicity). Responses to the knowledge, attitude, and belief questions will be compared between ad-viewing and control participants to identify any statistically

significant differences. Findings from these analyses will be used to optimize video ads for FDA's *The Real Cost* campaign.

Reporting

The reporting and dissemination mechanism will consist of one primary component: summary statistics (in the form of PowerPoint presentations and other briefings) on participant reactions to video ads and potential unintended consequences. The key events and reports to be prepared are listed in Exhibit 4.

Exhibit 4. Project Schedule

Project Activity	Date
Survey	June 2018 to August 2018 (Approximate)
Data analysis	September 2018 to January 2019 (Approximate)
Presentation of findings	February 2019 to March 2019 (Approximate)

17. 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.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. There are no exceptions to the certification statement.

References

Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. In: U.S. Census Bureau. *Proceedings of the Survey Research Methods*, 533-538.

Booker, C.L., Harding, S., Benzeval, M. (2011). A systematic review of the effect of retention methods in population-based cohort studies. *BMC Public Health*, *11*, 249.

Caldwell, P.H., Hamilton, S., Tan, A., & Craig, J.C. (2010). Strategies for increasing recruitment to randomised controlled trials: Systematic review. *PLoS Medicine*, *7*(11), e1000368.

Castiglioni, L., Pforr, K., Krieger, U. (2008). The effect of incentives on response rates and panel attrition: Results of a controlled experiment. *Survey Research Methods*, *2*(3), 151-158.

Centers for Disease Control (CDC). (2010). Tobacco Use Among Middle and High School Students-United States, 2000-2009. *Morbidity and Mortality Weekly Report*, *59*(33), 1063-1068.

Giuliano, A.R., Mokuau, N., Hughes, C., Tortolero-Luna, G., Risendal, B., Ho, R.C.S., … McCaskill-Stevens, W.J. (2000). Participation of miniorities in cancer research. *Annals of Epidemiology*, *10*(8 Suppl 1), S22-S34.

Hooven, C., Walsh, E., Willgerodt, M., & Salazar, A. (2011). Increasing participation in prevention research: Strategies for youth, parents, and schools. *Journal of Child and Adolescent Psychiatric Nursing*, *24*(3), 137-149.

Jäckle, A., & Lynn, P. (2008). Offre de primes d'encouragement aux répondants dans une enquête par panel multimodes: effets cumulatifs sur la non-réponse et le biais. *Techniques d'enquête*, *34*(1), 115-130.

Jamal, A., Gentzke, A., Hu, S.S., Cullen, K.A., Apelberg, B.J., Homa, D.M., & King, B.A. (2017). Tobacco Use Among Middle and High School Students – United States, 2011-2016. *Morbidity and Mortality Weekly Report*, *66*(23), 597-603.

Jordan, J.W., Stalgaitis, C.A., Charles, J., Madden, P.A., Radhakrishnan, A.G., & Saggese, D. (2018). Peer crowds and adolescent health behaviors: Results from a statewide representative study. *Health Education & Behavior*. Advance online publication. doi: https://doi.org/10.1177/1090198118759148 .

Lee, Y. O., Jordan, J. W., Djakaria, M., & Ling, P. M. (2014). Using peer crowds to segment Black youth for smoking intervention. *Health Promotion Practice*, *15*(4), 530-537.

Martinson, B.C., Lazovich, D., Lando, H.A., Perry, C.L., McGovern, P.G., & Boyle, R.G. (2000). Effectiveness of monetary incentives for recruiting adolescents to an intervention trial to reduce smoking. *Preventive Medicine*, *31*(6), 706-713.

Murthy, V.H., Krumholz, H.M., & Gross, C.P. (2004). Participation in cancer clinical trials: Race-, sex-, and age-based disparities. *Journal of the American Medical Association*, *291*(22), 2720-

2726.

Patel, M.X., Doku, V., Tennakoon, L. (2003). Challenges in recruitment of research participants. *Advances in Psychiatric Treathment*, *9*(3), 229-238.

Post, A., Gilljam, H., Bremberg, S., & Galanti, M.R. (2012). Psychosocial determinants of attrition in a longitudinal study of tobacco use in youth. *Scientific World Journal*, *2012*, 654030.

Siddiqui, O., Flay, B.R., & Hu, F.B. (1996). Factors affecting attrition in a longitudinal smoking prevention study. *Preventive Medicine*, *25*(5), 554-560.

Singer, E. (2002). The use of incentives to reduce nonresponse in household surveys. In: Wiley, ed. *Survey nonresponse*, *51*, 163-177.

Shettle, C., & Mooney, G. (1999). Monetary incentives in US government surveys. *Journal of Official Statistics*, *15*(2), 231.

U.S. Department of Health and Human Services (USDHHS). (2014). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

Van der Rijt, G. A., d'Haenens, L. S., & van Straten, P. (2002). Smoking and other substance use as distinct features of teenage subcultures. *Journal of Adolescent Health*, *31*(5), 433-435.

Walter, J.K., Burke, J.F., & Davis, M.M. (2013). Research participation by low-income and racial/ethnic minority groups: How payment may change the balance. *Clinical and Translational Science*, *6*, 363-371.

Zand, D., Thomson, N.R., Budan, M., Braun, J.A., Holterman-Hommes, P., & Hunter, P.L. (2006). Predictors of retention in an alcohol, tobacco, and other drug prevention study. *Evaluation Review*, *30*(2), 209-222.