General Market Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use

0910-0810

Supporting Statement: Summary

- The goal of this study is to conduct quantitative copy testing to determine whether a third wave of advertisements, under *The Real Cost* (TRC) brand, provide an understandable and engaging message about the harms of tobacco use without potential unintended adverse or counterproductive effects. The study will be conducted among youth aged 13 to 17 who have either experimented with smoking (i.e., have reported smoking fewer than 100 cigarettes in lifetime) or are at risk of initiating smoking (e.g., would smoke if a friend offered them a cigarette).

- Participants will be recruited and screened via mall intercepts across the United States. The study will be conducted using web-based surveys that are self-administered. The study will use an online survey to target 1,292 youth who are 13-17 years old and who have experimented with cigarettes or who are at risk of experimenting with cigarettes. The parental consent/opt-out form; youth assent form; and screener will take approximately 5 minutes each; and the questionnaire will take approximately 10 minutes to complete, per respondent.

- The outcome of the study will be an understanding of overall ad performance and potential unintended consequences for Wave 3 advertisements for FDA's TRC campaign. Understanding teen receptivity of these ads can help optimize messaging for TRC.

- 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 participants' reactions to Wave 3 ads for TRC; they will also include questions to collect basic demographic and tobacco use information in order to understand whether and how these factors may influence individuals' responses to the ads.

Assent & Consent Forms

- Attachment A: Parental Consent/Opt Out Form
- Attachment B: Youth Assent Form
- Attachment F: Email Scripts

Data Collection Instruments

- Attachment C: Screener
- Attachment D: Copy Testing Questionnaire

Study Stimuli

- Attachment E: Advertisement Stimuli

IRB Approval

- Attachment G: IRB Approval Letter

Study Locations

- Attachment H: Recruitment Sites

General Market Campaign: Wave 3 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

Tobacco use is the leading preventable cause of disease, disability, and death in the United States (USDHHS, 2014). More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2014). Tobacco use is almost always initiated and established during adolescence. Most first use of cigarettes occurs by 18 years of age (87%), with nearly all first use by 26 years of age (98%) (USDHHS, 2014). Each day, more than 2,600 youth in the United States try their first cigarette, and nearly 600 youth become daily smokers (SAMHSA, 2015).

On June 22, 2009, the Food and Drug Administration (FDA) was granted new authority to regulate the manufacture, marketing, and distribution of tobacco products and to educate the public about the dangers of tobacco use. Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (P.L. 111-31), FDA is responsible for protecting the public health and reducing tobacco use among minors. The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 Tobacco Control Act to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information. Section 1003(d)(2)(D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the Tobacco Control Act support the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is implementing a multi-strategy youth-targeted public education campaign to reduce the public health burden of tobacco.

Specifically, FDA has contracted with an advertising firm, FCB, for the development of FDA's *The Real Cost* (TRC) campaign. This campaign, which launched in February 2014, utilizes a paid media campaign, community engagement activations, and a comprehensive social media effort targeted to youth aged 12-17 who are at risk for or experimenting with cigarettes with a tobacco prevention message. The aim of the campaign is to help prevent tobacco use among youth by educating the public—especially young people—about the harms of tobacco products and their use. Research has found that reaching and motivating at-risk youth requires constant and novel messaging. As such, FDA plans to refresh the campaign with new advertisements to keep these high sensation-seeking youth engaged with our messages.

As part of developing new, effective messages, FDA must conduct additional research with the target audience to gain further insight into their tobacco-related knowledge, attitudes, beliefs, and behaviors. Therefore, information obtained through this research study will be used to inform FDA's ongoing public education campaign efforts to prevent

and reduce tobacco use among youth aged 12–17, with a focus on those who have experimented with cigarettes or who are at risk of initiating cigarette use.

This study is designed to measure youth reactions to four advertisements (Attachment E). The study will recruit up to 1,292 youth who are 13-17 years old, who have experimented with cigarettes (i.e., have reported smoking at least 1 puff of a cigarette, but no more than 99 cigarettes in their lifetime) or who are at-risk for experimenting with cigarettes (e.g., would smoke if a friend offered them a cigarette). Participants will be recruited in the summer of 2016. They will be recruited and screened via predetermined mall intercepts across the United States. A more detailed timeline can be found in Table 5, in Section 16 of this document. Sites are selected based on a desire for geographic diversity and density of target audience.

Specifically, the multiple mall facilities where recruitment will occur are managed through one company with whom our study team contracts. This company was chosen because they have worked with us previously in successfully completing earlier waves of this study, and because they have the largest number of malls available to us. Each location in the study has an on-site research facility located within the confines of the mall. Malls are chosen by the partner for their overall traffic, representation of the surrounding area, and overall desirability as research location among those seeking research services. Attachment H has a list of the study locations.

Qualified youth will be invited to complete the copy testing questionnaire (Attachment D). Participants will be randomly assigned to a control group, in which they will not view any ads, or to an ad-viewing group, in which they will be asked to view one of four randomly assigned ads and provide quantitative and qualitative feedback about the ad. All participants will be asked to answer questions about their knowledge, attitudes and beliefs about tobacco use. Approximately one-fifth of the sample will be chosen at random to be control participants. Differences in responses from the control group will be compared with those from the ad viewing group as a check for potential unintended consequences of viewing the ads. Specifically, participants in the control condition are compared to the exposure condition to assess unintended consequences based on responses to cigarette related knowledge, attitudes, and beliefs. Randomization is used to prevent bias resulting from participant group selection and order effect.

All participants will complete a short series of questions in the questionnaire to assess participants' current use of any tobacco products, household use of any tobacco products, and peer cigarette use. These questions will be used to assess the effectiveness of the randomization process and ensure there are no confounding differences between groups. 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, angry, motivated, surprised), and, among other things, whether they felt the ad was interesting, powerful, informative, meaningful, funny, confusing, or worth remembering. 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 the actions they might take in response to the ad (e.g., sharing the ad, mentioning it to a friend). All participants will also be asked to answer questions about their knowledge, attitudes and beliefs about tobacco use as a check for potential unintended consequences of viewing the ads.

Table 1 below indicates the variables to be assessed during the Copy Testing Questionnaire and the participant groups that will be exposed to these variables (see Copy Testing Questionnaire). We have also included more detailed descriptions of the variables below.

Table 1. Structure of the Copy Testing Process and Questionnaire

Table 2. Structure of the Copy Testing Process and Questionnaire			
Action or Variable	**Description**	**Presented to Ad-Viewing Participants**	**Presented to Control Participants**
Ad exposure	Each of the ad-viewing participants will view one unique video ad.	X	
Tobacco use and peer tobacco use	Items on household tobacco use, peer cigarette use, and participant past 30-day tobacco use.	X	X
Perceived ad effectiveness	Ad-viewing participants will be presented with items to assess ad effectiveness immediately following exposure to each video ad.	X	
Tobacco-related attitudes, beliefs and risk perceptions	Items tailored to align with the tobacco facts chosen for inclusion in the video ads. Items assessing participants' attitudes, beliefs, and risk perceptions related to tobacco use.	X	X

A more Ad

Tobacco use and peer tobacco use: Prior to ad exposure, a short series of questions in the survey will assess the participant's current use of any tobacco products, household use of any tobacco products, and peer cigarette use. These questions will be used to assess the effectiveness of the randomization process and ensure there are no confounding differences between groups.

Perceived ad effectiveness: 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, angry, motivated, surprised), and, among other things, whether they felt the ad was interesting, powerful, informative, meaningful, funny, confusing, or worth remembering. 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 the actions they might take in response to the ad (e.g. sharing the ad, mentioning it to a friend). To protect against order effects, questions assessing emotional response and ad effectiveness will be presented in a randomized order.

Tobacco-related attitudes, beliefs, and risk perceptions: All groups will complete a series of questions assessing understanding of the health consequences of tobacco, whether smoking cigarettes is good or bad, enjoyable or not enjoyable, and other attitudes about tobacco use. These questions are used to examine for the presence of unintended consequences.

It is anticipated that data collection will take approximately 6 weeks. The outcome of the survey will be an understanding of youth receptivity to and potential unintended consequences of the ads created for FDA's TRC campaign. Understanding teen

perceptions of ads created to reduce tobacco initiation and use among at-risk youth will help to guide the optimization of these ads.

2. Purpose and Use of the Information

This study is part of a phased approach to develop new advertisements for FDA's *The Real Cost* campaign. The information obtained from the proposed data collection activities will be collected from youth ages 13-17 living in the United States and will be used to inform FDA about youth's reception of and potential unintended consequences of four new advertisements. The study results for each advertisement will be assessed individually, as well as compared across all four tested advertisements in order to address the following questions:

- Does the advertisement provide an understandable message about the harms of cigarette use?
- Does the advertisement provide an engaging message about the harms of cigarette use?
- Does the advertisement have any potential unintended adverse or counterproductive effects related to beliefs around the harms of cigarette use?

The information used to answer the above questions will be collected by a contractor, Marketing Workshop, using an online self-administered survey. The online quantitative research tasks will include direct responses to advertisements and general smoking perceptions.

The study participants will consist of youth aged 13–17 who have experimented with cigarettes (i.e., have reported smoking fewer than 100 cigarettes in lifetime) and youth aged 13-17 who are at risk of initiating (e.g., would smoke if a friend offered them a cigarette). It is anticipated that these two groups will be roughly equal in sample size. Although 12 year-olds are part of the campaign target audience, quantitative testing will only be conducted among those 13-17 in order to adhere to regulations set forth in the Children's Online Privacy Protection Act (COPPA). Efforts will be made during recruitment to ensure that the participant pool represents a diverse population by the distribution of recruitment sites and in terms of race, age, and gender. The study will not, however, be stratified for any other participant demographics beyond age.

To determine the total sample size needed for this study, an a priori power analysis was conducted that included a single advertisement exposure group and a single non-advertisement viewing group. This sample size was determined to account for testing a total of four advertisements. With four advertisement groups and one control group in this study, there will be five groups. Assuming a two-tailed test, a small effect size (Cohen's d = 0.20) and an alpha of 0.05, the required sample size for both phases of this study to achieve a power of 0.80, which is generally considered adequate in social science research, is N=1,230 (246 participants in each of the five groups). Because study enrollment will be occurring simultaneously in multiple malls and geographical locations, it is possible that over-enrollment will occur. Accordingly, a five percent buffer (n=62) will be incorporated into the anticipated N, so that final enrollment numbers will fall between N=1,230 (to achieve adequate power) and a maximum of N=1,292.

Recruiters from Marketing Workshop will partner with 30-50 mall facilities across the nation to recruit a diverse population of potential study participants from all racial/ethnic and socio-economic backgrounds. All participants will be recruited through in-mall intercepts. Eligible participants will be required to self-identify as having experimented with cigarettes or be at risk of experimenting with cigarettes in the future. Only participants aged 13-17 will be included in the study. If they have participated in a research study in within the past 6 months, they will be excluded. Participants who indicate that a member of their immediate family or a close friend works for the tobacco industry will be excluded from the study. Other demographic questions contained in the screener (e.g., race/ethnicity, education) will not be used as inclusion/exclusion criteria, but will be included in the final data set for data analysis purposes. Participants will not be stratified by race/ethnicity or other demographic characteristics, but demographic questions will be used to ensure that enrollment includes a diverse population of youth. Researchers will not inform ineligible individuals that they are being excluded as a result of anything related to their demographic profile or tobacco use behavior.

Specific cigarette use status inclusion and exclusion criteria are:

1. Youth who indicate in the Screener that they satisfy the criteria of an "experimenter" – that is, have smoked at least one puff of a cigarette but have smoked no more than 99 cigarettes in their lifetime – will qualify for study participation.
2. Youth who indicate in the Screener that they satisfy the criteria of an "at-risk non-trier" – that is, they have never used cigarettes in their lifetime, not even one puff of a cigarette, but answered with an affirmative response to any of the susceptibility questions (i.e., did not answer "definitely not" to all questions) – will qualify for study participation.
3. Youth who respond that they have never used cigarettes, not even taken a puff of a cigarette, and respond "definitely not" to all questions assessing susceptibility to future smoking will be defined as "non-at-risk non-trier" and be excluded from participation.
4. Youth who respond that they have smoked more than 99 cigarettes in their lifetime will be designated as established users because they have crossed the threshold of experimenter and will be excluded from participation.

During the screening process, potential participants will be asked for personal information including their email address, their parent or guardian's email address, and sensitive questions about their cigarette use behavior. This information will be used to determine eligibility, and to contact potential participants and/or their parents or guardians to provide parental consent/opt-out, administer the incentive, and to administer the survey. Attachment F includes the scripts for these emails. The final data set will not contain any personally identifiable information from screening, and all screening information, including email addresses, will be destroyed by deletion once the study is completed.

During recruitment, participants will receive a youth assent form, which they will need to complete before enrollment in the study; they will also provide an email address for a parent or guardian. Using the email provided by the participant, parents or guardians will be emailed a blank copy of the youth assent form and a copy of the parental consent/opt-out form, which includes instructions for how to un-enroll their child from the study.

Parents or guardians will have 24 hours to opt their child out of the study either via telephone or email before their child is emailed a link to the study. A reminder email will be sent after 12 hours; additionally, if the opt-out email "bounces back," indicating that the email is invalid, the youth will not be allowed to participate in this study. If a parent or guardian contacts the study team within 24 hours of screening to opt their child out of the study, the child will be removed from the list of potential participants.

Parental opt-out methodology has been used by CTP for the past 3 years on several IRB and OMB approved studies. We queried IRB about this approach and they did raise any issues of ethics with this approach. Given that this study only includes 13-17 years old youth, we only use opt-out for participants who are 13 years old or older. We have examined and have seen similar proportions of parental permissions in cases where parental consent is required, and where we use the 24-hour opt out. Furthermore, we have seen parents of 13-17 year old year old youth opt their children out of studies, indicating the waiting period works. Over the past three years, we have not received any complaints from participants, parents, or IRB administrators about using an opt-out approach.

Further, due to the target population of this study, traditional written parental consent procedures would screen out the very subjects most appropriate for the aims of this study. Many youth who smoke or are at-risk for smoking are unlikely to seek out parental consent or have parents who provide written consent for their children's participation in prevention programs, making the evaluations of such programs problematic (Levine, 1995; Pokorny et al., 2001; Unger et al., 2004; Severson and Ary, 1983). Demonstrating this point, there is consistent evidence of quantifiable differences in the characteristics of youth who participate in smoking cessation research when traditional written consent is required compared to waived parental consent, including participant demographics and smoking history. For instance, Kearney et al. (1983) found that explicit written consent procedure produced a sample that was approximately half the size of the eligible population and over-represented White students while under-representing Blacks and Asian Americans. Anderman et al. (1995) found differences between 9th- and 12th-grade students with and without written parental consent for a sensitive health survey. Participants with written consent were more likely to be White, live in two-parent households, and have a grade point average of "B" or above. Cigarette smoking was also less prevalent in the written consent group. Severson and Ary (1983) found that youth participants who gained consent were more likely to be nonsmokers compared to those non-consent participants.

Because obtaining written consent for at-risk youth will result in a sample with different characteristics than the target group, a 24-hour parental opt-out approach is being requested for participants (and has already received approval from IRB).

If no opt-out is indicated, eligible participants will be emailed a link to the study 24 hours after completing the screener. The email will contain a link that will take the participant directly to the study for completion; survey links are unique and can only be used one time. Qualified participants who do not complete the study within the 48 hours will receive a second email reminding them about the study that also contains a link to the study.

In order to ensure that all youth provide informed assent in the same manner, youth will review and provide assent via the Participant Assent Form (attached) prior to the start of the Copy Testing Questionnaire. Youth must complete the Participant Assent Form to take the Copy Testing Questionnaire; if they do not provide assent, they will not be able to complete the Copy Testing Questionnaire.

3. Use of Information Technology and Burden Reduction

In-person recruitment methods offer benefits in terms of burden reduction and increased efficiencies. Conducting in-person recruitment at malls provides a number of methodological benefits, including increasing efficiency and reducing burden by accessing the target audience by reaching teens in an environment they frequent often.

The use of electronic 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, surveys can be programmed to implement skip patterns based on a participant's previous answers and/or assigned treatment group. 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 questionnaire can be programmed to identify inconsistent or incomplete 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 and format of data transmission, as well as receipt in a format suitable for analysis. Fourth, this approach can increase participation rates by reducing the number of youth needed to complete the Screener in order to achieve the desired enrolled sample size (i.e., by reducing drop off between the screener and questionnaire, because youth can complete the questionnaire on their own time and on their own devices, thus making study participation more convenient). This will also decrease time and costs related to recruitment. Finally, this technology permits participants to complete the instruments in private. Providing the participant 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

The ads being tested in this study are original to FDA's TRC campaign and have not previously been copy tested or publically aired. As such, there are no existing datasets that can be used or modified to address FDA's need for information on youth reactions to these ads. Therefore, the proposed information collection does not duplicate previous efforts.

5. Impact on Small Businesses or Other Small Entities

Participants in this study will be members of the general public, 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 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 reactions to video ads for FDA's TRC campaign. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for youth at risk for tobacco use 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 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:

Tesfa Alexander
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-796-9335
E-mail: Tesfa.Alexander@fda.hhs.gov

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

Michael Murray
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-4234

E-mail: Michael.Murray@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.

Dimas Adiwiyoto
Account Director
FCB
100 West 33rd Street
New York, NY 10001
Phone: 212-885-3283
Email: Dimas.Adiwiyoto@fcb.com

David Cortés
Senior Strategic Planner
FCB
100 West 33rd Street
New York, NY 10001
Phone: 212-885-3743
Email: David.Cortes@fcb.com

Mark Hall
Senior Strategic Planner
FCB
100 West 33rd Street
New York, NY 10001
Phone: 212-885-3372
Email: Mark.W.Hall@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. <u>Explanation of Any Payment or Gift to Respondents</u>

The amount of the incentive is $20. The incentives will be provided in the form of an electronic gift card. Following the completion of the study, participants will automatically be re-directed to a third-party incentive site for immediate redemption. This site will require them to enter their email address in order to receive their gift card. The site itself is password protected and the information collected to issue the gift cards (i.e., participants' email addresses) will not be shared with anyone. There will be no paper trail between issuing the gift card and the participants' enrollment in the study. Additionally, no first- or third-party cookies will be stored during questionnaire completion and/or during the gift card distribution process.

As participants often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research participants are asked to access the study link at a later time, following recruitment and to provide thought-intensive feedback on concepts that require a high level of participation. When applied in a reasonable manner, incentives are not an unjust inducement, but are instead a way to acknowledge respondents for their participation (Halpern, et al., 2004).

Incentives must be high enough to equalize the burden placed on participants with respect to their time and cost of participation (Russell, Moralejo, & Burgess, 2000), as well as provide enough motivation for them to participate in the study rather than another activity. If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with facility rental and costs with setting up the research (Morgan & Scannell, 1998).

Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research, both of which lead to increased costs. Incentives are also necessary to ensure adequate representation among harder-to-recruit populations such as youth, low socio-economic groups, and high-risk populations (e.g., current or former tobacco users and those susceptible to tobacco use) (Groth, 2010).

In the context of this study, the target population is considered a harder-to-recruit population on multiple counts (i.e., youth aged 13–17 who are also at-risk of or currently experimenting with cigarette use). The study also requires participants to comment on an activity that is a sensitive subject matter and could cause them to be reluctant to participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among the limited number of potential youth participants.

If a participant does not take the survey, they do not get the incentive. In accordance with IRB requirements, if participants begin the study, then have to leave for personal reasons or because they became uncomfortable then they will receive the incentive.

10. Assurance of Confidentiality Provided to Respondents

CTP and FDA IRB reviewed and approved the protocols and consent forms for this study. The letter of approval can be found in Attachment G. The IRBs' primary concern is protecting respondents' rights, one of which is maintaining the privacy of participant information to the fullest extent of the law.

Overview of Data Collection System and Data Security

All data will be collected with an assurance that the participants' responses will remain private to the extent allowable by law. The parental consent/opt-out form will include the following statement: “Your child’s answers will be kept private to the extent allowable by law. That means we will not share your child’s answers with anyone outside the study unless it is necessary to protect them, or if it is required by law (e.g., abuse, neglect, self-harm).” The youth assent and parental consent/opt-out forms contain statements that no one will be able to link the participant’s identity to his/her responses. Additionally, survey questions will not ask participants to provide other identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency. Additionally, IP addresses will not be collected by the online survey system, and survey links and access codes that are uniquely coded for each participant will not be used to identify participants or link them to the results. As noted above, no first- or third-party cookies will be stored during questionnaire completion and/or during the gift card distribution process.

All researchers handling data have completed training and obtained CITI or NIH human subjects protection (HSP) training certificates. These individuals will be the only staff with access to raw data files and will be responsible for keeping all data files secured. All data received by the FDA will be de-identified. Documents with personally identifiable information such as assent and parental consent/opt-out forms will remain on a password-protected computer and/or in locked cabinets for a period of three years, and then will be destroyed either by the secure shredding of documents or the permanent deletion of electronic information.

Overview of How Information will be Shared and for What Purposes

Information from this study will be used to inform FDA’s ongoing TRC campaign efforts to prevent and reduce tobacco use among youth aged 12–17, with a focus on those who have experimented with cigarettes or who are at risk of initiating cigarette use. Data will be used to gain insight into target audience perceptions of four new advertisements developed for TRC to determine whether the new advertisements provide an understandable and engaging message about the harms of tobacco use without potential unintended adverse or counterproductive effects. Data from this study may also appear in professional journals or at scientific conferences. Participants’ identifying information will not be included in any report or presentation. All analyses will be done in the aggregate and participant identifying information will not be appended to the data file used.

Neither contractors nor subcontractors associated with this project will share personal information regarding participants with any third party without the participant’s written permission unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or other legal process. The recruitment firm will not have access or privilege to any of the data collected in this study; their chief responsibility is in conducting mall intercepts and attaining enrollment goals. All recruiters are CASRO members that abide by the CASRO Code of Conduct, which aligns closely with CITI standards of research. Marketing Workshop adheres to appropriate research practices including those set forth by industry regulating agencies such as the MRA, CASRO, HIPAA, and COPPA. Among other areas, recruiters are trained in understanding

participant risk; privacy and confidentiality; online research; and unanticipated issues with participants.

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

Participants will be informed that their participation in the study is voluntary and that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer. Parents or guardians are also provided 24 hour to opt their child out of the study.

The potential risks to participants' privacy in this study are minimal. As with any research study there is a chance that privacy could be compromised as a result of an accidental error or a security breach, however no other risks are anticipated. In the event a breach occurs, all participants will be contacted and notified as to the extent of the breach, any damages incurred, and future potential risks; contact information for additional inquiries will also be provided.

Participants' responses will in no way be linked to identifying information; identifying information is collected at participant recruitment/screening only. Eligible participants will be emailed a link to access questionnaires and, for some, rough cut advertisements. Any and all files that include identifying information and/or information related to a participant's cigarette-use status will be kept in a locked filing cabinet (electronic files will be password protected with limited access) and separate from any and all data collected during the course of this study. When parents or guardians are emailed with the parental consent/opt-out form, they will not know the answers to their child's questions at recruitment/screening, but they will be informed that their child is participating in a study on their attitudes and beliefs about tobacco use. Parents or guardians will not have access to their child's answers, but they will be given a blank copy of the questions their child will be asked, upon request.

11. Justification for Sensitive Questions

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 cigarette smoking. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., cigarette smoking behavior) and some demographic information, such as race/ethnicity, could 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 apprise youth 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:

- 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.
- The questionnaire is entirely self-administered and maximizes participant privacy by being conducted online, without the need to verbalize responses.

- Participants will be provided with a phone number for the FCB project manager and a phone number and email for FDA RIHSC (IRB) should they have any questions or concerns about the study or their rights as a study participant.

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 969 hours (Table 2). This includes the time burden associated with the parental consent/opt-out form, the youth assent form and screener, and the questionnaire. Based on previous experience, it is estimated that youth assent form and screener completion will take approximately 5 minutes per youth. Questionnaire completion will take approximately 10 minutes. A total of 5 minutes has been estimated for parents or guardians to review the opt-out form.

To obtain a final sample of 1,292 participants, it is estimated that approximately 3,876 potential respondents (three times the number of participants enrolled) will need to be screened. This number is based on previous rounds of data collection for TRC copy testing.

Table 2. 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
Screened Youth	Screener Completion	3,876	1	3,876	0.083	323
Parents or Guardians of Screened Youth	Parental Consent or Opt-Out process	3,876	1	3,876	0.083	323
Youth Participants	Youth Assent	1,292	1	1,292	0.083	108
	Questionnaire Completion	1,292	1	1,292	0.167	215
Total Annualized Hours						**969**

[1] The total number of respondents is 3,876; for this study 1,292 represents the total number of participants

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. The contractors have conducted many surveys of similar length and content among youth. To calculate estimated burden costs, the mean hourly wage of $7.25 was used for youth and $22.33 for parents. The youth price represents the minimum wage, and the parental price represents 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 study. Thus, assuming an average hourly wage of $7.25 and $22.33 (youth and parent), the estimated cost to participants will be $11,896.09. The estimated value of respondents' time for participating in the information collection is summarized in Table 3 below.

Table 3. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Youth	Screener completion	323	$7.25	$2,341.75
Parents or Guardians of Screened Youth	Parental Consent/Opt-Out	323	$22.33	$7,212.59
Participants	Youth Assent	108	$7.25	$783.00
	Questionnaire completion	215	$7.25	$1,558.75
Total		**969**		**$11,896.09**

13. Estimates of Other Total Annual Costs 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

This information collection is funded through a contract with FCB. The total estimated costs attributable to this data collection are $257,590 (Table 4). 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 2016.

Table 4. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-12	5%	$77,490	$3,875
GS-13	10%	$92,145	$9,215
		Total Salary Costs	$13,090
		Contract Cost	$244,500
		Total	**$257,590**

15. Explanation for Program Changes or Adjustments

This is a new individual generic collection of information.

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 completion method (i.e. study session or online) and 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 TRC Campaign.

The reporting and dissemination mechanism will consist of one primary component: summary statistics (in the form of PowerPoint presentations and other briefings) on youth reactions to video ads and potential unintended consequences. The key events and reports to be prepared are listed in Table 5.

Table 5. Project Schedule

Project Activity	Date
Survey	June 2016 (Approximate)
Data analysis	July 2016 (Approximate)
Presentation of findings	August 2016 (Approximate)

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

An exemption to this requirement is not being requested. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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

References

Anderman, C., Cheadle, A., Curry, S., Diehr, P., Shultz, L., & Wagner, E. (1995). Selection bias related to parental consent in school-based survey research. *Evaluation Review*, *19*(6), 663-674.

CASRO. (2013). *CASRO Code of Standards and Ethics*. Retrieved 6/7/2013 from: http://www.casro.org/?page=TheCASROCode

Chartier, M., Stoep, A. V., McCauley, E., Herting, J. R., Tracy, M., & Lymp, J. (2008). Passive versus active parental permission: Implications for the ability of school-based depression screening to reach youth at risk. *Journal of School Health*, *78*(3), 157-164.

Diviak, K. R., Curry, S. J., Emery, S. L., & Mermelstein, R. J. (2004). Human participants challenges in youth tobacco cessation research: researchers' perspectives. *Ethics & Behavior*, *14*(4), 321-334.

Groth, S.W. (2010). Honorarium or coercion: Use of incentives for participants in clinical research. *Journal of the New York State Nurses Association, 41*(1), 11.

Halpern, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(7), 80l-803.

Horn, K. A., Branstetter, S. A., Dino, G. A., Jarrett, T. D., Tworek, C., & Zhang, J. (2009). Potential effects of active parental consent: Enrolling teen smokers into a school-based cessation program. *Nicotine & Tobacco Research*, ntp146.

Jelsma, J., Burgess, T., & Henley, L. (2012). Does the requirement of getting active consent from parents in school-based research result in a biased sample? An empirical study. *Journal of Empirical Research on Human Research Ethics: An International Journal*, *7*(5), 56-62.

Kearney, K. A., Hopkins, R. H., Mauss, A. L., & Weisheit, R. A. (1983). Sample bias resulting from a requirement for written parental consent. *Public Opinion Quarterly*, *47*(1), 96-102.

Levine, R. J. (1995). Adolescents as research subjects without permission of their parents or guardians: Ethical considerations. *Journal of Adolescent Health*, *17*(5), 287-297.

Morgan, D.L. & Scannell, A.N. (1998). *Planning Focus Groups.* Thousand Oaks, CA: Sage.

Pokorny, S. B., Jason, L. A., Schoeny, M. E., Townsend, S. M., & Curie, C. J. (2001). Do participation rates change when active consent procedures replace passive consent. *Evaluation Review*, *25*(5), 567-580.

Rojas, N. L., Sherrit, L., Harris, S., & Knight, J. R. (2008). The role of parental consent in adolescent substance use research. *Journal of Adolescent Health, 42*(2), 192-197.

Ruiz-Canela, M., Lopez-del Burgo, C., Carlos, S., Calatrava, M., Beltramo, C., Osorio, A., & de Irala, J. (2013). Observational research with adolescents: A framework for the management of the parental permission. *BMC Medical Ethics*, *14*(1), 2.

Russell, ML., Moralejo, DG., Burgess, ED. (2000). Paying research subjects: Participants' perspectives. *Journal of Medical Ethics*, *26*(2), 126-130.

Shaw, T., Cross, D., Thomas, L. T., & Zubrick, S. R. (2014). Bias in student survey findings from active parental consent procedures. *British Educational Research Journal*.

Substance Abuse and Mental Health Services Administration (SAMHSA). (2015). Results from the 2014 National Survey on Drug Use and Health: Detailed Tables. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.pdf. Accessed September 11, 2015.

Severson, H. H., & Ary, D. V. (1983). Sampling bias due to consent procedures with adolescents. *Addictive Behaviors, 8*(4), 433-437.

Tigges, B. B. (2003). Parental consent and adolescent risk behavior research. *Journal of Nursing Scholarship*, *35*(3), 283-289.

Unger, J. B., Gallaher, P., Palmer, P. H., Baezconde-Garbanati, L., Trinidad, D. R., Cen, S., & Johnson, C. A. (2004). No news is bad news characteristics of adolescents who provide neither parental consent nor refusal for participation in school-based survey research. *Evaluation Review*, *28*(1), 52-63.

U.S. Department of Health and Human Services (HHS). (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.