

Point-of-Sale Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Encourage Adult Smokers to Quit Smoking

0910-0810

Supporting Statement: Summary

- The goal of this study is to conduct quantitative copy testing of print advertisements to be placed in the tobacco point of sale environment to determine whether these advertisements provide an understandable and engaging message to encourage a future quit attempt without potential unintended adverse or counterproductive effects. The study will be conducted among current adult cigarette smokers who have attempted to quit smoking in the past year.
- Participants will be recruited and screened via an online survey. The sample will be provided from an opt-in panel and will consist of participants from across the United States. The study will be conducted using web-based surveys that are self-administered and will target up to 2,844 current adult smokers who have attempted to quit smoking in the past year. The consent form and screener will take approximately 5 minutes total; the questionnaire will take up to 20 minutes to complete, per respondent.
- The outcome of the study will be an understanding of overall ad performance and potential unintended consequences for advertisements to support FDA's Center for Tobacco Products (CTP) Point-of-Sale campaign. Understanding the target audience's receptivity to and engagement with these ads can help to optimize messaging for this new campaign. Additionally, the outcome of the study will lead to further creative refinement and ultimately placement of the advertisements in the point-of-sale environment.
- The resulting data will be analyzed using conventional statistical techniques for quantitative data. Qualitative coding and analysis of open-ended items will also be conducted. The survey questionnaire collects information about participants' reactions to advertisements for the Point-of-Sale campaign, which is designed to provide encouraging messaging to smokers in, around, and surrounding convenience stores. The analysis will also include basic demographic and tobacco use information in order to understand whether and how these factors may influence individuals' responses to the ads.

Consent Form

- Attachment A: Informed Consent Form

Data Collection Instruments

- Attachment B: Screener
- Attachment C: Copy Testing Questionnaire
- Attachment F: Recruitment Email Script

Study Stimuli

- Attachment D: Advertisement Stimuli

IRB Approval

- Attachment E: IRB Approval Letter

Point-of-Sale Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Encourage Adult Smokers to Quit Smoking

0910-0810

Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Data suggest that in 2010, 68.9% of U.S. adult smokers reported wanting to quit smoking cigarettes completely, yet only 46.7% of smokers attempted to quit (CDC, 2011). Further, in 2014, although 45.9% of smokers had made a quit attempt, only 7.2% were successful in quitting (USDHHS, 2014). Past research has indicated that convenience stores account for 86.2% of total cigarette sales (NACS, 2011), and that tobacco advertising placed at the point-of-sale (POS) can make it more difficult to quit smoking cigarettes (Clattenburg & Apelberg, 2012). In response, CTP's Office of Health Communication and Education (OHCE) contracted FCB New York to develop a point-of-sale campaign that will encourage and support adult cigarette smokers who have previously made a quit attempt to take actionable steps towards their next quit attempt.

The POS campaign will complement other tobacco use prevention and cessation campaigns (e.g. the Centers for Disease Control's *Tips from Former Smokers* - "*Tips*" campaign). The *Tips* campaign, for example, uses graphic messaging (specifically personal stories of Americans suffering from smoking related illnesses) to motivate smokers to quit for good; the POS campaign uses a different approach and provides non-graphic, motivational messages that encourage smokers to take small steps towards their next quit attempt. Additionally, there have been limited tobacco cessation initiatives conducted in the tobacco retail environment; thus the POS campaign will leverage these opportunities by motivating smokers to make a quit attempt by placing ads directly at the point-of-sale.

In order to develop the appropriate messaging for current smokers to encourage future quit attempts, it is important for FDA to conduct a quantitative copy test in order to provide insights into how members of the target audience react to several advertisements. Information obtained through this research study will be used to inform FDA's ongoing public education campaign efforts to reduce tobacco use, with a focus on encouraging current cigarette smokers to make another quit attempt.

The study is designed to measure reactions to eight different advertisements (Attachment D). Results for each advertisement will be assessed both individually and compared across all eight advertisements.

Online surveys will be conducted with up to 2,844 current adult smokers (i.e., have reported smoking at least 100 cigarettes in their lifetime and who currently smoke every day or some days), ages 25 to 54, who have attempted to quit smoking within the past year. Eligible participants must also report visiting a convenience store at least once a month and at least occasionally buying cigarettes at convenience stores. Additionally, the

sample will include a mix of ages within the 25–54 demographic and will be diverse with regard to gender, race/ethnicity, and cigarette smokers only versus poly-users (Table 1 below). Poly-users are defined as participants who currently use one or more other types of tobacco products (i.e., cigars, little cigars, cigarillos, smokeless tobacco, electronic nicotine delivery systems, and/or hookah/waterpipe) in addition to smoking cigarettes.

Participants in exposure groups will each initially view one advertisement (single exposure). An additional section of the survey will present participants in the exposure groups with multiple advertisements together. The minimum sample size needed to achieve adequate power for this study is an n of 310 in each of the exposure groups and the control group for a total N of 2,790. In order to account for possible over enrollment due to simultaneous recruitment, a buffer of two percent ($n = 54$) will be incorporated into the anticipated N . Thus, there will be at most 316 participants assigned to each of the eight exposure groups and the one control group for a total maximum of 2,844 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 and smoking cessation related knowledge, attitudes, and beliefs. Randomization is used to prevent bias resulting from participant group selection and to mitigate systematic order effects.

The questionnaire will be completed by eligible participants based on screener responses and acceptance to participate via the consent form. As described above, 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 provide quantitative and qualitative feedback on an ad randomly assigned to them. All participants will be asked to answer questions about their knowledge, attitudes and beliefs about tobacco use.

Participants in the ad exposure conditions will view one single ad and respond to a series of questions. Exposure group participants will first answer questions designed to assess their initial reaction to the ad (including questions on how much they like/dislike the ad and how comprehensible they perceive the main message to be). They will then be asked how the ad made them feel (e.g., motivated, discouraged) and whether they felt the advertisement was compelling, attention-grabbing, and meaningful. Additionally, questions will be asked on whether the ad influenced the participant's to attempt to quit smoking or think about the quitting process in a different way. Afterwards, participants in the exposure conditions will view the ad they just viewed in addition to three additional ads and respond to items assessing their understanding of the overall campaign and similar question on their attitudes and intentions to engage in the quit process. Participants in the control group will not view any ads and respond only to questions measuring attitudes towards the quit process and overall intentions to quit smoking within the year.

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 (Attachment C).

Table 1. Structure of the Copy Testing Process and Questionnaire

A
more

Table 2. Structure of the Copy Testing Process and Questionnaire			
Action or Variable	Description	Presented to Ad-Viewing Participants	Presented to Control Participants
Tobacco use and smoking cessation behavior	Items on tobacco use, past quit attempts, and motivation to engage in smoking cessation.	X	X
Advertisement exposure	Each participant in an exposure group will be randomly assigned to view one of the eight print advertisements.	X	
Perceived ad effectiveness	Participants in an advertisement exposure group will be presented with items to assess the ad effectiveness immediately following exposure to the print advertisement.	X	
Tobacco-related attitudes, beliefs and risk perceptions	Items tailored to align with knowledge, attitudes, and beliefs related to tobacco use and cessation. Additionally, items will assess participants' motivation to quit smoking and their perceived self-efficacy to quit smoking.	X	X
Full campaign exposure	Each participant in an exposure group will view the first ad along with three additional advertisements and answer evaluative questions on the entire campaign design.	X	

Ad

Tobac

F

It is anticipated that the entire study will take approximately 8 weeks inclusive of analysis and reporting. The outcome of the survey will help to determine ad effectiveness and identify any potential unintended adverse or counterproductive effects. These results will help to optimize the ads before release into market.

2. Purpose and Use of the Information

This study is part of a phased approach to develop new advertisements for FDA's POS campaign aimed to encourage current adult smokers to make another quit attempt. The campaign advertisements will be placed in and around the tobacco retail environment at convenience stores in several geographically diverse markets. The information obtained from the proposed data collection will inform the development of the advertisements and help FDA to design the optimal advertisements before releasing into the market. The study results for each advertisement will be both assessed individually and compared

across all eight advertisements that will be tested in this round of research. The study will be conducted by Fors Marsh Group, an applied research company and subcontractor to FCB New York. All advertisements will be tested to address the following questions:

- Does the advertisement give smokers confidence to make another attempt to quit smoking?
- Would the advertisement stand out in the point-of-sale environment?
- What is the level of engagement after viewing one of the advertisements?
- Does the advertisement have any potential unintended adverse or counterproductive effects related to beliefs and attitudes of quitting smoking?

A power analysis was conducted to determine the appropriate sample size for this study in order to effectively detect differences between exposure and control groups. Because there will be eight advertisements, there will be eight exposure groups and one control group, for a total of nine groups. Assuming a one-tailed test, a small effect size of 0.20 (Cohen's $d=0.20$), an alpha of 0.05, and a minimum power of 0.80, which is generally considered appropriate for social science research, the required sample size for this study is $n = 2,790$. Because study enrollment will be occurring simultaneously online, a buffer of approximately two percent ($n = 54$) will be applied in order to account for possible over-enrollment in any of the groups for a maximum sample size of $n = 2,844$. Thus up to 316 participants will view and give feedback on each advertisement, and up to 316 participants will be in the control group, representing a sufficient sample size to allow for between and within group comparisons. Please refer to Supporting Statement Part B for additional information on sampling.

Participants will be recruited in October 2016. Fors Marsh Group will be working with Survey Sampling International (SSI)—a volunteer opt-in online panel provider, in order to provide the sample. SSI will invite panel members to participate in the study based on their likelihood to be within the target population (e.g., known smoker status). No geographic restrictions will be placed during sampling to ensure respondents are selected from areas nationwide. The screening, consent, randomization to groups, and survey will all be administered online and will be one unified experience for the respondents. Fors Marsh Group will handle all data collection and survey management. The invitation will include a link that will direct participants first to the screener. If they are eligible to participate, they will be directed to the consent form, which they can review and provide consent. Those who agree to participate will then be randomized to either an experimental or control group and will be directed through their appropriate survey. After completing the survey, respondents will be directed back to SSI, where they will go to a thank you language landing page and then be given their “e-reward” incentive.

The screener is designed to minimize burden on ineligible participants and includes: (a) demographic questions including: gender and race/ethnicity; (b) questions to determine cigarette smoking status using the definitions provided by the Behavioral Risk Factor Surveillance System (BRFSS); (c) items pertaining to where they purchased cigarettes in the last month, and (d) items pertaining to their past quit attempts from the CDC National Health Interview Survey (NHIS) to identify current adult smokers who have attempted to quit within the past year, that is, the target audience for the campaign. To prevent respondent bias from previous exposure to market research or from affiliation with a related industry, the inclusion/exclusion criteria will ascertain whether the potential participants, their family member or their close friends work for the tobacco industry or

certain other types of business, such as an ad agency, and whether they have recently participated in other tobacco-related research. Table 2 contains an overview and justification of the questions in the screener.

Table 2 – Rationale & Justification for Screener Items

Item(s)	Rationale/Justification
1	Verify age. Ensure all participants are ages 25–54.
	<i>Termination point for people who are less than 25 years old or more than 54 years old.</i>
2	Verify that person, their family member or close friend does not have an affiliation with a market research firm, ad agency, tobacco company, or the federal government.
	<i>Termination point for people who do not meet criteria in 2.</i>
3	Verify that person has not participated in research related to tobacco within the past 6 months.
	<i>Termination point for people who do not meet criteria in 3.</i>
4,5	Verify that person is a current smoker.
	<i>Termination point for people who do not meet criteria in 4, 5.</i>
6	Verify that person has attempted to quit smoking in the past 12 months.
	<i>Termination point for people who do not meet criteria in 6.</i>
7	Verify that person buys cigarettes at convenience stores/gas stations at least occasionally.
	<i>Termination point for people who do not meet criteria in 7.</i>
8	Verify that person visits a convenience store at least once a month.
	<i>Termination point for people who do not meet criteria in 8.</i>
9,10	Verify that person is either a poly-user of tobacco or a current cigarette smoker only. Recruit a diverse sample.
11	Verify gender. Ensure a diverse sample.
12	Verify race/ethnicity. Ensure a diverse sample.
13	Verify/Validate age from before.
14	Verify zip code. Ensure a diverse sample.

Soft quotas (Table 3) will be used to help ensure that the study sample represents individuals from a variety of demographic backgrounds. Soft quotas are not used to strictly enforce a quota or limit for any category and are not meant to be nationally representative. They are instead used to ensure a variety of individuals are accounted for in the survey results. Gender, race/ethnicity, age, and user type are self-identified by participants during the screening process. Soft quota proportions for this research study are based on soft quotas used for recruitment for the previous point-of-sale creative concepts research (Point-of-Sale Creative Concept Testing – Focus Groups with Current Adult Smokers), which was conducted by CTP in May and June of 2016.

Throughout the data collection process, Fors Marsh Group will evaluate the respondent pool daily to adjust for any demographic over/under sampling. These requirements will be communicated to SSI who will then make the adjustments in order to reach the desired target populations. SSI may be asked to contact more or fewer participants of a given demographic background based on the progress of meeting soft quotas. Fors Marsh Group will provide twice weekly updates on recruitment to FCB and CTP. The reports will be sent electronically and will show the total number of respondents from each subgroup. Based on these updates, it will be determined if any subgroup is being over- or

under-recruited (based on the study’s soft quotas). If so, Fors Marsh Group will be instructed to adjust their recruitment strategies accordingly.

Table 3 – Demographic Recruitment Goals

Demographic Category	Soft Quota
Hispanic	10%
Caucasian	55%
African American	30%
Other	5%
Male	50%
Female	50%
Poly-Tobacco Users	50%
Smokers	50%

Eligible participants will be randomly assigned to either an exposure or control group. Each online survey will take participants in the exposure groups approximately 15-20 minutes to complete. Participants in the control group are likely to complete their surveys in 3-5 minutes. No personally identifying information from participants will be collected in the online survey.

3. Use of Information Technology and Burden Reduction

The sample will be provided by the online panel provider, Survey Sampling International (SSI), with the management and oversight of Fors Marsh Group. Utilizing online panels is a commonly used method to conduct quantitative research that allows a large targeted sample size to be reached on a broad scale. That said, because participants self-select to participate in these panels, the study uses a non-probability sample. For this phase of research, a non-probability sample is justified, though, as the primary focus is on a controlled test of the impact of advertisement exposure (rather than gathering representative data).

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 adults 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 adult 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 allows for 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 Point-of-Sale 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 adults’ 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 print advertisements for FDA’s Point-of-Sale campaign. Failure to collect these data could reduce effectiveness of the FDA’s messaging, and therefore reduce the benefit of the messages intended to ultimately decrease 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 CFR 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:

Chaunetta Jones
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-0427
E-mail: Chaunetta.Jones@fda.hhs.gov

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

Maria Reditis
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-1928
E-mail: Maria.Reditis@fda.hhs.gov

Janine Delahanty
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-9705
E-mail: Janine.Delahanty@fda.hhs.gov

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

Sarah Evans
Director of Communication Research
Fors Marsh Group
1010 N. Glebe Road Suite 510
Arlington, VA 22201
Phone: 571-858-3752
Email: sevans@forsmarshgroup.com

Cameron Wimpy
Senior Researcher
Fors Marsh Group
1010 N. Glebe Road Suite 510
Arlington, VA 22201
Phone: 571-858-3763
Email: cwimpy@forsmarshgroup.com

Caitlin Krulikowski
Senior Researcher
Fors Marsh Group
1010 N. Glebe Road Suite 510
Arlington, VA 22201
Phone: 571-858-3771
Email: ckrukowski@forsmarshgroup.com

Nikkita Sarna
Researcher
Fors Marsh Group
1010 N. Glebe Road Suite 510
Arlington, VA 22201
Phone: 571-858-3826
Email: nsarna@forsmarshgroup.com

Carol Issa
Account Supervisor
FCB
100 West 33rd Street
New York, NY 10001
Phone: 212- 716 7608
Email: Carol.Issa@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

9. Explanation of Any Payment or Gift to Respondents

Eligible participants who partake in the online survey will receive an “e-reward,” equal to approximately \$1.50, through the online panel provider, SSI, as an incentive. This is a typical amount for rewards-based panel systems such as this. The proposed incentive amount will be provided to participants for their entire burden time, which includes screening time and completing the survey. The survey will take most participants no longer than 20 minutes. Only participants who are eligible will receive an incentive, as is common procedure for online research studies.

In the market research community, incentives are standard practice and are suggested by organizations that set the standards for conducting ethical market research among human subjects (CASRO Code of Standards and Ethics for Survey Research). An incentive less than the standard amount offered by the vendor will greatly inhibit the ability to successfully recruit participants. In the context of FDA’s efforts to inform the public on tobacco-related health issues, this is the first time that FDA is expanding such efforts to target adult smokers with advertising within the tobacco retail environment; as such it is particularly imperative to provide adequate incentives to encourage and retain participation.

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 we are asking participants to provide thought-intensive feedback on advertisements 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 drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with setting up the research (Morgan & Scannell, 1998).

Additionally, low incentives 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 (Groth, 2010). In the context of this research study, the target population is considered a harder-to-recruit population because of the screening criteria (e.g., current smokers who have made a quit attempt in the past year).

10. Assurance of Confidentiality Provided to Respondents

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

The following measures will be used to ensure confidentiality once the survey process begins: (1) full names of the participants are never used on any survey materials; (2) the surveys do not ask for the recording of any personally identifying information; (3) any lists or logs with names are stored securely on a password-protected computer; and (4) given responses to the survey are not attributed to the individual. No identifying information will be included in any data, reports or slides delivered to FDA.

The following processes are in place to protect personal and sensitive data: (1) raw data from data collections that include sensitive information will be destroyed by deletion or secure shredding once the non-personally identifying data have been extracted and aggregated; (2) unused information from screening never becomes part of a system of records containing permanent identifiers that can be used for retrieval; and (3) no datasets generated from the study will include any personal information that can be tied to individual responses to sensitive questions.

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.

Overview of How Information will be Shared and for What Purposes

All data will be reported in aggregate form such that data collected cannot be traced back to particular participants. Researchers will never tie respondents' personal information to their answers. All analyses will also be done in the aggregate and respondent information will not be appended to the data file used.

All data will be collected with an assurance that participants' responses will remain private to the extent allowable by law. All data will be encrypted in transit using HTTPS. All equipment will be operated and maintained according to industry standard practices, and all software validated using industry standard quality assurance practices. All identifiable information will be destroyed upon completion of the study by Fors Marsh Group before any reports are delivered to FDA. Any report delivered to FDA will not include identifying information. De-identified screener information or survey results will be used by FDA to assist in material development. All data received by FDA will remain stored on a password protected computer and/or in locked file cabinets. After three years, all of the collected data will be destroyed by securely shredding documents or permanently deleting electronic information.

The online panel provider and contractor will not share personal information regarding participants with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other

legal process. This possibility will be disclosed in the informed consent form. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

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

After screening, eligible participants will be directed to read and sign an informed consent form online. A copy of the informed consent form is included in the attachments (Attachment A). According to the Readability Test Tool available at www.read-able.com, the informed consent form was determined to be at or under the 9.0 Flesch-Kincaid grade level.

The potential risks to participants in this study are minimal. Participants may be exposed to tobacco-related advertisements. Although the messaging in the advertisements is designed to motivate smokers to make another quit attempt, as in any message-testing, there is the possibility that messaging may have the opposite effect. A link to a smoking cessation resource will be provided at the end of the survey for participants who want more information about quitting. Participants will receive contact information for the research leads and IRB chair and will be told that they can contact researchers before, during, and following their participation in the study if they have questions or concerns about the study or their rights as a participant.

Although the research will not directly benefit the participants, based on this study being of minimal risk to participants, the potential benefit of information gained outweighs any risks involved.

11. Justification for Sensitive Questions

We will ask potential participants a series of screening questions as part of the recruitment process. In order to reach a wide range of participants, this may require asking questions about race/ethnicity. Respondents will be assured that providing this information is completely voluntary and will be treated as private to the extent allowed by law.

In addition, given the nature of this research effort, participants will be asked about their smoking status and their perceptions of personal risk for serious illness as a consequence of their smoking behavior. This information is necessary in order to gain insight into which types of messages, strategies, and materials will be most effective among the target audience. Though not as personal as questions about sexual behavior or religious beliefs, for instance, questions of this nature still require some sensitivity in how they are worded and approached. Participants will be informed prior to actual participation about the nature of the project, and the consent form will emphasize that their participation is completely voluntary, they can skip any questions they do not feel comfortable answering, and they may leave the study at any time for any reason and will still receive their incentive.

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 1,152 hours (Table 4). This includes the time burden associated with the screener, consent form, and the questionnaire. Based on previous experience, it is estimated that the screener and consent form completion will take approximately 5 minutes. Questionnaire completion will take up to 20 minutes.

To obtain a final sample of 2,844 participants, it is estimated that approximately 8,816 potential respondents (three times the number of participants enrolled) will need to be screened. This number is based on previous rounds of data collection and Survey Sampling International (SSI) estimates based on prior studies and experience.

Table 4. Estimated Annual Reporting Burden¹

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours	
Screened Respondents	Screener Completion	8,816	1	8,816	0.03	294	
Eligible Participants	Consent Form Completion	2,844	1	2,844	0.05	142	
	Questionnaire Completion	Ad Exposure Group	2,528	1	2,528	0.33	843
		Control Group	316	1	316	0.08	26
Total Annualized Hours						1,305	

¹The total number of respondents is 8,816; for this study 2,844 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. To calculate estimated burden costs, the mean hourly wage of \$25.61 for adults. The 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 \$25.61, the estimated cost to participants will be \$33,421.05. The estimated value of respondents' time for participating in the information collection is summarized in Table 6 below.

Table 5. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Respondents	Screener completion	294	\$25.61	\$7,529.34
Eligible Participants	Questionnaire/Consent completion	1,011	\$25.61	\$25,891.71
Total		1,305		\$33,421.05

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 New York. The total estimated costs attributable to this data collection are \$257,590 (Table 6). 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 6. 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

To assess FDA's POS advertising materials for adult smokers, participants will be asked a series of questions including their assessment of the main message of the ad, their assessment of believability of the ad, and their assessment of the perceived effectiveness of the ad using the Perceived Effectiveness scale. Additionally, participants will be asked if their perception of the main message of the ad changes once they have seen all the ads

together. Data will be checked in a statistical program, such as Stata®, to assess the degree of completeness; any variables with more than 5% missing data will be identified and reported. Data describing the sample of participants will be calculated. Sample characteristics for participants endorsing each response category will be analyzed and reported.

Before conducting analyses comparing results from the ad groups and the control group, we must ensure that the underlying samples of individuals receiving each condition are not significantly different in any way. A randomization check will be conducted to ensure the randomization process worked as expected with equivalent resulting groups on measured descriptive variables and cigarette smoking or quitting behavior. Specifically, the distribution of the demographic variables of age, gender, race/ethnicity, and smoking/poly-use status will be compared. A categorical Chi-Square analysis will be employed to determine if any differences in sample composition occur beyond what would be considered random. If any significant differences exist between groups, subsequent analyses will account for these differences by controlling for the items on which groups differ. The likelihood of randomization issues is relatively low given the overall sample size and 1:1 group allocation ratios. The expectation is that the likelihood of assignment to one of the exposure or control groups or another is the same for all participants in the sample. Fors Marsh Group will consistently monitor group assignment and progressive levels to ensure that randomization is consistent.

The surveys will yield quantitative data that can be used for certain types of statistical analyses. Statistical software (such as R, SPSS, or Stata) will be used to clean and organize the data before analyses. The analyses may include, but are not limited to, comparisons of means, *t*-tests, regression, calculation of summary statistics and cross-tabulations, and any appropriate estimates of uncertainty. Although some statistics will be calculated, the convenience sampling procedures for the survey do not allow for results that are nationally-representative, and any point estimates may not represent the population at-large.

The reporting and dissemination mechanism will consist of one primary component: summary statistics (in the form of PowerPoint presentations and other briefings) on reactions to ads and potential unintended consequences. The key events and reports to be prepared are listed in Table 7.

Table 7. Project Schedule

Project Activity	Date
Recruitment and Fielding	October - November 2016 (Approximate)
Data analysis	December 2016 (Approximate)
Presentation of findings	December 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

- CASRO. (2013) *CASRO Code of Standards and Ethics*, Available at: <http://www.casro.org/?page=TheCASROCode> Accessed on: 06/07/2013
- Centers for Disease Control and Prevention. (2011) Quitting smoking among adults—United States, 2001–2010. *Morbidity and Mortality Weekly Report*, 60(44), 1513–19.
- Clattenburg, E.J., Elf, J.L., & Apelberg, B.J. (2012). Unplanned cigarette purchases and tobacco point of sale advertising: A potential barrier to smoking cessation. *Tobacco Control*, 22(6), 376-381.
- Groth, S.W. (2010). Honorarium or coercion: Use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*, 41, 11-13.
- 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), 801-803.
- Morgan, D.L. and A.N. Scannell. (1998) *Planning Focus Groups*. Thousand Oaks, CA: Sage.
- National Association of Convenience Stores (NACS). (2011). *State of the Industry Report; 2011*. Retrieved from:
http://www.nacsonline.com/News/Press_Releases/2012/Pages/PR062512.aspx#.VBsMNFeZjJp
- Russell, M.L., Moralejo, D.G., Burgess, E.D. (2000). Paying research subjects: participants' perspectives. *Journal of Medical Ethics*; 26, 126-130.
- 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.