SUPPORTING STATEMENT FOR THE

National Tobacco Education Campaign

Creative Concept Testing

(OMB No. 0920-0910, Exp. Date 03/31/2018)

PART A: JUSTIFICATION

April 19, 2017

Submitted by:

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A. JUSTIFICATION

LIST OF ATTACHMENTS

Notes on Excluded Attachments. In this information collection request, CDC outlines a plan to test creative concepts with content that may be considered sensitive. The draft materials are not included because the creative concepts have not been approved for public distribution by HHS/Assistant Secretary for Public Affairs (ASPA). To support adequate review of this Gen IC by OMB, the Centers for Disease Control and Prevention requests permission to provide OMB with a secure link to the draft materials.

Supporting Statement: Summary

- **Goal of the Study:** The goal of this study is to evaluate four creative concepts that focus on the consequences of smoking and the benefits of quitting prior to the production of an advertisement. The resulting information will be used to select the concept with the greatest impact and will inform the development of rough-cut advertisements (which include the near-final version of advertisements, with unedited photos, placeholder voiceovers, etc.) for a future National Tobacco Education Campaign (NTEC).

- **Intended use of the resulting data:** This study will help determine which concept will have the greatest likelihood of motivating the largest number of people to quit smoking conventional cigarettes completely. The resulting data will ensure that future rough-cut versions of the advertisements are clear, credible, believable, and effective in motivating smokers to quit smoking conventional cigarettes completely. Obtaining target audience insight at this phase of the campaign development will help ensure that resources are used more efficiently.

- **Methods to be used to collect data:** Quantitative and qualitative methods will be used to collect data on four creative concepts. Quantitative data will be collected through 15-minute online surveys (which include a screener and a questionnaire) of 10,748 respondents. Quantitative testing will collect information about the respondents' reactions to the creative concepts, as well as basic demographic and cigarette and e-cigarette use information to assess whether responses to creative concepts differ across and within concepts. Qualitative data will be collected through 12 in-person 90-minute focus groups, with a total of 120 participants, across three U.S. cities. Qualitative testing will result in a deeper understanding of which of the four concepts is most clear, credible, and effective in prompting changes in tobacco-related knowledge, attitudes, beliefs, and behavior, as well as provide insight as to why that is the case.

- **Populations to be studied:** The study population will be adult smokers 18-54 years old, categorized as either: (1) exclusive smokers of conventional cigarettes, or (2) concurrent users of conventional cigarettes and e-cigarettes (dual users). Study participants will be sampled from these two different populations to test four creative concepts. Exclusive e-cigarette smokers will not be included in the study.

- **How data will be analyzed:** The resulting quantitative data will be analyzed using aggregate measures such as percentages and means. The qualitative data will be analyzed using thematic analysis. Focus group responses will be completely transcribed and read thoroughly, and codes will be created manually to identify themes and patterns of response. The qualitative data will add rich detail, depth, and context to the quantitative results and will help provide insight into the reasons for participants' reactions to the concepts.

Part A. Justification for Information Collection

A.1 Circumstances Making the Collection of Information Necessary

While significant improvements have been made in reducing the smoking rate in the United States since the first Surgeon's General Report came out more than 50 years ago, cigarette smoking is still the leading cause of preventable disease and death in the United States, accounting for more than 480,000 deaths every year, or one of every five deaths (U.S.Department of Health and Human Services (HHS), 2014). The prevalence of cigarette smoking among adults has declined from 42% in 1965 to 15.1% in 2015 (DHHS, 2014; CDC 2016). In addition, more than 16 million Americans live with a smoking-related disease (DHHS, 2014). In 2012, for the first time, the Department of Health & Human Service (HHS), through the Centers for Disease Control and Prevention (CDC), aired the adult-focused National Tobacco Education Campaign (NTEC) called *Tips from Former Smokers*™ (*Tips*™). The primary NTEC audience is smokers ages 18 through 54. Secondary audiences include parents, family members, and adolescents. The goals of the *Tips*™ campaign are to:

- Build public awareness of the immediate health damage caused by smoking and exposure to secondhand smoke;
- Encourage smokers to quit, and make free help available, and;
- Encourage smokers not to smoke around others and encourage nonsmokers to protect themselves and their families from exposure to secondhand smoke.

To date, accomplishments of the NTEC formative research have led to the development of effective hard-hitting antismoking advertisements that raise awareness about the dangers of smoking and motivate smokers to quit. For example, the 2012 campaign motivated 1.64 million smokers to make a quit attempt (McAfee, Davis, Alexander, Pechacek, & Bunnell, 2013), and after the launch of the nine-week 2014 campaign, 1.83 million smokers attempted to quit smoking, 1.73 million additional smokers intending to quit within six months, and 104,000 sustained quits of at least 6 months (CDC, 2016). To keep the target audience engaged with the NTEC and ensure continued effectiveness of the campaign, ads and ad messages must be continually refreshed. As such, CDC plans to develop another set of ads. CDC's Office on Smoking and Health (OSH), in collaboration with their contractors, The Plowshare Group, and subcontractors, Qualtrics, and Battelle, will first test a set of "creative concepts" for ads.

Initial *Tips*™ messages focused on real people who are living with serious long-term health effects from smoking and secondhand smoke exposure. Building on this success, the breadth and scope of the NTEC will be inclusive of both exclusive smokers of conventional cigarettes and dual users of conventional cigarettes and e-cigarettes. In recent years, the use of e-cigarettes has rapidly increased; in 2014, almost one-half of current cigarette smokers (47.6%) had ever tried an e-cigarette, and about one in six current cigarette smokers (15.9%) currently used e-cigarettes (Schoenborn & Gindi, 2015). Thus, it is important to create messages that motivate dual users, in addition to exclusive conventional cigarette smokers, to quit smoking conventional cigarettes. The prior round of testing for this campaign (which tested "message platforms" with both exclusive conventional cigarette smokers and dual users) focused on a variety of messages including ones about effective quit methods, the lifestyle effects of smoking, and the effects of secondhand smoke, in addition to hard-hitting messages about health effects. Results of this

study demonstrate that these hard-hitting messages about the health consequences of smoking show the potential for promise with both exclusive conventional cigarette smokers and dual users; this round of creative concept testing will further explore this.

Creative concept testing evaluates participants' reactions to a concept prior to the production of an advertisement. It is used to ensure the message and call to action are clear and determine how well the specific concept informs the target audience of the health consequences caused by smoking conventional cigarettes and motivates them to take action (e.g., quit smoking conventional cigarettes or talk to a loved one about the dangers of smoking conventional cigarettes). The objective of the proposed study is to test four creative concepts among adult smokers (ages 18-54) with different tobacco use behaviors (exclusive conventional cigarette smokers and dual users of conventional cigarettes and e-cigarettes). OSH has also identified several subpopulations of interest, based on either higher than average smoking prevalence or based on potentially different reactions to concepts.

The creative concepts that will be tested include three hard-hitting, emotionally impactful concepts focused on the health consequences of smoking and one concept that highlights the benefits of quitting smoking. In order to identify the concept that is the most motivating to the target audience, an average of 2,687 respondents in the overall quantitative sample will view each concept. Approximately 120 participants will also view each concept during the qualitative portion of this study. This information will inform the development of future NTEC advertisements.

A.2 Purpose and Use of Information Collection

The overall purpose of the project is to assess which of the four creative concepts are perceived as most credible, comprehensible, and persuasive among exclusive conventional cigarettes smokers and dual users ages 18-54. The goal is to evaluate participant reactions to these creative concepts that focus on the consequences of smoking and the benefits of quitting prior to the production of an advertisement. From the results of the quantitative and qualitative testing, one concept will be selected that will be used to inform the development of rough-cut advertisements for a future national tobacco education campaign. This concept will also serve as the foundation for a number of individual executions. Additionally, because smoking rates vary by subpopulation, this information collection will also assess whether perceptions of these creative concepts differ for subpopulations with higher rates of cigarette smoking than the general population and who are disproportionately affected by smoking-related illness. Included among these are individuals who are low-socioeconomic status (SES), have anxiety or depression, or are racial and ethnic minorities (Hispanic and African-American) (Campaign for Tobacco Free Kids, 2015; CDC, 2013, 2015; HHS, 2014).

The proposed testing is part of a collection of ICRs that will be submitted under a dedicated generic clearance to develop advertisements for a future NTEC. The program received OMB approval for a previous data collection request in July 2016 (OMB No. 0920-0910). If this data collection is not performed, CDC will not know whether these creative concepts communicate credibly and effectively with the main target audience and across varying audience segments. This could result in the production of ads that are less effective in encouraging smokers to quit.

Additionally, creative concept testing is a way to measure any unanticipated confusion, ambiguity, or lack of understanding of the advertisement's message.

Quantitative: Online Questionnaire. The quantitative portion of this study will collect data via the Online Questionnaire (Attachment 3). Potential participants will be recruited from an existing, online, convenience panel managed by Toluna (see http://www.toluna-group.com//choose-the-people#global-reach for more detail on this panel). The panel provider maintains demographic information about panelists in its proprietary database, which is not released (see Toluna Privacy Policy, Attachment 11), and this information will be used to ensure that the invitation to participate in this project will target only individuals who are likely to be eligible. Specifically, the invitation (Attachment 1) will be sent to panel members.
An online, project-specific screener (Attachment 2) will be used to assess respondent characteristics such as age, smoking, and e-cigarette behavior. In addition to confirming eligibility, the screening information will be used to assign participants to one or two strata (exclusive conventional cigarette smokers or dual users). Following the screening process, eligible respondents will complete the online questionnaire.

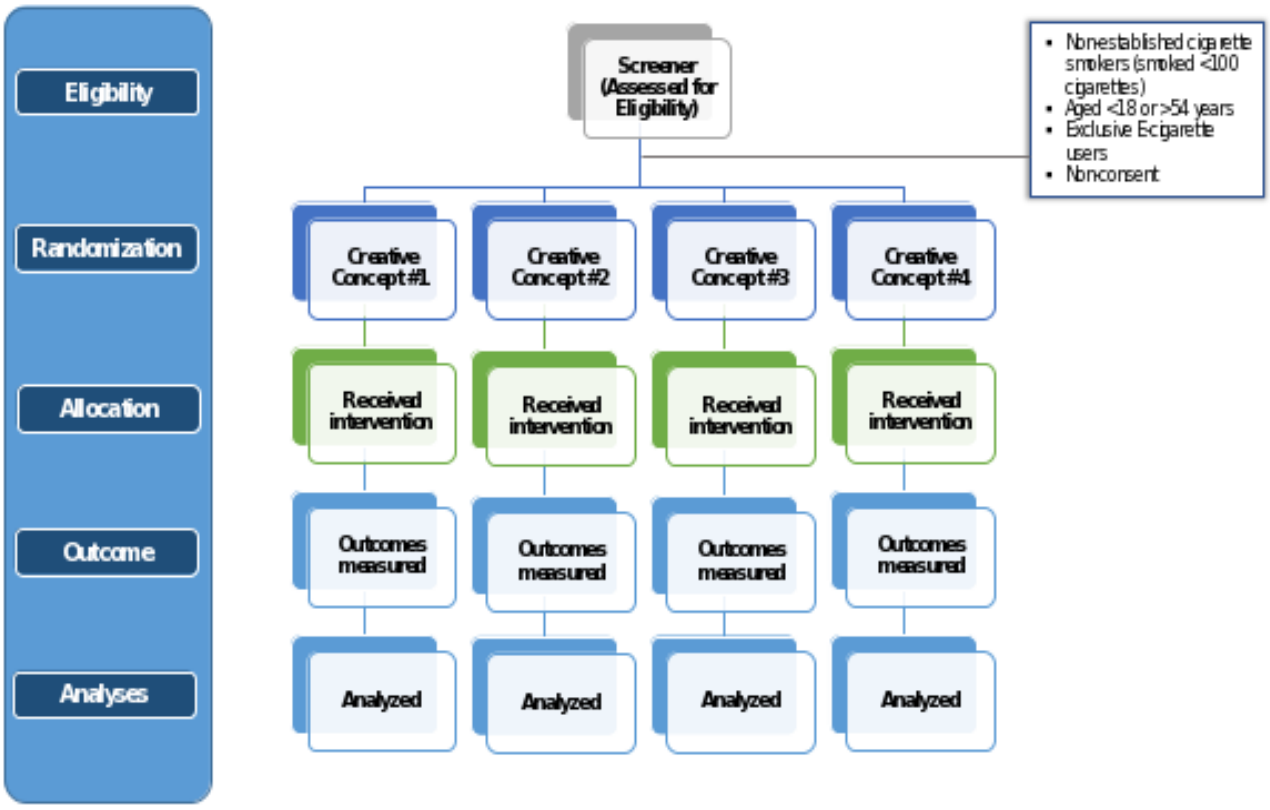
The purpose of the online questionnaire is to show participants the creative concepts and collect quantitative information on the relevance, acceptability, and effectiveness of the concepts. Specifically, the questionnaire will measure demographic characteristics, tobacco use behaviors and perceptions, and reactions to the concepts (e.g., perceived effectiveness (PE), confusion, believability, emotional response, effect on motivation to quit smoking, etc.).

Within each of the two strata within the study, individuals will be randomized to one of the four concepts being tested, which are: (1) "Concept #1; (2) "Concept #2" (3) "Concept #3" and (4) "Concept #4" Six separate pair-wise comparisons (XI, X2, X3, X4, X5, and X6) will be conducted within each of the two strata. The issue of multiple comparisons has been accounted for in the sample size calculation by using a Bonferroni-adjusted critical α threshold. These comparisons will allow for a determination of which concept elicits the strongest reaction among participants.

	Concept #1	Concept #2	Concept #3	Concept #4
Concept #1		X1	X2	X3
Concept #2			X4	X5
Concept #3				X6
Concept #4				

Randomization of participants into the different concepts being tested ensures that there is a similar distribution of individuals with different measured and unmeasured characteristics across the different concept arms. A block design will be used to ensure that the number of persons in each arm is approximately even to ensure robust statistical comparisons. Overall, the study design guarantees high internal validity even though external validity (i.e., generalizability) is low because of the volunteer sample. Within the different strata, detailed analyses of tabulation variables such as sex, race/ethnicity, and other demographic characteristics will allow investigators to determine whether receptivity to the messages differs within the different groups.

Figure 1. Diagram for study design, enrollment, allocation, and analyses



All information collected in the online questionnaire will allow for study outcomes to be measured, and confounding influences controlled for. Some of the key variables measured are summarized in the Table A.2. below:

Table A.2. Rationale for variables measured in online survey

Measure	Construct	Questions
Stratification variables	Socio-economic status and tobacco use behavior	SES1-SES3, TS1a-TS8, E1-EC13, QA1-QA8a, P1-P6, D21a-D211, P7a, P7b.
Tabulation variables	Age, sex, race/ethnicity	DEMO1-DEMO5
Study arms (exposures)	The four concepts being tested	Exposure to the concepts will occur via digital media. The concepts are (1) Concept #1; (2) Concept #2" (3) Concept #3 and (4) Concept #4
Key Outcomes	Perceived effectiveness of ad	M1-M32
Potential confounding variables	Moderators, confounders, or contextual variables	DEMO1-DEMO5
Other	Behavioral beliefs,	TS8, E1, E2, EC13, QA4, P1, P5a-P6, D21a-P7b, M2-M4,

contextual variables	Normative beliefs, control beliefs	M6a-M32

Qualitative: In-Person Focus Groups. The qualitative portion of data collection will involve conducting focus groups to gain in-depth information about participants' reactions to the four creative concepts. Focus groups will be conducted in three cities: Louisville, KY; Philadelphia, PA; and Phoenix, AZ. These locations were chosen because each is in a state that has a higher than average smoking prevalence (according to CDC statistics: http://www.cdc.gov/statesystem/) and a higher than average e-cigarette purchase rate (based on scanner data from RTI). Additionally, locations were chosen to maximize geographic diversity. Schlesinger Associates will host the focus groups in each city. The testing facilities will utilize their existing pre-profiled panels to identify potential participants and a phone screener (Attachment 4) provided by CDC to determine participant eligibility. The identifiable information about panelists is maintained in proprietary records systems of the focus group facilities and is not released (see Schlesinger Privacy Policy, Attachment 12).

Before participating in the focus groups, eligible persons will be asked to complete a pre-focus group questionnaire that also contains the informed consent form (Attachment 5). This questionnaire will include the same questions as the screener for quantitative data collection and will be used to reconfirm their eligibility to participate in the study. During the focus group, participants will complete the Participant Feedback Questionnaire (Attachment 8). This questionnaire contains close- and open-ended questions to collect information about potentially sensitive reactions to the concepts and any opinions that participants did not feel comfortable sharing with the group.

Following the Pre-Focus Group Questionnaire and Informed Consent process, the moderator will use the Moderator's Guides, tailored for exclusive conventional cigarette smokers or dual users (Attachments 6 and 7) to lead each focus group. The Moderator's Guides include a preamble which explains to the participants the purpose, sequence, and ground rules of the focus group, several general questions about their smoking behavior, and finally, questions that elicit discussion of four proposed creative concepts, each with two TV ad executions (variations of the concept). The concepts will be presented using non-animated storyboards including relevant images accompanied by an audio track. Part B includes additional information on the format of these concepts and executions, in addition to how they will be viewed by participants. The goal of these discussions is to solicit feedback about participants' reactions to the concepts, in order to select one concept and determine ways in which the concept can be made more compelling and can motivate smokers to quit smoking conventional cigarettes. Ultimately, this qualitative data will be used in combination with the quantitative data to determine which concept should be developed into rough-cut advertisements for a future campaign.

A.3 Use of Improved Information Technology and Burden Reduction

During the quantitative stage of data collection, all information (from the Screener and the

Questionnaire) will be collected electronically by utilizing an integrated Web-based software platform. Web-based surveys are an especially convenient option for eliciting feedback on visual and textual stimuli such as the creative concepts to be tested. The use of a web-based platform also offers a number of benefits for managing the quantitative data collection:

- First, use of an existing online panel system will allow CDC to obtain information quickly so that needed adjustments to health messaging can be made expeditiously and campaign development can progress rapidly from planning to implementation. The panel used for this testing is very large (more than 1.7 million people in the U.S.), allowing quick selection of participants from extremely small subgroups of the population. Samples from this panel are not designed to generate nationally representative samples or precise population parameters but rather are used as a highly efficient, low cost, and low burden method of data collection for formative copy testing.
- Second, when a respondent enters the screener for this project, the link to his or her identifiable information is severed (i.e., the link to the identifiable information maintained by the panel provider). None of the information collected through screening or the online questionnaire is identifiable, providing a secure environment for participants.
- Third, 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.
- Finally, the web-based software system includes embedded logic that will route respondents efficiently through the screener and onto the online questionnaire (or a "thank you" screen, if the respondent is found to be ineligible). This approach can increase participation rates (which decreases time and costs related to information collection procedures) by reducing the number of respondents 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).

Overall, the software supports an efficient assignment and routing process, as well as a smooth user experience that would be difficult to attain in other modes of data collection.

During the qualitative data collection, focus group facilities will recruit and screen the focus group participants using phone calls to eligible panelists. Focus group discussions will be video streamed live using FocusVision, a high-definition video streaming service, or similar service. The use of this streaming service will facilitate and expedite the focus group transcription and analysis process. Additionally, the streaming process will keep travel-related costs down and will support quality control measures, as CDC staff and other contractor staff will be able to remotely observe the focus group discussions. The secure link, password-protected, will be available to view the live stream through a password-protected secured link.

A.4 Efforts to Identify Duplication and Use of Similar Information

This Information Collection Request (ICR) is designed to test creative concepts to support the development efforts of future NTEC advertisements. To prepare for data collection, CDC reviewed existing published literature, Food and Drug Administration (FDA)'s Deeming Rule,

and unpublished qualitative pretesting reports (e.g., the findings of the recent "message platform" testing) when they were available.

CDC's Office on Smoking and Health (OSH) collaborates with other federal government agencies that sponsor or endorse health communication projects, such as FDA's Center for Tobacco Products (CTP). Staff members in OSH's Health Communications Branch work closely with staff in CTP's Office of Health Communication and Education. Regularly scheduled conference calls are held to review plans and share research findings of mutual interest. These collaborations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include the review of data collection instruments and other support materials for testing purposes.

FDA CTP is currently developing creative concepts based on cessation to support the development effort of their point of sale campaign. FDA's concepts take a motivational approach to encourage the target audience to make quit attempts sooner and more frequently, rather than a graphic, hard-hitting approach as seen in CDC's *Tips From Former Smokers*™. FDA's media placement will be exclusively in and around convenience stores and will target smokers ages 25-54 who have been unsuccessful in their past quit attempts. CDC's media placement will be national mass media targeting smokers ages 18-54.

Given that CDC and FDA are developing complementary but distinct messages to educate the public about the harmful effects of tobacco products, CDC will also share the findings of this information collection effort with CTP to ensure that future duplication of efforts is preempted.

Points of contact for this coordination are:

- CDC: Diane Beistle, Chief, Health Communication Branch, telephone (770) 488-5066, email zgv1@cdc.gov

- CDC: Lindsey McCarter, Team Lead, Campaign Development, Health Communication Branch, telephone (770) 488-4239, email lpq4@cdc.gov
- CDC: Michelle O'Hegarty, Health Communications Specialist, Campaign Development, Health Communication Branch, telephone (770) 488-5582, email mohegarty@cdc.gov

- CDC: Sarah Lewis, Health Communications Specialist, Campaign Development, Health Communication Branch, telephone (770) 488-7424, email irr6@cdc.gov

- FDA: Tesfa Alexander, Health Communication Specialist, Office of Health Communication and Education, telephone (301) 796-9335, email Tesfa.Alexander@fda.hhs.gov

A.5 Impact on Small Business or Other Small Entities

This data collection will not involve small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time information collection request.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require data collection to be conducted in a manner inconsistent with 5 CFR 1320.5 (d) (2). The information collection fully complies with the guidelines in 5 CFR 1320.5.

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

A.8.a Federal Register Announcement

A Notice was published in the Federal Register on August 11, 2014, volume 79, number 154, pp. 46829-46830). CDC received one comment stating that the respondent did not agree with ongoing data collection on smoking that is "wasteful" to taxpayers. CDC provided a courtesy response.

A.8.b Consultations

CDC's NTEC has been funded primarily with funds from the Affordable Care Act/Public Health Fund designated for smoking education since 2010. CDC did not consult outside of the agency on the creative concepts.

A.9 Explanation of Any Payments or Gift to Respondents

For the quantitative data collection, participants will be drawn from the established Toluna panel system, which provides points to panelists to encourage participation (see Attachment 9: Toluna's Terms and Conditions). Immediately upon completion of the survey, each respondent will be provided with points equivalent to $0.50. These points are accrued with other points when the panelist takes part in other surveys. At any time, the panelist is able to redeem their points for different products, such as gift cards. For the qualitative data collection, we will give participants a monetary gift of $75 cash to participate in a 90-minute focus group. This proposed gift of $75 is intended to offset costs related to traveling to the focus group facility and childcare costs, and to convey appreciation for contributing to this important study. Studies have indicated that a monetary gift can increase response rates (Church, 1993; Greenbaum, 2000; Haveman, 2010).

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act does not apply. This determination is based on the fact no personal identifiers will be collected in this study to reduce the likelihood of identification or re-identification. All data collected and delivered to CDC from The PlowShare Group's data collection and formative research subcontractors Qualtrics and Battelle, will be in aggregate form only. Further, the information that will be reported to and maintained by CDC is not considered a record as defined by the Privacy Act: it will not include individuals' education, financial transactions, medical history, and criminal or employment history and name, or the identifying number, symbol, or other identifying particular assigned to any individual, such as a finger or voice print or a photograph. CDC has contracted with The PlowShare Group for this information collection. The PlowShare Group's data collection and

formative research subcontractors are Qualtrics and Battelle. CDC, Qualtrics, and Battelle participated in planning the information collection; staff from each will interpret data but will not receive any Personally Identifiable Information (PII) on the respondents. Battelle's Institutional Review Board (IRB) reviewed and approved this study (Attachment 10: Battelle Institutional Review Board Approval). 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.

Data Collection System

Quantitative: Online Questionnaire. All information for the self-administered screening process and self-administered questionnaire will be collected electronically in a secure, online, web-based data collection system (as described in Section A2 and Part B). The identifiable information about Toluna panelists is maintained in a proprietary records system and is not released to CDC or other contractors/subcontractors (see Attachment 11: Toluna Privacy Policy). Although demographic information (e.g., age) will be confirmed through screening, no direct personal identifiers (e.g., date of birth [including day, month, year], name, phone number, address, email address, social security number, photograph, biometric information, or any other unique identifier that can be linked to an individual etc.) will be collected or maintained as part of the Screener or Questionnaire (Attachments 2 and 3). A system of records notice (SORN) is not required because (1) the information collected is not considered a record as defined by the Privacy Act (2) The records are not retrieved using a personal identifier.

When the respondent begins the questionnaire, all identifiable links to the existing system of records are severed. As such, because it does not exist, CDC will not have direct contact with or access to any PII about participants during this stage. Toluna does have access to the email address of panel subscribers, but no match back is possible with the survey response data. IP addresses will not be stored by the online questionnaire system, and no first- or third-party cookies will be stored during questionnaire completion. No link between the respondent's email and the specific survey is made after the potential respondent clicks on the link to start the survey.

Qualitative: In-Person Focus Groups. During the qualitative stage of data collection, the focus group facilities will recruit respondents using their own respondent panels, similar to those used by Toluna. The identifiable information about panelists is maintained in proprietary records systems of the focus group facilities and is not released (see Schlesinger Privacy Policy, Attachment 12). Neither CDC nor the contractors/subcontractors will have access to participants' PII at any point. Although demographic information (e.g., age) will be confirmed through the Pre-Focus Group Questionnaire, no direct personal identifiers (e.g., name, phone number, social security number, etc.) will be collected or maintained as part of the Pre-Focus Group Questionnaire or the Participant Feedback Questionnaire (Attachments 5 and 8) or during the focus groups. All information that is collected from the paper Pre-Focus Group Questionnaire and the Participant Feedback Questionnaire will be immediately entered into Qualtrics' password-protected database, then all paper copies will be shredded and disposed of the same day. The originals entered into the database will not be shared with OSH until de-identified, with any PII removed.

The consent form for the qualitative study (included in Attachment 5) will describe the study and

will include a statement that their responses will remain private to the extent allowable by law (i.e., privacy will be broken if it is necessary to protect them or if it is required by law, such as in the case of abuse, neglect, self-harm). The consent form will also contain the statement that participation is voluntary and no one will be able to link the respondent's identity to his/her responses. It will also provide contact information for the Principal Investigator, if the participants have any questions about the study.

Data Security

All findings will be reported in the aggregate only. All information will be stored on password-protected databases to which only Qualtrics employees working on this project have access. Qualtrics will keep the quantitative data in non-aggregate form for six months after information collection has been completed, and then the respondent-level data will be deleted from the password-protected databases. Qualtrics will also store focus group videos and de-identified transcripts on a password-protected database for six months, after which all video files will be deleted. Qualtrics will provide CDC and Battelle with the de-identified data, to be used for analyses. Only CDC, Qualtrics, and Battelle employees involved in data analysis will have access to the data. CDC will handle the de-identified data in accordance with the record control schedule (maintained at least six years, but no longer than ten years). No desktop or laptop computer will contain any PII. To prevent unauthorized access to their data servers (such as "hacking"), Qualtrics is currently certified and has achieved the distinguished ISO 27001 accreditation. With this achievement, Qualtrics' data systems have assurance that all data will be managed in a secure environment. This means that Qualtrics has been formally audited and has been certified compliant with the standard ISO 27001 accreditation. CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule (Table A.3.).

Table A.3. Access Controls

Technical Controls	**Physical Controls**	**Administrative Controls**
• User identification • Passwords • Firewall • Virtual Private Network (VPN)	• Guards/Security Officers • 24-hour maintenance of Video/Audio of all data centers and all offices • Identification badges • Key Cards	1. The system security plan for the information collection is that survey data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. 2. The contingency plan for this information collection is that the screeners will be kept only on password-protected computer files stored on a Qualtrics server. No directly identifying information will be transmitted to CDC/OSH (thus, the Privacy Act does not apply). 3. Backup file storage: Qualtrics has a redundancy system stored on a FedRAMP server farm for data security and quality. Transcripts and reports will not include any identifiable information. 4. There will not be user manuals for this information collection effort. 5. Personnel who use the system will be trained to protect the information being collected and maintained by

		adhering to a procedure that removes identifiers from response data. 6. Contractors who are operating/using the system will include clauses in the contracts that adhere to privacy provisions and practices. 7. Methods will be in place to ensure least privilege. Data and all identifying information about respondents will be handled in ways that prevent unauthorized access at any point during the study. 8. There are policies/guidelines in place with regard to the retention and destruction of PII: PII will not be transmitted to CDC, and PII will not be linked to response data.

A.11 Institutional Review Board (IRB) and Justification for Sensitive Questions.

IRB Approval

All procedures have been developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. Battelle's IRB has reviewed the Creative Concept application and determined it to be exempt (Attachment 10: Battelle Institutional Review Board Approval).

Sensitive Questions

The majority of questions asked in the Online Questionnaire (Attachment 3) and the Moderator's Guides (Attachments 6 and 7) will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN). Questions asked during the screening about conventional cigarette or e-cigarette use, and some demographic information (e.g., age) could be considered sensitive, although these items would not generally be considered highly sensitive. It will also be necessary to ask some questions considered to be sensitive in order to assess individuals' attitudes and behaviors about conventional cigarettes or e-cigarettes or to test concepts about the specific health behavior of conventional cigarette smoking. These items are not generally considered highly sensitive. Participants will be informed of the applicable privacy safeguards. Sensitive information will only be requested when necessary (e.g., sexual orientation). Such questions will include a "prefer not to answer" option. Participants in the qualitative portion of the study will be told in the informed consent form that they can refuse to answer any question or leave the focus group at any time, and they will still receive their incentive. This study also includes a number of procedures and methodological characteristics that will minimize potential negative reactions to potentially-sensitive questions, including the following:

- The online questionnaire is entirely self-administered and maximizes participant privacy by being conducted online, without the need to verbalize responses.
- The focus group moderators are trained to navigate sensitive topics.
- Participants will be provided with a phone number and email for the principal investigator and for the IRB, should they have any questions or concerns about the study or their rights as a study participant.

A.12 Estimates of Annualized Burden Hours and Costs

The quantitative data collection includes a 15-minute screener and online questionnaire. The four creative concepts will be tested with approximately 2,687 respondents for each concept, for a total of 10,748 respondents. See Part B for an explanation of how this sample size was calculated.

To obtain a sample size of 10,748, approximately 15,828 respondents are anticipated to complete the online screener (Attachment 2). Part B explains the calculations behind this sample size, and the screener figure is based on prior experiences in the field, which indicate that roughly 30 percent of screener respondents (n=4,749) will be deemed ineligible for the study because of not meeting inclusion criteria by age (18-54 years) or tobacco use status. Those who meet the inclusion criteria will be administered the online questionnaire (Attachment 3). Of those 11,080 deemed eligible, an estimated additional approximately three percent (n=332) will start but not complete the questionnaire.

The burden per respondent for completing the screener is two minutes. The total estimated burden for completing the screener is 528 hours. The burden per respondent for completing the online questionnaire is 13 minutes. Those who start but do not complete the questionnaire are estimated to spend about one-half of that time (6.5 minutes) on the questionnaire. Thus, the total estimated burden for completing the online questionnaire is 2,365 hours.

In the qualitative portion of the study, up to 400 total participants across three target cities will be recruited and screened to participate in 90-minute focus groups. Eligible participants will be scheduled to attend a focus group at a later time. Preceding and following the focus group, participants will complete self-administered questionnaires, which will each take five minutes to complete. The pre-focus group questionnaire also includes the consent form.

A total of 120 persons located in the three target cities will be selected to participate in in-person focus groups (roughly one-half low SES exclusive conventional cigarette smokers and one-half all-SES dual users). See Part B for information on how the estimated sample size was calculated. To obtain this sample size, it is expected that 400 respondents will need to complete the screener. The burden per respondent for completing the screener to participate in the focus group is two minutes. The total estimated burden for completing the screener is 14 hours. The focus groups will include 10 participants. So, if eligible, 12 participants will be invited to participate in the focus groups, anticipating that some will not attend. If more than 10 attend, the additional two (24, across the 12 focus groups) will still complete the pre-focus groups questionnaire, as this will provide demographic information that can inform the decision about who to send home. Therefore, as many as 144 participants may complete this form, which entails 12 burden hours. The burden per respondent for completing the focus group is 95 minutes (90-minute focus group discussion + 5-minute Participant Feedback Questionnaire). Although there are two Moderator's Guides, the estimated burden is the same for both, thus the burden estimate for the two guides has been combined. The total estimated burden for completing the focus groups is 190 hours. As outlined in Table A.4., the total estimated burden for the entire project is 3,109 hours.

Table A.4. Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours) *
Adult smokers who are 18-54 (exclusive smokers of conventional cigarettes and dual users of conventional cigarettes and e-cigarettes)	Recruitment Screener for Online Questionnaire (Attachment 2)	15,828	1	2/60	528
	Online Questionnaire (Attachment 3)	10,748	1	13/60	2,365
		332	1	6.5/60	
	Focus Group Screener (Attachment 4)	400	1	2/60	14
	Pre-Focus Group Questionnaire and Informed Consent (Attachment 5)	144	1	5/60	12
	Moderator's Guides for Focus Groups (Attachments 6 and 7)	120	1	90/60	180
	Participant Feedback Questionnaire (Attachment 8)	120	1	5/60	10
					Total 3,109

* Burden hour estimates have been rounded up.

The estimated cost of the time devoted to this information collection by respondents is $71,507 as summarized in Table A.5. To calculate this cost, we used the mean hourly wage of $23, which represents the Department of Labor estimated mean for state, local, and private industry earnings (Bureau of Labor Statistics, 2016). There are no direct costs to respondents associated with participation in this information collection.

Table A.5 Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)	Hour Wage Rate	Total Cost
Adult smokers who are 18-54 (exclusive smokers of conventional cigarettes and dual users of conventional cigarettes and e-cigarettes)	Recruitment Screener for Questionnaire (Attachment 2)	15,828	1	2/60	528	$23	$12,144
	Questionnaire (Attachment 3)	10,748	1	13/60	2,365	$23	$54,395
		332	1	6.5/60			
	Focus Group Screener (Attachment 4)	400	1	2/60	14	$23	$322
	Pre-Focus Group Questionnaire and Informed Consent (Attachment 5)	144	1	5/60	12	$23	$276
	Moderator's Guides for Focus Groups (Attachment 6 and 7)	120	1	90/60	180	$23	$4,140
	Participant Feedback Questionnaire (Attachment 8)	120	1	5/60	10	$23	$230
							Total $71,507

A.13 Estimates of Other Annual Cost Burden to Respondents and Record Keepers

There will be no respondent capital and maintenance costs.

A.14 Annualized Cost to the Government

Approximately 6.25% of one full-time equivalent (FTE) and 1.9% of one senior manager will be required to oversee the information collection activities for one month. Responsibilities will include internal coordination and review of materials and reports and maintaining proper accounting of burden hours. The agency estimates that it will take a GS-13, at a wage rate of $55.01/hour, approximately 10 hours to manage the project, totaling about $550.00. It is

estimated to take a GS-15, at a wage rate of $64.70/hour, approximately three hours to oversee the total project, totaling $194.00. The total average annualized cost to the government for CDC oversight is $744.

Contractors will conduct the majority of information collection and management activities on CDC's behalf. The total cost of the data collection contractors is $250,000 which includes consultation, instrument design and development, respondent incentives, data collection, top line analyses, full qualitative and quantitative analyses, and final report. Qualtrics will collect the information from the participants. Activities are coordinated through a contract with The PlowShare Group, a specialist in media campaigns. The grand total cost for the project, including government and contractor cost, is $250,744.

Table A.6. Total Project Costs

Government Personnel	Percent Time Commitment	Hour Time Commitment	Hourly Basic Rate	Total
GS-13	6.25%	10	$55.01	$550
GS-15	1.9%	3	$64.70	$194
Subtotal, Government Personnel				$744
Contract Costs				$250,000
Total Costs				$250,744

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Data Tabulation Plans

The information will be used to inform the development of future NTEC advertisements. It is anticipated that information collection will begin April 10, 2017, so an OMB approval date of April 7, 2017 is requested. The resulting quantitative data will be analyzed using conventional tabulation techniques and the resulting qualitative data will be analyzed using thematic analysis. The data will be read thoroughly and initial codes will be created manually, identifying themes and patterns of responses. These dates may be adjusted depending on the approval process of this package.

Publication and Dissemination Plans

This information will be used to inform the development of rough-cut advertisements, for adult smokers of conventional cigarettes and adult dual users. Rough-cut advertisements are used to assess whether the near-final version of future NTEC advertisements are effective (clear, credible, believable and persuasive) with the target audience, using measures such as memorability, and motivation to quit.

Project Time Schedule

Table A.7 Project Time Schedule

Activity	*Time Schedule*
Email invitations sent to respondents for qualitative testing	1-20 days after OMB approval
Focus group recruitment	1-12 days after OMB approval
Online information/data collection	1-20 days after OMB approval
Focus group data collection	2-4 weeks after OMB approval
Complete field work	30-45 days after OMB approval
Validation	45-55 days after OMB approval
Data analysis	55-65 days after OMB approval
Report writing	65-110 days after OMB approval

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

An exemption to this requirement is not being requested. The expiration date of OMB approval will be displayed on all information collection instruments.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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