FDA CTP Public Education Materials Study
0910-0810

Supporting Statement: Part A

Supporting Statement: Summary

- The goal of the FDA Center for Tobacco Products (CTP) Public Education Materials Study is to collect feedback on CTP tobacco education materials, and to obtain feedback on ways of engaging more effectively with CTP's audiences.
- The study will be conducted using a web-based anonymous survey, using Qualtrics software, which is self-administered on a study-provided tablet. The study will use an online survey to target up to 1,300 CTP-related professional and public-facing conference, expo, and exhibit attendees. The survey will take approximately 5 to 6 minutes to complete per respondent.
- The outcome of the study will be to guide CTP in content development and promotion of specific materials at relevant conferences.
- The study questions collect information on: awareness of CTP; jobs of survey respondents; populations survey respondents serve; conference attendees' reactions to CTP tobacco education materials; and how well CTP is serving the tobacco education informational needs of respondents. To assess how demographic and other variables and survey items may be associated, the survey also asks respondents a few basic demographic questions.
- The resulting data will be analyzed using cross tab tables for quantitative data as well as running descriptive statistics such as means and frequencies.
- **REQUESTED APPROVAL DATE:** February 2nd, 2018

Background Materials and Consent Forms

- Attachment A: Informed Consent Information
- Attachment B: List of Proposed Conferences
- Attachment C: Materials to Test
- Attachment D: IRB Letter

Data Collection Instruments

- Attachment E: Survey Instrument

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Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act, signed into law on June 22, 2009. Also, section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) provides that FDA may take appropriate action to protect the public's health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to the FDA for the enforcement of the FD&C Act. Further, the FD&C Act also authorizes the FDA to conduct educational and public information programs (21 U.S.C. Section 393(d)(2)(D)). In addition to regulating the manufacture, distribution, and promotion of tobacco products, CTP conducts studies to inform regulatory actions and communications.

The Center for Tobacco Products (CTP) develops tobacco education materials and engages in communication efforts to inform CTP target audiences of the availability of these tobacco education materials. This study aims to investigate the effectiveness of these tobacco education materials as well as the effectiveness of communications efforts to inform CTP target audiences of these materials and to engage them in meaningful ways.

The Center for Tobacco Products (CTP) attends many professional and public-facing conferences and expos throughout the year, in an effort to familiarize CTP target audience members with the purpose of and work at the CTP. Specifically, CTP's exhibit outreach program informs and increases awareness among conference attendees of CTP's efforts to support tobacco regulatory research, public health education campaigns, and health education resources and tools. Given that CTP has pre-approved plans to exhibit at these conferences, this is an opportune time to obtain feedback from individuals already at the conferences—many, if not most, of whom represent CTP target audiences. Creating a dual purpose for CTP's attendance at these conferences is a cost-effective manner for seeking input from CTP target audience members.

The objectives of the FDA CTP Public Education Materials Study is to determine the target populations of CTP, the needs of these respondents, the needs of the target populations, the types of topics needed, the formats of

these topics, the preferred channels to receive information, and engagement opportunities, while also measuring their response to public education materials.

This study will be conducted using a web-based survey that is self-administered on a study-provided tablet at conferences that CTP attends. The study will recruit up to 1,300 CTP-related professional and public-facing conference, expo, and exhibit attendees to participate in the online survey.

The opportunity to take the survey will be on a "first-come, first-served" basis—in other words, survey respondents will be recruited when they walk up to the CTP exhibit booth (survey respondents will NOT be recruited actively by walking around conference/exhibit spaces). At that point, CTP exhibit booth field researchers will verbally ask the potential survey respondent the following question.

> We are asking conference attendees to complete an anonymous survey related to tobacco education materials. It takes about 5 to 6 minutes to complete. Would you be interested in completing this survey?
>
> _____ Yes [Great, thank you. The survey is on this tablet, and the materials that you will be reacting to will be presented as screenshots on the tablet. I also will show you the sample materials in hard copy.]
> _____ No [Okay, thank you.]

The first page of the survey will include informed consent information as well as the contact information of the study's Principal Investigator should a respondent wish to contact a study team member for any reason (see **Appendix A**, **Informed Consent Information**).

Data collection will occur at 13 CTP-relevant conferences taking place in 2018 (see **Appendix B**, **List of Proposed Conferences**). CTP chose these conferences as they are appropriate for public health and tobacco research audiences that typically receive information or would benefit from information from CTP. The outcome of the survey will be to guide CTP in content development and promotion of specific materials at relevant conferences.

2. <u>Purpose and Use of the Information</u>

The information obtained from the proposed research activity will be collected from CTP-related professional and public-facing conference, expo, and exhibit attendees. The purposes and uses for the proposed information collection includes understanding the following among CTP-related professional and public-facing conference, expo, and exhibit attendees:

- Their current level of awareness of CTP.
- Their current job.
- The populations they serve.
- Their reactions to CTP tobacco education materials.
- Which specific populations need additional tobacco education materials.
- Which topics are in need of more tobacco education materials.
- Preferences for ways to receive tobacco education materials.
- CTP engagement opportunities of most interest.

To achieve the above, data collection will consist of one, one-time online anonymous survey completed by up to 1,300 CTP-related professional and public-facing conference, expo, and exhibit attendees. The survey dissemination will occur during conferences held over a 12-month period (throughout the 2018 year; Attachment B). All participants will complete an Informed Consent form using the tablet (Attachment A), prior to the online-based survey. The Informed Consent form is given electronically, via the tablet. To assure that participants may give their consent and are of eligible age, participants will be asked a question of the year of their birth. This will allow participants to give consent and take the survey if they are 18 years or older. Once the informed consent form is given, participants will automatically be given the survey instrument (Attachment D) via the tablet.

The survey will begin with questions regarding awareness of CTP and the participant's current job role. After these questions, the survey instrument will randomly assign the viewing of four out of 10 materials (Attachment C). Five of the materials are CTP materials (i.e., infographics and print graphics) while the other five are CTP posters. Participants will be randomly assigned to view two of each. The FDA CTP exhibit booth field researchers managing the CTP Public Education Materials Study processes will have the set of the 10 materials to be tested on flashcards. Each printed flashcard will be 3"x4.5", 4.5"x3", or 8.5"x11" in size, depending on the material or poster. Each printed flashcard, regardless of size, will be easily legible to the respondent. Each two-sided flashcard will have the English version of a material on one side and the Spanish version on the other. Each material on the flashcards will have a pre-assigned identification code (such as "K7").

Immediately after the Qualtrics software program presents a material for the survey respondent to review in electronic form (English and Spanish, side by side, on the tablet screen), the survey will automatically display this instruction: "Please ask the CTP exhibit booth staff person now to show you the hard copy/print version of material [ENTER MATERIAL ID CODE NUMBER HERE]." The CTP exhibit booth field researcher will show only the four materials the respondent is asked to review on the survey, one by one per the sequence determined by the survey's preprogrammed coding.

Because respondents, when prompted by the survey, initiate the question asking CTP exhibit booth field researchers to show them the hard copy materials, CTP staff will not see their answers to the survey questions; only

the respondent will view the tablet screen during the survey. Again, to assure privacy, the survey respondent will be seated in a separate location.

Participants will then be asked four questions about each material. Participants will be asked if they had seen the material before, if the material provides any new information, if the material is useful to them, and if the material is easy to understand. Participants will be then be asked about what populations they believe need additional tobacco education materials, for which topics they would like to see more materials developed, the format they would like to see used, the preferred delivery method of the materials, which engagement opportunities interest them, and what country they live in.

All tracking of surveys will be conducted by IQ Solutions.

3. Use of Information Technology and Burden Reduction

This study will rely on web-based survey data collection on reactions to CTP tobacco education materials, populations in need of additional tobacco education materials, and characteristics of respondents. Using an anonymous survey allows respondents to be more candid with their responses. An anonymous study approach allows for more accurate data collected compared with other types of research methodologies because respondents provide more honest responses. In addition, using a survey will allow for a higher number of respondents to respond in a cost-effective and timely manner. Also, the self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically immediately to cloud storage, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. The web-based survey allows for skip logic, or instrument routing, to ask specific questions of participants who should be asked the follow-up question. This eliminates any room for interviewer error or respondent error from manual skipping of questions. Finally, as noted above, this technology permits respondents to complete the survey in privacy. Providing respondents with a methodology that assures privacy makes reporting of potentially uncomfortable comments less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

FDA CTP's tobacco education materials—for which we are seeking feedback—are relatively new, and therefore it is important to assess what is working well and areas for improvement to best meet CTP target audience needs and sustain CTP target audience interest.

To date, there have been no data collection activities for the purpose of obtaining reactions to recently developed CTP tobacco education materials and suggestions for new tobacco education materials to develop to fill current gaps. The materials used in the current study have not been used in any other study and are being tested for the first time. This study therefore does not duplicate any existing efforts.

5. Impact on Small Businesses or Other Small Entities

We anticipate that most respondents in this study will be public health professionals, healthcare professionals, tobacco experts and representatives, and members of the general public. Because we do not know the exact profiles of attendees at different conferences, we will be asking respondents to select on the study's survey which of various job categories best describes them. While there is potential for small businesses to complete a survey, no impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

To ensure that the participant burden is as low as possible, respondents to this collection of information will answer only once. Without the information collection requested for this evaluation study, it would be difficult to describe CTP-related professional and public-facing conference, expo, and exhibit attendees and obtain feedback from these target audiences on CTP tobacco education materials. Failure to collect these data could reduce the effectiveness of CTP's tobacco education materials and therefore reduce the benefit of CTP's tobacco education materials to CTP's target audiences.

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). This study's data collection 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 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:

Mario Navarro
Office of Health Communication & Education
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-4963
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The following individuals outside of the agency have been consulted on questionnaire development:

Everly Macario
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9. Explanation of Any Payment or Gift to Respondents

Since engagement in the study is minimal, no respondents will be paid an incentive to participate in the survey. However, we plan to offer respondents who complete the survey an FDA CTP-branded promotional giveaway item not to exceed $5.00 in value (e.g., water bottle, lunch cooler) as a token of our appreciation. The giveaways are intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for contributing to this important study and are similar to incentives that are offered for most surveys of this type. Numerous empirical studies have shown that incentives can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002).

10. Privacy Impact Assessment Information

FDA's Research Involving Human Subjects Committee (RIHSC) will review and approve the protocols and consent form for the study prior to any respondent contact. The RIHSC's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

All information will be collected electronically through a self-administered anonymous survey instrument hosted in a secure, online, web-based data collection system. The survey is classified as anonymous as no Personally Identifiable Information [PII] is asked of respondents.) IP addresses are also masked and not included in collection. None of the study team members will have access to any respondent PII. All data will remain on a password-protected computer and/or in locked cabinets for a period of three years after the end of the study, and then will be shredded and/or destroyed. Great effort is taken to protect participant identity and all responses will be private.

Data Management

Data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations. As the survey is an online survey, Qualtrics will be used for data collection and storage. Qualtrics is a survey tool used by researchers and various marketing companies. Qualtrics uses an Application Service Producer, which stores data in a single secure data center. All Qualtrics data are stored in a cloud and are encrypted at rest, and in transit, under password protection in both instances. Data will be stored via the Qualtrics data center under secure monitoring by Qualtrics staff. As the privacy of their customers is of utmost importance to Qualtrics, only the researchers will have access to the data.

For raw data collected during this research, all servers are hosted using industry standard firewalls. Industry standard firewalls include the ability to allow or block traffic based on multiple forms of connection (e.g., state, port, and protocol), rather than only one connection, meaning that access is limited to those who are allowed entry. In addition, IQ Solutions will follow the Standard of Good Practice (SoGP, https://www.securityforum.org/research/thestandardofgoodpractice2016/) security practices which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and safety of the end-user environment. Following these guidelines, the monitoring of data and sensitive information will take place following the SoGP security practices such as limiting access to information and data encryption. Members of the research team will access the information through a secure log-in using a password on an HTTPS site, which ensures that data will be in an encrypted format when it is transmitted. This data transfer will occur via an encrypted and secure broadband connection.

Overview of How Information will be Shared and for What Purposes

The CTP research team will program the online survey of the CTP Public Education Materials Study using Qualtrics software. The survey includes 25 closed-ended questions where the respondent must select one of various response category options.

To analyze the quantitative data collected from the online survey's closed-ended questions, the CTP research team will summarize the descriptive statistics, such as means, standard deviations, and percentages, generated by the Qualtrics software as well as create cross-tabs, using statistical software, to assess how demographic and other variables and survey items may be associated.

Although demographic information (i.e., year of birth, country of residence, and state of employment [if in the United States]) will be gathered, no direct personal identifiers (e.g., full name, phone number, social security number, etc.) will be collected or maintained as part of the survey. As such, because Personally Identifiable Information (PII) does not exist, no individually identifiable information or PII is being collected, and thus, the Privacy Act does not apply.

Overview of Voluntary Participation

When potential respondents click on the online survey link, they will be advised of the nature of the survey and length of time it will require to complete the survey, as well as that participation is voluntary. Respondents will be assured that they will incur no penalties if they wish not to respond to the information collection as a whole or to any specific questions. Respondents on the web-based survey will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

All web-based respondents will use a link to enter the survey and the Qualtrics software will assign them a unique ID and the responses will be anonymous. As mentioned previously, no Personally Identifiable Information (PII) will be collected. All those who handle or analyze data will be required to adhere to standard data security policies. All data will be reported in the aggregate only. During data collection, all data will be stored on password-protected databases to which only IQ Solutions employees working on this project have access. IQ Solutions will keep the data for three years after data collection has been completed, and then the data will be deleted from the password-protected databases. All data will be sent to IQ Solutions using a password protected, encrypted file. IQ Solutions will limit access to this portion of the shared drive by limiting the personnel with access to this shared drive to appropriate project staff.

11. Justification for Sensitive Questions

Almost all, if not all, of the questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN) or IP address. Demographic questions (i.e., year of birth, country of residence, and state of employment [if in the United States]) could be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents 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:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

- Should respondents have any questions or concerns about the study or their rights as a study participant, respondents will be provided with the telephone number of the study's Principal Investigator.

- This survey is anonymous and no Personally Identifiable Information (PII) will be collected.

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 152 hours (Table 1).

Given CTP's previous experiences staffing the Center's exhibit booth at conferences and observations of the number of attendees who approach the exhibit booth, CTP expects each conference to yield between 25 and 100 completed surveys. Between 25 and 100 conference attendees tend to stop by the CTP exhibit booth at any one conference. Because we expect to attend 13 conferences in 2018, we expect to receive a total of approximately 325 and 1,300 completed surveys in that period. To be conservative for the purposes of calculating the estimated annual reporting burden, we will assume that the total sample size is 1,300.

Table 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
CTP-related professional and public-facing conference, expo, and exhibit attendee	Review and complete informed consent form	1,300	1	1,300	.017	**22**
CTP-related professional and public-facing conference, expo, and exhibit attendee	Click on survey link; agree to take the anonymous survey voluntarily; take survey.	1,300	1	1,300	0.10	**130**
Total Annualized Hours						**152**

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. IQ Solutions has conducted many online surveys of similar length and eight IQ Solutions staff members took the survey for this study, with an average completion time of five to six minutes.

To calculate the cost, the mean hourly wage of $22.33 was used for the respondents. This cost represents the Department of Labor estimated mean for state, local, and private industry earnings (Bureau of Labor Statistics, National Compensation Survey–Wages https://www.bls.gov/ncs/ncswage2008.htm#Wage_Tables). There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an

average hourly wage of $22.33, the estimated one-year annualized cost to participants will be $3,394.16. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
CTP-related professional and public-facing conference, expo, and exhibit attendee	Review and complete informed consent form	22	$22.33	$491.26
CTP-related professional and public-facing conference, expo, and exhibit attendee	Click on survey link; agree to take the anonymous survey voluntarily; take survey.	130	$22.33	$ 2,902.90
Total				$3,394.16

13. Estimates of Other Total Annual Cost Burden 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

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	10%	$94,796	$9,479.60
		Total Salary Costs	$9,479.60
		Contract Cost	$93,000
		Total	**$102,479.60**

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

The CTP research team will program the online survey of the CTP Public Education Materials Study using Qualtrics software. The survey includes 25 closed-ended questions where the respondent must select one of various response category options.

To analyze the quantitative data collected from the online survey's closed-ended questions, the CTP research team will summarize the descriptive statistics, such as means, standard deviations, and percentages, generated by the Qualtrics software as well as create cross-tabs, using statistical software, to assess how demographic and other variables and survey items may be associated.

This study's aims are to assess: (1) who at these conferences is currently aware of CTP; (2) jobs these survey respondents have; (3) which populations do survey respondents serve; (4) what are conference attendees' reactions to CTP tobacco education materials; and (5) how well is CTP serving the tobacco education informational needs of attendees. The findings from this study will help guide CTP in content development and promotion of specific materials at relevant conferences.

Reporting

The reporting and dissemination mechanism for this study's findings will consist of two primary components: (1) summary statistics in the form of a PowerPoint presentation and other briefings and (2) a comprehensive evaluation report summarizing findings from this information collection. The key events and reports to be prepared are listed in Table 4.

Table 4. Project Schedule

Project Activity	Projected Schedule
Survey	Ongoing, from February 2018 through November 2018
Data Analysis	Ongoing, from February 2018 through November 2018
Report Writing and Dissemination	December 2018 through February 2019 (Approximate)

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

We are not requesting an exemption to this requirement. All data collection instruments will display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

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

References

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

Castiglioni, L., Pforr, K., & Krieger, U. (2008, December). The effect of incentives on response rates and panel attrition: Results of a controlled experiment. *Survey Research Methods (*Vol. 2, No. 3, pp. 151-158).

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

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

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