

**FDA CTP Public Education Materials Study
0910-0810**

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

FDA 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.

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 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. The study will use the online survey to target up to 1,300 CTP-related professional and public-facing conference, expo, and exhibit attendees.

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.

Sample Size

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.

Only individuals 18 years of age or older will be eligible for this study. To ensure this, the survey will include the following screener question.

What year were you born?

[Drop-down menu]

[TERMINATE SURVEY AND GO TO TERMINATION TEXT 2 IF RESPONDENT WAS BORN IN 1999 OR LATER]; THIS WILL BE ALTERED SO ONLY THOSE 18 YEARS OR OLDER MAY PARTICIPATE]

[TERMINATION TEXT 2:] Based on your answer, you do not qualify for this survey. Thank you very much for your time and consideration.

This method is not intended to generate a nationally representative sample or a precise estimate of population parameters. The sample drawn here is designed primarily to provide information on CTP-related professional and public-facing conference, expo, and exhibit attendees.

The one-time actual burden figures are listed in Tables 1, 2 & 3, Part A.

2. Procedures for the Collection of Information

This section describes the procedures for the survey data collection.

CTP has identified a list of 13 professional and public-facing conferences and expos in 2018 to which it would be relevant for CTP to attend and display a CTP exhibit booth. These conferences are ones for which CTP target audiences are mostly likely to attend, as they are public health or tobacco specific or even focused on diseases affected by tobacco use—these conferences are attended by members with goals similar to those of CTP. Some of these conferences are also ones for which CTP has exhibited at previously. (See **Appendix B, List of Proposed Conferences.**)

Data collection will occur through the use of a brief, one-time survey at these conferences. The survey, programmed using the online software program Qualtrics, will be available on a tablet (e.g., iPad) at the FDA CTP exhibit booth.

As conference attendees approach the FDA CTP exhibit booth, CTP field researchers will invite attendees to complete the survey. Field researchers will not actively recruit people from the crowd. After a collection, CTP field researchers will complete the following information, located in a document separate from the survey on the tablet:

Instructions to CTP exhibit booth field researchers:

Please tally the number of conference participants that you asked to complete the survey, and whether they agreed or did not agree to take the survey.

_____ Total number of conference participants that I approached at _____ [name of conference] on _____ [date].

_____ Total number of conference participants that I approached at _____ [name of conference] on _____ [date] that agreed to take the survey.

_____ Total number of conference participants that I approached at _____ [name of conference] on _____ [date] that declined to take the survey.

CTP field researchers will then ask the conference attendees who approach the FDA CTP exhibit booth the following:

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.]

If a potential survey respondent says, “Yes,” to the above question, CTP field researchers will give the respondent the tablet containing the survey. In a separate location to assure privacy, the survey respondent will then review the informed consent information and begin the survey. The first question in the survey asks whether the respondent was aware of the existence of the FDA CTP before today, the second question in the survey asks the respondent to select which of many job categories best describes them, and the third question in the survey asks the respondents to select which of many population categories they mostly serve. The remaining questions in the survey ask the respondent to provide feedback on CTP materials and on their tobacco education information needs. The last two questions in the survey ask respondents to check in which country they live, in which state they work.

CTP will test a total of 10 CTP tobacco education materials (five are informational materials and five are posters), ones that are currently available to the public online and have already been exhibited at conferences in the past. (See **Appendix C, Materials to Test.**) Each survey respondent will review two of five randomly generated informational materials and two of five randomly generated posters. The order in which they see the informational materials or posters is randomized as well. The random rotation will be programmed in Qualtrics survey software.

Each respondent will complete the same survey. The survey will be available in English only. All FDA CTP English-language materials to be tested have a Spanish-language equivalent. Survey respondents will be able to easily view both English and Spanish versions next to each other—electronically on the tablet and in hard copy hand-delivered by CTP exhibit booth field researchers (at the time the survey respondent is prompted by the survey to ask to see the printed materials to which they are reacting). (See **Appendix E, Survey Instrument.**)

Because the materials to be tested are able electronically and in print by mail order, the survey respondents will see the materials both in digital and print formats.

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.

The survey will test the materials listed below, all of which are available in both English and Spanish.

CTP Materials

1. CTP-55 / CTP-55-S: Deeming Print Graphic: All Tobacco Products Now Regulated by FDA
2. CTP-72 / CTP 72-S: FDA Rules for Electronic Nicotine Delivery System (ENDS) Sales
3. CTP-92-R1 / CTP-92-R1S: 5 Tips to Help Avoid “Vape” Battery Explosions
4. CTP-93 /CTP-93-S: Chemicals in Cigarettes: From Plant to Product to Puff
5. CTP-100 / CTP-100-S: National Youth Tobacco Survey 2016 Infographic: Youth Tobacco Use in the U.S.

CTP Posters

6. CTP-78 / CTP-78-S: Smoking can cause stained teeth and gum disease, which can lead to tooth loss.

7. CTP-81 / CTP-81-S: It hit me...Each puff is a POW!
8. CTP-83 / CTP-83-S: Be Shareable: Smoking can speed up skin aging and lead to early wrinkles
9. CTP-88 / CTP-88-S: Want your smile to look like this?
10. CTP-89 / CTP 89-S: So What if I do? Cravings

CTP staff selected the above representative and diverse sample of 10 materials from all available CTP tobacco education materials to ensure an adequate number of survey respondents provides feedback on each material to yield meaningful results. While some of these materials are currently available to the public for download or order, by the time of this survey launch all of the materials will be available at <https://digitalmedia.hhs.gov/tobacco/>.

Summary of Protocol

The list of study procedures is as follows:

1. CTP field researchers managing the CTP exhibit booth at 13 conferences being held in 2018 will ask conference attendees who approach the FDA CTP exhibit booth whether they would be interested in completing a survey related to tobacco education materials. Information in the survey instrument will provide the approximate amount of time it will take to complete the survey (6 minutes) and information about the anonymity of the survey.
2. If the potential respondent decides they would like to take the survey, they will say “yes” to the CTP field researcher’s invitation to complete the survey.
3. If the respondent indicates that they are 17 years of age or younger, the survey program will terminate this respondent’s survey.
4. Informed consent information is given and then invites the potential respondent to click “Start survey now” or “Exit survey” to assure that those respondents who complete the survey are doing so voluntarily.
5. If the respondent does not qualify for the survey, he or she will receive text thanking them for their time and explaining that they do not qualify for the survey.
6. If the respondent does qualify for the survey, they will continue to answer 25 closed-ended questions.
7. During the survey, participants will be shown CTP tobacco education materials. Materials are randomized so that each respondent views a particular subset of these materials. When this occurs, the CTP field researchers will give the participant a hard copy version of the materials they were assigned.
8. Following the demonstration of CTP education materials, participants will complete the rest of the closed-ended questions.

Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are involved.

Use of Periodic Data Collection Cycles to Reduce Burden

This is a one-time survey data collection effort.

3. Methods to Maximize Response Rates

The ability to obtain the cooperation of potential respondents in the survey will be important to the success of this study. CTP field researchers will maintain the survey link live for the duration of each of the 13 -preplanned conference exhibits throughout the year 2018 to encourage response rates during this period.

Since engagement in the study is minimal, no respondents will be paid an incentive to participate in the survey. However, we plan to offer FDA CTP exhibit booth visitors 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. All participation in this study is voluntary.

4. Tests of Procedures or Methods

The evaluation contractor, IQ Solutions, will conduct rigorous internal testing of the online survey instrument prior to its fielding. Evaluators will review the online test version of the instrument to verify that instrument skip patterns are functioning properly and that all survey questions are worded correctly and are in accordance with the instrument approved by OMB.

5. Individuals Involved in Statistical Consultation and Information Collection

The following individuals inside the agency have been consulted on the design of survey:

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