

United States Food and Drug Administration  
Generic Clearance: Customer Satisfaction Surveys  
OMB Control Number 0910-0360  
Gen IC Request for Approval

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

**Title of Gen IC:** FDA CTP 2021 Scholastic Vaping Education Materials Survey

**1. Statement of Need:**

Since 2018, the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) has collaborated with Scholastic, Inc.—a leading provider of core literacy curriculum and professional services for educators—to develop and distribute *The Real Cost of Vaping* tobacco education and prevention materials to middle and high school teachers across the United States. The materials, available in both English and Spanish, include:

- ▶ A multi-subject curriculum consisting of lesson plans and classroom activities to educate middle and high school students about the risks of e-cigarette use.
- ▶ Videos with original illustrations and animations that explain how e-cigarettes work, how they harm teens’ health, and how they are marketed.
- ▶ The interactive infographic, “What You Need to Know About Vaping.”
- ▶ A classroom magazine, parent flyer, and myth-busting infographic.
- ▶ A nation-wide *Vaping’s Not My Thing* Challenge contest in which students created public service announcement (PSA) posters to help youth understand the harms of e-cigarettes.
- ▶ A list of related resources and vetted partner materials to supplement classroom instruction (e.g., vaping cessation information from the National Cancer Institute’s teen.smokefree.gov; the American Lung Association’s Vape-Free Schools Initiative, and FDA’s video-recorded interviews with pediatricians from the American Academy of Pediatrics).

The goal of this collection is to better understand the characteristics of teachers using *The Real Cost of Vaping* materials and to obtain their feedback on: (1) which materials are most/least useful and why; and (2) what additional tobacco prevention topics and resources they would like to see offered in the future.

**2. Intended Use of the Information:**

Information from this collection will be used to improve FDA’s *The Real Cost of Vaping* tobacco education and prevention materials to better serve the resource needs of middle and high school teachers across the United States.

**3. Description of Respondents:**

Respondents will consist of 600-800 middle school and 600-800 high school teachers who: (1) currently teach or have taught during the 2019–2020 and/or 2020–2021 academic years; and (2) have used FDA’s *The Real Cost of Vaping* materials and/or participated in the recent *Vaping’s Not My Thing* PSA contest sponsored by FDA and Scholastic. Respondents will include a mix of

genders and race/ethnicities, and represent an array of school types (public, private), school enrollment sizes, and urban, rural, and suburban school districts from each geographic region of the country.

The demographics section of the survey asks teachers to describe their ethnicity as follows: (1) Mexican, Mexican American, Chicano or Chicana; (2) Puerto Rican; (3) Cuban; or (4) another Hispanic, Latino/a, or Spanish origin with an optional text entry field. Enabling teachers to describe their ethnicity in this manner will be important in understanding whether FDA's Spanish-language version of *The Real Cost of Vaping* materials are similarly effective across teacher ethnicity or should be revised. For example, comparing the responses of teachers of different ethnicities may help us determine if teachers' satisfaction with the Spanish-language materials are associated with differences in dialects (forms of language peculiar to a specific country of origin and/or specific region; this includes differences in intonation and pronunciation as well as words and expressions that exist in some branches of the Spanish language and are absent or different in another). We can then use that information to improve our materials—this includes aiming for linguistically accurate as well as culturally appropriate materials (for example, Puerto Rican and Cuban respondents may have a unique lens through which to view tobacco given their countries' histories cultivating tobacco and potential pride in their countries' production of tobacco products such as cigars). An understanding of regional translation issues is important when developing culturally appropriate Spanish-language materials (see Brelsford et al., 2019, for an example of the importance of Spanish dialect when engaging with Spanish-speaking research participants). This will also ensure that our materials comport with the federal government's requirement that all citizens deserve clear communication from the government through the use of plain language (see plainlanguage.gov).

As noted in the Brelsford et al. (2019) article, this regulatory requirement is often limited to English-language materials. We strive for our Spanish-language materials to be just as easily understood with plain language and developed with the proper tone, formality, accuracy, comprehensibility, and linguistic and cultural competence. We will use findings from the survey to help inform how we “transcreate” (translate plus culturally adapt, not translate verbatim from English to Spanish) any new Spanish-language tobacco education and prevention curricula to be developed.

#### **4. How the Information is Collected:**

To identify eligible respondents, Scholastic will send emails with a link to the online screener to middle and high school teachers who have voluntarily opted-in to receive materials from Scholastic and have interacted (e.g., opened, clicked through) with previous Scholastic emails that promoted FDA's *The Real Cost of Vaping* materials. Scholastic will also send emails to teachers who participated in the recent *Vaping's Not My Thing* PSA contest sponsored by FDA CTP and Scholastic. Only teachers who have used FDA's *The Real Cost of Vaping* materials and/or participated in the PSA contest will be eligible to participate in the survey.

Eligible teachers will complete the 20-minute survey online after reading the informed consent information and indicating their consent to participate. The study contractor, IQ Solutions, will program the survey using Qualtrics software and host the survey on their secure network server. Only teachers who are identified as eligible for the survey and have provided informed consent will have access to the survey link.

The FDA CTP 2021 Scholastic Vaping Education Materials Survey was pretested with a group of five middle and high school health educators to assess survey length and flag any confusing or potentially offensive questions. Via Google Forms, health educators provided open-ended input on question wording, content, and response categories. They also timed themselves when taking the survey, which resulted in an average completion time of 19.6 minutes across the five health educators.

## 5. Confidentiality of Respondents:

The following will be provided as an assurance of confidentiality to all respondents:

This anonymous survey is completely voluntary and takes about 20 minutes to complete. If you feel uncomfortable answering any survey question, you may skip that question and advance to the next question; you do not have to respond to any question that you do not want to answer. Choosing not to participate in the survey will not affect your ability to access future tobacco prevention resources from FDA.

We anticipate that up to 1,600 educators will complete this survey. Your responses will be reported at the aggregate level. Your name and email address will not be associated with your response, nor will they appear in any report to FDA CTP. Other teachers from your school may be invited to participate, but your answers will not be shared with other teachers or administrators at your school or other schools.

This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection ensures that researchers involved in this study protect your privacy as much as possible within the law. This means researchers generally cannot provide your name, or any other information that could identify you to anyone who is not part of the research team. Researchers cannot share this information in court or during other legal proceedings, even if there is a court order for the information. However, researchers may share study information that could identify you if:

- You agree to share information (for example, to get medical treatment);
- The study information is used for other scientific research, as allowed by law;
- The FDA, which is paying for the study, needs information to check how their research money is being spent; and/or
- A law requires sharing information (for example, when researchers must report to FDA, or if researchers hear threats of harm to yourself or others or reports of child abuse).

You can share any information you want to with others. For example, you can share that you are in this research study or your history of tobacco use.

## 6. Amount and Justification for Proposed Incentive:

Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? [ X ] Yes [ ] No

As a token of appreciation, FDA CTP will offer each teacher a \$10 electronic gift card via Giftbit, a third-party online gift card distributor, which they can use with selected retailers (i.e., Target, Walmart) for the purpose of purchasing school supplies. Teachers will be given the option of receiving a gift card by providing their name and email address at the end of the survey. Those who choose to do so will receive a link via email to the Giftbit secure website to select their electronic gift card within a week following completion of the survey.

Educators at the middle and high school level are known to be a hard-to-recruit population of professionals given the multiple competing demands on their time (Mokher, 2017). These competing demands have been greatly compounded over the current school year due to the COVID-19 pandemic and will likely be amplified during the early 2021 back-to-school period in August and September when this survey is fielded. Given these additional responsibilities and constraints on their time, not offering a token of appreciation could greatly inhibit our ability to successfully recruit this specialized group of teachers who have used FDA's *The Real Cost of Vaping* tobacco prevention materials. Therefore, the proposed token of appreciation for participation by this hard-to-recruit and specialized group of respondents is warranted. The mean annual wage for secondary school teachers is \$67,340 (U.S. Department of Labor and Statistics - [May 2020 data](#)).

Incentives are often used to encourage participation in research. When applied in a reasonable manner, incentives are viewed as an acknowledgement of participation rather than an unjust inducement (Groth, 2010; Halpern, et al 2004). Indeed, experimental studies have found that a small incentive is more cost-effective and can more than double the participation rate of teachers and school administrators in surveys when compared to no incentive (Jacob & Jacob, 2012; Robbins, et al, 2018). The study contractor, IQ Solutions, has successfully used a token of appreciation in prior surveys of FDA CTP customers (FDA CTP Exchange Lab Syndication: Current Users Study 2019, OMB 0910-0697) and found them necessary to complete data collection in a timely manner, reduce non-response bias, and minimize government costs associated with recruitment.

#### **7. Questions of a Sensitive Nature:**

The majority of questions asked will not be of a sensitive nature. However, the survey does include questions on teachers' race/ethnicity; type of school, geographic region, and state where they teach; and the school's Title I status. (Title I of the Elementary and Secondary Education Act of 1965 provides federal funds to schools with high percentages of low-income students.) The purpose of these questions is to better understand FDA's *The Real Cost of Vaping* customers and potentially tailor FDA's future tobacco prevention materials to teachers and schools with different resource needs. Although we do not anticipate any risks to respondents in answering these questions, some respondents may perceive the questions as sensitive. To allay potential concerns, respondents will be assured during the informed consent process that the information they provide is voluntary, will be treated as private and anonymous, and that they may skip any question they wish. Respondents will also be provided with the principal investigator's phone number and email address if they have any questions about the survey.

**8. Description of Statistical Methods:**

Scholastic will send emails with a link to the online screener to middle and high school teachers who have voluntarily opted-in to receive materials from Scholastic and have interacted (e.g., opened, clicked through) with previous Scholastic emails that promoted FDA’s *The Real Cost of Vaping* materials. Scholastic will also send emails to teachers who participated in the recent *Vaping’s Not My Thing* PSA contest sponsored by FDA CTP and Scholastic. Only teachers who have used FDA’s *The Real Cost of Vaping* materials and/or participated in the PSA contest will be invited to complete the survey. We anticipate that up to 800 middle school and 800 high school teachers will complete the 20-minute survey.

This survey of teachers’ experiences and satisfaction with FDA’s *The Real Cost of Vaping* prevention materials will provide useful qualitative information on how materials can be improved, but will not yield statistically reliable results or data generalizable to the overall population. Survey results will be used to improve FDA’s existing school-based tobacco education and prevention materials provided to teachers in partnership with Scholastic, but are not intended for publication or other forms of public release outside of FDA.

**9. Burden:** [Complete the table below.]

*Burden Hour Computation -- (Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours).*

**Example:**

Type of information collection/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Individuals; Middle & High School Educators – Screener	3,000	2 minutes (0.03 hours)	100
Individuals; Middle & High School Educators – Informed Consent	1,600	5 minutes (0.08 hours)	133
Individuals; Middle & High School Educators - Survey	1,600	20 minutes (0.33 hours)	533
<b>Totals</b>			<b>766</b>

**10. Date(s) to be Conducted:** August 15 – September 30, 2021

**11. Requested Approval Date:** 07/15/2021

**12. FDA Contacts:**

Program Office Contact	FDA PRA Contact
Debra Mekos, PhD <a href="mailto:debra.mekos@fda.hhs.gov">debra.mekos@fda.hhs.gov</a> 240-994-3243	Ila S. Mizrachi <a href="mailto:Ila.Mizrachi@fda.hhs.gov">Ila.Mizrachi@fda.hhs.gov</a> 301-796-7726

13. **Certification:** In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
- c) The collections are noncontroversial;
- d) Personally identifiable information (PII) is collected only to the extent necessary<sup>1</sup> and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.<sup>2</sup>

## References

Brelsford, K.M., Ruiz, E., Hammack, C.M., & Beskow, L.M. (2019). Improving translation and cultural appropriateness of spanish-language consent materials for biobanks. *Ethics & Human Research, 41*, 16-27.

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

Halpern, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(7), 801-803.

Jacob, R.T., & Jacob, B. (2012). Prenotification, incentives, and survey modality: An experimental test of methods to increase survey response rates of school principals. *Journal of Research on Educational Effectiveness, 5*:4, 401-418.

Mokher, C. & Pearson, J.L. (2017). The complexities of recruiting participants for a statewide education survey. *Survey Practice 10* (4).

Robbins, M.W., Grimm, G., Stecher, B., & Opfer, V.D. (2018). A comparison of strategies for recruiting teachers into survey panels. *SAGE Open*,1-12.

---

<sup>1</sup> For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

<sup>2</sup> As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."