

**Request for Approval under the “Generic Clearance for the Collection of  
Qualitative Feedback on FDA Service Delivery”  
(OMB Control Number: 0910-0697)**

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**A. TITLE OF INFORMATION COLLECTION:** FDA CTP 2021 Educational Outreach  
Focus Groups with Health Educators

1. PURPOSE:

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 tobacco education and prevention materials (e.g., lesson plans, classroom activities, posters) to middle and high school teachers across the United States. The goal of this collection is to obtain feedback from health education teachers about their access to, experiences with, and preferences for skills-based tobacco prevention curricula. Information from this collection will be used to improve FDA CTP’s current tobacco education and prevention materials to better serve the resource needs of middle and high school teachers in educating students about the harms of tobacco use.

2. DESCRIPTION OF RESPONDENTS:

Respondents will include adult health education teachers at the middle and high school level identified through outreach to health education professional organizations and a professional research recruitment vendor that manages a database of potential participants who have voluntarily opted-in to be contacted for focus group opportunities. Respondents must currently teach or have taught middle or high school health education during the 2019/2020 and/or 2020/21 school years. Respondents will include a mix of genders and race/ethnicities, and represent an array of school types (public, private), school enrollment sizes, and geographic regions of the country.

The 2020 U.S. Census and 2020 NYTS (National Youth Tobacco Survey) asked the race/ethnicity question at the same level of specificity that we are proposing for the focus groups. By using the Hispanic/Latino ethnicity question with expanded response options in the focus group recruitment screener, we will be able to document each potential focus group participant’s country of origin (e.g., Mexico, Puerto Rico, Cuba, The Dominican Republic, El Salvador, Colombia, Venezuela, Nicaragua, Costa Rica, etc.). By having this smaller level of granularity, we will be able – via purposive sampling – to recruit a diverse mix of Hispanic/Latino participants and aim to include at least one Hispanic/Latino participant in each of the 18 total focus groups. This is important as it will more accurately reflect the highly heterogeneous population of at least 60 million Hispanic/Latino people in the U.S. (18% of the U.S. population), representing 20 countries of Spanish-speaking origin. This would help to avoid the possibility that the Hispanic/Latino participants we recruit only represent one country of origin, such as Mexico, only. Including Hispanic/Latino participants of a variety of countries of origin and of different races will offer a wider range of experiences and perspectives. Although the focus groups will not be segmented by

race/ethnicity, aiming for a mix of participants in each of the 18 focus groups will reflect the diversity of the U.S. population and thus be more representative. We do not have hard quotas for race/ethnicity; rather these will be soft quotas as we will aim for maximum diversity across participants per focus group as possible during the recruitment phase. A previous CDC focus group study ("Health Communication Message Testing on Tuberculosis") that also included this level of Hispanic/Latino ethnic category specificity in the research participant recruitment screener received OMB approval in 2019. Here is the link to the Office of Information and Regulatory Affairs at OMB with all of the OMB approved materials for that CDC study: [https://www.reginfo.gov/public/do/PRAViewIC?ref\\_nbr=201808-0920-023&icID=235026](https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201808-0920-023&icID=235026)

3. TYPE OF COLLECTION: (Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.)

- |  |   |
|--|---|
| <input type="checkbox"/> Customer Comment Card/Complaint Form          | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group       |
| <input checked="" type="checkbox"/> Focus Group                        | <input type="checkbox"/> Other: _____                 |

4. CERTIFICATION: Please read the certification carefully. If you incorrectly certify, OMB will return the generic as improperly submitted or it will be disapproved.

I certify the following to be true:

- a) The collection is voluntary.
- b) The collection is low-burden for respondents and low-cost for the Federal Government.
- c) The collection is non-controversial and does not raise issues of concern to other Federal Agencies.
- d) The results are not intended to be disseminated to the public.
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.
- f) The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

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To assist review, please provide answers to the following question:

5. PERSONALLY IDENTIFIABLE INFORMATION (PII): Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.

- a) Is personally identifiable information (PII) collected?  Yes  No

- b) If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [X] No
- c) If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [ ] No

6. GIFTS OR PAYMENT: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

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

FDA CTP will offer each teacher a \$40 prepaid gift card as a token of appreciation for their participation in the 90-minute focus group discussion. Secondary school teachers have multiple competing demands on their time, which have been greatly compounded over the current school year due to the COVID-19 pandemic and increased responsibilities placed on them to ensure that students continue to learn and thrive in a virtual school environment. Given these additional responsibilities and constraints on their time, an incentive less than the proposed amount could greatly inhibit our ability to successfully recruit teachers to participate in a 90-minute discussion of their experiences teaching tobacco prevention. Therefore, the proposed incentive amount for participation in this information collection 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). If the incentive is not adequate, participants may initially agree to participate and then not show up at the scheduled time, resulting in incomplete data collection and potential loss of government funds associated with recruitment costs and moderator time (Morgan & Scannell, 1998). Indeed, experimental studies on the effects of incentives on participation by educators, who tend to be a hard-to-recruit population, have found that a small incentive more than doubled the participation rate when compared to the no-incentive conditions (Jacob & Jacob, 2012).

**BURDEN HOURS:** Identify who you expect the respondents to be in terms of the following categories:

- (1) Individuals or Households;
- (2) Private Sector;
- (3) State, local, or tribal governments;
- (4) Federal Government.

Only one type of respondent can be selected per row.

**No. of Respondents:** Provide an estimate of the Number of respondents.

**Participation Time:** Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)

7. **BURDEN:** Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

<b>Category of Respondent</b>	<b>No. of Respondents</b>	<b>Participation Time</b>	<b>Burden (Rounded)</b>
Individuals; Health Education Teachers – Recruitment Materials; Initial Email Screener	378	5 mins (0.083 hours)	32
Individuals; Health Education Teachers – Follow up Phone Screener	108	5 mins (0.083 hours)	9
Individuals; Health Education Teachers – Informed Consent	108	5 mins (0.083 hours)	9
Individuals; Health Education Teachers – Focus Groups	108	90 mins (1.5 hours)	162
<b>Totals</b>			<b>212</b>

8. FEDERAL COST: The estimated annual cost to the Federal government is approximately \$41,000 (one-time cost).

## **B. STATISTICAL METHODS**

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents:** Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

Yes  No

If the answer is yes, please provide a description of both below (or attach the sampling plan). If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

A professional research recruitment vendor will be responsible for selecting respondents for the focus groups using a combination of postings to health education professional organization listservs, newsletters, and social media sites and their own database of potential respondents who have voluntarily opted-in to be contacted for focus group opportunities. The selection of respondents will be based on their interest in participating and responses to the initial email screener to determine if they meet the eligibility criteria, as well as their responses to the follow-up phone screener with the subset of eligible respondents to confirm eligibility. To ensure the

focus groups represent a wide array of health teacher experiences and needs, the recruitment vendor will strive to select a diverse group of respondents with respect to gender, race/ethnicity, type and size of school where they teach, and geographic location (region/state; urban, rural, suburban).

**Administration of the Instrument:** Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used

1. How will you collect the information? (Check all that apply)

- Web-based or other forms of Social Media
- Telephone
- In-person
- Mail
- Other, Explain – Virtual focus groups held online via the contractor’s Zoom account

2. Will interviewers or facilitators be used?  Yes  No

**Please make sure that all instruments, instructions, and scripts are submitted with the request.**

**REQUESTED APPROVAL DATE: July 7, 2021**

**NAME OF PRA ANALYST**

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**FDA CENTER:** Center for Tobacco Products

**REFERENCES:**

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.

Morgan, D.L. & A.N. Scannell. (1998) *Planning Focus Groups*. Thousand Oaks, CA: Sage.