

U.S. Food and Drug Administration

Center for Tobacco Products

Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages

OMB Control Number 0910-NEW

SUPPORTING STATEMENT A

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This collection of information supports Food and Drug Administration (FDA) programs. FDA uses tobacco education campaigns to educate citizens about the risks and harms of tobacco. To identify effective message strategies, research on the self-reported, physiological, and neural response to these education messages is needed. Our research will be used to identify effective tobacco prevention and education message strategies. Additionally, there is a need to triangulate data collected through physiological and neuroimaging-based approaches with self-reported measures to better understand how self-reported measures can be implemented to predict behavior change more accurately. Ultimately, this research is necessary for the FDA to best understand how to improve the public's health and minimize tobacco use in the US.

2. Purpose and Use of the Information Collection

The FDA's Center for Tobacco Products provided funding to Johns Hopkins Bloomberg School of Public Health (JHSPH) via Johns Hopkins Center for Excellence in Regulatory Science and Innovation to conduct an in-person study with a sample size of 100 youth and young adults aged 13-24. Participants will complete one study visit (about 90 minutes) in which self-reported, physiological, and neural response to FDA tobacco education and prevention messages will be assessed.

The results of this survey will be used to inform specific recommendations around FDA's public education programs' impact and effectiveness in reducing tobacco-related death and disease. Information gathered will not be used for the purpose of substantially informing influential policy decisions. The information gathered is also not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

The information collected in this study will be used to target these aims and answer the associated research questions:

- Assess physiological response to FDA's tobacco prevention and education messages using galvanic skin response, facial electromyography and heart rate variability. *RQ1: How does (a) arousal and (b) positive or negative emotional response vary in response to different tobacco prevention and education messages?*
- Assess cognitive response to FDA tobacco education and prevention messages using eye tracking and neuroimaging (fNIRS: functional near-infrared spectroscopy). *RQ2: How*

does (a) message attention and (b) neural response vary in response to different tobacco prevention and education messages?

- Compare different self-reported measures of message response by triangulating self-report data with physiological and neural response. *RQ3: Which self-report measures of message response correlate most strongly with (a) physiological and (b) neural response?*
- Exploratory aim: Describe the mechanisms underlying effective messages. *RQ4: What physiological and neural responses are associated with message effects (i.e., message comprehension, belief change, attitude change)?*

3. Use of Improved Information Technology and Burden Reduction

This study collects data using web-based surveys, a functional near infrared spectroscopy (fNIRS) device placed on the participant's head, and electronic sensors placed on the participant's skin. All participants will have data collected using these data collection methods. Interested participants may complete an online eligibility screener. Participants who are eligible and enroll in the study will visit the study lab at JHSPH where data will be collected via the fNIRS device, electronic sensors, and a second web-based survey. These data collection techniques are necessary to fulfill the aims of the study. Data collection via fNIRS is an efficient way to assess participants' neural responses. The fNIRS device is akin to a headband that wraps around the participant's head. This device allows participants to be mobile and is expected to be more comfortable and less burdensome than a similar data collection technique, such as fMRI (functional magnetic resonance imaging). The electronic sensors used to collect data are non-invasive, placed on participant's skin, and are wireless, similarly allowing the participant to be mobile, which maximizes participant comfort.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequences of Collecting the Information Less Frequently

Respondents to this data collection will answer only once to ensure the participant burden is as low as possible. Failing to collect data in this frequency could prevent us from fully understanding the target audience's response to the messages, and maximizing the impact of these messages, and could therefore reduce the benefit of the messages for youth and young adults in the United States. There are no legal obstacles to reduce the burden.

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

This information collection fully complies with 5 CFR 1320.5(d)(2). No special circumstances are associated with this information collection that would be inconsistent with the regulation.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of November 22, 2022 (87 FR 71335). One non-PRA related comment was received.

The following individuals inside the agency have been consulted on the design of the study, instrument development, or intra-agency coordination of information collection efforts:

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Additionally, FDA collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health National Cancer Institute (NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for advertisements;
- Review of surveys for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

The following individuals outside of the agency have been consulted on survey development.

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9. Explanation of Any Payment or Gift to Respondents

There is no token of appreciation for solely completing the screener. A \$50 Visa gift card will be distributed to all participants at the end of their 90-minute in-person study as a token of appreciation for their participation in the study. Additionally, a separate \$25 Visa gift card will be distributed to participants aged 16-24 to cover the direct costs of their participation (e.g., gas, parking, public transportation). For youth ages 13-15, the \$25 Visa gift card will be given to the adult who accompanies them to the study to cover the adult's direct costs of bringing the youth participant to the study. These amounts not only reflect the burden of time to participate, but it will also ensure that the respondent pool is recruited within a tight timeframe.

Additionally, tokens of appreciation are important to recruit at-risk populations. Such populations are important to this research because of the risk factors for tobacco use; those population are also historically difficult to recruit and retain in health research (Hooven et al., 2011; Murthy et al., 2004; Post et al., 2012; Siddiqui et al., 1996; Zand et al., 2006). A token of appreciation is necessary to minimize non-response bias, complete data collection goals in a timely manner, reduce overall burden, and reduce costs. Smaller token amounts are associated with slower movement on recruitment. These token of appreciation amounts are in line with in-person studies previously approved by OMB with similar burden, topic area, and at-risk populations, such as a AI/AN youth focus groups and 90-minute focus groups with young adult ENDS users (both under OMB Control Number 0910-0796).

Finally, the token of appreciation allows us to treat participants justly and with respect by acknowledging competing demands for their time and the effort they spend participating and reflects our human subjects' commitment to equity in research participation. Additional logistical challenges related to an in-person study merit consideration in determining incentive amounts; specifically that childcare considerations, transportation and parking may be challenging and expensive for participants and the adults who accompany them.

10. Assurance of Confidentiality Provided to Respondents

OMB Control Number 0910-NEW is covered underneath a Privacy Impact Assessment that has been approved by the Department of Health and Human Services on February 15, 2023.

Concern for privacy and protection of respondents' rights will play a central role in the study implementation, storage and handling of data, and data analysis and reporting. The Institutional Review Board (IRB) of Johns Hopkins Bloomberg School of Public Health, the research organization contracted to manage data collection, reviewed and approved the protocols for the

survey. The primary concern of IRB is protecting respondents' rights, one of which is maintaining the privacy of respondent information.

As part of this study, JHSPH will collect and temporarily maintain personally identifiable information (PII). During various stages of the study, the PII collected for each potential participant includes their name and contact information (phone number and email address) used for study scheduling, and a physical form with some PII collected at the study for gift card distribution. If the individual is younger than 18 years old, the parent's first name is also collected. These identifiers will be retained until the participant's study visit is complete. Once the study visit is complete, electronic participant identifiers used for scheduling will be destroyed by deletion. At the conclusion of the study, all physical PII forms for gift card distribution will be submitted to the JHU Finance Department for processing.

Privacy will be ensured in several ways:

- Survey data will be downloaded from Qualtrics and stored on JHSPH SharePoint and File Shares. These systems provide a managed and secure platform for research projects. They also provide a built-in encrypted backup solution.
- Qualtrics will use a unique alphanumeric ID for each survey participant. Only JHSPH maintains a link between alphanumeric IDs, PII, and screener responses. JHSPH will use this information for fraud detection, and the link between PII and study responses will not be maintained once the participant's in-person data has been collected. Only JHSPH maintains a link between code numbers and PII; FDA will not receive data containing the link between code numbers and the PII.
- To provide participants with gift cards, JHSPH requires participants to fill out a physical form with PII (name, address, and phone number). These forms will be kept in a locked filing cabinet in the study lab, which is locked when not in use. These forms will not in any way be linked to participant data.
- The resulting deidentified dataset will not include any PII. Each respondent will only be known by a unique alphanumeric ID variable. During the analysis portion of the study, deidentified data may be analyzed on personal computers. Deidentified data may be shared via Dropbox.
- When taking the screener on-line, respondents are not able to back up in the survey to view previous responses. For example, if a youth were to leave the survey part of the way through, the parent could not view previously entered responses. JHSPH will confirm this prior to publishing the survey.
- When data collection is complete, the deidentified data file will be transmitted from JHSPH to FDA via a website with an SSL certificate applied. The data file, which contains no PII, will be stored by JHSPH and FDA on a restricted-access folder on a shared network drive, and only authorized project members will have access. JHSPH and FDA will store deidentified data for 3 years before deletion.

11. Justification for Sensitive Questions

Most questions in this study are not of a sensitive nature. However, this study does ask questions that may be considered sensitive in order to screen for study eligibility and to assess study outcomes related to tobacco. It is necessary that these questions are asked to achieve the

objectives of this information collection: namely, to assess how different audiences respond to FDA tobacco education messages in regard to their perceptions of tobacco.

There are questions regarding tobacco use which may be sensitive questions to participants under the age of 21 as sales of tobacco to individuals under age 21 are illegal nationwide. However, it is critical for us to assess the participant's tobacco use in order to ensure the sample of study participants accurately reflects the target audience of FDA's messages. There are also questions regarding participant's race/ethnicity, age, sex, gender, and sexual orientation that may be considered sensitive questions. These questions are present because both tobacco use and response to FDA's messages may vary along these demographics. These questions are essential to address the aims and research questions presented by this study. Decades of research has shown significant disparities in tobacco use by race/ethnicity (e.g., Harlow et al., 2019; Odani et al, 2018), gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019), and sexual orientation (e.g., Johnson et al, 2019; McCabe et al., 2018). Therefore, collecting detailed information on these demographic characteristics will allow us to understand these differences with the goal of reducing these disparities. As multiple studies of youth and young adults have reported approximately 12-15% of the sample identified as gender non-conforming/non-binary (e.g., The Human Rights Campaign 2018 LGBTQ+ Youth Report; The Trevor Project 2020 National Survey on LGBT Youth Mental Health; CTP's evaluation of *This Free Life* campaign), including gender non-conforming/non-binary response options is necessary to identify and assess tobacco use and campaign effectiveness among this population. Gender identity questions with genderqueer/gender non-conforming/non-binary response options as well as sexual orientation questions have been approved by OMB for ExPECTT FU3 and for RESPECT (0910-0808) as well as for ExPECTT 0910-0753. The project team will not conduct or report on statistical analysis for demographic groups for which there is insufficient statistical power.

There are several tactics used throughout the process of the study to minimize the possible negative impact of these questions, including:

- During the consent process, participants are told about the study procedures, including the types of questions asked in the survey.
- Participants are also informed that they do not have to answer all questions in the survey, and they may stop at any time.
- After receiving this information, participants can choose not to join the study.
- At the start of the in-person portion of the study this information is reiterated to the participants, and again, they have the option not to continue.
- The web-based surveys are self-administered, to maximize participant privacy without the need to verbalize responses.
- Participants will be provided with contact information for the JHSPH Institutional Review Board in case they have a question or concern about the sensitive issue.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Applying assumptions from previous experience in conducting similar studies, approximately 150 youth and 150 young adults would take the eligibility screener,

which is estimated to take 5 minutes to read and respond. An estimated 75 parents of youth participants will provide parental permission and schedule a site visit (10 minutes total); and an estimated 50 young adults will schedule a site visit (5 minutes). Finally, approximately 50 youth and 50 young adults will complete an in-person study visit that consists of the consent/assent (5 minutes) and complete the main study (85 minutes) to yield the desired sample size of 100 total. The total estimated burden for the data collection is 193 hours. Table 1 details these estimates.

Table 1.--Estimated Annual Reporting Burden

Participant Subgroup	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Number to take the eligibility screener					
Youth (aged 13-17)	150	1	150	0.083 (5 minutes)	13
Young adults (aged 18-24)	150	1	150	0.083 (5 minutes)	13
Total					26
Number to obtain parental permission process (for parents of youth only) and schedule site visit					
Parents of youth participants	75	1	75	0.167 (10 minutes)	13
Young adults (aged 18-24)	50	1	50	0.083 (5 minutes)	4
Total					17
Number to complete consent (5 min) and main study (85 min)					
Youth (aged 13-17)	50	1	50	1.50 (90 minutes)	75
Young adults (aged 18-24)	50	1	50	1.50 (90 minutes)	75
Total					150
Total					193

12b. Annualized Cost Burden Estimate

To calculate the estimated annual cost, the mean hourly wage of \$7.25 was used for youth and \$28.01 was used for young adults and parents of youth. The youth price represents the minimum wage, and the young adult costs represent the mean hourly wage for other occupation earnings from the U.S. Department of Labor Bureau of Labor Statistics (May 2021 data). There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of \$7.25 and \$28.01 (youth and young adult), the estimated one-year annualized cost to participants will be \$3,579.05. The estimated value of respondents' time for participating in the information collection is summarized in Exhibit 2.

Exhibit 2. Estimated Annual Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Youth	88	\$7.25	\$638.00
Parents of youth	13	\$28.01	\$364.13
Young adults	92	\$28.01	\$2,576.92
Total			\$3,579.05

1. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection of information.

2. Annualized Cost to the Federal Government

This information collection is funded through a collaborative agreement with Johns Hopkins University. The estimated costs attributable to this data collection are \$178,313 per year. (Table 3). There are additional grant-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, instrument development, reporting, IRB, project management and progress reporting. This information collection will occur for one year.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total ¹
GS-12	5%	\$86,335	\$4,317
GS-13	10%	\$102,663	\$10,266
		Total Annual Salary Costs	\$14,583
Annual Collaborative Agreement Cost			\$163,730
Total Annual Cost			\$178,313

¹ Cost was rounded up to the next dollar.

3. Explanation for Program Changes or Adjustments

This is a new information collection.

4. Plans for Tabulation and Publication and Project Time Schedule

Data from this information collection will enable the FDA to gain insight into youth and young adults' perceptions of ENDS and cigarettes and reactions to advertising concepts. This activity will allow the FDA to develop and refine messaging related to preventing ENDS and cigarette use among youth aged 13 to 17 who are at risk of initiating or who have experimented with

tobacco products. Findings from these analyses will be used to inform FDA CTP health communication strategy and messaging.

Reporting

At the end of the study, a final report containing background information on the project objectives, scope and methodology, and key findings and conclusions will be completed. The approximate dates for completing project tasks are listed in Table 4.

Table 4. Approximate Project Schedule

The project schedule is shown in Table 4. Future development and research activities are dependent on the timely completion of the present study.

Table 4. Project Schedule

Project Activity	Approximate Date
Data Collection	September 2023-July 2024
Summary Report	February 2025

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

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. The OMB approval and expiration date will be displayed on the relevant materials associated with the study.

6. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.